Agenda

July 12, 2024 at 9:00 a.m.

Via Webex

1. Call to Order and Welcome – Dr. Thomas Eppes, Jr., Chair
2. Roll Call
3. Review of Agenda – Joseph Hilbert, Deputy Commissioner for Governmental & Regulatory Affairs
4. Review of Meeting Materials – Allyson Flinn, Policy Analyst
5. Approval of Prior Meeting Minutes
6. Public Comment Period
7. Task Force Vote on Psychiatric Recommendations
    a. Review of Policy Options
    b. Discussion
    c. Vote

Break

8. Expedited Review Projects & Process Options
    a. Review of remaining projects
    b. Review of potential process options and criteria for consideration
    c. Discussion
9. Wrap-Up and Next Steps
    a. August Meeting
10. Meeting Adjournment

State Health Services Plan Task Force
May 30th, 2024
Time 9:00 a.m.
Perimeter Center, Board Room 2
9960 Mayland Drive
Henrico, VA 23233

Task Force Members in Attendance In-Person – Entire Meeting (alphabetical by last name): Jeannie Adams; Dr. Kathy Baker; Dr. Keith E. Berger; Karen Cameron; Carrie Davis; Michael Desjadon; Paul Dreyer; Amanda Dulin; Dr. Thomas Eppes, Jr.; Paul Hedrick; Shaila Camile Menees.

Task Force Members in Attendance Virtually – Entire Meeting: Rufus Phillips.

Staff in Attendance (alphabetical by last name): –Erik O. Bodin, COPN Director, VDH OLC; Michael Capps, Senior Policy Analyst, VDH Office of Governmental and Regulatory Affairs; Allyson Flinn, Policy Analyst, VDH OLC; Joseph Hilbert, Deputy Commissioner of Governmental and Regulatory Affairs, VDH; Val Hornsby, Policy Analyst, VDH OLC; Dr. Karen Shelton, State Health Commissioner, VDH.

Dr. Marilyn West joined the meeting virtually at 9:07 am and left the meeting at 10:47 am.

1. **Call to Order and Welcome**

   Dr. Thomas Eppes, Jr. called the meeting to order at 9:04 a.m. Dr. Eppes reminded the meeting members that private conversations would be picked up by the microphones in the room.

2. **Roll Call**

   Allyson Flinn called the roll of the members. Ms. Flinn noted that Rufus Phillips had joined the meeting virtually, and that Kyle Elliott and Dr. Marilyn West would be joining the meeting virtually.

3. **Review of Mandate**

   Ms. Flinn reviewed the statutory mandate within § 32.1-102.2:1 of the Code of Virginia and Chapter 423 of the 2024 Acts of Assembly.

4. **Review of Agenda**

   Joseph Hilbert reviewed the agenda.

5. **Approval of Meeting Minutes from March 8 Meeting**

   The minutes from the March 8, 2024 meeting were reviewed. Michael Desjadon made a motion to amend the minutes by changing the adjournment at 12:10 a.m. to p.m.

Amanda Dulin seconded the amendments and the motion passed unanimously by voice vote. The meeting minutes as amended were approved without objection.

6. Adoption of Updated Remote Participation Policy

Ms. Flinn reviewed the amendments to the remote participation policy. Karen Cameron motioned to adopt the updated remote participation policy with Dr. Eppes seconding that motion. The policy was adopted unanimously by voice vote.

7. Presentation from the Department of Behavioral Health and Developmental Services

Nelson Smith, Commissioner for the Department of Behavioral Health and Developmental Services presented to the Task Force on the following topics: (i) Governor Youngkin's *Right Help, Right Now Plan* and its Crisis Pillar, (ii) an update on the *Right Help, Right Now* plan, (iii) Public and Private Psychiatric Bed Estimates, (iv) Temporary Detention Orders, (v) Psychiatric Bed Capacity, and (vi) a Nationwide COPN Overview.

There was discussion regarding the licensure of crisis centers, exclusionary criteria, private vs public bed capacity, the effectiveness of crisis centers in keeping people from requiring inpatient care, school education initiatives, the number of crisis stabilization centers and the capacity of those centers, and the 988 number.

8. Review of Meeting Materials

Ms. Flinn reviewed the meeting materials with the Task Force, concluding the review with a brief overview of VDH's data observations. There was discussion about the most recent COPN denial for a psychiatric project, and the regulation of state hospitals in Oregon.

9. Public Comment Period

Two members of the public signed up to give public comment, Brent Rawlings from the Virginia Hospital and Healthcare Association and Clark Barrineau from the Medical Society of Virginia regarding the Task Force's upcoming votes on recommendations.

10. Psychiatric Beds and Services & Expedited Review

10.1. Staff Presentation

Ms. Flinn discussed the break-out session groups with the Task Force and requested that Mr. Desjadon move from Group 1 to Group 3 due to absences, to which Mr. Desjadon agreed.

There was discussion regarding the mandate found in Chapter 423 of the 2024 Acts of Assembly, the future meeting schedule, and the options for consideration by the Task Force.

10.2. Breakout Sessions

Dr. Eppes announced that the Task Force members would be breaking into three smaller groups for breakout sessions. Ms. Flinn explained that Task Force members would go across the hall the hearing rooms according to which group they had been randomly assigned.

Group 1 – Hearing Room 4

Group 1 consisted of Jeannie Adams, Dr. Kathy Baker, and Paul Hedrick.

The breakout group discussions consisted of the interest in closing the loop that allows a psychiatric beds to be converted to a non-psychiatric bed, the ability for members of the public to voice their opinions on expedited projects, the acceptance of TDOs by private hospitals and the potential to condition COPNs on that, the difference between civil TDOs and forensic TDOs, and general discussion regarding the current COPN landscape in Virginia. The group then ended its breakout session and returned to Board Room 2.

Group 2 – Hearing Room 3

Group 2 consisted of Dr. Keith Berger, Carrie Davis, Shaila Camile Menees, and Amanda Dulin

The breakout group discussions consisted of the concerns with psychiatric staffing, the merits of COPN and its ability to regulate the market, COPN deregulation, an increase in the number of application batch cycles, the unregulated conversion of psychiatric beds to non-psychiatric beds, the interest in ensuring expedited projects include a charity care requirement, the complexities of TDOs and the acceptance of them by facilities, and general discussion regarding economic arguments for COPN regulations. The group then ended its breakout session and returned to Board Room 2.

Group 3 – Hearing Room 2

Group 3 consisted of Paul Dreyer, Karen Cameron, Dr. Thomas Eppes, Jr., and Michael Desjadon

The breakout group discussions consisted of the current efforts aimed at addressing the behavioral health crisis in Virginia, whether COPN plays a role in regulating the market, what barrier, if any, COPN introduces for psychiatric care, the staffing of psychiatric beds and potential shortages that may exist, the staff time and resources it takes to review applications, concerns surrounding the current expedited process and its lack of public participation, whether a recommendation should include a request for the General Assembly to fund the regional health planning agencies that have shut down, the addition of a batch cycle for expedited review projects, and the reasons for why a project should be moved from expedited review into full review. The group then ended its breakout session and returned to Board Room 2.

10.3. Group Discussion

Dr. Eppes called the Task Force back for a group discussion at 11:42 am. Dr. Kathy Baker gave the group 1 report. Option 1 & Option 2 opposed, Option 3 support on caveat of 90-day extension of expedited review, Option 4, 5, and 6 support, Option 7 oppose, Option 8 highly support, Option 9 oppose at face value, but need more information, Option 10 support, but not as a mandate, Option 11 & 12 support, and Option 13 need more information, but had discussion on diagnostic imaging.

Shaila Menees gave the group 2 report. With option 1 3 group members support and 1 would like to repeal COPN, option 2 maybe add another cycle for psychiatric services rather than expedited review, option 3 and 4 similar proposition to option 2, option 5 support, option 6, 7, and 8 3 group members oppose and 1 would like to repeal COPN, option 9 support, option 10 need more information regarding accepting TDOs, option 11 support, option 12 oppose, option 13 need more information and there was further discussion on conversion from psychiatric to medical-surgical beds.

Mr. Desjadon gave the group 3 report with the following options and reasonings – Option 1 support, option 2 table for further discussion, option 3 support, option 4 support with caveat of in the same PD, option 5 support, option 6 support with caveat of in the same PD, option 7 no consensus, option 8 support, options 9 & 10 support, option 11 tabled for further discussion, option 12 support, option 13 tabled, option 14 discussion of addition of batch cycle.

There was discussion regarding the fiscal and staffing impacts the presented options would have, the scope of each proposed change, and potential impacts of the various proposed options.

11. Wrap-Up and Next Steps

Mr. Hilbert requested that the Task Force members fill out the worksheets when they are sent to them in order to prepare them for the next meeting. Dr. Keith E. Berger handed out two documents to the Task Force members for their review (these can be viewed at the end of this document). Dr. Eppes proposed a July 12th all-virtual meeting to vote on the options for recommendation.

12. Meeting Adjournment

The meeting adjourned at 12:22 p.m.

State Health Services Plan Task Force

May 30, 2024 Meeting

Task Force Mandate

- § 32.1-102.2:1. State Health Services Plan; Task Force
- The Board of Health shall appoint and convene a State Health Services Plan Task Force for the purpose of advising the Board on the content of the State Health Services Plan (SHSP)
- Provide recommendations related to:
    - Periodic revisions to the SHSP
    - Specific objective standards of review for each type of medical care facility of project type for which a certificate of public need is required
    - Project types that are generally noncontested and present limited health planning impacts
    - Whether certain projects should be subject to expedited review rather than full review process
    - Improvements in the certificate of public need process

Task Force Mandate – Cont

- Chapter 423 of the 2024 Acts of Assembly
- Develop recommendations on expedited review of project types subject to certificate of public need (COPN) requirements that are generally non contested and present limited health planning impacts. The Task Force shall also create recommendations regarding:
  - What facilities and projects listed in § 32.1-102.1:3 of the Code of Virginia should be added to the expedited review process;
  - Criteria that should apply to any project types subject to expedited review; and
  - A framework for the application and approval process of such projects.
- Project types for consideration shall include:
  - Increases in inpatient psychiatric beds;
  - Relocation of inpatient psychiatric beds;
  - Introduction of psychiatric services into an existing medical care facility; and
  - Conversion of beds in an existing medical care facility to psychiatric inpatient beds.
- Report findings to the the Secretary of Health and Human Resources, the Chairman of the Senate Committee on Education and Health, and the Chairman of the House Committee on Health and Human Services by November 1, 2024

Review of the Agenda

Approval of Prior Meeting Minutes

Adoption of Updated Remote Participation Policy

- Chapter 56 of the 2024 Acts of Assembly amended § 2.2-3708.3 of the Code of Virginia, requiring an update to the Task Force’s Remote Participation and All-Virtual Meeting Policy. The updates to conform to the mandate are as follows:
  - Inserted a provision on page 1 section 1.0 to require the Task Force to update its Remote Participation and All-Virtual Meeting Policy annually.
  - Inserted a provision on page 3 section 6.0 to make any member absent from any portion of the meeting during which visual communication with the member is voluntarily disconnected or otherwise fails or during which audio communication involuntarily fails, when audio-visual technology is available.
  - Amended the provision on page 4 section 7.1, changing the all-virtual meeting allowance from 25 percent to 50 percent of the meetings held per calendar year.

Presentation – Nelson Smith, Commissioner, Virginia Department of Behavioral Health & Developmental Services

Break

Review of Meeting Materials

Meeting materials

- Tableau Dashboard
- Past Legislative Efforts
  - Spreadsheet & One-pager
- State Comparison Data
  - Spreadsheet
- Process Change Analysis
- Analysis on the Impacts of Medicaid Expansion on Psychiatric Services

Data Observations

- Virginia has an estimated total of 17,186 staffed hospital beds, with Medical-surgical and Pediatric beds having the lowest staffing rates (73% and 65%)*
  - Adult ICU - 1,673
  - Adult psychiatric - 2,795
  - Alcohol/Drug - 66
  - Medical Rehabilitation - 960
  - Medical-Surgical - 9,457
  - Obstetric - 1,172
  - Pediatric - 388
  - Pediatric ICU - 188
  - Pediatric psychiatric - 487
- Virginia private hospitals staff almost all of their licensed beds
  - 83% of all licensed beds in the Commonwealth are staffed
  - 90% of all adult psychiatric beds are staffed
    - 92% of all pediatric psychiatric beds are staffed
  - Southwest Virginia has the lowest percentages of licensed beds staffed

*Bed count includes psychiatric beds found in state hospitals

Data Observations – Cont.

- TDO admissions for state hospitals have decreased, but admissions at private hospitals have stayed relatively consistent
  - Increase in wait time for TDO bed has led to overall decrease in TDOs
  - In FY23, state hospitals admitted 1920 TDOs while private hospitals admitted an estimated 18,335 TDOs
- COPN projects for psychiatric services are rarely denied in Virginia
  - Since SFY2013, there have been 38 decisions for psychiatric services
    - 35 were approved (673 beds)
    - 3 were denied (147 beds)
      - One was ultimately approved when resubmitted (33 beds)

Data Observations – Cont.

- COPN expedited review processes vary from state to state
  - Average review time of 47 days nationally
  - 20 states have expedited review, with 6 of those having some form of public participation
  - Most common projects types are non-substantial change, capital expenditures under certain amounts, and emergency projects
  - 3 states specifically include psychiatric projects in their expedited review processes
    - Kentucky - Change of location or relocation of beds to a psychiatric treatment facility for a proposal that involves an application to establish an inpatient psychiatric unit in an existing licensed acute care hospital
    - Michigan - Acquisition of a psychiatric hospital or replacement of a psychiatric hospital in new construction or contiguous space not currently licensed as part of the existing health facility
    - Oregon - Development of a new Oregon State Hospital facility

Public Comment Period

Break Out Session

Break out groups

Group 1	Group 2	Group 3
Jeannie Adams	Dr. Keith Berger	Paul Dreyer
Dr. Kathy Baker	Carrie Davis	Karen Cameron
Maribel Ramos	Shaila Camile Menees	Dr. Thomas Eppes, Jr.
Paul Hedrick	Amanda Dulin	Dr. Marilyn West
Michael Desjadon		Kyle Elliott

Break

Discussion

Wrap-Up and Next Steps

Meeting Adjournment

DBHDS

Governor Youngkin's *Right Help, Right Now* and status of Virginia Psychiatric Inpatient Beds

State Health Facilities Task Force

Nelson Smith, Commissioner
Department of Behavioral Health & Developmental Services

May 30, 2024

DBHDS

Governor Youngkin's *Right Help, Right Now* Plan

1. Ensure same-day care for individuals experiencing behavioral health crises
2. Relieve law enforcement's burden and reduce the criminalization of mental health
3. Develop more capacity throughout the system, going beyond hospitals, especially community-based services
4. Provide targeted support for substance use disorder and efforts to prevent overdose
5. Make the behavioral health workforce a priority, particularly in underserved communities
6. Identify service innovations and best practices in pre-crisis prevention services, crisis care, post-crisis recovery and support and develop tangible and achievable means to close capacity gaps

Pillar 1: Crisis

988 SUICIDE & CRISIS LIFELINE
24/7 CALL, TEXT, CHAT

Call Center
- *Standardized risk assessment*

Virginia 988:

Dispatch
- *Clinician or former 911 dispatcher*
- *Reviews call Conducts assessment*

Resolve on Phone

Mobile Crisis
- *Voluntary service*
- *Resolves 70% of calls*

30% of calls

911 Police • Fire • Medical EMERGENCY

911
- *Life threatening emergencies*
- *Backup to mobile crisis*

80% resolved on the phone through 988	70% resolved in the field through mobile crisis	65% discharged to the community from crisis receiving centers

- Crisis Now

988

New 988va.org website

- 988 is like 911 for mental health concerns.
- Anyone in mental distress can call or text 988 and trained crisis call center staff will help right away.
- Virginia averages about 8,000 calls per month
- About 80% of calls to 988 can be resolved on the phone

988 SUICIDE & CRISIS LIFELINE

- National and Virginia marketing is under-way to spread the word

The Behavioral Health Services of Virginia Mobile Crisis Response team works 24 hours a day, seven days a week helping people experiencing a mental health, substance use, or suicide crisis. – WTVR, July 23, 2023

Mobile Crisis

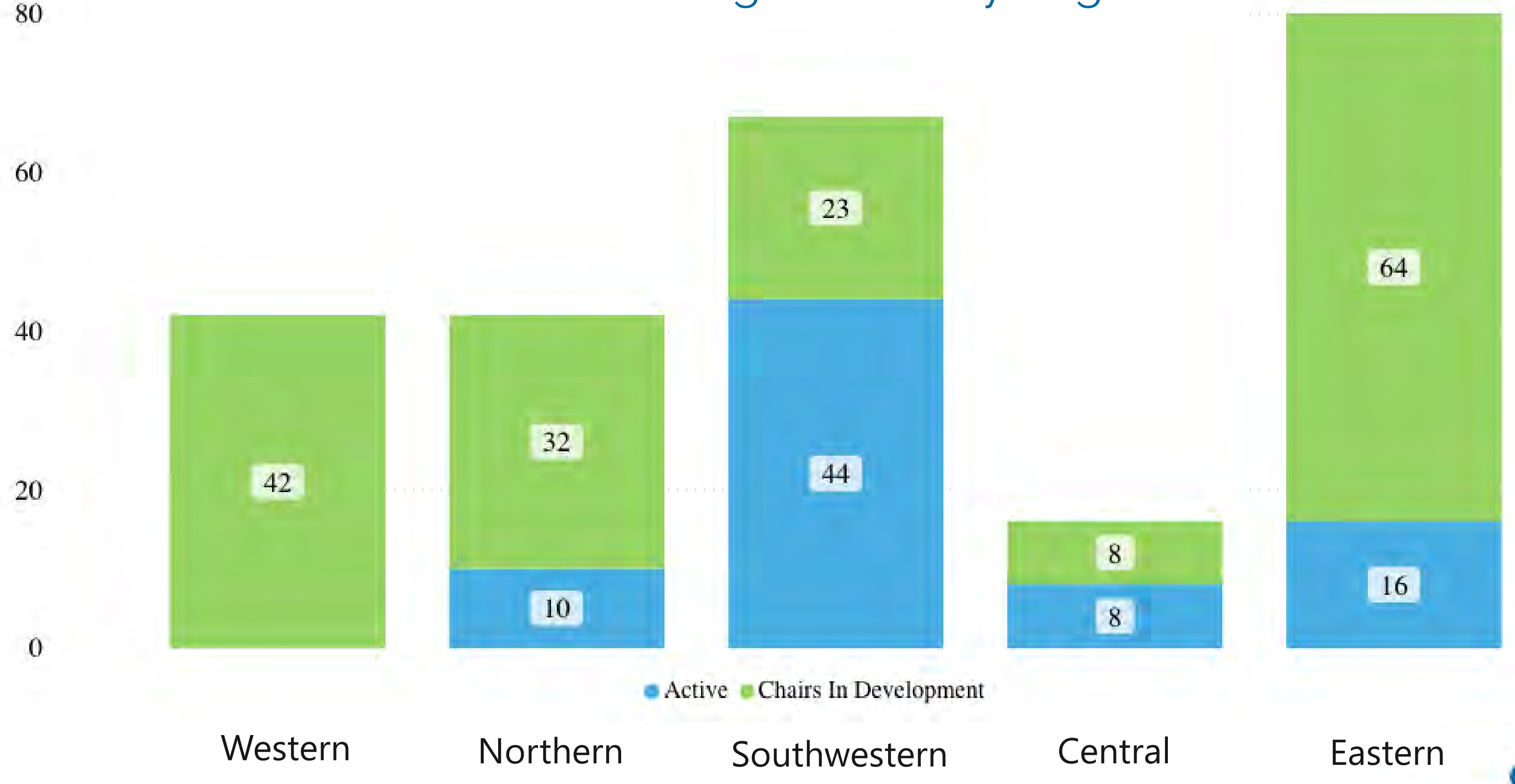
- Teams are deployed by 988 or regions to race directly to people in crisis.
- Mobile crisis teams can resolve 70% of the cases they handle
- Virginia now has 98 mobile crisis teams.
- The goal is 140 teams across Virginia

Pillar 1: Crisis

Crisis Receiving Centers/ Crisis Stabilization Units

- Community stabilization of mental health crises for walk-ins, ambulance, fire and police drop-offs
- Stabilize crises and safely discharge about 65% of individuals without needing longer-term inpatient care
- Virginia currently has 236 active beds and chairs, with 307 more in development
- More projects will be underway later in 2024

Crisis Receiving Centers by Region



WS 2: Alleviating Law Enforcement Burden	WS 3: Building Capacity	WS 4: Substance Use Disorders	WS 5: Workforce	WS 6: Innovation
• Advances in alternative custody and alternative transportation • Statewide surveys shows positive impacts of the alternative transportation program	• Developing strategies and seeking feedback on regulatory process, peer-to-peer support, evaluative and redesign conversations specific to hospital discharges and readiness, and emphasizing school-based services	• Increasing availability of Naloxone • Assessing the needs for community SUD services	• Collecting baseline data • Developing strategies, particularly in underserved areas	• Implementing legislation to mandate commercial insurance for mobile crisis and residential crisis • Reprocuring of the Medicaid MCOs

For more details about Right Help, Right Now: www.hhr.virginia.gov

DBHDS

Public and Private Psychiatric Bed ESTIMATES

Statewide Totals	
Private	2,075
State	1,379

63.6% of state beds are held by forensic patients

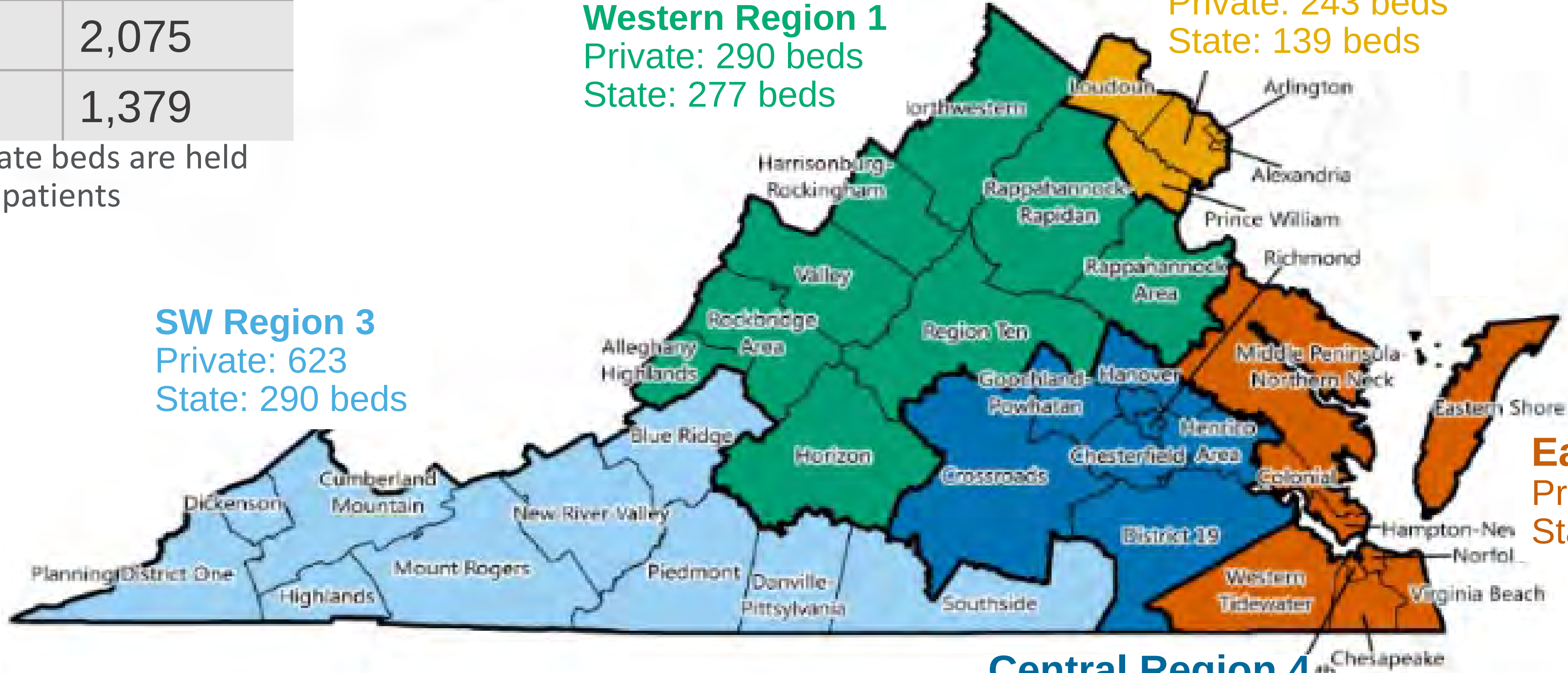
Western Region 1
Private: 290 beds
State: 277 beds

Northern Region 2
Private: 243 beds
State: 139 beds

SW Region 3
Private: 623
State: 290 beds

Central Region 4
Private: 553 beds
State: 366 beds

Eastern Region 5
Private: 366 beds
State: 307 beds



Notes: Private psych beds licensed by DBHDS as of April 2022; not all private beds may be open. 25 children's state beds divided equally among regions. Excludes max security; totals artificially high as forensic patients are included in the bed count

DBHDS

State Hospital Census (May 2024)

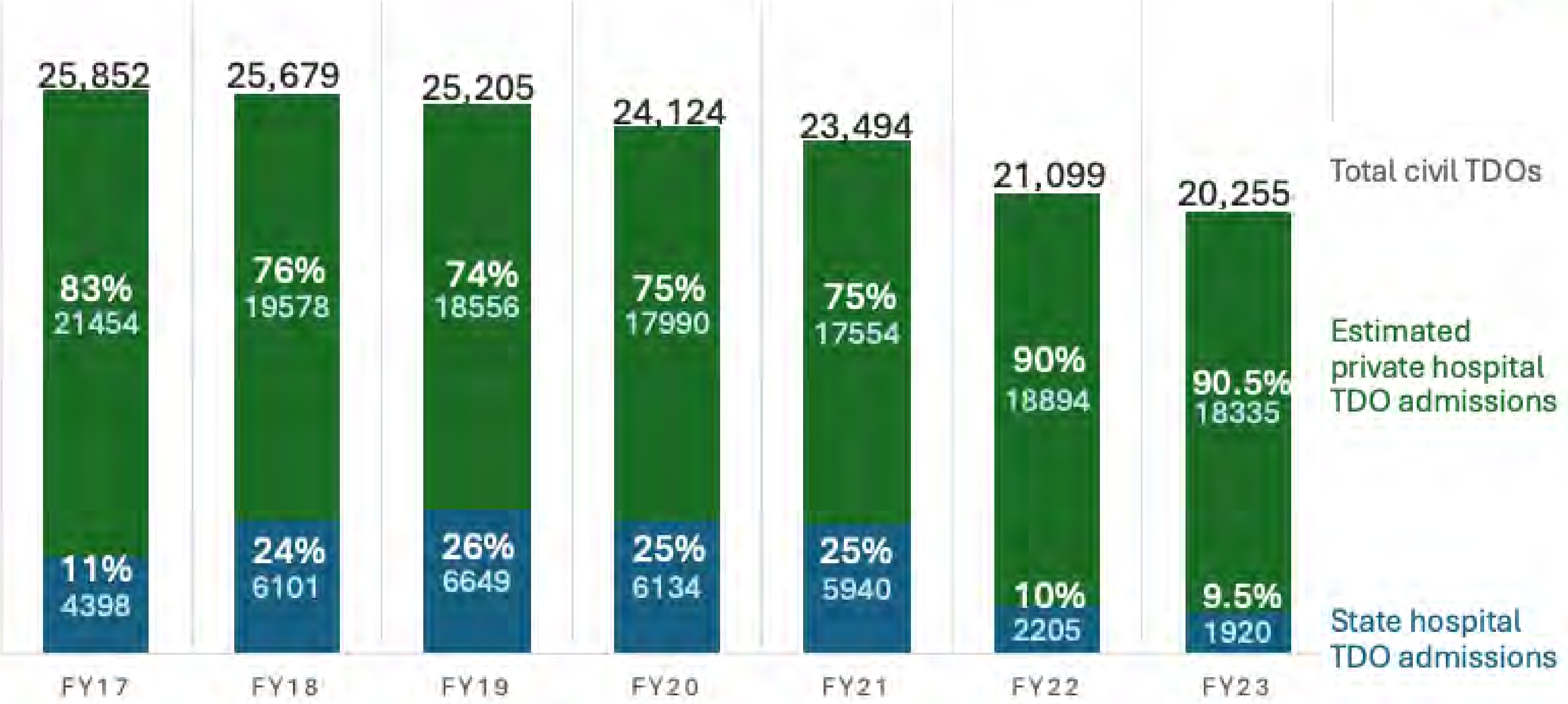
	Total Capacity	Current Census	% Current Utilization	% Current Forensic Beds
Catawba (adult and geriatric)	110	103	94%	26%
Central State (excluding VA's only max security unit)	166	165	99%	84%
Eastern State (adult and geriatric)*	302	270	96%	89%
Northern VA Mental Health Institute	134	135	101%	50%
Piedmont (all geriatric)	123	112	91%	17%
Southern VA Mental Health Institute	72	62	86%	77%
SW VA Mental Health Institute (adult and geriatric)	175	164	94%	27%
Western State	272	265	97%	72%
Commonwealth Center for Children & Adolescents	25	25	100%	--

* Eastern State has 22 of its 302 beds offline for a renovation project

DBHDS

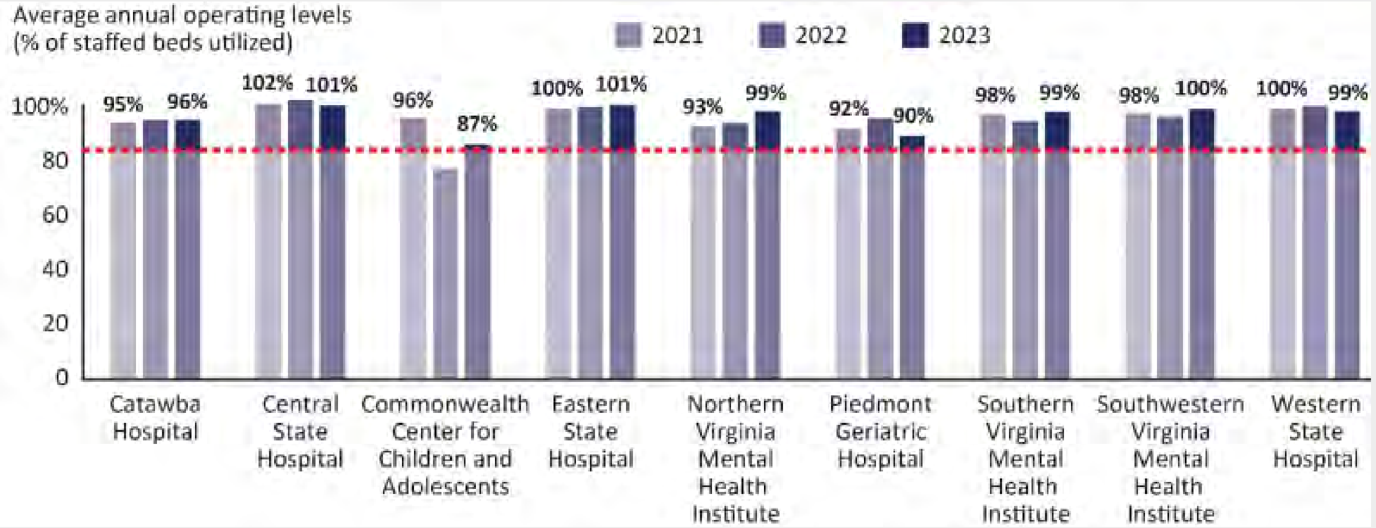
Temporary Detention Orders (TDOs)

- TDO numbers skyrocketed in 2014 with new Bed of Last Resort laws, but % of private TDO admissions dropped.
- Staffing crisis in the pandemic caused many state hospital beds to close.
- Since wait times for TDO beds began increasing, total numbers of TDOs has declined.
- Private hospitals average 18,265 TDO admissions over the last 5 years.
- Reduction of state hospital civil TDO admissions, but forensic admissions increased **93%** from FY14 – FY23.

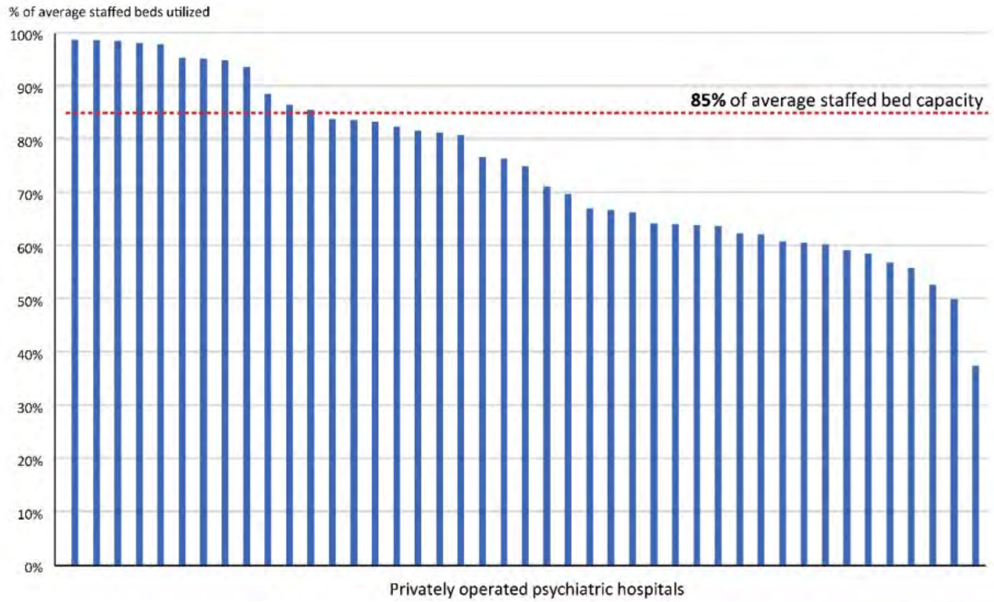


Psychiatric Bed Capacity

All state hospitals have been regularly operating OVER the industry standard for safe operating levels of 85%



About 2/3 of private psych hospitals operated BELOW 85% of staffed capacity



No Exclusionary Criteria

- Prohibit discrimination in admission based on the acuteness of behavioral health conditions.
- Contractual agreements may require acceptance of ECO/TDO patients (no exclusionary criteria) and participation in the Virginia Crisis Connect bed registry.

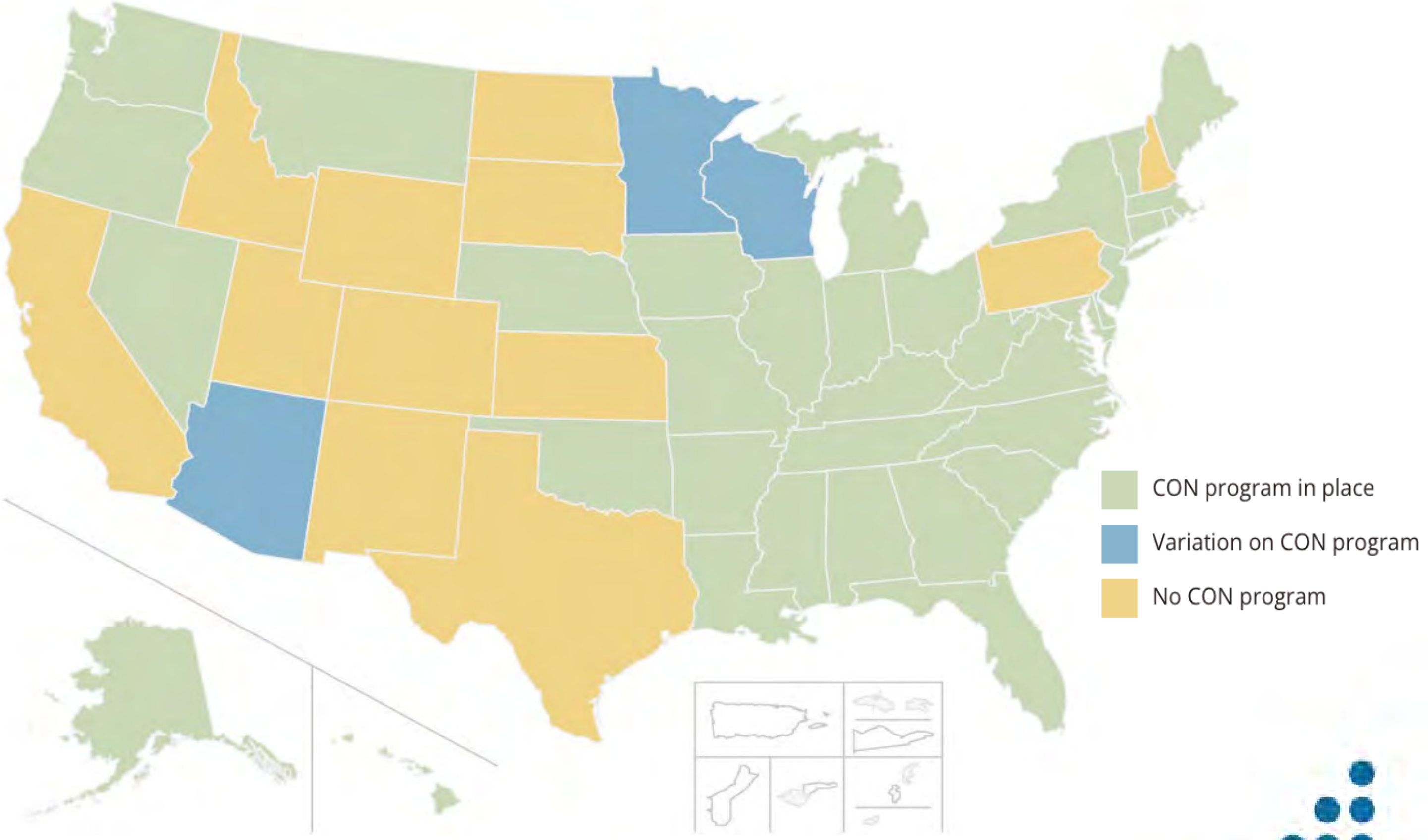
Oversight and Reporting

- Include reporting requirements to monitor and address cases where admission to behavioral health services is denied.
- Private hospitals shall regularly report any denial of admission of TDO patients/very acute behavioral health patients to DBHDS.

Nationwide COPN Overview

NCSL
NATIONAL CONFERENCE OF STATE LEGISLATURES

- 12 states have repealed COPN or allowed programs to expire
- 11 states specifically add psychiatric facilities as regulated under COPN
- 5 states regulate ICFs under COPN but do not specify mental illness or developmental disability (Iowa includes MI and DD)
- 4 states recently exempted mental health facilities from COPN review in varying extents



VIRGINIA HOSPITAL & HEALTHCARE ASSOCIATION

4200 INNSLAKE DRIVE, SUITE 203, GLEN ALLEN, VIRGINIA 23060-6772
P.O. BOX 31394, RICHMOND, VIRGINIA 23294-1394
(804) 965-1227 FAX (804) 965-0475

SUBMITTED ONLINE AT regulatory.comment@vdh.virginia.gov

May 23, 2024

Karen Shelton, MD
State Health Commissioner
Virginia Department of Health
P.O. Box 2448
Richmond, Virginia 23218-2448

Re: Public Comment to State Health Services Plan Task Force, May 30, 2024, Meeting

Dear Commissioner Shelton,

Thank you for the opportunity to submit this public comment to the State Health Services Plan (SHSP) Task Force in advance of its May 30, 2024, meeting. Members of the Task Force were notified that the Virginia Department of Health has established a mechanism for the members of the Task Force, their organizations, and the public, to submit comment for consideration by the Task Force to regulatory.comment@vdh.virginia.gov at least 5 days before the start of each meeting of the Task Force, and this public comment is submitted accordingly.

General Comment on Needed Updates to the SHSP

As an initial matter, we are grateful that the work of the Task Force is underway. The Task Force plays an important role in the COPN Program, including completing a number activities required by statute. Most notable of these required activities is the development of a comprehensive SHSP (formerly the "State Medical Facilities Plan" or "SMFP") for adoption by the Board of Health. The COPN law at Va. Code § 32.1-102.2:1 required the Task Force to develop recommendations for a comprehensive SHSP for adoption by the Board of Health by November 1, 2022. That work has not yet commenced, which is particularly troubling considering the SHSP/SMFP - a critical health planning document - has not been updated since 2009.

We understand that the Task Force is currently focused on recommendations for expedited review pursuant to Chapter 423 of the 2024 Acts of Assembly, but we urge you and the Task Force to not delay work on its recommendations for a comprehensive SHSP for adoption by the Board as required by law and we submit it should be a priority that can be undertaken in parallel with any work on expedited review.

VHHA Perspective on COPN and Behavioral Health Services

With respect to the Task Force's current work on expedited review, the Task Force has understandably focused on the challenges faced by the state hospitals and private hospitals and has heard from industry experts that the capacity and capabilities of psychiatric beds in the state, and access to them, is a multifaceted concern impacted in large part by a behavioral health care workforce shortage and increasingly complex patient care needs.

Unlike state hospitals, psychiatric services provided by private hospitals are regulated under COPN. These private hospitals accommodate the substantial majority of behavioral health inpatient admissions in the state. In FY22, private hospitals admitted 92% of all behavioral health patients, including 100% of all voluntary admissions and 87% of involuntary TDOs. In addition, in 2022, private hospitals saw 393,294 behavioral health emergency department visits equating to 13% of all visits in that year.

VHHA has historically supported the use of expedited review for certain projects that are typically non-contested and/or raise comparatively few health planning concerns. As it pertains to psychiatric projects, VHHA maintains that the existing process for COPN review does not appear to be creating a barrier to expanding available bed capacity:

- The high rate of approvals demonstrates that COPN review is not creating a barrier.
- The workforce shortage is the greatest barrier to expanding available bed capacity.

In many ways, COPN applications for psychiatric projects are a great example of how COPN works well:

- Hundreds of psychiatric beds have been added under COPN in the last ten years and no COPN application has been denied in that period.
- The last denial was in 2015, for a 40-bed psychiatric hospital on the grounds that it would have had a significant adverse impact on existing providers.
- The private hospitals for which these COPNs have been approved are treating the substantial majority of voluntary and involuntary patients in the Commonwealth.

Insufficient Time Has Been Allowed for Public Input on Proposed Options

The meeting materials for the May 30, 2024, meeting of the Task Force include a document titled "VDH Analysis on Potential Expedited and Psychiatric Process Changes," which sets forth a series of options for moving various psychiatric projects from standard review to expedited review. The analysis should be helpful for the Task Force to consider possible recommendations around which there may be consensus, but insufficient time has been allowed for thorough consideration of these options.

The materials were distributed on May 20, 2024, only seven business days prior to the meeting date and only two business days before public comments are due to the Task Force. The materials were not posted on Regulatory Town Hall and available to the public to prepare public comment until May 22, 2024, only one business day before public comments are due to the Task Force. <u>Due to the lack of appropriate notice, it would be premature for the Task Force to take any formal action to adopt any recommendations on these options at the May 30, 2024, meeting.</u>

Likewise, due to the lack of appropriate notice, VHHA is unable to provide specific responses to each of the various options presented. Doing so will require additional time to process this information with our members in an effort to determine whether there is consensus to definitively support any one of them.

<u>If the Task Force is considering moving any psychiatric projects to expedited review, then there are, however, some bright lines we can draw in response to the options presented based upon VHHA's policy position on COPN</u>:

- VHHA would not support moving the establishment of psychiatric *facilities* or psychiatric *services* from standard review to expedited review and would be opposed to any such recommendation by the Task Force. Such projects are not non-contested and can raise health planning concerns.
- Any project that is contested by a member of the public, to include a competing applicant, should not be eligible for expedited review and should be moved into standard review.
- All other provisions of COPN law and regulations applicable to COPN applications, approvals, and enforcement under standard review must likewise apply to expedited review (e.g., calculation and application of fee amounts, determination that the proposed project is consistent with the provisions of the State Health Services Plan, capital expenditure requirements, conditions on certificates, etc.).

VHHA support for expedited review is limited to certain projects that are non-contested and/or raise comparatively few health planning concerns. Accordingly, expedited review should not be considered for competitive projects such as establishing outpatient surgical hospitals, expanding operating room capacity, or establishing or expanding CT/MRI/PET imaging. Further, as reflected in legislative mandates, the Task Force is to develop recommendations on expedited review of project types "that are generally non contested and present limited health planning impacts" and it is submitted that such competitive projects would go well beyond the scope of the Task Force.

We look forward to the Task Force's May 30, 2024, meeting and continued deliberation regarding options for expedited review. We anticipate that, depending upon the outcome of these discussions, VHHA will submit further public comment in response to the options that VDH has presented. Within these options we are hopeful that the Task Force will find a reasonable path forward that includes appropriate safeguards to prevent a negative impact on the ability of existing acute psychiatric providers to continue to provide historic levels of services to patients in the community, including Medicaid or other indigent patients.

Again, we are grateful for the work that you and the Task Force are undertaking to improve Virginia's COPN Program. The COPN Program is a critical policy function of the Commonwealth and reforms to modernize this program present a great opportunity to produce greater efficiencies and generate even better outcomes.

Thank you for your consideration of this public comment.

Sincerely,

R. Brent Rawlings
Senior Vice President & General Counsel

Analysis on Potential Expedited and Psychiatric Process Changes

Legislative Mandate: Chapter 423 of the 2024 Acts of Assembly mandates the State Health Services Plan Task Force to develop recommendations on expedited review of project types subject to certificate of public need (COPN) requirements that are generally non contested and present limited health planning impacts. The Task Force shall also create recommendations regarding:

1. What facilities and projects listed in § 32.1-102.1:3 of the Code of Virginia should be added to the expedited review process;
2. Criteria that should apply to any project types subject to expedited review; and
3. A framework for the application and approval process of such projects.

Project types for consideration shall include:

1. Increases in inpatient psychiatric beds;
2. Relocation of inpatient psychiatric beds;
3. Introduction of psychiatric services into an existing medical care facility; and
4. Conversion of beds in an existing medical care facility to psychiatric inpatient beds.

Potential Expedited and Psychiatric Process Changes:

Option	How it works now	How it would change	Alternative?	Vote Support, Oppose, No Position, or Undecided
1. Move psychiatric beds from full COPN review to expedited review*	Psychiatric beds are required to be requested using the full 190-day COPN process during the C application cycle.	Psychiatric beds could be requested at any time and would be reviewed during a 45-day review period.		
2. Move the establishment of a	In order to establish a psychiatric facility, a	A person could apply for a COPN for a		

psychiatric facility from full COPN review to expedited review*	person is required to apply during the C application cycle for the full 190-day review process.	psychiatric facility at any time and would be reviewed during the 45-day review period.		
3. Allow facilities that already provide psychiatric services to add beds using the expedited review process*	All facilities, whether they already have psychiatric beds or not, are required to submit an application using the full 190-day COPN process during the C application cycle.	Facilities with psychiatric beds would be able to request beds through the 45-day expedited process.		
4. Allow facilities to relocate psychiatric beds through the expedited process*	All facilities are required to obtain a COPN through the full 190-day review cycle to relocate beds. If the bed relocation is 10 beds or 10%, whichever is less, and when the cost of relocation is less than $5 million, facilities may apply for a COPN through the 45-day expedited review process.	Facilities could obtain a COPN through the 45-day expedited review process to relocate any number of beds.		
5. Require facilities to request a COPN in	Facilities are able to convert psychiatric	Facilities would be required to request a		

order to convert beds from psychiatric beds to non-psychiatric beds*	beds to non-psychiatric beds freely (this does not apply to beds added through the RFA process).	COPN in order to convert beds from psychiatric beds to non-psychiatric beds.		
6. Allow facilities that already provide psychiatric services to establish a new psychiatric facility through the expedited review process*	All projects involving a new psychiatric facility are required to obtain a COPN.	Facilities that already provide psychiatric services would be able to utilize the expedited process in order to establish a new psychiatric facility under its current hospital license.		
7. Move the addition of psychiatric services from full COPN review to expedited review*	A facility is required to obtain a COPN in order to add new psychiatric services that have not been provided in the previous 12 months.	To add new psychiatric services, a facility would be able to apply at any time and the application would be reviewed during the 45-day review cycle.		
8. Extend expedited review from 45 days to 90 days	Expedited review projects adhere to a 45-day review cycle that begins when an application is submitted and ends with a decision from the Commissioner by the 45th day.	Expedited review projects would adhere to a 90-day review cycle that begins when an application is submitted and ends with a decision from the Commissioner by the 90th day.		

9. Require the Commissioner to condition expedited review applications on providing a specified level of charity care*	The Commissioner does not have the authority to condition expedited review projects.	The Commissioner would be required to condition all approved expedited project COPNs on providing a specified level of charity care.		
10. Require the Commissioner to condition psychiatric projects on the acceptance of Temporary Detention Orders (TDOs)*	The Commissioner does not have the authority to condition COPNs on the acceptance of TDOs.	The Commissioner would be required to condition all approved psychiatric project COPNs on the acceptance of TDOs.		
11. Require any project that is contested to be pulled from expedited review and placed into full review	There is no requirement regarding contested projects in the regulation.	Any project that is contested by a member of the public would be pulled out of expedited review and placed into full review.		
12. Allow for members of the public to request a hearing for an expedited project	There is no public participation requirement in the regulation.	Members of the public would be able to request a public hearing for an expedited project to be held during the 45-day review cycle.		
13. Add the following COPN projects to the expedited review	Any facility interested in adding any items from the list are required to obtain a	Facilities that already provide the applicable services for the corresponding listed		

process for existing medical care facilities that already provide the applicable existing service:* • Medical-surgical beds • Hospice beds • Psychiatric beds • Rehabilitation beds • Cardiac catheterization laboratories • Operating rooms • CT machines • MRI machines • PET machines • Linear accelerators	COPN through the 190-day process.	items may request a COPN through the expedited review process to add any of the projects listed.		
14.				

15.				
16.				

17.				

*Requires a legislative change

MERCATUS CENTER
George Mason University

TESTIMONY

Virginia's Certificate-of-Public-Need Law: A Comparison with Other States

Matthew D. Mitchell, PhD
Senior Research Fellow
Director, Project for the Study of American Capitalism
Mercatus Center at George Mason University

Virginia House of Delegates
Health, Welfare, and Institutions Committee

April 18, 2018

Chairman Orrock, Vice Chairman Garrett, and distinguished members of the House of Delegates Health, Welfare, and Institutions Committee:

My name is Matthew Mitchell. I am an economist at the Mercatus Center at George Mason University where I am an adjunct professor of economics. In recent years, my colleagues and I have been studying certificate-of-need laws in healthcare. I am grateful for the opportunity to discuss our findings with you today.

INTRODUCTION TO CON LAWS

Certificate-of-need (CON) laws—or certificate-of-public-need (COPN) laws, as they are called in Virginia—require healthcare providers wishing to open or expand a healthcare facility to first prove to a regulatory body that their community needs the services the facility would provide. The regulations are typically *not* designed to assess a provider's qualifications or safety record. Other regulations such as occupational licensing aim to do that. Instead, the process aims to determine whether or not a service is economically viable and valuable. The process for obtaining a CON or COPN can take years and tens or even hundreds of thousands of dollars in preparation costs.[1] While these regulations appear to benefit incumbent providers by limiting their competition, their effects on patients and taxpayers have generally been found to be negative. This helps explain why antitrust authorities at the Federal Trade Commission (FTC) and at the US Department of Justice (DOJ) have long taken the position that these rules are anticompetitive. In a joint report from 2004, for example, the FTC and DOJ declared,

> The Agencies believe that, on balance, CON programs are not successful in containing health care costs, and that they pose serious anticompetitive risks that usually outweigh their purported economic benefits.[2]

---

[1] Kent Hoover, "Doctors Challenge Virginia's Certificate-of-Need Requirement," *Business Journals*, June 5, 2012.
[2] Federal Trade Commission and US Department of Justice, *Improving Health Care: A Dose of Competition*, July, 2004, 22. For more recent examples, see *Competition in Healthcare and Certificates of Need, Hearing before a Joint Session of the Health and Human Services Committee of the State Senate and the CON Special Committee of the State House of Representatives of the General Assembly of the State of Georgia*, 149th Gen. Assemb. (2007) (statement of Mark J. Botti, Chief, Litigation I Section, US

In the remainder of my testimony today, I will offer a brief history of CON laws and an overview of the economic evidence that has led many, including the FTC and DOJ, to conclude that these laws pose anticompetitive risks to consumers and taxpayers. Finally, I compare Virginia's COPN program to the CON programs in surrounding states.

A BRIEF HISTORY OF CERTIFICATE-OF-NEED REGULATION

More than four decades ago, Congress passed and President Ford signed the National Health Planning and Resources Development Act of 1974.[3] The statute enabled the federal government to withhold federal funds from states that failed to adopt CON regulations in healthcare.

New York had already enacted the first CON program in 1964; by the early 1980s, with the federal government's encouragement, every state except Louisiana had implemented some version of a CON program.[4] Policymakers hoped these programs would restrain healthcare costs, increase healthcare quality, and improve access to care for poor and underserved communities.

In 1986—after Medicare changed its reimbursement practices and as evidence mounted that CON laws were failing to achieve their stated goals—Congress repealed the federal act, eliminating federal incentives for states to maintain their CON programs.[5] Since then, 15 states, representing about 40 percent of the US population, have done away with their CON regulations, and many have pared them back.[6] A majority of states still maintain CON programs, however, and vestiges of the National Health Planning and Resources Development Act can be seen in the justifications that state legislatures offer in support of these regulations.[7]

THE ECONOMICS OF CERTIFICATE-OF-NEED REGULATION

Unfortunately, by limiting supply and undermining competition, CON laws may undercut each of the laudable aims that policymakers desire to achieve with CON regulation. In fact, research shows that CON laws *fail* to achieve the goals most often given when enacting such laws. These goals include

1. ensuring an adequate supply of healthcare resources,
2. ensuring access to healthcare for rural communities,
3. promoting high-quality healthcare,
4. ensuring charity care for those unable to pay or for otherwise underserved communities,

---

Department of Justice, Antitrust Division); Federal Trade Commission and US Department of Justice, *Joint Statement of the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice to the Virginia Certificate of Public Need Working Group*, October 2015; Federal Trade Commission and US Department of Justice, *Joint Statement of the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice on Certificate-of-Need Laws and South Carolina House Bill 3250*, January 2016; *Statement of the Federal Trade Commission to the Alaska Senate Committee on Labor & Commerce on Certificate-of-Need Laws and Alaska Senate Bill 62, Hearing before the Senate Labor and Commerce Standing Committee*, 30th Leg. (2018) (statement of Daniel Gilman, Attorney Advisor, Federal Trade Commission, Office of Policy Planning).

[3] National Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641, 88 Stat. 2225 (1975) (codified at 42 U.S.C. §§ 300k-300n-5), repealed by Pub. L. No. 99-660, § 701, 100 Stat. 3799 (1986).

[4] Matthew D. Mitchell and Christopher Koopman, "40 Years of Certificate-of-Need Laws across America," Mercatus Center at George Mason University, September 27, 2016.

[5] Patrick John McGinley, "Beyond Health Care Reform: Reconsidering Certificate of Need Laws in a 'Managed Competition' System," *Florida State University Law Review* 23, no. 1 (1995).

[6] New Hampshire is the state that most recently repealed its CON program, which it did in the summer of 2016. Mitchell and Koopman, "40 Years of Certificate-of-Need Laws across America."

[7] According to Virginia's CON website, "The program seeks to contain health care costs while ensuring financial viability and access to health care for all Virginia at a reasonable cost." Virginia Department of Health, Licensure and Certification, "Certificate of Public Need Program," accessed April 6, 2018, http://www.vdh.virginia.gov/licensure-and-certification/the-certificate-of-public-need-program/.

5. encouraging appropriate levels of hospital substitutes and healthcare alternatives, and
6. restraining the cost of healthcare services.[8]

We have quite a bit of information to help us predict what would happen if other states such as Virginia were to repeal their laws because 15 states have repealed their CON programs. Economists have been able to use modern statistical methods to compare outcomes in CON and non-CON states to estimate the effects of these regulations. These methods control for factors such as socioeconomic conditions that might confound the estimates. Table 1 summarizes some of this research. It is organized around the stated goals of CON laws.

TABLE 1. SUMMARY OF RESEARCH ADDRESSING THE GOALS OF CERTIFICATE-OF-NEED (CON) LAWS IN HEALTHCARE

Question	Answer	Research
1. Do CON programs help ensure an adequate supply of healthcare resources?	No. CON regulation explicitly limits the establishment and expansion of healthcare facilities and is associated with fewer hospitals, ambulatory surgical centers, dialysis clinics, and hospice care facilities. It is also associated with fewer hospital beds and decreased access to medical imaging technologies. Residents of CON states are more likely than residents of non-CON states to leave their counties in search of medical services. Regression analysis by Stratmann and Koopman (2016) suggests that a Virginia without COPN would have 42 percent more hospitals than it currently has.	Ford and Kaserman (1993); Carlson et al. (2010); Stratmann and Russ (2014); Stratmann and Baker (2017); and Stratmann and Koopman (2016)
2. Do CON programs help ensure access to healthcare for rural communities?	No. CON programs are associated with fewer hospitals overall, but also with fewer rural hospitals, rural hospital substitutes, and rural hospice care facilities. Residents of CON states must drive farther to obtain care than residents of non-CON states. Stratmann and Koopman's research suggests that a Virginia without COPN would have 44 percent more rural hospitals than it currently has.	Cutler, Huckman, and Kolstad (2010); Carlson et al. (2010); and Stratmann and Koopman (2016)
3. Do CON programs promote high-quality healthcare?	Most likely not. While early research was mixed, more recent research suggests that deaths from treatable complications following surgery and mortality rates from heart failure, pneumonia, and heart attacks are all statistically significantly higher among hospitals in CON states than hospitals in non-CON states. Also, in states with especially comprehensive programs such as Virginia, patients are less likely to rate hospitals highly.	Stratmann and Wille (2016)
4. Do CON programs help ensure charity care for those unable to pay or for otherwise underserved communities?	No. There is no difference in the provision of charity care between states with CON programs and states without them, and CON regulation is associated with greater racial disparities in access to care.	DeLia et al. (2009) and Stratmann and Russ (2014)
5. Do CON programs encourage appropriate levels of hospital substitutes and healthcare alternatives?	No. CON regulations have a disproportionate effect on new hospitals and nonhospital providers of medical imaging services. Research also finds that states such as Virginia that have an ambulatory surgical center–specific CON (COPN) have, on average, 14 percent fewer total ambulatory surgical centers.	Stratmann and Baker (2017) and Stratmann and Koopman (2016)

[8] Each of these goals was first articulated in the National Health Planning and Resources Development Act of 1974.

6. Do CON programs help restrain the cost of healthcare services?	No. By limiting supply, CON regulations increase per-service and per-procedure healthcare costs. Even though CON regulations might reduce overall healthcare spending by reducing the quantity of services that patients consume, the balance of evidence suggests that CON laws actually increase total healthcare spending.	Mitchell (2016) and Bailey (2016)

Sources: James Bailey, "Can Health Spending Be Reined In through Supply Constraints? An Evaluation of Certificate-of-Need Laws" (Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, August 2016); Melissa D. A. Carlson et al., "Geographic Access to Hospice in the United States," *Journal of Palliative Medicine* 13, no. 11 (2010); David M. Cutler, Robert S. Huckman, and Jonathan T. Kolstad, "Input Constraints and the Efficiency of Entry: Lessons from Cardiac Surgery," *American Economic Journal: Economic Policy* 2, no. 1 (2010); Derek DeLia et al., "Effects of Regulation and Competition on Health Care Disparities: The Case of Cardiac Angiography in New Jersey," *Journal of Health Politics, Policy and Law* 34, no. 1 (2009); Jon M. Ford and David L. Kaserman, "Certificate-of-Need Regulation and Entry: Evidence from the Dialysis Industry," *Southern Economic Journal* 59, no. 4 (1993); Matthew D. Mitchell, "Do Certificate-of-Need Laws Limit Spending?" (Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, September 2016); Thomas Stratmann and Matthew C. Baker, "Barriers to Entry in the Healthcare Markets: Winners and Losers from Certificate-of-Need Laws" (Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, August 2017); Thomas Stratmann and Christopher Koopman, "Entry Regulation and Rural Health Care: Certificate-of-Need Laws, Ambulatory Surgical Centers, and Community Hospitals" (Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, February 2016); Thomas Stratmann and Jacob W. Russ, "Do Certificate-of-Need Laws Increase Indigent Care?" (Working Paper No. 14-20, Mercatus Center at George Mason University, Arlington, VA, July 2014); Thomas Stratmann and David Wille, "Certificate-of-Need Laws and Hospital Quality" (Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, September 2016).

CERTIFICATE-OF-PUBLIC-NEED REGULATION IN VIRGINIA

Virginia's COPN program is one of the more comprehensive CON programs in the country. Among many other things, Virginia's program regulates acute hospital beds, ambulatory surgical centers, medical imaging technologies, rehabilitation centers, and psychiatric care facilities. Table 2 shows the number of technologies and procedures regulated by Virginia and surrounding states. Nationally, the average number of technologies and procedures regulated is 12, among CON states the number is 16, and among states in the Mid-Atlantic region it is 18. Virginia regulates 20 technologies and procedures.

TABLE 2. CERTIFICATE-OF-PUBLIC-NEED IN VIRGINIA AND CERTIFICATE-OF-NEED IN SURROUNDING STATES

State	Number of Technologies and Procedures Regulated
Delaware	8
Kentucky	21
Maryland	17
New Jersey	26
North Carolina	25
Ohio	1
Pennsylvania	0
South Carolina	22
Tennessee	23
Virginia	20
West Virginia	20
District of Columbia	28

Regional average	18
National average among CON states	16
National average among all states	12

Source: Christopher Koopman and Anne Philpot, "Certificate of Need Laws in 2016," Mercatus Center at George Mason University, September 27, 2016. West Virginia's number was updated by the author to reflect changes in 2017.

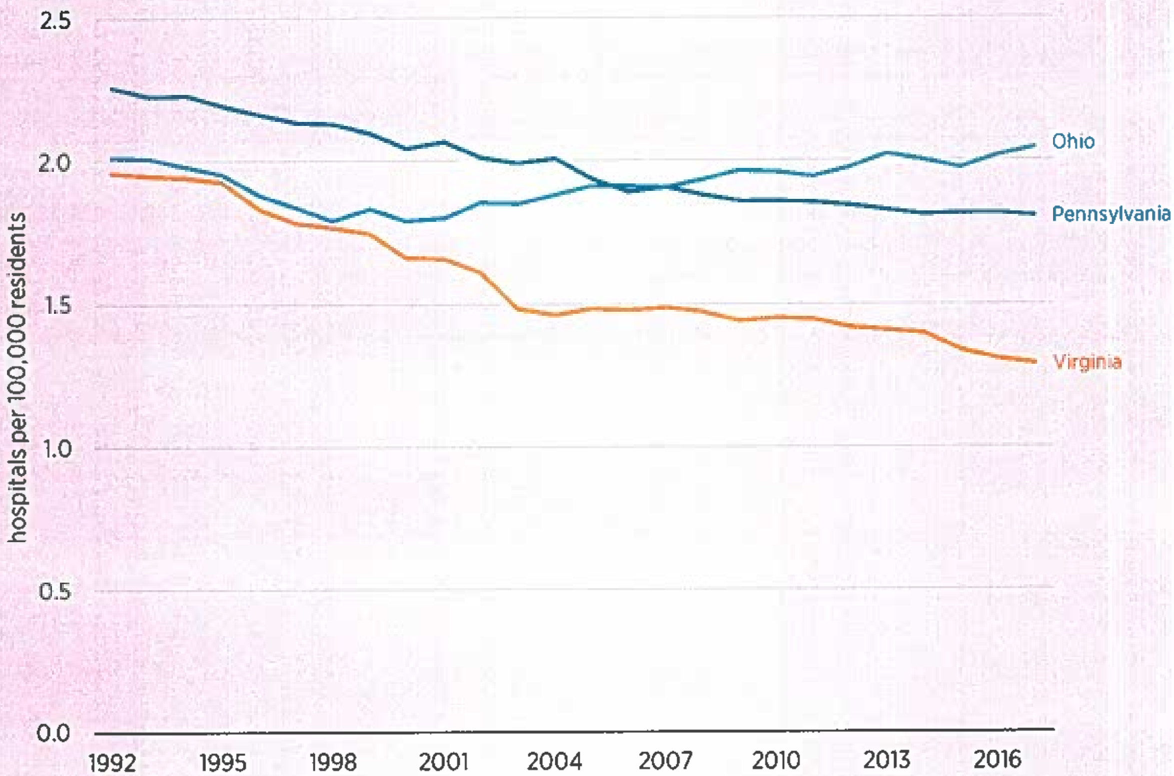
All of the evidence reviewed in table 1 was derived from point estimates in regression analyses. Though a regression is one of the best ways to assess the effect of a policy while controlling for other factors, it is not an intuitive concept for many. So to better illustrate the data behind these results, I have created four charts that show changes over time in healthcare facilities per capita in Virginia and the two states in the region with limited or no CON programs, Ohio and Pennsylvania. These states are illustrative because they are comparable in location, size, and socioeconomic makeup. The differences that do exist between these states would lead one to believe that Virginia has the advantage. For example, per capita personal income is higher in Virginia than in either Ohio or Pennsylvania, while poverty rates are lower in Virginia than in either of the other two states.[9]

As I have mentioned, Virginia regulates 20 different procedures and technologies. In contrast, Ohio's CON program regulates just one item, nursing home and long-term care beds, while Pennsylvania has no CON program at all, having repealed its program in 1996.

[9] For per capita income, see Bureau of Economic Analysis, "Personal Income, Population, Per Capita Personal Income, Disposable Personal Income, and Per Capita Disposable Income (SA1, SA51)," accessed April 10, 2018, https://www.bea.gov/iTable/iTable.cfm?reqid=70&step=1&isuri=1&acrdn=6#reqid=70&step=1&isuri=1&7022=21&7023=0&7033=-1&7024=non-industry&7025=0&7026=39000,42000,51000&7001=421&7027=2017,2016,2015,2014,2013,2012,2011,2010,2009,2008,2007,2006,2005,2004,2003,2002,2001,2000,1999,1998,1997,1996,1995,1994,1993,1992&7028=-1&7031=0. For poverty rates, see Jessica L. Semega, Kayla R. Fontenot, and Melissa A. Kollar, *Income and Poverty in the United States: 2016*, (Washington, DC: US Census Bureau, 2017).

Figure 1 shows hospitals per 100,000 residents. In Ohio, the number of hospitals per 100,000 residents rose slightly. Over the same period, in both Virginia and Pennsylvania, the number has fallen. In Virginia, however, the decline was sharper, falling 34 percent, compared with a 20 percent decline in Pennsylvania. On a per-resident basis, Virginia now has seven-tenths as many hospitals as Pennsylvania and a little more than six-tenths as many as Ohio.

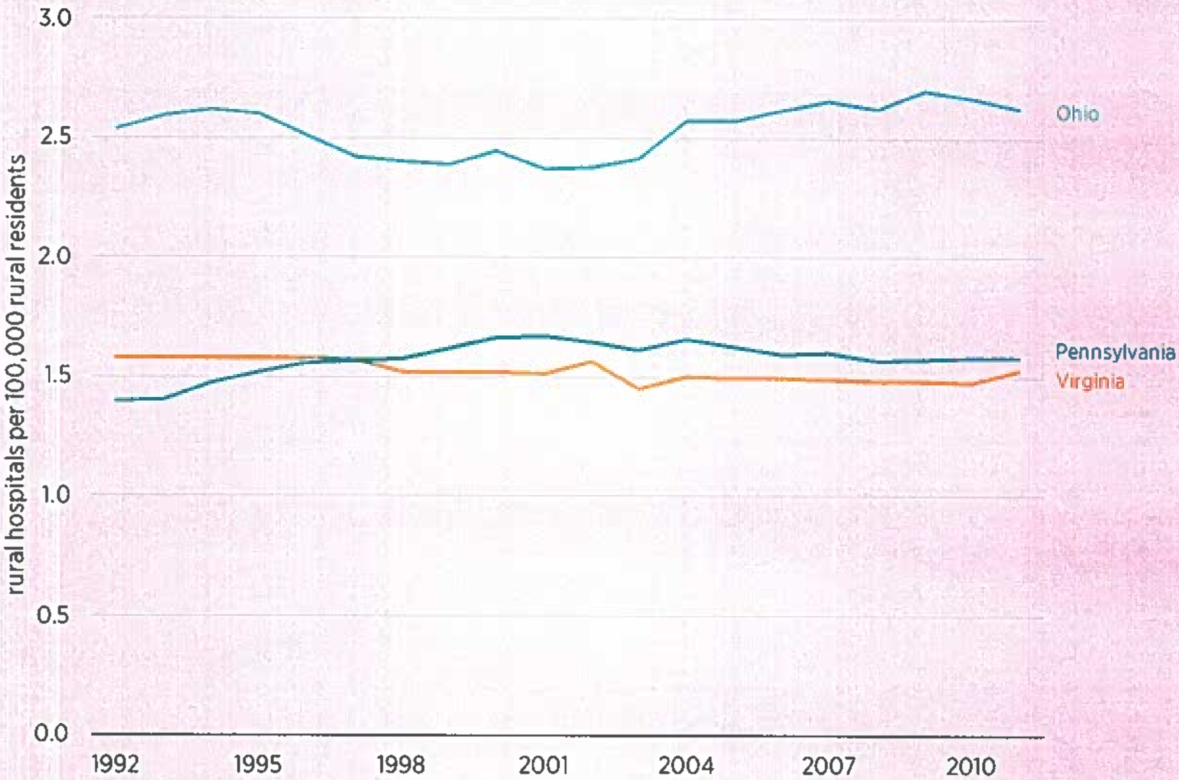
FIGURE 1. HOSPITALS PER 100,000 RESIDENTS



Sources: Provider Data: US Centers for Medicare & Medicaid Services, "Provider of Services Current Files," accessed April 10, 2018, https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Provider-of-Services/. Population Data: US Census Bureau, "State Population Totals and Component of Change: 2010–2017," accessed April 20, 2018, https://www.census.gov/data/tables/2017/demo/popest/state-total.html.

Figure 2 shows rural hospitals per 100,000 rural residents. Virginia not only has fewer rural hospitals per rural resident than either of the other two states; it is the only one of the three that has seen a decline in that figure over time.

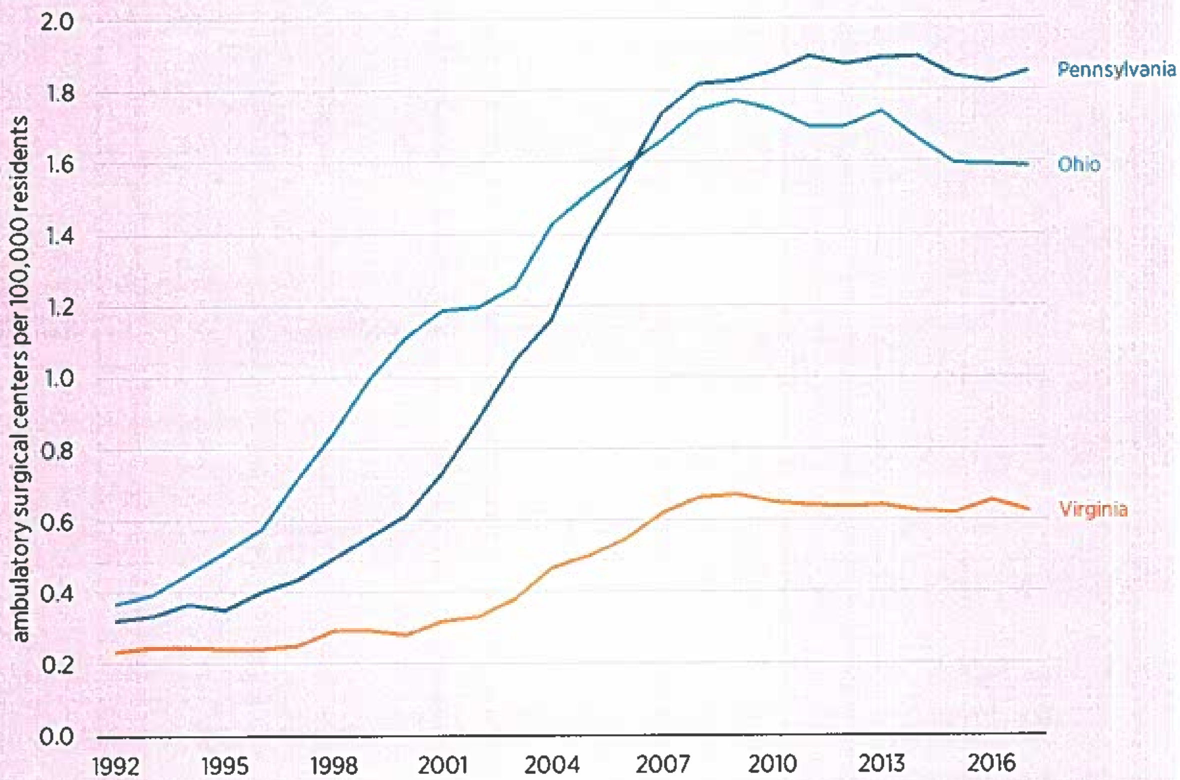
FIGURE 2. RURAL HOSPITALS PER 100,000 RURAL RESIDENTS



Sources: Provider Data: US Centers for Medicare & Medicaid Services, "Provider of Services Current Files," accessed April 10, 2018, https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Provider-of-Services/. Population Data: US Census Bureau, "Population and Housing Unit Estimates Tables," accessed April 10, 2018, https://www.census.gov/programs-surveys/popest/data/tables.html.

Figure 3 shows ambulatory surgical centers (ASCs) per 100,000 residents over time. In all three states, the number of these centers per resident has been rising. In Virginia—the only state of the three that regulates ASCs through COPN—the rise has been the most modest. On a per capita basis, Virginia has about one-third as many ASCs as Pennsylvania and four-tenths as many as Ohio.

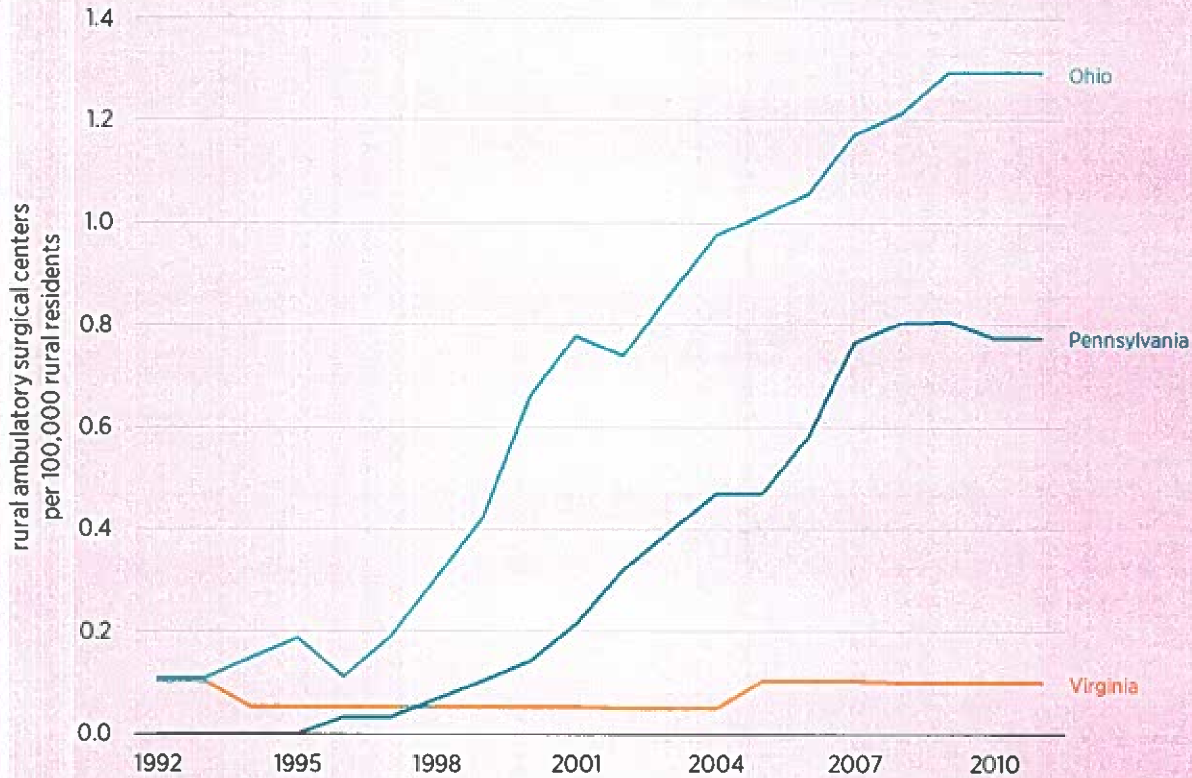
FIGURE 3. AMBULATORY SURGICAL CENTERS PER 100,000 RESIDENTS



Sources: Provider Data: US Centers for Medicare & Medicaid Services, "Provider of Services Current Files," accessed April 10, 2018, https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Provider-of-Services/. Population Data: US Census Bureau, "State Population Totals and Component of Change: 2010–2017," accessed April 20, 2018, https://www.census.gov/data/tables/2017/demo/popest/state-total.html.

Figure 4 shows rural ASCs per 100,000 rural residents. Virginia is the only state of the three that has seen a decline in this figure over time. On a per-rural-resident basis, Virginia has one-eighth as many rural ASCs as Pennsylvania and one-twelfth as many as Ohio.

FIGURE 4. RURAL AMBULATORY SURGICAL CENTERS PER 100,000 RURAL RESIDENTS



Sources: Provider Data: US Centers for Medicare & Medicaid Services, "Provider of Services Current Files," accessed April 10, 2018, https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Provider-of-Services/. Population Data: US Census Bureau, "Population and Housing Unit Estimates Tables," accessed April 10, 2018, https://www.census.gov/programs-surveys/popest/data/tables.html.

None of these results should be surprising. CON laws are a restriction on the supply of facilities and services, and economic theory suggests that supply restrictions limit access to services while raising costs and undermining quality. Indeed—as shown in table 1—that is exactly what empirical studies of CON have consistently found.

CONCLUDING REMARKS

Given the substantial evidence that CON laws do not achieve their stated goals, one may wonder why these laws continue to exist in so much of the country. The explanation seems to lie in the special-interest theory of regulation.[10] Specifically, CON laws perform a valuable function for incumbent providers of healthcare services by limiting their exposure to new competition. Indeed, recent evidence

[10] This theory holds that regulations exist as a way to limit competition or raise rivals' costs, or both. See George J. Stigler, "The Theory of Economic Regulation," *Bell Journal of Economics and Management Science* 2, no. 1 (April 1, 1971): 3–21; Ernesto Dal Bó, "Regulatory Capture: A Review," *Oxford Review of Economic Policy* 22, no. 2 (June 20, 2006): 203–25; Matthew D. Mitchell, *The Pathology of Privilege: The Economic Consequences of Government Favoritism* (Arlington, VA: Mercatus Center at George Mason University, 2014).

suggests that special interests are able to use political donations to increase the odds that their CON requests will be granted.[11] This aspect of CON laws helps explain why economists as well as antitrust authorities have long argued that these regulations are anticompetitive and harmful to consumers.

For those who are interested in further details on the effects of CON on spending patterns, I have also attached my paper, "Do Certificate-of-Need Laws Limit Spending?" Like all Mercatus Center research, it has been through a rigorous, double-blind peer review process.

Thank you again for the opportunity to share my research with you. I look forward to answering any questions you may have.

Sincerely,

Matthew D. Mitchell, PhD

Senior Research Fellow
Director, Project for the Study of American Capitalism
Mercatus Center at George Mason University

ATTACHMENT

"Do Certificate-of-Need Laws Limit Spending?" (Mercatus Working Paper)

[11] Thomas Stratmann and Steven Monaghan, "The Effect of Interest Group Pressure on Favorable Regulatory Decisions: The Case of Certificate-of-Need Laws" (Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, 2017).

Do Certificate-of-Need Laws Limit Spending?

Matthew D. Mitchell

September 2016

MERCATUS WORKING PAPER

MERCATUS CENTER
George Mason University
3434 Washington Blvd., 4th Floor, Arlington, Virginia 22201
www.mercatus.org

Matthew D. Mitchell. "Do Certificate-of-Need Laws Limit Spending?" Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, September 2016.

Abstract

In 35 states, certificate-of-need (CON) laws in health care restrict the supply of medical services. These regulations require providers hoping to open a new healthcare facility, expand an existing facility, or purchase certain medical equipment such as an MRI machine or a hospital bed to first prove to a regulatory body that their community needs the service in question. The approval process can be time consuming and expensive, and it offers incumbent providers an opportunity to oppose the entrance of new competitors. However, it was originally hoped that these laws would, among other things, reduce healthcare price inflation. In this brief, I review the basic economic theory of a supply restriction like CON, then summarize four decades of empirical research on the effect of CON on healthcare spending. There is no evidence that CON regulations limit healthcare price inflation and little evidence that they reduce healthcare spending. In fact, the balance of evidence suggests that CON laws are associated with higher per unit costs and higher total healthcare spending.

JEL codes: D72, D78, H75, I1, L51

Keywords: economics of regulation, certificate of need, supply constraints, regulatory capture, special interests, rent-seeking

Author Affiliation and Contact Information

Matthew D. Mitchell
Senior Research Fellow, Mercatus Center at George Mason University
Director, Project for the Study of American Capitalism
Adjunct Professor of Economics, George Mason University
mmitchell@mercatus.gmu.edu

Acknowledgments

I thank Scott Eastman and Mohamad Elbarasse for their excellent research assistance on this paper. I am also grateful to Nita Ghei, Christina Behe, and two anonymous reviewers for numerous helpful suggestions. I alone am responsible for any errors or omissions that remain.

Check for updates

Received: 3 November 2023 | Accepted: 11 April 2024

DOI: 10.1002/soej.12698

SYMPOSIUM ARTICLE

Southern Economic Journal WILEY

Certificate-of-Need laws in healthcare: A comprehensive review of the literature

Matthew D. Mitchell

Knee Regulatory Research Center, West Virginia University, Morgantown, West Virginia, USA

Correspondence
Matthew D. Mitchell, Knee Regulatory Research Center, West Virginia University, Morgantown, WV, USA.
Email: matthew.mitchell1@mail.wvu.edu

Abstract

Certificate-of-Need (CON) laws limit the supply of healthcare services in about two-thirds of U.S. states. The regulations require those who wish to open or expand their facilities to first prove that their services are needed. Once encouraged by the federal government, Congress eliminated the inducement in the 1980s and since then several states have either pared their CON programs back or eliminated them altogether. To date, there have been 128 academic assessments of CON laws and together these papers contain over 450 tests. In this paper, I review this literature, organizing the results around the most common rationales for CON laws. The accumulated evidence is overwhelming that CON laws do not achieve their purpose. Instead, the balance of evidence suggests that these regulations increase spending, reduce access to care, undermine quality, and fail to ensure care for underserved populations.

KEYWORDS

Certificate of Need, healthcare, regulation

JEL CLASSIFICATION

I11, I18, H75

1 | INTRODUCTION

A Certificate-of-Need (CON) law requires anyone hoping to open a new facility, expand an existing facility, or acquire certain equipment to first prove to a regulator that the new capacity is needed. Though the laws date back to the first decades of the 20th century and have been applied to various markets, New York was the first state to adopt a CON law in healthcare in 1964 (McGinley, 1995). A decade later, the federal government enacted the National Health Planning and Resources Development Act (NHPRDA), which encouraged states to adopt CON regulations by threatening to withhold federal funds from any state without such a program (NHPRDA, 1975). The threat never materialized as Congress repeatedly postponed the financial penalty (Conover & Bailey, 2020, p. 2). But the Act achieved its goal of encouraging state CON programs: By the 1980s, nearly every state in the country had instituted a CON program in healthcare (Mitchell et al., 2021).

The intellectual origins of healthcare CONs date to 1959, when UCLA health researcher Milton Roemer published a coauthored study reporting a positive correlation between the number of hospital beds available per capita and the number of used hospital days per capita (Shain & Roemer, 1959). The finding became known as "Roemer's Law" and was shortened to the pithy characterization that "in an insured population, a hospital bed built is a hospital bed filled (Page, 2001)." The phenomenon can be characterized as an example of supplier-induced demand, in which physicians use their informational advantage to encourage unneeded care. Auster and Oaxaca (1981) have argued that in the absence of supplier-induced demand, the "only purpose [of CON] is to prevent competition through which the efficient may take business away from the nonefficient" (Auster & Oaxaca, 1981, p. 340).

In encouraging CON, lawmakers hoped hospitals would acquire fewer beds, fill them with fewer patients, and spend less money. The main purpose of CON, therefore, was to reduce healthcare expenditures by rationing care. The authors of the NHPRDA also apparently believed that CON would restrain spending by encouraging "the use of appropriate alternative levels of healthcare, and for the substitution of ambulatory and intermediate care" which, presumably, would be less-costly than other modes of care (NHPRDA, 1975, 88:2). Beyond costs and expenditures, the authors of the NHPRDA also hoped to ensure an adequate supply of care, especially for "underserved populations," including "those which are located in rural or economically depressed areas" (NHPRDA, 1975, 88:3). Finally, they hoped to "achieve needed improvements in the quality of health services" (NHPRDA, 1975, 88:4). These goals—cost containment, greater access (especially for underserved populations), and quality improvement—continue to be widely-shared aims of health policy. They also constitute convenient buckets into which the empirical CON research can be sorted.

If the NHPRDA had been Congress's last word on CON, then research on the regulation's effects might have come to an end once CON was universally adopted. By the mid-1980s, however, Congress had concluded that CON laws were not achieving their goals and so the federal CON mandate was repealed in 1986 (Pub. L. 99-660, § 701, 100 Stat. 3799, 1986). Almost immediately, 12 states eliminated their CON programs and, in time, others followed suite. Over time, the trend has been for states to gradually pare their programs back either by eliminating CON requirements for certain categories of medical equipment, by raising the dollar threshold at which a CON is required, or by exempting certain areas, such as rural counties, from the requirement. This history has yielded wide variation in CON regulation across time and states (Mitchell et al., 2021). And this, in part, explains why CON laws have been so widely studied.

2 | CON TODAY

Today, 39 states and the District of Columbia require a CON for at least one healthcare service or technology.[1] In many of these states, however, the CON regime is quite limited. For example, Arizona, Minnesota, and New Mexico only require CONs for ambulance services. Indiana, Montana, Ohio (and soon, South Carolina) only require CONs for nursing homes.[2] Hawaii, which requires a CON for 28 services and technologies, regulates more activities than any other state.

The most-common CON requirement is for nursing home beds, found in 34 states (including DC). The next-most-common requirements are for psychiatric services (31 states), new hospitals (29 states), and intermediate care facilities for those with intellectual disabilities (28 states). The least-common CONs are for ultrasounds (required in 2 states) and subacute services (only regulated by Illinois).

In about half of CON states, the decision to grant a CON is made by a board whose members are appointed by the governor; in the rest, the decision is made by governor-appointed officials. Employees of incumbent providers are typically allowed to serve on this board, earning the regulation the moniker "competitor's vetoes" (Ohlhausen & Luib, 2015; Sandefur, 2015). In all but six CON states, incumbent providers are allowed to participate in the CON process and object to the application of a would-be competitor.[3] Even when competitors do not object, statutes and regulations typically require regulators to deny CONs if they believe the applicant's services will duplicate an existing service, virtually guaranteeing a local monopoly.

We lack systematic data on application costs, the length of review, or approval rates. And all of these factors would be good candidates for future study. Anecdotal evidence suggests, however, that the CON process is typically long and expensive. It can take years and can cost providers tens or even hundreds of thousands of dollars in opportunity costs (Hoover, 2012). One analysis found that the approval in Virginia was 51%, in Georgia it was 57%, and in Michigan it was 77% (Stratmann & Monaghan, 2017). Another found that when Georgia competitors object to an application it adds about 520 days to the wait time for a final decision, while each additional party who objects adds another 129 days (Denson & Mitchell, 2023).

3 | METHODS

The goal of this study is to identify and classify every peer-reviewed original empirical analysis of healthcare CON laws. To identify relevant papers, I relied on previous overviews,[4] internet

[1]Some states, such as Wisconsin, cap the total number of pieces of equipment. For example, they may cap the total number of beds in the state at 20,000. If the cap is set low enough it will be *more* restrictive than a CON regulation because there is no way for a provider to request to exceed the cap. If, on the other hand, the cap is set high enough (as is currently the case in Wisconsin), then the cap will be non-binding. Some researchers treat caps as equivalent to CONs. But given the fact that most caps are currently non-binding, I will ignore these regulations for the remainder of this piece.

[2]On October 3, 2023, South Carolina Governor Henry McMaster signed Senate Bill 164. It immediately eliminated the CON requirement for all services except for hospitals and nursing homes. The requirement for hospitals will be phased out over 3 years, though it will not be enforced in counties that currently lack hospitals.

[3]These are Indiana, Louisiana, Michigan, Nebraska, New Jersey, and New York. For more details, see Cavanaugh et al. (2020, 4, 61, 75, 89, 117, 131).

[4]Conover and Bailey's (2020) review was especially helpful.

and library search engines, and helpful suggestions from others.[5] I primarily focused on academic publications, but I also included a handful of academic-quality analyses by government agencies such as the Federal Trade Commission that appeared to have gone through a peer-review process. I only focused on original empirical analyses; I ignored literature reviews or studies that employed previous estimates to illustrate the effects of CON. I made no judgments about the quality of the empirical tests, though by only including peer reviewed material, I believe my approach ensured a minimal threshold for quality.

Most studies included more than one test of CON and so my unit of observation is each empirical test, rather than each paper. This allows me to characterize the literature in more detail and to avoid using the vague catch-all "mixed results" if a paper has multiple regressions, some positive and some negative. I do often code results as "negligible or insignificant," however. In these cases, I rely on the authors' assessments to make these judgments about economic and statistical significance. In some cases, it was not always clear how one can define a distinct "test" and I did have to use some discretion. My general approach was to define a test as a unique dependent and independent variable combination, without regard to mathematical transformation. For example, if a paper reported a regression of the form $Y = a + b^{*}\text{CON}$ and another regression of the form $\ln(Y) = a + b^{*}\text{CON}$, then I just considered this as one test since the underlying variables were identical in both tests.

As the analysis proceeded, it became clear that there were certain patterns to the literature and the patterns that emerged helped inform the organization of this review. Occasionally, some tests fit a pattern without the author's knowing or emphasizing it. For example, some papers assess the effect of CON on efficiency by looking at output/input. In these tests, a higher output/input is generally interpreted as a "good" result because it implies greater technical efficiency. In my own test of bed shortages during COVID, coauthored with Thomas Stratmann, we found that there were higher bed utilization rates in CON states than in non-CON states (Mitchell & Stratmann, 2022). At the time, we did not view this as a "good" result, focusing instead on the fact that hospitals were more likely to run out of beds in CON states than in non-CON states. Nevertheless, since several other authors interpret higher output/input to be a good result, I feel compelled to categorize our finding as such to be consistent.

Finally, I should note that this approach does lead to some double counting. For example, one way that authors assess quality is to see if CON is associated with a costly or unwarranted treatment. If a paper finds that CON encourages an unwarranted treatment then I will code it as being associated with greater utilization of a procedure (good) *and* lower quality (bad), even though there was only one empirical test involved.

4 | RESULTS

My approach identifies 128 papers that together contain 458 tests.[6] The bulk of these tests focus on the four aims of CON identified in the NHPRDA: reducing spending, increasing access,

[5]Angela Erickson of the Pacific Legal Foundation generously shared a quite helpful spreadsheet with many references. If you are aware of any articles that I have missed, please share them with me: matthew.mitchell1@mail.wvu.edu.
[6]For full coding see: https://docs.google.com/spreadsheets/d/1-xZKWcEzqnptxPtkS7h6_EwapMfwub_o/edit?usp=sharing&ouid=102779922122058875161&rtpof=true&sd=true.

enhancing quality, and encouraging care for underserved populations. My summary begins with those four categories. To these we can add one other area of the literature with an obvious normative interpretation: The effects of CON on competition. Then I turn to several sets of tests with less obvious (but still interesting) normative implications. These tests focus on provider volume, provider profits, and the political economy of CON. For the sake of brevity, I will not detail the results of each test in the body of this paper but I do report them in the Table A1.

Before digging into the specific subcategories of the literature, however, let me briefly summarize the broad results of those tests that have relatively obvious normative implications.[7] Figure 1 summarizes these tests. It shows that among 433 tests with an obvious normative implication, a slight majority (212) associate CON with a "bad" outcome. These bad outcomes include higher spending, less access, lower quality, diminished care for underserved populations, or less competition. The next-most-common result, found in 157 tests (36%) was a neutral or insignificant result. Finally, 54 tests (12%) associate CON with a "good" outcome such as less spending or higher quality. Tests associating CON with a bad outcome are four times more common than tests associating CON with a good outcome. With these broad patterns established, I now turn to more specific findings, starting with spending.

4.1 | CON and spending

Do CON laws restrain spending? The first stated aim of CON was to reduce spending. In total, 107 tests assess the effect of CON on spending. But authors approach question in three different ways: spending per service, which I will denote by the shorthand $/Q; spending per person, or $/capita; and efficiency, as measured by output/input. I will take each in turn.

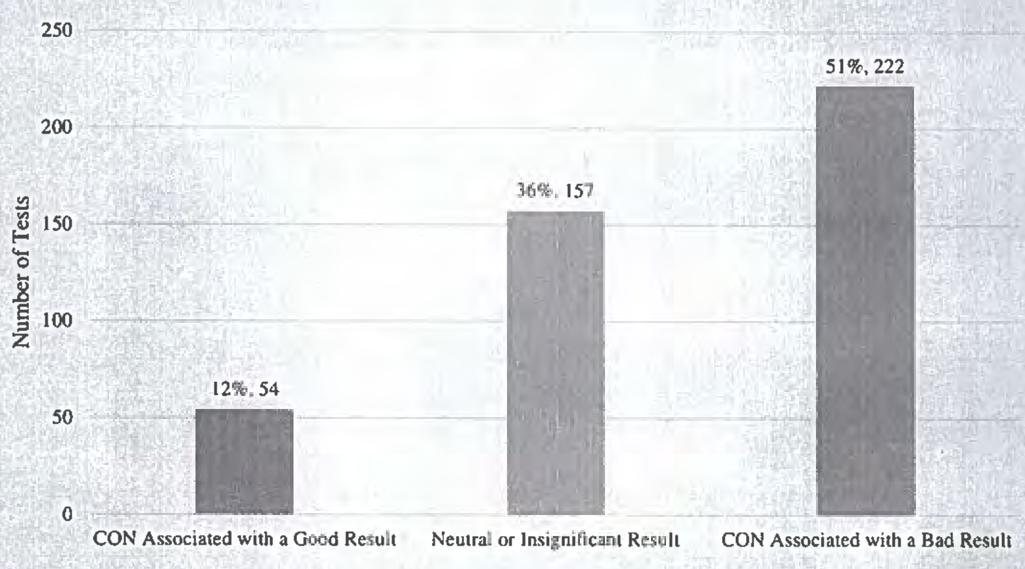


FIGURE 1 Summary of tests with an obvious normative implication. [Color figure can be viewed at wileyonlinelibrary.com]

[7]As will become clear, I don't always agree with the normative interpretations here. But enough researchers evidently do that it is relatively straightforward to categorize results as "good," "bad," or "neutral."

4.1.1 | CON and spending per service rendered ($/Q)

Forty-five tests assess the effect of CON on charges, reimbursements, prices, or per-unit costs. What sets these tests apart from others is that they look at spending *per service rendered*, or $/Q. This is an intuitive way to think about spending because it is analogous to a market price, which is expressed in per-unit or per-service terms. It is also a normatively appealing way to assess the regulation because we typically want to know the financial sacrifice per service rendered.

Standard economic theory offers two reasons to suppose that CON regulation might increase spending per service. First, CON is a supply restriction. As Ford and Kasserman explained nearly three decades ago, "the economic effect [of CON] is to shift the supply curve of the affected service back to the left," and "the effect of such supply shifts is to raise... [the] equilibrium price" (Ford & Kaserman, 1993, pp. 783–784). Second, because of its anticompetitive properties, CON seems likely to permit some degree of pricing power. The empirical literature on spending per service, summarized in Figure 2, is consistent with these expectations.

Among the 45 tests that assess the effects of CON on spending per service, 27 of them—60%—find CON is associated with higher spending per service. Just three tests (7%) associate CON with lower spending per service. Fifteen tests (33%) find insignificant or negligible results. For every test associating CON with lower spending per service, there are nine associating it with higher spending per service.

4.1.2 | CON and spending per capita ($/capita)

Fifty-two tests assess the effect of CON on spending per patient or per person ($/capita). If $/Q is analogous to a market price, then $/capita is analogous to total expenditures, adjusted for the population.[8] That is, it indicates the total amount spent, irrespective of the quantity of services rendered. The $/capita metric seems to align with the initial goals of CON advocates. And in

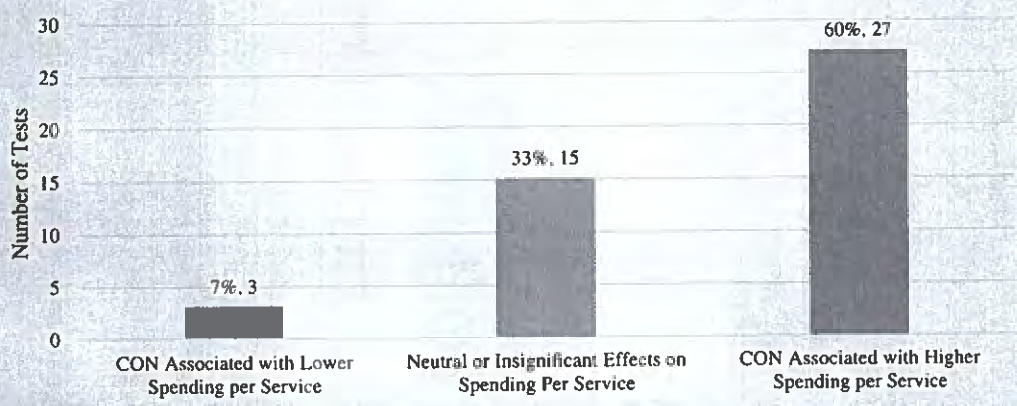


FIGURE 2 Tests assessing the effect of CON on spending per service ($/Q). [Color figure can be viewed at wileyonlinelibrary.com]

[8]In some cases, the line between $/Q and $/capita is not obvious. This is especially true in the case of home health agencies, where the quantity of services rendered is often measured in patient days. In these cases, I coded these as $/capita studies, though others might as easily consider them $/Q studies.

contrast with $/Q, it is more plausible that CON might reduce $/capita. After all, an extremely restrictive CON that did not permit *any* healthcare resources, would result in $0/capita. Under less extreme regimes, we can expect CON to reduce $/capita in cases where the service in question is elastically demanded. In this case, the Q-reducing effect of CON will dominate the $/Q-increasing effect of CON (Bailey, 2018a; Bailey & Hamami, 2019; Ford & Kaserman, 1993; Mitchell, 2016). Most healthcare services, however, are thought to be inelastically demanded (Ringel et al., 2002). So even this theoretically possible effect of CON seems unlikely.

In contrast with the $/Q metric, the $/capita metric has a weaker connection to welfare. A reduction in expenditures per capita is only desirable in cases where marginal services are unwarranted or not cost-effective. As we will see when we consider the quality literature below, this is sometimes the case. However, CON is often applied to procedures and technologies that are thought to be desirable on the margin such as burn care, psychiatric care, substance abuse services, neo-natal intensive care, and hospice care. In short, while less spending per *service* is clearly desirable, it is not always the case that less spending per *person* is desirable. With these caveats in mind, let's turn to the data.

Figure 3 summarizes this subset of the literature. Among the 52 tests, the most-common finding, obtained in 23 tests (44%), associated CON with greater spending per capita. The next-most-common finding is a negligible or insignificant result (21 tests, 40%). Finally, eight tests, representing 15% of the sample, associate CON with lower spending per capita. For each test associating CON with less spending per person there are about three that associate it with more spending per person.

4.1.3 | CON and efficiency (output/input)

Ten tests assess the effect of CON on efficiency as measured by output/input. These tests look at whether inputs such as labor or capital are more intensely used in the presence of the regulation. Theory offers no clear prediction with these tests. On one hand, by limiting the number of healthcare resources, CON might result in greater utilization of each resource, permitting providers to realize economies of scale. On the other, by undermining competition, CON might make providers inattentive to cost containment, resulting in greater x-inefficiency (Leibenstein, 1966; Robinson, 2011; Stensland et al., 2010). Like spending per capita, this metric

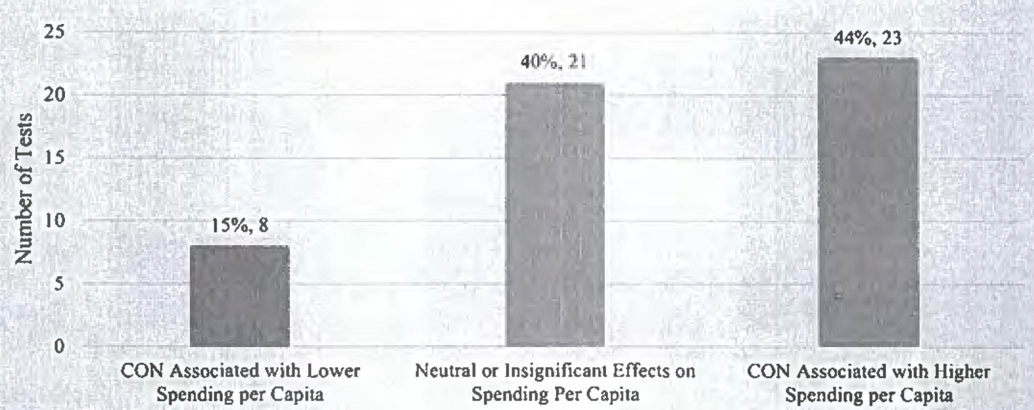


FIGURE 3 Tests assessing the effect of CON on spending per capita ($/Capita). [Color figure can be viewed at wileyonlinelibrary.com]

is also not an especially useful gauge of welfare, but it does give us a sense of how CON affects technical (if not economic) efficiency. The empirical literature, shown in Figure 4, reflects this ambiguity. Four tests associate CON with greater output/input. Four associated it with lower output/input, and two tests find negligible or insignificant results.

4.1.4 | Summary of CON and spending

Overall, the results cast doubt on the main rationale for CON. Most tests associate CON with either more spending or less efficiency and for every one test that associates CON with better spending outcomes, there are nearly four that associate it with worse outcomes. What's more, the results are more mixed in the $/capita and output/input tests where the normative interpretation is weakest but more consistently bad in the $/Q tests where the normative implications are clearest.

4.2 | CON and access

Do CON laws improve access to care? This is the most-studied effect of CON. In total, 190 tests examine whether CON laws impede or enhance access to care. The literature takes two distinct approaches to this question, however: "availability tests" and "utilization tests."

4.2.1 | CON and availability of services

Eighty-three tests measure access by looking at the availability of healthcare services. Some count the number of service providers or units of medical technology per capita. Some measure how far patients must travel to obtain care or how long patients must wait until they can be served. The important distinction with these tests is that they look at the availability of healthcare services, not at whether these services are used.

The theoretical expectation here is *relatively* straightforward. As a supply restriction, one would expect CON to reduce the overall availability of healthcare resources. It is possible,

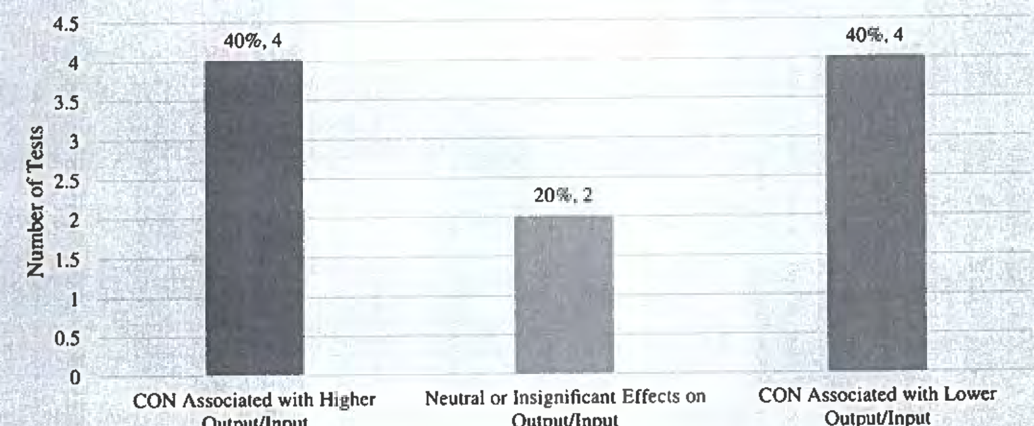


FIGURE 4 Tests assessing the effect of CON on output/input. [Color figure can be viewed at wileyonlinelibrary.com]

however, to imagine scenarios in which CON might increase the availability of *some* specific resources. For example, if CON applies to certain technologies or capital expenditures and not to others, or if regulators are more restrictive with some investments than others, then we might expect to see the latter become more available.

Note that this possibility is consistent with both the public interest theory and the special interest theories of regulation. On the one hand, publicly spirited regulators might throttle costly or ineffective care in hopes of encouraging more efficient or effective modes. On the other, special interests might seek to restrict their competition or raise their rivals' costs and this might make the special interest's services relatively more abundant (Salop & Scheffman, 1983; Tullock, 1967).

As shown in Figure 5, the empirical literature on CON and availability of care is lopsided. Of the 83 tests, 65 (78%) associate CON with diminished availability of services. Twelve tests (14%) find negligible or inconclusive results. And just six tests (7%) associate CON with greater availability of resources.

4.2.2 | CON and the utilization of services

The other common way to assess access is to see if CON correlates with the utilization of services. Here, too, it is reasonable to expect CON will tend to reduce the utilization of services by restraining supply. As with availability, though, it is possible that CON may increase the utilization of some services if it restrains the use of substitutes. Moreover, because healthcare is inelastically demanded, patients may still seek care even if it is costly or difficult to obtain. The results, shown in Figure 6, are consistent with this ambiguity. In total, 107 tests assess the effect of CON on utilization of services, and 60 (56%) find negligible or statistically insignificant effects of CON on utilization. Thirty-four tests (32%) associate CON with diminished utilization of services. And 13 tests (12) associate CON with increased utilization of services.

4.3 | CON and quality

Do CON laws improve the quality of care? CON advocates often make the case that CON ensures quality. How? The most-common rationale relates to the quality-volume relationship.

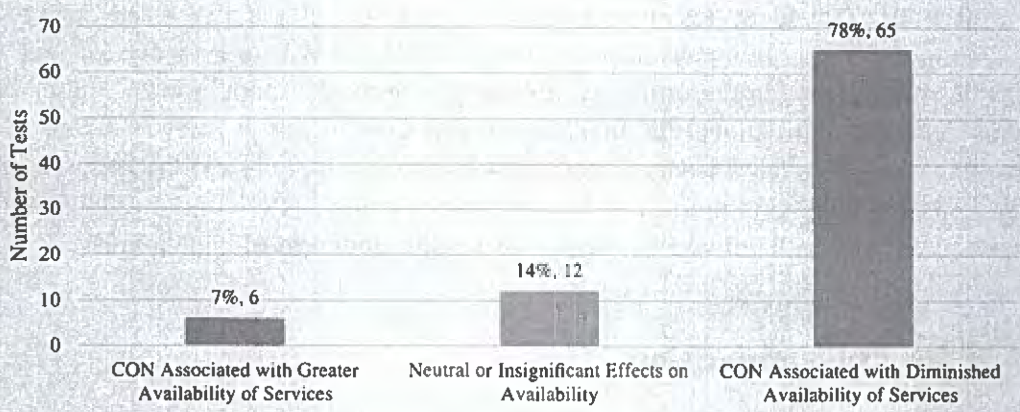


FIGURE 5 Tests assessing the effect of CON on availability of services. [Color figure can be viewed at wileyonlinelibrary.com]

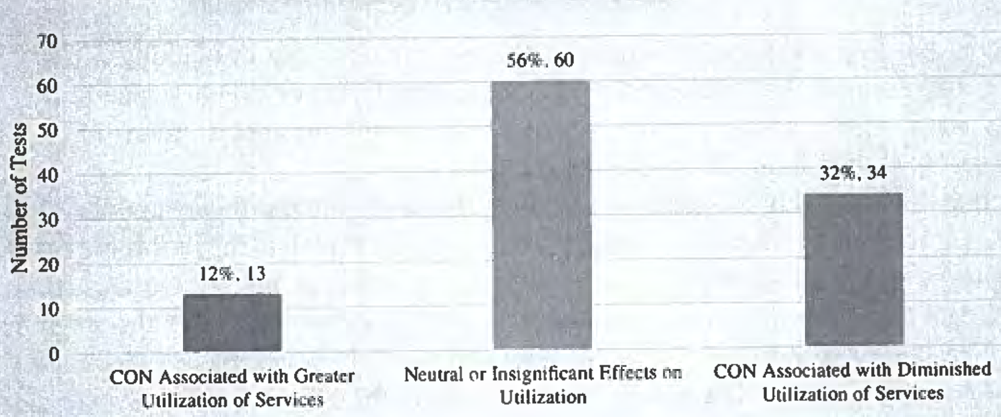


FIGURE 6 Tests assessing the effect of CON on utilization of services. [Color figure can be viewed at wileyonlinelibrary.com]

It is well documented that providers who frequently perform a procedure tend to get better at it (it is possible, of course, that causality could run in the opposite direction; especially competent providers may be in especially high demand). If CON results in fewer providers, and if each provider ends up doing more procedures, then it is possible that it might indirectly enhance quality. On the other hand, competition tends to enhance quality as well. And so it is possible that by undermining competition, CON will undermine quality. What do the data say?

One-hundred-and-fourteen tests assess the effect of CON on quality. One common technique is to see if CON correlates with outcome measures such as mortality rates, readmission rates, or infection rates. Another is to see if CON discourages the use of unwarranted procedures (in this case, what will be coded here as a "good" quality outcome will be coded above as a bad "volume" outcome). Figure 7 summarizes this literature. Of 114 tests, 52 (46%) associate CON with diminished quality of care. Fort-four (39%) find either neutral or insignificant effects of CON on quality. And 18 tests, (16%) associate CON with better quality.

Nearly three times as many tests associate CON with lower quality outcomes as with higher quality.

4.4 | CON and underserved populations

Do CON laws improve the provision of care for underserved populations? Though CON is a supply restriction, CON advocates believe that the regulation diverts healthcare resources from overserved populations to underserved populations. So far, there is no evidence for this.

Figure 8 summarizes the literature on CON and underserved populations. These tests look at whether CON has undermined the financing or provision of care to rural or otherwise underserved populations. There have been 17 tests in this category and of these, 14 (82%) associate CON with weaker provision of care to underserved populations while 3 (18%) find no significant effects. No tests associate CON with enhanced provision of care for underserved populations.

4.5 | CON and competition

The final set of tests with normatively clear implications address the effect of CON on competition. These tests usually measure the degree of competition with the Herfindahl–Hirschman

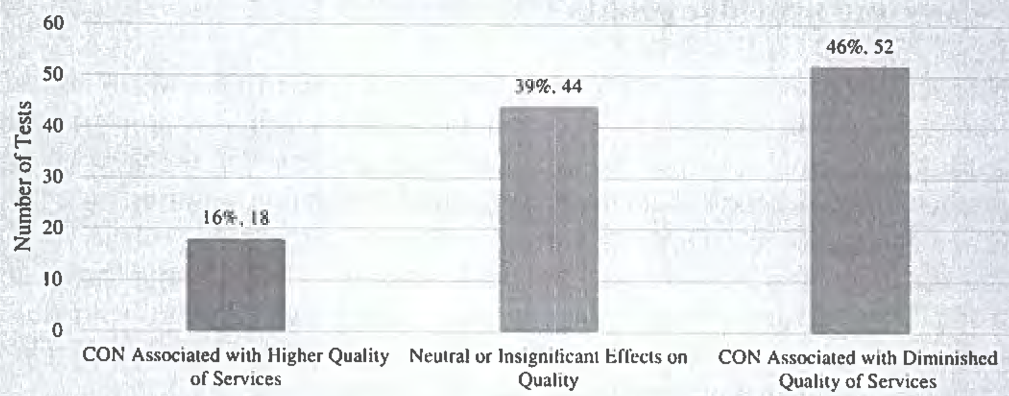


FIGURE 7 Tests assessing the effect of CON on quality of care. [Color figure can be viewed at wileyonlinelibrary.com]

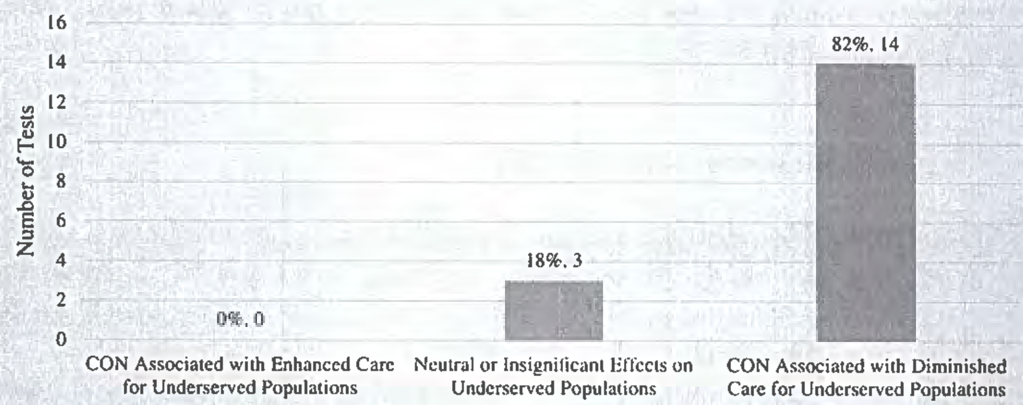


FIGURE 8 Tests assessing the effect of CON on underserved populations. [Color figure can be viewed at wileyonlinelibrary.com]

Index. Among five tests, three associate CON with less competition and two associate it with more competition.

4.6 | CON and provider volume

So far it has been relatively easy to characterize results as "good," "neutral," or "bad." Now I turn to a set of tests that are not so easily characterized. The first of these is provider volume. These tests assess whether CON increases or decreases the average provider's volume of services. By limiting the number of providers, we would expect CON to lead to higher volumes by provider. Some scholars *infer* that this is a good result because it might allow providers to achieve economies of scale or to improve their quality through repetition. These outcomes, however, are better measured directly through the tests summarized above.

Among 20 tests, 17 (85%) associate the regulation with greater provider volume. Two tests find neutral or negligible results and another associates CON with diminished provider volume.

4.7 | CON and provider profits

Are CON laws profitable? As a barrier to entry, one would expect CON laws to lead to higher profits among incumbent providers in the short run. These incumbent providers vigorously lobby against any proposals to repeal CON, and this, too, suggests that the laws are profitable (or at least that providers believe them to be so). Political economists, however, have long noted that contrived privileges only offer above-normal returns in the short run (Tullock, 1975). Competition can occur along multiple margins and barriers to entry rarely succeed in covering all of these margins. Over longer periods, providers may expend costly resources seeking CONs, opposing the CONs of their competitors, and maintaining the CON process itself. These costs may erode the extra-normal profits conferred by CON (Tullock, 1967, 1980).

This is a relatively understudied phenomenon. There have only been three papers assessing the effect of CON on profitability and together they contain four tests. Among the four tests, three associate CON with diminished profitability while one associates it with enhanced profitability. Together, the results suggest that, if anything, CON depresses rather than enhances hospital profitability. But we should be cautious with these results given how limited this subcategory of the literature is.

4.8 | The political economy of CON

A small but interesting subset of tests examine the political economy of CON laws. These tests are idiosyncratic and their results are not easy to aggregate. Teske and Chard (2004) study the factors that make a state likely to retain its CON law, making this paper one of the few that study CON as a dependent variable.[9] They find that CON laws were more likely to be retained in states with more Democrats in the upper and lower houses, higher hospital costs, more affluent and better-educated citizens, fewer physicians, and stronger hospital interests. Eichmann and Santerre (2011) study the degree to which hospital executives capture the rents generated by CON laws, finding that urban CEOs earn $91,000 more in CON than in non-CON states. Finally, Stratmann and Monaghan (2017) study whether political action committee (PAC) contributions affect CON approval rates in three states. They find that a 1% increase in PAC contributions from an applicant firm is associated with 6.7% greater odds of approval in Georgia, 1.8% greater odds of approval in Michigan, and 3.6% greater odds of approval in Virginia.

5 | DISCUSSION AND CONCLUSION

The state experiment with CONs in healthcare began in New York in 1964. A decade later, federal legislators encouraged the regulation through the National Health Planning and Resources Development Act of 1974. The federal inducement was eliminated in the mid-1980s, however, and since then about a third of states have repealed their health care CON laws and others have pared their programs back.

[9]Note that because they find that CON is positively related to hospital costs and negatively related to the number of physicians, I have included this paper in the previous sections and coded it as indicating CON is associated with higher $/Q and lower availability of healthcare.

Few state policy experiments have been as thoroughly examined as CON laws in healthcare. I have identified and coded 128 papers that together contain over 450 tests. The bulk of these address the stated goals of the regulation, assessing the effect of CON on spending, access, quality, and underserved populations. Other tests assess the effect of CON laws on competition, provider volume, and profits. And others assess the political economy of CON laws.

The balance of research suggests that CON laws do not achieve their stated goals. There is little evidence that they restrain spending, increase access, enhance quality, or improve the provision of care to underserved populations. In fact, the most-common finding is that CON laws undermine each of these goals. For every test associating CON with a "good" outcome, there are more than 4 that associate it with a "bad" outcome.

These findings are consistent with standard economic theory. They suggest that CON laws are barriers to entry that enhance the business of incumbent providers, increase costs, and limit access to care. These barriers likely enhance the profits of incumbent providers in the short run but not necessarily in the long run.

Though CON laws have been exhaustively studied, there are some understudied aspects of the regulation. First, CON law data is fragmentary and inaccessible. Though there have been hundreds of tests assessing the effect of CON laws, the data that these researchers have collected largely remains private. Future researchers would make a mighty contribution to the public good simply by collecting and posting their panel data on CON laws.

Second, while there have been some attempts to measure the stringency of CON laws, these tests have been relatively rare. Here again, it would be helpful if future researchers collected and disseminated data on approval rates, thresholds, and wait times. Though more difficult, it would be especially helpful to know the compliance and opportunity costs involved in seeking a CON. How much revenue is forgone in the CON process? How many patients are not served while providers navigate the process? And how many providers are discouraged by these costs and fail to even apply? In some cases, qualitative case studies may be better at answering these questions than large cross section time series data analyses.

Third, little is known about the political economy of CON laws. To my knowledge, no one has studied whether the institutional environment affects CON decisions. For example, are CON applications more likely to be granted in states where the decisionmaker is a board rather than an administrator? Does the composition of the board make a difference? Do regulatory guidelines make a difference? We have some data that suggests that politically active applicants are more likely to be successful in seeking CONs (Stratmann & Monaghan, 2017). Does the applicant's size, profitability, employment, nonprofit status, location, or political connections matter? Though one study (Teske & Chard, 2004) has examined why states retain their CON laws, it is now nearly two decades old and it may be time to revisit this question. This area is especially ripe for investigation given several high-profile proposals to eliminate or pare back CON programs in several states in recent years.

Finally, while the "public interest" theory of CON has been well studied (and found lacking), the "special interest" theory of CON has been relatively understudied. Which interests benefit from CON laws? And which interests benefit from their repeal? How do CON laws affect employment and compensation in different health sectors? In many states, boutique consulting firms profit by shepherding providers through the CON process. To my knowledge, these entities have been entirely unstudied.

ACKNOWLEDGMENTS

I thank Jaimie Cavanaugh, Angela Erickson, Thomas Stratmann, Edward Timmons, participants at the Certificate-of-Need Research Conference held at West Virginia University on June 2nd–3rd, 2023, and two anonymous reviewers for numerous helpful suggestions. I am solely responsible for any remaining errors or omissions.

FUNDING INFORMATION

I received no financial support for the production of this article.

REFERENCES

Anderson, K.B. (1991) Regulation, market structure, and hospital costs: comment. *Southern Economic Journal*, 58(2), 528–534. Available from: https://doi.org/10.2307/1060194

Anderson, K.B. & Kass, D.I. (1986) *Certificate of need regulation of entry into home health care: a multi-product cost function analysis*. Washington, DC: Federal Trade Commission.

Antel, J.J., Ohsfeldt, R.L. & Becker, E.R. (1995) State regulation and hospital costs. *The Review of Economics and Statistics*, 77(3), 416–422. Available from: https://doi.org/10.2307/2109904

Ashby, J.L. (1984) The impact of hospital regulatory programs on per capita costs, utilization, and capital investment. *Inquiry*, 21(1), 45–59.

Auster, R.D. & Oaxaca, R.L. (1981) Identification of supplier induced demand in the health care sector. *The Journal of Human Resources*, 16(3), 327–342. Available from: https://doi.org/10.2307/145624

Averett, S.L., Terrizzi, S. & Wang, Y. (2019) Taking the CON out of Pennsylvania: did hip/knee replacement patients benefit? A retrospective analysis. *Health Policy and Technology*, 8(4), 349–355. Available from: https://doi.org/10.1016/j.hlpt.2019.09.006

Bailey, J. (2016) *Can health spending be reined in through supply constraints? An evaluation of certificate-of-need laws*." Mercatus Working Paper. Arlington, VA: Mercatus Center at George Mason University. https://www.mercatus.org/publications/certificate-need/can-health-spending-be-reined-through-supply-constraints-evaluation

Bailey, J. (2018a) Does 'excess supply' drive excessive health spending? The case of certificate-of-need laws. *The Journal of Private Enterprise*, 33(4), 91–109.

Bailey, J. (2018b) The effect of certificate of need laws on all-cause mortality. *Health Services Research*, 53(1), 49–62. Available from: https://doi.org/10.1111/1475-6773.12619

Bailey, J. (2019) Can health spending be reined in through supply restraints? An evaluation of certificate-of-need laws. *Journal of Public Health*, 27(6), 755–760. Available from: https://doi.org/10.1007/s10389-018-0998-1

Bailey, J. & Hamami, T. (2019) *Competition and health-care spending: theory and application to certificate of need laws*." Working Paper 19-38. Philadelphia, PA: Federal Reserve Bank of Philadelphia. http://www.philadelphiafed.org/the-economy/competition-and-health-care-spending-theory-and-application-to-certificate-of-need-laws

Bailey, J. & Hamami, T. (2023) Competition and health-care spending: theory and application to certificate of need laws. *Contemporary Economic Policy*, 41(1), 128–145. Available from: https://doi.org/10.1111/coep.12584

Bailey, J., Hamami, T. & McCorry, D. (2017) Certificate of need laws and health care prices. *Journal of Health Care Finance*, 43(4), 1–7. http://healthfinancejournal.com/index.php/johcf/article/view/128

Bailey, J. & Lewin, E. (2021) Certificate of need and inpatient psychiatric services. *The Journal of Mental Health Policy and Economics*, 24(4), 117–124.

Bailey, J., Lu, T. & Vogt, P. (2022) Certificate-of-need laws and substance use treatment. *Substance Abuse Treatment, Prevention, and Policy*, 17, 1–7. Available from: https://doi.org/10.1186/s13011-022-00469-z

Baker, M.C. & Stratmann, T. (2021) Barriers to entry in the healthcare markets: winners and losers from certificate-of-need laws. *Socio-Economic Planning Sciences*, 77, 101007. Available from: https://doi.org/10.1016/j.seps.2020.101007

Bates, L.J., Mukherjee, K. & Santerre, R.E. (2006) Market structure and technical efficiency in the hospital services industry: a DEA approach. *Medical Care Research and Review*, 63(4), 499–524. Available from: https://doi.org/10.1177/1077558706288842

Browne, J.A., Cancienne, J.M., Casp, A.J., Novicoff, W.M. & Werner, B.C. (2018) Certificate-of-need state laws and total knee arthroplasty. *The Journal of Arthroplasty*, 33(7), 2020–2024.

Cancienne, J.M., Browning, R., Haug, E., Browne, J.A. & Werner, B.C. (2020) Certificate-of-need programs are associated with a reduced incidence, expenditure, and rate of complications with respect to knee arthroscopy in the Medicare population. *HSS Journal: The Musculoskeletal Journal of Hospital for Special Surgery*, 16-(Supplement 2), 264–271. Available from: https://doi.org/10.1007/s11420-019-09693-z

Cantor, J.C., DeLia, D., Tiedemann, A., Stanley, A. & Kronebusch, K. (2009) Reducing racial disparities in coronary angiography. *Health Affairs*, 28(5), 1521–1531. Available from: https://doi.org/10.1377/hlthaff.28.5.1521

Carlson, M.D.A., Bradley, E.H., Qingling, D. & Sean Morrison, R. (2010) Geographic access to hospice in the United States. *Journal of Palliative Medicine*, 13(11), 1331–1338. Available from: https://doi.org/10.1089/jpm.2010.0209

Casp, A.J., Durig, N.E., Cancienne, J.M., Werner, B.C. & Browne, J.A. (2019) Certificate-of-need state laws and total hip arthroplasty. *The Journal of Arthroplasty*, 34(3), 401–407. Available from: https://doi.org/10.1016/j.arth.2018.11.038

Caudill, S.B., Ford, J.M. & Kaserman, D.L. (1995) Certificate-of-need regulation and the diffusion of innovations: a random coefficient model. *Journal of Applied Econometrics*, 10(1), 73–78.

Cavanaugh, J., Brothers, C.G., Griffin, A., Hoover, R., LoPresti, M. & Wrench, J. (2020) *Conning the competition: a nationwide survey of certificate of need laws*. Arlington, VA: Institute for Justice. https://ij.org/wp-content/uploads/2020/08/Conning-the-Competition-WEB-08.11.2020.pdf

Chen, C.-C. (2005) Estimating nursing home cost and production functions: application of stochastic frontier models for the analysis of efficiency. *ProQuest Dissertations and Theses*. PhD, Tulane University. http://www.proquest.com/docview/305399421/abstract/F9AE5D67757C4ACAPQ/1

Chiu, K. (2021) The impact of certificate of need laws on heart attack mortality: evidence from county borders. *Journal of Health Economics*, 79, 102518. Available from: https://doi.org/10.2139/ssrn.3678714

Chui, P.W., Parzynski, C.S., Ross, J.S., Desai, N.R., Gurm, H.S., Spertus, J.A. et al. (2019) Association of statewide certificate of need regulations with percutaneous coronary intervention appropriateness and outcomes. *Journal of the American Heart Association*, 8(2), e010373. Available from: https://doi.org/10.1161/JAHA.118.010373

Chui, P.W., Parzynski, C.S., Ross, J.S., Ho, V., Spertus, J.A., Gurm, H.S. et al. (2015) Association of state certificate of need regulations with the appropriateness of PCI procedures. *Circulation*, 132(Supplement 3), A18805. Available from: https://doi.org/10.1161/circ.132.suppl_3.18805

Coelen, C. & Sullivan, D. (1981) An analysis of the effects of prospective reimbursement programs on hospital expenditures. *Health Care Financing Review*, 2(3), 1–40.

Conover, C.J. & Bailey, J. (2020) Certificate of need laws: a systematic review and cost-effectiveness analysis. *BMC Health Services Research*, 20(1), 748. Available from: https://doi.org/10.1186/s12913-020-05563-1

Conover, C.J. & Sloan, F.A. (1998) Does removing certificate-of-need regulations lead to a surge in health care spending? *Journal of Health Politics, Policy and Law*, 23(3), 455–481. Available from: https://doi.org/10.1215/03616878-23-3-455

Conover, C.J. & Sloan, F.A. (2003) *Evaluation of certificate of need in Michigan. Volume II: technical appendices*. Raleigh, NC: Duke University Center for Health Policy, Law and Management.

Cosby, C. (2011) *Analyzing the association of certificate of need regulationson volume and quality indicators for heart and kidney transplantation*. Richmond, VA: Virginia Commonwealth University. https://scholarscompass.vcu.edu/etd/2357

Cromwell, J. & Kanak, J.R. (1982) The effects of prospective reimbursement programs on hospital adoption and service sharing. *Health Care Financing Review*, 4(2), 67–88.

Custer, W.S., Ketscche, P., Sherman, B., Landers, G.M., Zhou, M., Ujamaa, D. et al. (2006) Report of data analyses to the Georgia Commission on the efficacy of the CON program. *Aysps.Gsu.Edu*. https://www.academia.edu/81395977/Report_of_Data_Analyses_to_the_Georgia_Commission_on_the_Efficacy_of_the_CON_Program

Cutler, D.M., Huckman, R.S. & Kolstad, J.T. (2010) Input constraints and the efficiency of entry: lessons from cardiac surgery. *American Economic Journal: Economic Policy*, 2(1), 51–76.

D'Aunno, T., Succi, M. & Alexander, J.A. (2000) The role of institutional and market forces in divergent organizational change. *Administrative Science Quarterly*, 45, 679–703.

DeLia, D., Cantor, J.C., Tiedemann, A. & Huang, C.S. (2009) Effects of regulation and competition on health care disparities: the case of cardiac angiography in New Jersey. *Journal of Health Politics, Policy and Law*, 34(1), 63–91. Available from: https://doi.org/10.1215/03616878-2008-992

Denduluri, S.K., Roe, A., Bala, A., Fogel, N., Ziino, C. & Kamal, R.N. (2021) The impact of certificate of need status on the utilization and reimbursement of open and endoscopic carpal tunnel release. *Journal of Surgical Orthopaedic Advances*, 30(2), 90–92.

Denson, C. & Mitchell, M.D. (2023) *Economic report on Georgia's certificate of need program*. Atlanta, GA: Georgia Public Policy Foundation.

DiSesa, V.J., O'Brien, S.M., Welke, K.F., Beland, S.M., Haan, C.K., Vaughan-Sarrazin, M.S. et al. (2006) Contemporary impact of state certificate-of-need regulations for cardiac surgery: an analysis using the Society of Thoracic Surgeons' National Cardiac Surgery Database. *Circulation*, 114(20), 2122–2129. Available from: https://doi.org/10.1161/CIRCULATIONAHA.105.591214

Dobson, A., Pete Welch, W., Bender, D., Ko, K.D., Sen, N., El-Gamil, A. et al. (2007) *An evaluation of Illinois' certificate of need program*. Springfield, IL: State of Illinois Commission on Government Forecasting and Accountability.

Drug Export. Amendments Act of 1986 Pub. L. 99-660, § 701, 100 Stat. 3799. (1986).

Eakin, B.K. (1991) Allocative inefficiency in the production of hospital services. *Southern Economic Journal*, 58(1), 240–248. Available from: https://doi.org/10.2307/1060045

Eastaugh, S.R. (1982) The effectiveness of community-based hospital planning: some recent evidence. *Applied Economics*, 14(5), 475–490. Available from: https://doi.org/10.1080/00036848200000043

Eichmann, T.L. & Santerre, R.E. (2011) Do hospital chief executive officers extract rents from certificate of need laws. *Journal of Health Care Finance*, 37(4), 1–14.

Ettner, S.L., Zinn, J.S., Haiyong, X., Ladd, H., Nuccio, E., Sorkin, D.H. et al. (2020) Certificate of need and the cost of competition in home healthcare markets. *Home Health Care Services Quarterly*, 39(2), 51–64. Available from: https://doi.org/10.1080/01621424.2020.1728464

Falchook, A.D. & Chen, R.C. (2015) Association between certificate of need legislation and radiation therapy use among elderly patients with early cancers. *International Journal of Radiation Oncology, Biology, Physics*, 91(2), 448–450. Available from: https://doi.org/10.1016/j.ijrobp.2014.10.033

Fayissa, B., Alsaif, S., Mansour, F., Leonce, T.E. & Mixon, F.G. (2020) Certificate-of-need regulation and healthcare service quality: evidence from the nursing home industry. *Healthcare (Basel, Switzerland)*, 8(4), E423. Available from: https://doi.org/10.3390/healthcare8040423

Ferrier, G.D., Leleu, H. & Valdmanis, V. (2010) The impact of CON regulation on hospital efficiency. *Health Care Management Science*, 13(1), 84–100.

Ford, J.M. & Kaserman, D.L. (1993) Certificate-of-need regulation and entry: evidence from the dialysis industry. *Southern Economic Journal*, 59(4), 783–791. Available from: https://doi.org/10.2307/1059739

Fric-Shamji, E.C. & Shamji, M.F. (2010) Effect of US state certificate of need regulation of operating rooms on surgical resident training. *Clinical and Investigative Medicine. Medecine Clinique et Experimentale*, 33(2), E78. Available from: https://doi.org/10.25011/cim.v33i2.12345

Gaines, A.G. & Cagle, J.G. (2023) Associations between certificate of need policies and hospice quality outcomes. *The American Journal of Hospice & Palliative Care*, 41(5), 10499091231180613. Available from: https://doi.org/10.1177/10499091231180613

Gertler, P.J. (1985) A latent variable model of quality determination. Working Paper 1750. National Bureau of Economic Research. https://doi.org/10.3386/w1750

Grabowski, D.C., Ohsfeldt, R.L. & Morrisey, M.A. (2003) The effects of CON repeal on Medicaid nursing home and long-term care expenditures. *Inquiry: A Journal of Medical Care Organization, Provision and Financing*, 40(2), 146–157.

Granderson, G. (2011) The impacts of hospital alliance membership, alliance size, and repealing certificate of need regulation, on the cost efficiency of non-profit hospitals. *Managerial and Decision Economics*, 32(3), 159–173. Available from: https://doi.org/10.1002/mde.1524

Gulley, O.D. & Santerre, R.E. (2003) The effect of public policies on nursing home care in the United States. *Eastern Economic Journal*, 29(1), 93–104.

Gutierrez, C., Lindor, R.A., Baker, O., Cutler, D. & Schuur, J.D. (2016) State regulation of freestanding emergency departments varies widely, affecting location, growth, and services provided. *Health Affairs*, 35(10), 1857–1866. Available from: https://doi.org/10.1377/hlthaff.2016.0412

Harrington, C., Swan, J.H., Nyman, J.A. & Carrillo, H. (1997) The effect of certificate of need and moratoria policy on change in nursing home beds in the United States. *Medical Care*, 35(6), 574–588.

Hellinger, F.J. (1976) The effect of certificate-of-need legislation on hospital investment. *Inquiry*, 13(2), 187–193.

Hellinger, F.J. (2009) The effect of certificate-of-need laws on hospital beds and healthcare expenditures: an empirical analysis. *The American Journal of Managed Care*, 15(10), 737–744.

Herb, J.N., Wolff, R.T., McDaniel, P.M., Mark Holmes, G., Royce, T.J. & Stitzenberg, K.B. (2021) Travel time to radiation oncology facilities in the United States and the influence of certificate of need policies. *International Journal of Radiation Oncology, Biology, Physics*, 109(2), 344–351. Available from: https://doi.org/10.1016/j.ijrobp.2020.08.059

Ho, V. (2004) Certificate of need, volume, and percutaneous transluminal coronary angioplasty outcomes. *American Heart Journal*, 147(3), 442–448. Available from: https://doi.org/10.1016/j.ahj.2003.05.002

Ho, V. (2007) Does certificate of need affect cardiac outcomes and costs? *International Journal of Health Care Finance and Economics*, 6(4), 300–324. Available from: https://doi.org/10.1007/s10754-007-9008-9

Ho, V. & Ku-Goto, M.-H. (2013) State deregulation and Medicare costs for acute cardiac care. *Medical Care Research and Review*, 70(2), 185–205. Available from: https://doi.org/10.1177/1077558712459681

Ho, V., Ku-Goto, M.-H. & Jollis, J.G. (2009) Certificate of need (CON) for cardiac care: controversy over the contributions of CON. *Health Services Research*, 44(2 Pt 1), 483–500. Available from: https://doi.org/10.1111/j.1475-6773.2008.00933.x

Ho, V., Ross, J.S., Nallamothu, B.K. & Krumholz, H.M. (2007) Cardiac certificate of need regulations and the availability and use of revascularization services. *American Heart Journal*, 154(4), 767–775. Available from: https://doi.org/10.1016/j.ahj.2007.06.031

Hoover, K. (2012) Doctors challenge Virginia's certificate-of-need requirement. *The Business Journals*. http://www.bizjournals.com/bizjournals/washingtonbureau/2012/06/05/doctors-challenge-virginias.html

Horwitz, J., Nichols, A., Colla, C. & Cutler, D. (2024) Technology regulation reconsidered: the effects of certificate of need policies on the quantity and quality of diagnostic imaging. NBER Working Paper 32143. National Bureau of Economic Research. https://econpapers.repec.org/paper/nbrnberwo/32143.htm

Horwitz, J.R. & Polsky, D. (2015) Cross border effects of state health technology regulation. *American Journal of Health Economics*, 1(1), 101–123. Available from: https://doi.org/10.1162/ajhe_a_00005

Jacobs, B.L., Zhang, Y. & Hollenbeck, B.K. (2012) 131 certificate of need Laws and the diffusion of intensity-modulated radiotherapy. *Journal of Urology*, 187(4S), e54. Available from: https://doi.org/10.1016/j.juro.2012.02.180

Jacobs, B.L., Zhang, Y., Skolarus, T.A., Wei, J.T., Montie, J.E., Schroeck, F.R. et al. (2012) Certificate of need regulations and the diffusion of intensity-modulated radiotherapy. *Urology*, 80(5), 1015–1020. Available from: https://doi.org/10.1016/j.urology.2012.07.042

Jacobs, B.L., Zhang, Y., Skolarus, T.A., Wei, J.T., Montie, J.E., Schroeck, F.R. et al. (2013) Certificate of need legislation and the dissemination of robotic surgery for prostate cancer. *Journal of Urology*, 189(1), 80–85. Available from: https://doi.org/10.1016/j.juro.2012.08.185

Joskow, P.L. (1980) The effects of competition and regulation on hospital bed supply and the reservation quality of the hospital. *The Bell Journal of Economics*, 11(2), 421–447. Available from: https://doi.org/10.2307/3003372

Kahn, J.M., Werner, R.M., Carson, S.S. & Iwashyna, T.J. (2012) Variation in long-term acute care hospital use after intensive care. *Medical Care Research and Review*, 69(3), 339–350. Available from: https://doi.org/10.1177/1077558711432889

Khanna, A., Hu, J.C., Xiangmei, G., Nguyen, P.L., Lipsitz, S. & Palapattu, G.S. (2013) Certificate of need programs, intensity modulated radiation therapy use and the cost of prostate cancer care. *The Journal of Urology*, 189(1), 75–79. Available from: https://doi.org/10.1016/j.juro.2012.08.181

Kim, S., Patel, A.N., Nelson, C., Shen, S., Mayer, T., Moore, D.F. et al. (2016) Does certificate of need minimize intensity modulated radiation therapy use in patients with low risk prostate cancer? *Urology Practice*, 3(5), 342–348. Available from: https://doi.org/10.1016/j.urpr.2015.09.001

Kolstad, J.T. (2009) *Essays on information, competition and quality in health care provider markets*. PhD Dissertation. Boston, MA: Harvard University. https://healthpolicy.fas.harvard.edu/people/jonathan-kolstad

Kosar, C.M. & Rahman, M. (2021) Early acceleration of COVID-19 in areas with larger nursing homes and certificate of need laws. *Journal of General Internal Medicine*, 36(4), 990–997. Available from: https://doi.org/10.1007/s11606-020-06518-2

Lanning, J.A., Morrisey, M.A. & Ohsfeldt, R.L. (1991) Endogenous hospital regulation and its effects on hospital and non-hospital expenditures. *Journal of Regulatory Economics*, 3(2), 137–154. Available from: https://doi.org/10.1007/BF00140955

Lee, J.A., Birnbaum, H. & Bishop, C. (1983) How nursing homes behave: a multi-equation model of nursing home behavior. *Social Science & Medicine (1982), Social Science & Medicine*, 17(23), 1897–1906. Available from: https://doi.org/10.1016/0277-9536(83)90167-3

Leibenstein, H. (1966) Allocative efficiency vs. 'X-efficiency'. *The American Economic Review*, 56(3), 392–415.

Li, S. & Dor, A. (2015) How do hospitals respond to market entry? Evidence from a deregulated market for cardiac revascularization. *Health Economics*, 24(8), 990–1008. Available from: https://doi.org/10.1002/hec.3079

Lorch, S.A., Maheshwari, P. & Even-Shoshan, O. (2012) The impact of certificate of need programs on neonatal intensive care units. *Journal of Perinatology*, 32(1), 39–44. Available from: https://doi.org/10.1038/jp.2011.47

Lu-Yao, G.L., Nelson, C., Shen, S., Shao, Y.-H., Li, H., Mayer, T.M. et al. (2013) Certificate of need and use of IMRT in elderly patients with low-risk prostate cancer. *Journal of Clinical Oncology*, 31(6 Supplement), 204. Available from: https://doi.org/10.1200/jco.2013.31.6_suppl.204

Malik, A.T., Phillips, F.M., Retchin, S., Wendy, X. & Khan, S.N. (2019) Certificate-of-need state laws and elective posterior lumbar fusions: a Medicare trends, costs and outcomes analysis. *The Spine Journal*, 19(9, Supplement), S45. Available from: https://doi.org/10.1016/j.spinee.2019.05.106

Mayo, J.W. & McFarland, D.A. (1989) Regulation, market structure, and hospital costs. *Southern Economic Journal*, 55(3), 559–569. Available from: https://doi.org/10.2307/1059572

Mayo, J.W. & McFarland, D.A. (1991) Regulation, market structure, and hospital costs: reply. *Southern Economic Journal*, 58(2), 535–538. Available from: https://doi.org/10.2307/1060195

McGinley, P.J. (1995) Beyond health care reform: reconsidering certificate of need laws in a 'managed competition' system. *Florida State University Law Review*, 23(1), 147. http://papers.ssrn.com/abstract=2671862

Miller, N.A., Harrington, C. & Goldstein, E. (2002) Access to community-based long-term care: Medicaid's role. *Journal of Aging and Health*, 14(1), 138–159.

Mitchell, M.D. (2016) *Do certificate-of-need Laws limit spending? Mercatus Working Paper*. Arlington, VA: Mercatus Center at George Mason University. https://www.mercatus.org/system/files/mercatus-mitchell-con-healthcare-spending-v3.pdf

Mitchell, M.D., Philpot, A. & McBirney, J. (2021) *The state of certificate-of-need Laws in 2020*. Arlington, VA: Mercatus Center at George Mason University. https://www.mercatus.org/publications/healthcare/con-laws-2020-about-update

Mitchell, M.D. & Stratmann, T. (2022) The economics of a bed shortage: certificate-of-need regulation and hospital bed utilization during the COVID-19 pandemic. *Journal of Risk and Financial Management*, 15(1), 10. Available from: https://doi.org/10.3390/jrfm15010010

Mitchell, M.D., Stratmann, T. & Bailey, J. (2020) *Raising the Bar: ICU beds and certificates of need*. Arlington, VA: Mercatus Center at George Mason University. https://www.mercatus.org/publications/covid-19-crisis-response/raising-bar-icu-beds-and-certificates-need

Myers, M.S. & Sheehan, K.M. (2020) The impact of certificate of need laws on emergency department wait times. *Journal of Private Enterprise*, 35(1), 59–75.

Nelson, C., Kim, S., Shen, S., Shao, Y., Mayer, T., Moore, D. et al. (2012) Certificate of need (CON) status and its impact on overtreatment of low-risk prostate cancer in the elderly. *International Journal of Radiation Oncology, Biology, Physics*, 84(3), S123–S124. Available from: https://doi.org/10.1016/j.ijrobp.2012.07.121

NHPRDA. (1975) U.S.C. https://www.gpo.gov/fdsys/pkg/STATUTE-88/pdf/STATUTE-88-Pg2225.pdf

Ni, H., Paul, J.A. & Bagchi, A. (2017) Effect of certificate of need law on the intensity of competition: the market for emergency care. *Socio-Economic Planning Sciences*, 60, 34–48. Available from: https://doi.org/10.1016/j.seps.2017.02.002

Noether, M. (1988) Competition among hospitals. *Journal of Health Economics*, 7(3), 259–284. Available from: https://doi.org/10.1016/0167-6296(88)90028-8

Noh, S. & Brown, C.H. (2018) Factors associated with the number of substance abuse nonprofits in the U.S. states: focusing on Medicaid expansion, certificate of need, and ownership. *Nonprofit Policy Forum*, 9(2), 20170010. Available from: https://doi.org/10.1515/npf-2017-0010

Ohlhausen, M. & Luib, G. (2015) Brother, may I?: the challenge of competitor control over market entry. *Journal of Antitrust Enforcement*, 4, jnv028. Available from: https://doi.org/10.1093/jaenfo/jnv028

Ohsfeldt, R.L. & Li, P. (2018) State entry regulation and home health agency quality ratings. *Journal of Regulatory Economics*, 53(1), 1–19. Available from: https://doi.org/10.1007/s11149-018-9351-4

Page, D. (2001) Obituary: Milton I. Roemer, pioneering UCLA Health services professor and professional who defined health policy in U.S., abroad. *UCLA School of Public Health Press Release*. https://web.archive.org/web/20120304021055/http://www.ph.ucla.edu/pr/miroemer.html

Paul, J.A., Ni, H. & Bagchi, A. (2019a) A study of the effects of certificate of need law on inpatient occupancy rates. *Service Science*, 11(1), 1–15. Available from: https://doi.org/10.1287/serv.2018.0228

Paul, J.A., Ni, H. & Bagchi, A. (2019b) Does certificate of need law enhance competition in inpatient care market? An empirical analysis. *Health Economics, Policy and Law*, 14(3), 400–420. Available from: https://doi.org/10.1017/S1744133117000184

Paul, J.A., Ni, H. & Bagchi, A. (2014) Effect of certificate of need law on emergency department length of stay. *The Journal of Emergency Medicine*, 47(4), 453–461. Available from: https://doi.org/10.1016/j.jemermed.2014.04.027

Perry, B. (2017) Certificate of need regulation and hospital behavior: evidence from MRIs in North Carolina. *Radiology & Medical Imaging*. Available from: https://doi.org/10.2139/ssrn.3225741

Polsky, D., David, G., Yang, J., Kinosian, B. & Werner, R.M. (2014) The effect of entry regulation in the health care sector: the case of home health. *Journal of Public Economics*, 110, 1–14. Available from: https://doi.org/10.1016/j.jpubeco.2013.11.003

Popescu, I., Vaughan-Sarrazin, M.S. & Rosenthal, G.E. (2006) Certificate of need regulations and use of coronary revascularization after acute myocardial infarction. *The Journal of the American Medical Association*, 295(18), 2141–2147. Available from: https://doi.org/10.1001/jama.295.18.2141

Rahman, M., Galarraga, O., Zinn, J.S., Grabowski, D.C. & Mor, V. (2016) The impact of certificate-of-need laws on nursing home and home health care expenditures. *Medical Care Research and Review: MCRR*, 73(1), 85–105.

Ringel, J.S., Hosek, S.D., Vollaard, B.A. & Mahnovski, S. (2002) The elasticity of demand for health care: a review of the literature and its application to the military health system. RAND Corporation. https://www.rand.org/pubs/monograph_reports/MR1355.html

Rivers, P.A., Fottler, M.D. & Frimpong, J.A. (2010) The effects of certificate of need regulation on hospital costs. *Journal of Health Care Finance*, 36(4), 1–16.

Rivers, P.A., Fottler, M.D. & Younis, M.Z. (2007) Does certificate of need really contain hospital costs in the United States? *Health Education Journal*, 66(3), 229–244. Available from: https://doi.org/10.1177/0017896907080127

Robinson, J. (2011) Hospitals respond to Medicare payment shortfalls by both shifting costs and cutting them, based on market concentration. *Health Affairs (Project Hope)*, 30(7), 1265–1271. Available from: https://doi.org/10.1377/hlthaff.2011.0220

Robinson, J.L., Nash, D.B., Moxey, E. & O'Connor, J.P. (2001) Certificate of need and the quality of cardiac surgery. *American Journal of Medical Quality*, 16(5), 155–160. Available from: https://doi.org/10.1177/106286060101600502

Rosko, M.D. & Mutter, R.L. (2014) The association of hospital cost-inefficiency with certificate-of-need regulation. *Medical Care Research and Review*, 71(3), 280–298.

Ross, J.S., Ho, V., Wang, Y., Cha, S.S., Epstein, A.J., Masoudi, F.A. et al. (2007) Certificate of need regulation and cardiac catheterization appropriateness after acute myocardial infarction. *Circulation*, 115(8), 1012–1019. Available from: https://doi.org/10.1161/CIRCULATIONAHA.106.658377

Roy, C., Agnitra, S.G. & Plemmons, A. (2022) Certificate of need laws and health care use during the COVID-19 pandemic. *Journal of Risk and Financial Management*, 15(2), 76. Available from: https://doi.org/10.3390/jrfm15020076

Salkever, D.S. & Bice, T.W. (1976) The impact of certificate-of need controls on hospital investment. *The Milbank Memorial Fund Quarterly. Health and Society*, 54(2), 185–214. Available from: https://doi.org/10.2307/3349587

Salkever, D.S. & Bice, T.W. (1979) *Hospital certificate-of-need controls: impact on investment, costs, and use*. Washington, DC: American Enterprise Institute. https://www.aei.org/research-products/book/hospital-certificate-of-need-controls-impact-on-investment-costs-and-use/

Salop, S.C. & Scheffman, D.T. (1983) Raising rivals' costs. *The American Economic Review*, 73(2), 267–271. Available from: https://doi.org/10.2307/1816853

Sandefur, T. (2015) State 'Competitor's Veto' laws and the right to earn a living: some paths to federal reform. *Harvard Journal of Law and Public Policy*, 38(June), 1009–1072.

Schultz, O.A., Shi, L. & Lee, M. (2021) Assessing the efficacy of certificate of need laws through total joint arthroplasty. *Journal for Healthcare Quality*, 43(1), e1–e7. Available from: https://doi.org/10.1097/JHQ.0000000000000286

Shain, M. & Roemer, M.I. (1959) Hospital costs relate to the supply of beds. *Modern Hospital*, 92(4), 71–73.

Sherman, D. (1988) *The effect of state certificate-of-need laws on hospital costs: an economic policy analysis | Federal Trade Commission*. Staff report of the Bureau of Economics. Washington, DC: Federal Trade Commission. https://www.ftc.gov/reports/effect-state-certificate-need-laws-hospital-costs-economic-policy-analysis

Short, M.N., Aloia, T.A. & Ho, V. (2008) Certificate of need regulations and the availability and use of cancer resections. *Annals of Surgical Oncology*, 15(7), 1837–1845. Available from: https://doi.org/10.1245/s10434-008-9914-1

Shortell, S.M. & Hughes, E.F. (1988) The effects of regulation, competition, and ownership on mortality rates among hospital inpatients. *The New England Journal of Medicine*, 318(17), 1100–1107. Available from: https://doi.org/10.1056/NEJM198804283181705

Silveira, M.J., Connor, S.R., Goold, S.D., McMahon, L.F. & Feudtner, C. (2011) Community supply of hospice: does wealth play a role? *Journal of Pain and Symptom Management*, 42(1), 76–82. Available from: https://doi.org/10.1016/j.jpainsymman.2010.09.016

Sloan, F.A. (1981) Regulation and the rising cost of hospital care. *The Review of Economics and Statistics*, 63(4), 479–487. Available from: https://doi.org/10.2307/1935842

Sloan, F.A. (1983) Rate regulation as a strategy for hospital cost control: evidence from the last decade. *The Milbank Memorial Fund Quarterly. Health and Society*, 61(2), 195–221. Available from: https://doi.org/10.2307/3349905

Sloan, F.A. & Steinwald, B. (1980) Effects of regulation on hospital costs and input use. *The Journal of Law & Economics*, 23(1), 81–109.

Sridharan, M., Malik, A.T., Phillips, F.M., Retchin, S., Wendy, X., Elizabeth, Y. et al. (2020) Certificate-of-need state laws and elective posterior lumbar fusions: is it time to repeal the mandate? *World Neurosurgery*, 144, e495–e499. Available from: https://doi.org/10.1016/j.wneu.2020.08.201

Stensland, J., Gaumer, Z.R. & Miller, M.E. (2010) Private-payer profits can induce negative Medicare margins. *Health Affairs*, 29(5), 1045–1051. Available from: https://doi.org/10.1377/hlthaff.2009.0599

Stratmann, T. (2022) The effects of certificate-of-need laws on the quality of hospital medical services. *Journal of Risk and Financial Management*, 15(6), 272. Available from: https://doi.org/10.3390/jrfm15060272

Stratmann, T. & Baker, M. (2020) *Examining certificate-of-need laws in the context of the rural health crisis. Mercatus Working Paper*. Arlington, VA: Mercatus Center at George Mason University. https://www.mercatus.org/publications/healthcare/examining-certificate-need-laws-context-rural-health-crisis

Stratmann, T. & Koopman, C. (2016) *Entry regulation and rural health care: certificate-of-need laws, ambulatory surgical centers, and community. Working Paper*. Arlington, VA: Mercatus Center at George Mason University. http://mercatus.org/sites/default/files/Stratmann-Rural-Health-Care-v1.pdf

Stratmann, T. & Monaghan, S. (2017) *The effect of interest group pressure on favorable regulatory decisions: the case of certificate-of-need Laws*." Mercatus Working Paper. Arlington, VA: Mercatus Center at George Mason University. https://www.mercatus.org/publications/interest-group-pressure-favorable-regulatory-decisions-certificate-of-need

Stratmann, T. & Russ, J. (2014) *Do certificate-of-need laws increase indigent care? Working Paper 14–20*. Arlington, VA: Mercatus Center at George Mason University. http://mercatus.org/sites/default/files/Stratmann-Certificate-of-Need.pdf

Swan, J. & Harrington, C. (1990) Certificate of need and nursing home bed capacity in states. *Journal of Health & Social Policy*, 2(2), 87–105. Available from: https://doi.org/10.1300/j045v02n02_06

Teske, P. & Chard, R. (2004) Hospital certificates-of-need. In: Teske, P. (Ed.) *Regulation in the states*. Washington, DC: Brookings Institution, pp. 125–132.

Tullock, G. (1967) The welfare costs of tariffs, monopolies, and theft. *Western Economic Journal [Economic Inquiry]*, 5(3), 224–232. Available from: https://doi.org/10.1111/j.1465-7295.1967.tb01923.x

Tullock, G. (1975) The transitional gains trap. *The Bell Journal of Economics*, 6(2), 671–678. Available from: https://doi.org/10.2307/3003249

Tullock, G. (1980) Efficient Rent Seeking. In: Buchanan, J.M., Tollison, R.D. & Tullock, G. (Eds.) *Toward a theory of the rent-seeking society*. College Station: Texas A&M University Press, pp. 97–112.

Vaughan, S., Mary, S., Bayman, L. & Cram, P. (2010) Trends during 1993-2004 in the availability and use of revascularization after acute myocardial infarction in markets affected by certificate of need regulations. *Medical Care Research and Review*, 67(2), 213–231. Available from: https://doi.org/10.1177/1077558709346565

Vaughan-Sarrazin, M.S., Hannan, E.L., Gormley, C.J. & Rosenthal, G.E. (2002) Mortality in Medicare beneficiaries following coronary artery bypass graft surgery in states with and without certificate of need regulation. *JAMA*, 288(15), 1859–1866.

Wu, B., Jung, J., Kim, H. & Polsky, D. (2019) Entry regulation and the effect of public reporting: evidence from home health compare. *Health Economics*, 28(4), 492–516.

Yuce, T.K., Chung, J.W., Barnard, C. & Bilimoria, K.Y. (2020) Association of state certificate of need regulation with procedural volume, market share, and outcomes among Medicare beneficiaries. *JAMA*, 324(20), 2058–2068. Available from: https://doi.org/10.1001/jama.2020.21115

Zhang, L. (2008) *Uncompensated care provision and the economic behavior of hospitals: the influence of the regulatory environment*. PhD Dissertation. Atlanta, GA: Georgia State University. http://scholarworks.gsu.edu/pmap_diss/19

Ziino, C., Bala, A. & Cheng, I. (2020a) Does certificate-of-need status impact lumbar microdecompression reimbursement and utilization? A retrospective database review. *Current Orthopaedic Practice*, 31(1), 85–89. Available from: https://doi.org/10.1097/BCO.0000000000000828

Ziino, C., Bala, A. & Cheng, I. (2020b) Does ACDF utilization and reimbursement change based on certificate of need status? *Clinical Spine Surgery*, 33(3), E92–E95. Available from: https://doi.org/10.1097/BSD.0000000000000914

Ziino, C., Bala, A. & Cheng, I. (2021) Utilization and reimbursement trends based on certificate of need in single-level cervical discectomy. *The Journal of the American Academy of Orthopaedic Surgeons*, 29(10), e518–e522. Available from: https://doi.org/10.5435/JAAOS-D-19-00224

Zinn, J.S. (1994) Market competition and the quality of nursing home care. *Journal of Health Politics, Policy and Law*, 19(3), 555–582. Available from: https://doi.org/10.1215/03616878-19-3-555

How to cite this article: Mitchell, M. D. (2024). Certificate-of-Need laws in healthcare: A comprehensive review of the literature. *Southern Economic Journal*, 1–38. https://doi.org/10.1002/soej.12698

APPENDIX

TABLE A1 Summary of all direct tests of CON.

Paper	Summary
Hellinger (1976)	CON legislation induced hospitals to increase investments before CON took effect. He interprets this as a bad result. I code it as increasing access (in the short run).
Salkever and Bice (1976)	CON does not decrease investment but does change its composition.
Salkever and Bice (1979)	They assess the effect of CON on a cross section, time series data set cover all states from 1968 to 1972. They find that CON is associated with: (1) At best, a modest reduction in total spending per capita, (2) A small increase in average inpatient cost per inpatient day, (3) Reduced inpatient days per capita.
Sloan and Steinwald (1980)	Comprehensive CON programs have no effect on hospital expenditures per patient day, while noncomprehensive programs increase hospital expenditures by 5% per patient day.
Joskow (1980)	CON reduces bed supply by about 6% and makes it more likely that a hospital will turn away patients.
Coelen and Sullivan (1981)	Though their primary interest is in prospective reimbursement programs, they also included CON as a covariate. They find no evidence that CON reduces spending per patient day, per admission, or per capita, and some evidence that it increases expenditures. In about half the states they find evidence that it is associated with higher spending per patient day, per admission, and per capita.
Sloan (1981)	He studies the effects of both mature and new CON regulations on hospital costs and profits. He finds: (1) Total expense per admission was lower in the years after CON was implemented for part of the period studied, (2) Expense per adjusted admission was not statistically significantly different after CON was implemented, (3) Expense per patient day was not statistically significantly different after CON was implemented, (4) Expense per adjusted patient day was not statistically significantly different after CON was implemented, and (5) Profits were lower after CON was implemented.
Eastaugh (1982)	He finds CON has: (1) A marginally significant, positive effect on change in plant assets (percentage and log), which he interprets as a negative result, (2) No statistically significant effect on change in beds (percentage and log), which he interprets as a negative result, and (3) A significant, positive effect on change in plant assets per bed (percentage and log), which he interprets as a negative result.
Cromwell and Kanak (1982)	Their primary focus is on prospective reimbursement programs and their effect on the diffusion of services, but they use CON as a control variable and find that it has no effect on the diffusion of services.

TABLE A1 (Continued)

Paper	Summary
Lee et al. (1983)	The paper assesses the effect of various policies on nursing home behavior using the 1973 National Nursing Home Survey. Of relevance here, they find that CON is associated with: (1) Higher operating costs per patient day, and (2) Higher average annual occupancy.
Sloan (1983)	His primary interest is the effect of rate regulation on hospital costs, but he includes CON as a control. His measures of spending are total hospital expense per admission, per "adjusted" admission (adjusted for hospital outpatient activity), per patient day, per adjusted patient day, and per length of stay. He finds no evidence that CON reduces spending per patient.
Ashby (1984)	He assesses the effect of CON and other regulatory programs on five outcomes. His unit of analysis is each state in each year from 1971 to 1977. He finds that: (1) CON is associated with statistically significant positive growth in hospital costs per capita, (2) CON has no statistically significant effect on percentage change in average length of stay, (3) CON has no statistically significant effect on percentage change in total admissions per capita, and (4) CON has no statistically significant effect on percentage change in plant assets.
Gertler (1985)	He finds that under a binding CON capacity constraint, increases in Medicaid rates are associated with lower quality in New York state nursing home facilities.
Anderson and Kass (1986)	They examined the effect of CON on economies of scale and cost in the home healthcare industry. They find: (1) Costs are 2% higher in CON states relative to non-CON states, (2) No substantial economies of scale in the home health industry overall, and (3) No difference in economies of scale in CON and non-CON states.
Noether (1988)	CON increases the average price and expense for several disease categories including: (1) Diabetes mellitus, (2) Cataract surgery, (3) Acute myocardial infarction, (4) Congestive heart failure, (5) Acute, cerebrovascular disease, (6) Pneumonia, (7) Respiratory system disease, other, (8) Inguinal hernia, (9) Diverticula of intestine, (10) Hyperplasia of prostate, and (11) Fracture of neck and femur.
Sherman (1988)	He estimates the effects of CON on cost functions using a sample of 3708 hospitals using data from 1983 to 1984. Though he uses the term costs, he is actually measuring operating expenditures. He finds that spending would fall by 1.4% if states relaxed CON by raising the thresholds at which it is applied.

(Continues)

TABLE A1 (Continued)

Paper	Summary
Shortell and Hughes (1988)	They examined the effect of CON (among other factors) on hospital quality, finding that the ratio of actual to predicted mortality rates among Medicare patients is 5%–6% higher in states with stringent CON regulation.
Mayo and McFarland (1989)	They study the effect of variation in CON approval in different service areas of Tennessee on the number of beds, finding it is associated with fewer beds. They also find that larger hospital size is associated with more spending and infer that CON is associated with lower average spending per patient day, though they do not directly measure it.
Swan and Harrington (1990)	They assess the effect of nursing home CONs on nursing home bed stock using cross-section, time-series data from 1981 to 1984. They find that: (1) Nursing home CONs constrain the bed stock, and (2) The greater the dollar amount of CON approvals per aged population (a measure of CON stringency), the greater the bed stock.
Eakin (1991)	CON hospitals are less efficient than non-CON hospitals.
Anderson (1991)	A reply to Mayo and McFarland's (1989) paper, he estimates the effects of CON (and the number of years it has been in effect) on average variable costs among 2069 general acute hospitals with 100 or more beds. He uses CON age as a measure of CON stringency under the theory that "the effect should increase the longer the regulation has been around." It enters the equation linearly and multiplied by the number of beds to see if CON has a different effect on large hospitals. He finds: (1) CON is associated with 10% higher variable costs, and (2) CON is associated with greater probability of a hospital having 100 or fewer beds.
Lanning et al. (1991)	They measure the effect of CON on hospital expenditures, finding that it is associated with 20.6% higher spending per capita.
Mayo and McFarland (1991)	This is a reply to Anderson's (1991) critique of their 1989 paper. Anderson worried CON might constrain hospitals on one dimension (say beds), but then cause them to substitute into other areas of spending (say labor). They tested this possibility and found mixed results. In a larger panel data set, they found support for Anderson's concern (CON increases spending) while in a 1984 cross-section they found support for their initial (implied) conclusion (CON decreases spending).
Ford and Kaserman (1993)	They assess the effect of CON on the number of dialysis clinics and stations, finding that it has limited new firm entry and total capacity.
Zinn (1994)	She examined the determinants of nursing home quality. One of her explanatory variables is nursing home construction moratoria. She finds these to be associated with lower RN staffing ratios and greater use of physical restraint.
Caudill et al. (1995)	They examine the effect of CON on the diffusion of hemodialysis, an effective and practical treatment for chronic renal failure. Their data span 50 states and 14 years. They find that CON regulation slows the spread of hemodialysis.
Antel et al. (1995)	They find that CON increases per-day and per-admission hospital expenditures but has no relationship to per capita hospital expenditures.

TABLE A1 (Continued)

Paper	Summary
Harrington et al. (1997)	In a two-stage least squares regression, they assess the effect of CON, and/or moratoria on the growth of nursing home beds and Medicaid nursing home reimbursement rates. They find: (1) CON has no effect on Medicaid nursing home reimbursement rates, and (2) CON reduces growth of beds.
Conover and Sloan (1998)	CON has no effect on total per capita health expenditures; there is no evidence of a surge in spending after repeal.
D'Aunno et al. (2000)	They study the market and institutional determinants of radical organizational change in rural hospitals. In particular, they study the factors that make a rural hospital likely to change to provide other types of services. They find that stronger CON regulation makes a rural hospital 8% less likely to change.
Robinson et al. (2001)	They examine the effect of CON elimination in PA (comparing it with NJ, which maintained CON), finding: (1) Open-heart surgery programs increased 25% following elimination of CON, (2) The total volume of CABG surgeries were unchanged following repeal, (3) Provider volume shifted from programs that had been established before CON repeal to programs that were established after CON repeal, and (4) The mortality rate was unchanged following repeal.
Miller et al. (2002)	They find that CON increases per capita Medicaid community-based care expenditures.
Vaughan-Sarrazin et al. (2002)	They assess the effect of CON on coronary artery bypass graft (CABG) surgery, finding: (1) Mean annual hospital volume is lower in states without CON, (2) More patients undergo CABG surgery in low-volume hospitals in states without CON, and (3) Mortality following CABG is higher in states without CON.
Grabowski et al. (2003)	CON repeal: (1) Has no statistically significant effect on per diem Medicaid nursing home charges, (2) No effect on per diem Medicaid long-term-care charges, (3) No effect on days.
Gulley and Santerre (2003)	They look at the effects of several public policies on nursing home residents and nursing home beds per persons 65 years old and older. Their data are from a cross section of counties in 1991. Their measure of CON is the number of years in which a CON law has been in effect. They find that in states where CON has been in effect for longer: (1) There are fewer nursing home beds per persons 65 years old and older, but the effect is not statistically significant, and (2) There are fewer nursing home patients per persons 65 and older, but this effect is also statistically insignificant.
Conover and Sloan (2003)	Dropping CON has 0% effect on all expenditures.
Teske and Chard (2004)	This study examines several political factors to determine the likelihood of a state retaining CON regulation. They find that the following factors are associated with CON regulation:

(Continues)

TABLE A1 (Continued)

Paper	Summary
	(1) Democrats in upper and lower houses, (2) Higher hospital costs, (3) More affluent and better-educated citizens, (4) Fewer physicians (which implies CON may reduce the number of physicians), and (5) A variable measuring hospital interests: the number of hospital industry-related interest groups active in a particular state multiplied by their average political action committee spending. This was found to be significantly associated with retention of CON, but legislative party makeup is more important.
Ho (2004)	She compares Florida, where there is a CON for percutaneous transluminal coronary angioplasty (PTCA) with California, where there is no such CON. She finds: (1) CON is associated with higher in-hospital volume for PTCA, and (2) There is a positive relationship between PTCA volume and mortality outcomes (though note that she does not directly study the relationship between CON and PTCA mortality outcomes).
Chen (2005)	Nursing home CONs are associated with greater cost efficiency, but diminished technical efficiency.
DiSesa et al. (2006)	They study CON, volume, and mortality in coronary artery bypass grafting (CABG). They find: (1) CON is positively associated with CABG volume within hospitals, and (2) There is no direct relationship between CON and mortality.
Bates et al. (2006)	CON hospitals are not any less efficient than non-CON hospitals.
Custer et al. (2006)	They use a cross-border design to study the effect of CON in hospital markets. This allows them to control for unobservable factors. They also used interviews and public information to develop an index measuring CON rigor based on fees, administrative requirements, reviewability, appeals, and administrative complexity. They assess the effects of CON on acute care, long term care, and home health markets. They find: (1) CON is associated with higher private inpatient acute care costs, (2) Acute care costs rise with the rigor of the CON program for the most resource-intensive acute care diagnoses, (3) Some evidence that CON is associated with higher Medicaid costs for home health services, (4) There is weak evidence that CON is associated with higher private long term care costs, (5) There is weak evidence that CON is associated higher Medicaid long term care costs, (6) Some evidence that CON is associated with higher per-capita costs for home health services, (7) CON is associated with fewer hospitals, (8) CON is associated with fewer hospital beds, (9) CON is associated with fewer home health agencies per 1000 residents, (10) CON is associated with fewer Medicare beneficiaries receiving home health services, (11) There is no significant relationship between the percent of hospital admissions that are self-pay, though when controlling for the number of

TABLE A1 (Continued)

Paper	Summary
	uninsured and family income, CON is positively related to self-pay admission per uninsured, (12) There is no apparent difference in acute care quality in CON and non-CON markets, (13) In long-term care, CON is associated with better quality on two measures but worse quality on six measures, (14) In home health markets, they find no evidence that CON affects any of 10 outcome measures of quality, (15) They find that acute care markets are less competitive when CON is rigorous, (16) CON is associated with lower levels of competition in home health agency markets.
Popescu et al. (2006)	They studied access and quality outcomes in revascularization. They found that patients in CON states: (1) Were less likely to be admitted to hospitals offering revascularization, (2) Were less likely to undergo revascularization, and (3) Had no difference in 30-day mortality rates relative to patients in non-CON states.
Dobson et al. (2007)	They find that safety-net hospitals in non-CON states had higher margins than those in CON states.
Ho (2007)	They study the association between cardiac CON regulations, availability of revascularization facilities, and revascularization rates, focusing on differences between the general population and the elderly and on differences between procedures (coronary artery bypass graft surgery [CABG] or a percutaneous coronary intervention [PCI]). They find that: (1) CON is associated with fewer hospitals offering CABG and PCI, (2) CON has no effect on overall CABG utilization, and (3) CON is associated with 19.2% fewer PCIs per 1000 elderly.
Ho et al. (2007)	The study assesses the effect of CON on cardiac costs and outcomes. She finds: (1) While CON is associated with lower average costs per patient, it also seems to be associated with more procedures and this is enough to offset the savings from lower average costs, (2) CON is associated with greater volume within hospitals, and (3) CON does not seem to be related to inpatient mortality.
Rivers et al. (2007)	They find CON laws increase hospital expenditures per adjusted admission.
Ross et al. (2007)	They examine the effect of CON on the volume of cardiac catheterization after admission for acute myocardial infarction. While CON did not seem to decrease the volume of strongly-indicated catheterization, it did reduce the volume of equivocally and weakly indicated catheterization. Because their interest is both overall volume and rates of catheterization when it is not warranted, I categorize in both the volume and the quality sections.
Short et al. (2008)	They studied Medicare data on beneficiaries treated with one of six cancer resections and an associated cancer diagnosis from 1989 to 2002. They find: (1) CON is associated with fewer hospitals per cancer incident for colectomy, rectal resection, and pulmonary lobectomy, (2) CON has no effect on the number of procedures per cancer incident, and

(Continues)

TABLE A1 (Continued)

Paper	Summary
	(3) CON is associated with greater hospital volume.
Zhang (2008)	He examined the effect of three regulatory policies—CON laws, uncompensated care pools, and community benefit requirement laws. CON is associated with small increases in uninsured admissions, though the results were small (0.07%) and not statistically significant when he attempted to control for endogeneity. Furthermore, he found that in the presence of all three policies, the number of uninsured admissions by nonprofit hospitals fell.
Cantor et al. (2009)	The authors studied a 1996 New Jersey reform that created a pilot program to license additional hospitals to perform coronary angiography. They find that the number of angiography facilities doubled following reform and a large black-white disparity disappeared after the reform.
DeLia et al. (2009)	This builds off of the authors' previous study, confirming the result (the reforms eliminated the black-white disparity) using additional techniques (weighting zip codes by the number of black and white residents). They also study the mechanism by which the disparity was eliminated, finding that incumbent hospitals served more black patients as new entrants cut into their market share for white patients.
Ho et al. (2009)	They use difference-in-difference regression analysis to compare states that dropped CON during the sample period with states that kept the regulation. They find that in states that dropped CON: (1) The number of hospitals in the state performing CABG and PCI went up following repeal, (2) Statewide procedural volume for CABG and PCI were unchanged, (3) Mean hospital volume declined for both procedures, and (4) Procedural CABG mortality declined after repeal, though the difference was not permanent.
Kolstad (2009)	He examined how the 1996 repeal of CON legislation in Pennsylvania affected the market for CABG surgery in the state, finding: (1) The number of CABG facilities increased 46%, and (2) Surgeries were more likely to be performed by high quality surgeons.
Hellinger (2009)	CON is associated with fewer hospital beds, which in turn are associated with slower growth in aggregate health expenditures per capita. But there is no direct relationship between CON and health expenditures per capita.
Ferrier et al. (2010)	CON hospitals are more efficient than non-CON hospitals.
Carlson et al. (2010)	This is a cross-sectional study of geographic access to U.S. hospices using multivariate logistic regression to identify gaps in hospice availability (measured by distance to hospice facilities) by community characteristics. CON was associated with longer travel distance to hospice care.
Cutler et al. (2010)	They assess the 1996 repeal of CON in Pennsylvania on CABG. They find: (1) Repeal of CON reduced travel distanced by 9%, (2) There was no statistically significant effect on total volume following CON repeal, (3) There were mixed results on scale; following CON repeal, fewer surgeries were performed by high-volume hospitals, but more were performed by high-volume surgeons,

TABLE A1 (Continued)

Paper	Summary
	(4) CON repeal led to a shift from standard quality to high quality surgeons, and (5) Incumbent hospital margins initially fell following repeal but these hospitals had regained profitability and were the most profitable by 2002.
Vaughan et al. (2010)	In a study design that exploits the fact that some markets cross boundaries between CON and non-CON states, they find: (1) A greater increase in coronary artery bypass graft surgery programs in states that reduced CON regulation, and (2) No change in percutaneous coronary intervention programs in states that reduced CON.
Rivers et al. (2010)	They find that stringent CON programs increase hospital expenditures per admission.
Fric-Shamji and Shamji (2010)	They evaluate the mean per capita rates of 26 diverse surgical procedures in 21 CON and 5 non-CON states between 2004 and 2006. The proportion of procedures performed in teaching facilities was also assessed. They find no significant difference in procedural rates between CON and non-CON states.
Silveira et al. (2011)	They study the number of hospice programs per county. Among other things, they find that CON regulations is associated with fewer hospice programs.
Cosby (2011)	She studies the effect of solid organ transplant CON regulations, finding: (1) CON is associated with fewer transplant centers, (2) CON has no statistically significant effect on provider volume, (3) CON has no statistically significant effect on graft failures or deaths.
Granderson (2011)	He studies the effect of hospital alliance membership, alliance size, and CON on hospital cost efficiency among 144 urban Midwest hospitals from 1996 to 1999. He finds that repeal of CON resulted in greater hospital efficiency, as measured by a stochastic cost frontier.
Eichmann and Santerre (2011)	They study the effects of CON on access and rents. They find CON is associated with: (1) 12% fewer beds per capita, (2) 48% fewer hospitals per capita, and (3) $91,000 more in urban hospital CEO pay.
Kahn et al. (2012)	They examine factors affecting utilization of long-term acute care (LTAC) hospitals. Among other things, they find that utilization is lower in the presence in CON laws.
Jacobs, Zhang, and Hollenbeck (2012)	They study the effect of CON on utilization of intensity-modulated radiotherapy (IMRT), an expensive procedure with unproven benefits. They find that CON does not reduce utilization of the procedure, which they interpret as a negative quality result.
Jacobs et al. (2012)	They examine whether CON reduces the use of a questionably warranted procedure, radiotherapy, for prostate cancer. They find no difference in use of the procedure in CON and non-CON health service areas. In fact, in HSAs with high-stringency CONs, they find greater use of the procedure.
Lorch et al. (2012)	They studied NICU CONs. They found: (1) CON is associated with fewer units; (2) CON is associated with fewer beds;

(Continues)

TABLE A1 (Continued)

Paper	Summary
	(3) CON is unrelated to very low birth weight (VLBW) infant mortality and low birth weight (LBW) infant mortality. (4) CON is associated with lower rates of all-infant mortality in states with a large metropolitan area.
Nelson et al. (2012)	They examine whether CON reduces the use of a questionably warranted procedure, definitive intensity modulated radiation therapy (IMRT), among 155,379 men between 2004 and 2007. They find no evidence that CON limits the use of the procedure.
Ho and Ku-Goto (2013)	Removing CON decreases the cost of coronary artery bypass grafts, but not for percutaneous coronary intervention. In Ohio, reimbursements fell 2.8% following repeal of CON and in Pennsylvania, they fell 8.8% following repeal.
Khanna et al. (2013)	The authors focus on intensity modulated radiation therapy. They find that: (1) CON is not associated with any difference in cost growth (2) CON is associated with greater growth in intensity modulated radiation therapy which is an expensive and no more effective treatment, so they interpret this as a negative quality result.
Jacobs et al. (2013)	They study whether CON restrains the use of a questionable procedure—robotic prostatectomy. They find that CON stringency had no effect on the use of the procedure.
Lu-Yao et al. (2013)	They study whether CON limits the use of IMRT in a population that would likely benefit from it the least: older or debilitated men with low-risk prostate cancer. They find that CON laws actually encourage the procedure.
Rosko and Mutter (2014)	CON hospitals are more efficient than non-CON hospitals.
Polsky et al. (2014)	They assess the effect of CON on home health agencies, using a research design that focuses on markets that straddle CON and non-CON states. They find that: (1) Medicare expenditures are not statistically significantly different between CON and non-CON states, (2) Non-CON states have roughly twice as many home health agencies per Medicare beneficiary, (3) CON states have 13.7% fewer home health admissions from hospitals, (4) 60 day (total) readmission rates are 5% higher in CON states than in non-CON states, though the effect is not sustained, (5) 60 day preventable readmission rates are 13% higher in CON states than in non-CON states, though the effect is not sustained. (6) In CON states there are fewer home health visits, fewer visits per week, and a lower proportion of visits by skilled nurses, but the effects are small and not statistically significant, (7) The Herfindahl Index in the home health market is approximately 1000 points lower in non-CON states.
Stratmann and Russ (2014)	They study the effects of CON on the supply and provision of services to indigent populations. They find: (1) CON programs are associated with 99 fewer hospital beds per 100,000 people, (2) Bed-specific CONs are associated with 131 fewer beds per 100,000 people,

TABLE A1 (Continued)

Paper	Summary
	(3) There are 4.7 fewer beds per 100,000 persons for each additional service covered by CON, (4) CON programs reduce the number of hospitals with MRI machines by 1–2 hospitals per 500,000 people, (5) CON programs that require charitable care are uncorrelated with uncompensated care.
Paul et al. (2014)	They assess the effect of CON and CON stringency on emergency department length of stay. They find that CON laws are associated with shorter stays, which they interpret as an indication of higher quality, but the effect diminishes with the stringency of CON laws (as measured by expenditure thresholds).
Chui et al. (2015)	To see if CON limits the use of inappropriate percutaneous coronary interventions, they looked at the share of procedures considered appropriate, uncertain, or inappropriate in CON and non-CON states. They found that states with CON have a lower proportion of inappropriate PCIs, but the differences were small.
Falchook and Chen (2015)	They examined utilization of radiation therapy when it is not warranted in CON and non-CON states, concluding that in CON states there is greater use of this treatment on elderly patients who may not need it.
Horwitz and Polsky (2015)	They use a cross-border design to estimate the effect of CON on MRI machines. They find that in a CON county that borders a non-CON county there are 6.4 fewer MRIs per million people.
Li and Dor (2015)	Removal of CON was associated with: (1) A substantial increase in the number of hospitals performing cardiac revascularization procedures, (2) An overall downward trend in CABG and an overall upward trend in the alternative procedure, PCI, (3) Entry led to a significant increase in the likelihood of CABG, relative to trend, but it did not contribute to the increase in PCI after adjusting for patient traits, market characteristics, and area-specific trends, (4) The probability of receiving PCI specifically at incumbent hospitals decreased with market entry, suggesting a volume shift from incumbents to entrants, (5) Entry shifted a disproportionate volume of low-severity patients from incumbent hospitals to entrants, and (6) Entry by new cardiac surgery centers tended to sort high-severity patients into the more invasive CABG procedure and low-severity patients into the less invasive PCI procedures, potentially improving quality of care.
Gutierrez et al. (2016)	They study the effect of CON on freestanding emergency departments, finding that those states that require a CON for EDs have fewer EDs per capita.
Bailey (2016)	Removing CON reduces hospital charges by 5.5% 5 years after repeal.
Kim et al. (2016)	They study the effect of CON laws on the use of intensity modulated radiation therapy when it is not warranted. They find that the therapy was actually used more often in CON states than in non-CON states, concluding that it failed to achieve its goal.
Stratmann and Koopman (2016)	They study the effect of CON on overall supply of services as well as rural supply of services. In particular, they find:

(Continues)

TABLE A1 (Continued)

Paper	Summary
	(1) CON programs are associated with 30% fewer hospitals per 100,000 residents across the entire state, (2) ASC-specific CONs are correlated with 14% fewer total ASCs per 100,000 residents, (3) CON programs are associated with 30% fewer rural hospitals per 100,000 rural residents, and (4) ASC-specific CONs are correlated with 13% fewer rural ASCs per 100,000 rural residents.
Rahman et al. (2016)	CON increases the growth in Medicare and Medicaid expenditures on nursing home care but decreases growth in home healthcare expenditures.
Bailey et al. (2017)	They find that prices are higher in CON states relative to non-CON states, but the difference isn't statistically significant.
Ni et al. (2017)	They assess the effect of CON on market concentration (as measured by the Herfindahl–Hirschman Index [HHI]) in emergency departments. They measure CON two ways—using a simple binary measure and a stringency measure based on the dollar threshold at which investments are subject to review. They use 2SLS to address concerns of endogeneity. Their (somewhat dubious) IVs in the binary tests are an index of science and technology and the unemployment rate, and in the stringency model, they are the CPI and the unemployment rate. They find that CON laws are associated with greater competition in emergency departments, concluding that they serve as a sort of anti-trust tool.
Perry (2017)	Service areas in NC are allocated a new machine when the number of MRI procedures performed in the area crosses a predetermined threshold. He compares service areas that are just below the threshold to areas just above the threshold to see the effect of a binding CON constraint. He finds: (1) By limiting the use of scanners, CON laws reduce spending on patients with low back pain by about $400 in the first month of diagnosis, (2) CON limits the number of MRI scanners in an area. When an area is allowed to obtain a scanner, they almost always do, (3) Providers get around this constraint, to some degree, by utilizing unregulated mobile scanners, (4) Patients in a region constrained by CON receive 34% fewer scans in the first month after diagnosis, (5) Medicare patients are disproportionately crowded out by CON; their fraction of MRIs performed jumps 10 percentage points after CON approval, and (6) CON seems to limit cancer patient access to scans, but not musculoskeletal disorder patient access to scans.
Bailey (2018b)	He uses fixed- and random-effects regressions to test how the effect of CON on all-cause mortality within US counties. Though he finds a positive relationship between CON laws and all-cause mortality, the results are not statistically significant.
Browne et al. (2018)	They examine the effect of CON on total knee arthroplasty (TKA) by comparing states with and without CON. They find: (1) Average Medicare reimbursements were 5%–10% lower in non-CON states,

TABLE A1 (Continued)

Paper	Summary
	(2) CON is associated with lower TKA utilization per capita, but faster growth in utilization per capita, (3) CON is associated with TKA in higher-volume hospitals, and (4) Examination of adverse event rates did not reveal any strong associations between adverse outcome and CON.
Ohsfeldt and Li (2018)	They examine the effect of CON on home health agency quality ratings from the Centers for Medicare and Medicaid Services (CMS). They find that: (1) HHAs in CON states were about 58% less likely to be rated as "High" quality ($p < .01$), (2) HHAs in CON states were about 30% more likely to be rated as "Medium" quality compared to HHAs in states without CON for HHAs.
Noh and Brown (2018)	The study the effects of CON on substance abuse facilities, finding: (1) CON laws are negatively associated with the number of nonprofit substance abuse facilities, but (2) In states with both CON laws and Medicaid expansion, the number of nonprofit substance abuse facilities tended to increase.
Casp et al. (2019)	They study the effect of CON on total hip arthroplasty. They find: (1) CON is associated with a lower volume of total hip arthroplasty, (2) CON is associated with more care in high-volume hospitals, and (3) No difference in postoperative complications between CON and non-CON states.
Chui et al. (2019)	Like their 2015 paper, this one assesses whether CON limits inappropriate percutaneous coronary interventions. And as with the other paper, they find a small but economically insignificant effect.
Averett et al. (2019)	They analyzed the effects of the expiration of Pennsylvania's CON law on hip and knee replacement surgeries. They assessed the effect of deregulation on one measure of cost per service (charges) and four measures of quality. They found that deregulation had: (1) No effect on total charges, (2) Increased the length of stay, (3) No effect on hospital acquired infections, and (4) Decreased mortality.
Paul et al. (2019a)	States with CON laws have lower bed occupancy rates. The authors speculate that while CON reduces the number of beds, it may also shorten the length of patient stay and the net effect is to reduce the occupancy rate. Note that this is the opposite of the intention (which was to reduce unused capacity).
Paul et al. (2019b)	They study the effect of CON on market concentration in the inpatient care market, as measured by a normalized Herfindahl–Hirschman Index (HHI) built using inpatient volume data of acute care hospitals in each health referral region (HRR). They find that CON is associated with less market concentration.
Malik et al. (2019)	The examined the effect of CON on elective posterior lumbar fusions (PLFs) from 2005 to 2014, finding: (1) Average 90-day reimbursements were slightly higher (1.4% higher) in non-CON states ($22,115 vs. $21,802), (2) CON laws are associated with lower per capita utilization of PLFs, (3) CON laws are associated with more high-volume facilities,

(Continues)

TABLE A1 (Continued)

Paper	Summary
	(4) CON laws are not associated with significant reduction in 90-day readmissions, and (5) CON laws are not associated with significant reduction in 90-day complications.
Bailey (2019)	States that eliminate CON experience 4% reductions in real per capita healthcare spending.
Wu et al. (2019)	They assess the effect of CON regulation on several measures of quality in home healthcare, using a cross-border design to control for endogeneity. They find that CON is uniformly associated with worse outcomes including: (1) Patients perform worse on functional improvement measures (bathing, ambulating, transferring to bed, managing oral medication, and less pain interfering with activity), (2) They are more likely to be admitted to the ER, and (3) More likely to be admitted to an acute care hospital.
Sridharan et al. (2020)	They study the effect of CON on elective posterior lumbar fusions. They find: (1) CON is associated with reduced utilization of the procedures, (2) CON has no statistically significant effect on reimbursements, (3) CON is associated with more high-volume facilities, and (4) CON has economically insignificant effects on readmissions or complications.
Fayissa et al. (2020)	In an IV study, they find that CON is associated with: (1) 18%–24% lower nursing home survey scores computed by healthcare professionals, and (2) The substitution of lower-quality certified nursing assistance care for higher-quality licensed practical nurse care.
Mitchell et al. (2020)	They studied the relationship between CON and projected ICU bed shortages over the course of the COVID-19 pandemic. They found that compared with non-CON states, in CON states, expected shortages were more than twice as likely and the shortages were about nine times greater in per capita terms.
Myers and Sheehan (2020)	They examine the effect of CON laws on wait times. They find CON programs: (1) Increase median wait times for medical examinations, (2) Increase wait times for pain medication administration, (3) Increase wait times for hospital admittance and (4) Increase wait times for hospital discharge.
Cancienne et al. (2020)	They examine the effect of CON on knee arthroscopy, assessing its effect on: (1) Charges and reimbursements: in t-tests without controls they found that charges (which are the prices set before any negotiation) were lower in CON states, while reimbursements (which are actual payments) were not statistically significantly different, (2) Total volume: total volume and growth in total volume was lower in CON states than in non-CON states, (3) Volume within facilities: CON is associated with the presence of more high-volume facilities, and (4) Quality: There were more ER visits within 30 days of operation and more infections within 6 months of operation in CON than in non-CON states;

TABLE A1 (Continued)

Paper	Summary
	there were no differences in in-hospital deaths or readmissions within 30 days of the operation between CON and non-CON states.
Ettner et al. (2020)	They examine the effects of home health agency CONs and nursing home CONs on home health agencies. They find that in states with home health agency CONs there are: (1) Lower per patient expenditures (they don't know if this is due to skimping or to economies of scale), (2) Higher expenditures per agency, (3) Higher expenditures per resident, (4) Slightly fewer home health agencies per capita, and (5) Higher caseloads (volume) within agencies (this is what drives the higher expenditures per agency).
Stratmann and Baker (2020)	They examine the effect of CON on two measures of spending and two measures of quality (all four are indicators of "overutilization or waste"): (1) Medicare spending per rural beneficiary (they found this was $295 higher in CON states than in non-CON states), (2) Ambulance spending per beneficiary ($2.54 higher in CON states), (3) Hospital readmission rates (1.2 percentage points higher in CON states), and (4) Emergency room visits per 1000 beneficiaries (35.1 more emergency department visits per 1000 beneficiaries in CON states).
Ziino et al. (2020b)	The paper looks at reimbursements for spinal surgery in CON and non-CON states, finding that reimbursements fell the most in non-CON outpatient settings (−11% compound annual growth) in non-CON states.
Yuce et al. (2020)	The assess the effect of CON on measures of volume and of quality. They find: (1) No significant difference between CON and non-CON states in county-level procedures per 10,000 persons, (2) No significant difference between CON and non-CON states for hospital procedural volume, (3) No difference in hospital market share, (4) No difference in risk-adjusted 30-day postoperative mortality, (5) No difference in surgical cite infection, and (6) No difference in readmission
Ziino et al. (2020a)	They examined the effect of CON in lumbar micro decompressions in both in-patient and out-patient settings, focusing on growth in utilization of the procedure over time and changes in reimbursement over time. These were simple comparisons, not regressions with controls. They found: (1) CON status did not affect overall reimbursement rates ("The ability of outpatient surgery to lower costs may, in fact, be more powerful than CON programs.") (2) Utilization of the procedure increased more in CON states than in non-CON states.
Denduluri et al. (2021)	They study the effect of CON on open and endoscopic carpal tunnel release finding that the regulation has no effect on utilization or spending on the procedures.

(Continues)

TABLE A1 (Continued)

Paper	Summary
Chiu (2021)	He uses a cross-border discontinuity design to study the effect of CON on heart attack mortality. He finds that it is associated with 6 to 10% higher mortality 3 years after enactment.
Kosar and Rahman (2021)	They study the effect of CON regulation on the size of nursing homes, positing that larger nursing homes may facilitate the spread of COVID. They find that counties with CON laws had more COVID cases.
Bailey and Lewin (2021)	They examine the effect of psychiatric service CONs. They find that psychiatric service CONs: (1) Reduce the number of psychiatric hospitals by 20%, (2) Reduce the likelihood that a hospital will accept Medicare by 5.35 percentage points, and (3) Reduce the number of psychiatric clients per capita by 56%.
Baker and Stratmann (2021)	They examine the effect of medical imaging CONs on medical imaging providers. They find: (1) CON laws are associated with 20%–33% fewer providers, (2) Residents of CON states are 3.4–5.3 percentage points more likely to travel out of state to obtain these services, (3) CON laws are associated with 27%–53% fewer scans by nonhospital providers per beneficiary, 23%–70% fewer scans by new hospitals, and 6 to 21% more scans by older hospitals.
Herb et al. (2021)	They measure the effect of CON on travel time to radiation oncology facilities, breaking down the effect by region. They find CON: (1) Has no association with prolonged travel in the West, (2) Is associated with lower odds of prolonged travel in both urban and rural tracts in the South, and (3) Is associated with increased odds of prolonged travel in both urban and rural tracts in the Midwest and Northeast.
Schultz et al. (2021)	They examined the effect of CON on total knee (TKA), hip (THA), and shoulder arthroplasty (TSA), finding: (1) TKA and TSA costs were higher in CON states than in non-CON states (and these results were statistically significant), THA costs were lower in CON states but these results were not statistically significant, (2) CON is associated with a lower volume of TKA and TSA procedures, though it was not statistically significant in the case of hip arthroplasty, and (3) CON has no statistically significant effect on complications (deep vein thrombosis and pulmonary embolism).
Ziino et al. (2021)	They studied inpatient cervical discectomy in CON and non-CON states in inpatient and outpatient setting. It appears that they did not use any controls, however. Regarding reimbursements, they find: (1) In the inpatient setting, reimbursement was lower in non-CON states ($1128.40) than in the CON states ($1223.56). But reimbursements in the CON states were falling faster over time. (2) In the outpatient setting reimbursement was higher in Non-CON states ($4237.01) than in CON states ($3859.31) and reimbursements were growing in the non-CON states but falling in the CON states. Regarding access:

TABLE A1 (Continued)

Paper	Summary
	(3) In the inpatient setting, there were more patients in the CON setting than in the non-CON setting (657 compared with 231) and utilization of the procedure was growing faster in CON than in non-CON states but this does not appear to control for the larger population of CON states than non-CON states. (4) Similarly, in the outpatient setting, there were more patients in the CON setting than in the non-CON setting (435 compared with 257) and utilization of the procedure was growing faster in CON than in non-CON states but again this does not appear to control for the larger population of CON states than non-CON states.
Roy et al. (2022)	They examined the relationship between CON and mortality associated with illnesses that require similar medical equipment as COVID. They find that: (1) There are higher mortality rates in CON states than in non-CON states, and (2) States with high healthcare utilization that reformed their CON laws during the pandemic saw lower mortality rates resulting from natural death, septicemia, diabetes, chronic lower respiratory disease, influenza or pneumonia, Alzheimer's, and COVID.
Stratmann (2022)	He studies the effect of CON on 9 measures of hospital quality: (1) Death among surgical inpatients with serious treatable complications, (2) Postoperative pulmonary embolism or deep vein thrombosis, (3) Percent of patients giving their hospital a 9 or 10 overall rating, (4) Pneumonia readmission rate, (5) Pneumonia mortality rate, (6) Heart failure readmission rate, (7) Heart failure mortality rate, (8) Heart attack readmission rate, (9) Heart attack mortality rate, Hospitals in CON states performed worse than those in non-CON states in 8 of the 9 categories, the exception being postoperative pulmonary embolism.
Bailey et al. (2022)	They measure how CON affects the number of substance abuse facilities and beds per capita in a state, and the effect of CON on the forms of payment that treatment facilities accept. They find that CON reduces the acceptance of private insurance but has no statistically significant effect on the number of facilities, beds, or clients and no significant effect on the acceptance of Medicare or Medicaid.
Mitchell and Stratmann (2022)	They examine the effect of bed CON on statewide bed utilization rates and on individual hospital shortages. They find: (1) States that require CONs for beds had 12% higher bed utilization rates, (2) States that require CONs for beds had 58% more days with more than 70% of their beds in use, (3) Hospitals in these states were 27% more likely to run out of beds, and (4) States that relaxed these rules for COVID saw no difference in utilization rates or shortages.
Gaines and Cagle (2023)	They study the effects of CON laws in a cross-sectional analysis of hospice quality outcomes using the hospice item set metric (HIS) developed by CMS. Controlling for ownership and size, they found hospice CON states had higher HIS ratings than those from Non-CON states along four dimensions:

(Continues)

TABLE A1 (Continued)

Paper	Summary
	(1) Beliefs and values addressed ($\beta = .05$, $p = .009$), (2) Pain assessment ($\beta = .05$, $p = .009$), (3) Dyspnea treatment ($\beta = .08$, $p < .001$), and (4) The composite measure ($\beta = .09$, $p < .001$). They also found that along four additional measures, the differences were statistically insignificant ($p > .05$): (5) Treatment preferences, (6) Pain screening, (7) Dyspnea screening, and (8) Opioid bowel treatment
Bailey and Hamami (2023)	CON causes spending on those with less than excellent health to be as much as 20% higher, though it has no statistically significant effect on spending on those in good health.
Horwitz et al. (2024)	They use a border discontinuity design to study the effect of CON on availability and utilization of CT and MRI imaging in both low-value and high-value settings. They find: (1) Moving across the border from a non-CON state to a CON state reduces the odds that the Census tract will have an MRI by 14%, (2) Moving across the border from a non-CON state to a CON state has no effect on the availability of CT scanners, (3) There is a 20%–26% reduction in seven measures of low-value imagining utilization, which they interpret as a potentially positive result, (4) There is no difference in high-value MRI utilization across the border, and (5) There is a 6% difference in high-value CT utilization across the border.

Potential Policy Options – Psychiatric and Expedited Review

Legislative Mandate: Chapter 423 of the 2024 Acts of Assembly mandates the State Health Services Plan Task Force to develop recommendations on expedited review of project types subject to certificate of public need (COPN) requirements that are generally non contested and present limited health planning impacts. The Task Force shall also create recommendations regarding:

1. What facilities and projects listed in § 32.1-102.1:3 of the Code of Virginia should be added to the expedited review process;
2. Criteria that should apply to any project types subject to expedited review; and
3. A framework for the application and approval process of such projects.

Project types for consideration shall include:

1. Increases in inpatient psychiatric beds;
2. Relocation of inpatient psychiatric beds;
3. Introduction of psychiatric services into an existing medical care facility; and
4. Conversion of beds in an existing medical care facility to psychiatric inpatient beds.

Group options from the May 30, 2024 State Health Services Plan Task Force Meeting

Option	Group 1	Group 2	Group 3
1. Move psychiatric beds from full COPN review to expedited review*	Oppose	Oppose	Support
2. Move the establishment of a psychiatric facility from full COPN review to expedited review*	Oppose	Oppose	Table for further discussion
3. Allow facilities that already provide psychiatric services to add beds using the expedited review process*	Support with the caveat that expedited review in extended to 90-days	Oppose	Support
4. Allow facilities to relocate psychiatric beds through the expedited process*	Support	Oppose	Support with the caveat that the relocation occurs within the same PD
5. Require facilities to request a COPN in order to convert beds	Support	Support	Support

from psychiatric beds to non-psychiatric beds*			
6. Allow facilities that already provide psychiatric services to establish a new psychiatric facility through the expedited review process*	Support	Oppose	Support with the caveat that the establishment occurs within the same PD
7. Move the addition of psychiatric services from full COPN review to expedited review*	Oppose	Oppose	No consensus
8. Extend expedited review from 45 days to 90 days	Highly Support	Oppose	Support
9. Require the Commissioner to condition expedited review applications on providing a specified level of charity care*	Oppose at face value – would like more information	Support	Support
10. Require the Commissioner to condition psychiatric projects on the acceptance of Temporary Detention Orders (TDOs)*	Support, but not as a mandate	Need more information, oppose as-is	Support
11. Require any project that is contested to be pulled from expedited review and placed into full review	Support	Support	Tabled for further discussion
12. Allow for members of the public to request a hearing for an expedited project	Oppose	Oppose	Support
13. Add the following COPN projects to the	Need more information	Need more information	Tabled for further discussion

expedited review process for existing medical care facilities that already provide the applicable existing service:* • Medical-surgical beds • Hospice beds • Psychiatric beds • Rehabilitation beds • Cardiac catheterization laboratories • Operating rooms • CT machines • MRI machines • PET machines Linear accelerators			

Individual member opinions

While groups reported on their respective group votes, individual members of the Task Force also submitted their own opinions and alternatives (see Appendix 1). 10 of the 16 Task Force Members submitted their individual opinions on the options presented.

Option	Positions	Recommended Qualifiers
1. Move psychiatric beds from full COPN review to expedited review*	Support: **4** Oppose: **5** Oppose with Qualifier: **1**	A. Oppose unless the applicant is an existing provider of inpatient psychiatric services
2. Move the establishment of a psychiatric facility from full COPN	Support: **5** Oppose: **5**	

review to expedited review*		
3. Allow facilities that already provide psychiatric services to add beds using the expedited review process*	Support: **6** Support with Qualifier: **4**	A. Support with caveat that psychiatric beds cannot be converted to non-psychiatric beds without review B. Support with the caveat that if opposition is filed with DCOPN, the project will be removed from expedited review to full review, and that expedited review is extended from 45 days to 90 days C. Support assuming review is limited to 10 or 10% of beds, whichever is less D. Qualified support with the conditions that they meet criteria below, and the loophole is closed
4. Allow facilities to relocate psychiatric beds through the expedited process*	Support: **5** Oppose: **1** Support with Qualifier: **4**	A. Support only if the facility already has a COPN for psychiatric services and there is a limit for the number of beds B. Support with the caveat that if opposition is filed with DCOPN, the project will be removed from expedited review to full review, and that expedited review is extended from 45 days to 90 days C. Support if expedited review is extended from 45 days to 90 days D. Support, assuming review is limited to 10 or 10% of beds, whichever is less
5. Require facilities to request a COPN in order to convert beds from psychiatric beds to non-psychiatric beds*	Support: **8** Oppose: **1** Support with Qualifier: **1**	A. Support, assuming review is limited to 10 or 10%, whichever is less
6. Allow facilities that already provide psychiatric services to establish a new psychiatric facility through the expedited review process*	Support: **5** Oppose: **3** Support with Qualifier: **2**	A. Support with the caveat that if opposition is filed with DCOPN, the project will be removed from expedited review to full review, and that expedited review is extended from 45 days to 90 days B. Support with the "establish a new psychiatric facility under its current hospital license" being important"
7. Move the addition of psychiatric services from full	Support: **3** Oppose: **7**	

COPN review to expedited review*		
8. Extend expedited review from 45 days to 90 days	Support: **3** Oppose: **5** Support with Qualifier: **2**	A. Support if combined with options 9, 10, and 11 B. Support and add batch cycles, either 3 per year or every other month
9. Require the Commissioner to condition expedited review applications on providing a specified level of charity care*	Support: **3** Oppose: **3** Undecided/No Position: **4**	
10. Require the Commissioner to condition psychiatric projects on the acceptance of Temporary Detention Orders (TDOs)*	Support: **2** Oppose:**1** Support with Qualifier: **5** Undecided/No Position: **2**	A. Support as an option but not as a mandate B. Support as an option for the Commissioner, depending on needs C. Support, but more information on the enforcement of facilities accepting TDO and forensic patients needed D. Support, but need more information to understand if patient is appropriate for setting
11. Require any project that is contested to be pulled from expedited review and placed into full review	Support: **6** Oppose: **1** Support with Qualifier: **2** Undecided/No Position: **1**	A. Support as long as the objection has substantiative grounds B. Support if good cause criteria is met
12. Allow for members of the public to request a hearing for an expedited project	Support: **5** Oppose: **2** Oppose with Qualifier: **1** Undecided/No Position: **2**	A. Oppose if all expedited review projects with opposition automatically become full review projects
This option will be considered during the August meeting 13. Add the following COPN projects to the expedited review process for existing medical care facilities that already provide	Support: **3** Oppose: **2** Undecided/No Position: **4**	

the applicable existing service:* • Medical-surgical beds • Hospice beds • Psychiatric beds • Rehabilitation beds • Cardiac catheterization laboratories • Operating rooms • CT machines • MRI machines • PET machines • Linear accelerators		

Additional Options for Consideration

During the May 30 meeting, Group 3 offered the following additional options during their report out:

Option	How it works now	How it would change
1. Add a batch cycle specifically for expedited review projects*	Expedited review applications can be submitted at any time for projects that meet the expedited review requirements.	Applications for expedited review projects could only be submitted for consideration during the expedited review batch cycle

There were 3 potential options offered for consideration by individual members submitted:

Option	How it works now	How it would change
1. Add batch cycles specifically for	Expedited review applications can be	Applications for expedited review projects could only be

expedited review projects*	submitted at any time for projects that meet the expedited review requirements.	submitted for consideration during the expedited review batch cycle
2. Move all COPN projects from full review to expedited review*	Medical care facilities must obtain a COPN for the projects listed in § 32.1-1-2.1:3 of the Code of Virginia.	All projects requiring a COPN would be reviewed using the expedited process.
3. Eliminate all psychiatric projects from requiring a COPN*	Medical care facilities are required to obtain a COPN for the establishment of psychiatric facilities, the addition of psychiatric beds, and the relocation of psychiatric beds.	Medical care facilities would no longer be required to obtain a COPN to establish a psychiatric facility, add psychiatric beds, or relocate psychiatric beds.

*Requires a legislative change

Voting Options for Psychiatric and Expedited Review

The proposed potential policy options presented for voting are listed below by legislative changes and regulatory changes, including the changes proposed by group members (italicized). The Task Force follows Roberts Rules of Order for voting. During the discussion of the options below, Task Force members are welcome to introduce their qualifiers for consideration.

Legislative Changes:

1. Move psychiatric beds from full COPN review to expedited review
2. Move the establishment of a psychiatric facility from full COPN review to expedited review[1]
3. Allow facilities that already provide psychiatric services to add beds using the expedited review process
4. Allow facilities to relocate psychiatric beds through the expedited process
5. Require facilities to request a COPN in order to convert beds from psychiatric beds to non-psychiatric beds
6. Allow facilities that already provide psychiatric services to establish a new psychiatric facility through the expedited review process
7. Move the addition of psychiatric services from full COPN review to expedited review
8. Require the Commissioner to condition psychiatric projects on the acceptance of Temporary Detention Orders
9. *Move all COPN projects from full review to expedited review*
10. *Eliminate all psychiatric projects from requiring a COPN*

[1] If adopted as a recommendation, the Task Force will not be required to vote on option 6.

Regulatory Changes:

1. Extend expedited review from 45 days to 90 days
2. Require the Commissioner to condition expedited review applications on providing a specified level of charity care
3. Require any project that is contested to be pulled from expedited review and placed into full review
4. Allow for members of the public to request a hearing for an expedited project
5. *Add batch cycles specifically for expedited review projects*

State Health Services Plan Task Force
Policy Option Voting Process to be Followed During the July 12, 2024 All-Virtual meeting

The Task Force will follow Roberts Rules of Order.

VDH staff will read the policy option and the text of the option will be displayed on the screen. Following presentation by VDH staff of the policy option, the Chair will ask for a motion to adopt the policy option. Upon receiving a second, the Chair will ask if there is any discussion concerning the motion. At that point, the policy option will be in the proper posture to be discussed and considered by the Task Force. It will also be in the proper posture at that point for any Task Force member to offer amendments to the policy option language.

Each Task Force member who wishes to participate in the discussion of any of the policy options needs to first be recognized by the Chair prior to speaking. If you wish to be recognized, simply raise your hand or use the "raise your hand" feature on the video conference.

- The Chair has the discretion to ask a member the purpose for which they wish to be recognized and if, in the Chair's opinion, such purpose is not germane to the current discussion, could cause confusion, or interfere with the efficient and orderly operation of the Task Force, the Chair may choose to delay recognition of the member until after the current discussion or item before the Task Force is completed.

Upon conclusion of discussion of the motion, or if there is no discussion, the Chair will call for a roll call vote and ask VDH staff to call the roll. A Task Force member may vote Yes, No, or Abstain.

If as part of the discussion any Task Force member wishes to offer an amendment to any policy option, the amendment (i.e. the proposed PRIMARY amendment) needs to be offered in the form of a motion. In making that motion, the member needs to state to the Task Force the language change or changes that they are proposing to the policy option text.

- Task Force members may provide VDH staff with proposed amendment language prior to the Task Force meeting. If any Task Force member wishes to make amendments but has not yet reduced them to writing, VDH will be able to type the proposed amendment into the computer and the proposed amendment language will be displayed on the screen for the Task Force's consideration prior to voting on the motion. The Chair will ask VDH staff to read the draft amendment aloud. Once the member is satisfied that the amendment has been correctly stated, the Chair will ask the member to offer the amendment in the form of a motion.

If that motion receives a second from another Task Force member, the Task Force will discuss and subsequently vote on the motion. Following completion of the discussion, the Chair will call for a roll call vote and ask VDH staff to call the roll.

If, upon hearing the proposed PRIMARY amendment, another Task Force member desires to further amend that amendment, that member must make a SECONDARY AMENDMENT in the form of a motion, which also must receive a second. VDH staff will display the text of the amendment on the screen.

Upon receiving a second, the Task Force will discuss, and then vote on the SECONDARY AMENDMENT prior to voting on the PRIMARY amendment. If the amendment(s) is(are) adopted, they will be added to the main motion to adopt the policy option. Please note that a secondary amendment that is worded such that it completely negates the primary amendment's meaning can get confusing, but if it is adopted, it will be attached to the main motion directly. After the vote(s) have been taken on any PRIMARY or SECONDARY amendments, the Task Force will vote on the main motion to adopt the policy option, as amended.

According to Robert's Rules, there can only be one secondary amendment offered. There can be no "amendment to the amendment to the amendment".

Analysis on Potential Expedited and Psychiatric Process Changes - Appendix 1

Legislative Mandate: Chapter 423 of the 2024 Acts of Assembly mandates the State Health Services Plan Task Force to develop recommendations on expedited review of project types subject to certificate of public need (COPN) requirements that are generally non contested and present limited health planning impacts. The Task Force shall also create recommendations regarding:

1. What facilities and projects listed in § 32.1-102.1:3 of the Code of Virginia should be added to the expedited review process;
2. Criteria that should apply to any project types subject to expedited review; and
3. A framework for the application and approval process of such projects.

Project types for consideration shall include:

1. Increases in inpatient psychiatric beds;
2. Relocation of inpatient psychiatric beds;
3. Introduction of psychiatric services into an existing medical care facility; and
4. Conversion of beds in an existing medical care facility to psychiatric inpatient beds.

Potential Expedited and Psychiatric Process Changes:

Option	How it works now	How it would change	Alternative?	Vote Support, Oppose, No Position, or Undecided
1. Move psychiatric beds from full COPN review to expedited review*	Psychiatric beds are required to be requested using the full 190-day COPN process during the C application cycle.	Psychiatric beds could be requested at any time and would be reviewed during a 45-day review period.		Oppose – do not support blanket move of psychiatric beds to full expedited review
2. Move the establishment of a	In order to establish a psychiatric facility, a	A person could apply for a COPN for a		Oppose – new projects should remain under full

Submission - Kathy Baker

psychiatric facility from full COPN review to expedited review*	person is required to apply during the C application cycle for the full 190-day review process.	psychiatric facility at any time and would be reviewed during the 45-day review period.		review to all time for all stakeholders to review and vet proposal.
3. Allow facilities that already provide psychiatric services to add beds using the expedited review process*	All facilities, whether they already have psychiatric beds or not, are required to submit an application using the full 190-day COPN process during the C application cycle.	Facilities with psychiatric beds would be able to request beds through the 45-day expedited process.		Support expedited review with the caveat that we also not allow psychiatric beds to be converted to med surg beds later without review. Would be helpful to limit the number of beds that can be added.
4. Allow facilities to relocate psychiatric beds through the expedited process*	All facilities are required to obtain a COPN through the full 190-day review cycle to relocate beds. If the bed relocation is 10 beds or 10%, whichever is less, and when the cost of relocation is less than $5 million, facilities may apply for a COPN through the 45-day expedited review process.	Facilities could obtain a COPN through the 45-day expedited review process to relocate any number of beds.		Support but only if the facility already has a COPN for psych services and limit the number of beds.
5. Require facilities to request a COPN in	Facilities are able to convert psychiatric	Facilities would be required to request a		Highly Support

order to convert beds from psychiatric beds to non-psychiatric beds*	beds to non-psychiatric beds freely (this does not apply to beds added through the RFA process).	COPN in order to convert beds from psychiatric beds to non-psychiatric beds.		
6. Allow facilities that already provide psychiatric services to establish a new psychiatric facility through the expedited review process*	All projects involving a new psychiatric facility are required to obtain a COPN.	Facilities that already provide psychiatric services would be able to utilize the expedited process in order to establish a new psychiatric facility under its current hospital license.		Oppose
7. Move the addition of psychiatric services from full COPN review to expedited review*	A facility is required to obtain a COPN in order to add new psychiatric services that have not been provided in the previous 12 months.	To add new psychiatric services, a facility would be able to apply at any time and the application would be reviewed during the 45-day review cycle.		Oppose – Need to continue the ability for stakeholder review and vetting
8. Extend expedited review from 45 days to 90 days	Expedited review projects adhere to a 45-day review cycle that begins when an application is submitted and ends with a decision from the Commissioner by the 45th day.	Expedited review projects would adhere to a 90-day review cycle that begins when an application is submitted and ends with a decision from the Commissioner by the 90th day.		Highly support – agree that the extension would allow for full vetting of any concern.

9. Require the Commissioner to condition expedited review applications on providing a specified level of charity care*	The Commissioner does not have the authority to condition expedited review projects.	The Commissioner would be required to condition all approved expedited project COPNs on providing a specified level of charity care.		Need more information – support charity conditioning at face value
10. Require the Commissioner to condition psychiatric projects on the acceptance of Temporary Detention Orders (TDOs)*	The Commissioner does not have the authority to condition COPNs on the acceptance of TDOs.	The Commissioner would be required to condition all approved psychiatric project COPNs on the acceptance of TDOs.		Support this as an option but not a mandate. Concern regarding the placement of forensic patients through the TDO process
11. Require any project that is contested to be pulled from expedited review and placed into full review	There is no requirement regarding contested projects in the regulation.	Any project that is contested by a member of the public would be pulled out of expedited review and placed into full review.		Support
12. Allow for members of the public to request a hearing for an expedited project	There is no public participation requirement in the regulation.	Members of the public would be able to request a public hearing for an expedited project to be held during the 45-day review cycle.		Support
13. Add the following COPN projects to the expedited review	Any facility interested in adding any items from the list are required to obtain a	Facilities that already provide the applicable services for the corresponding listed		Oppose expedited review for medical surgical beds; Hospice beds, Rehabilitation beds, cardiac catheterization

process for existing medical care facilities that already provide the applicable existing service:* • Medical-surgical beds • Hospice beds • Psychiatric beds • Rehabilitation beds • Cardiac catheterization laboratories • Operating rooms • CT machines • MRI machines • PET machines • Linear accelerators	COPN through the 190-day process.	items may request a COPN through the expedited review process to add any of the projects listed.		laboratories; operating rooms; and Linear accelerators. Oppose expedited review for all diagnostic imaging.
14.				

15.				
16.				

17.				

*Requires a legislative change

Analysis on Potential Expedited and Psychiatric Process Changes

Legislative Mandate: Chapter 423 of the 2024 Acts of Assembly mandates the State Health Services Plan Task Force to develop recommendations on expedited review of project types subject to certificate of public need (COPN) requirements that are generally non contested and present limited health planning impacts. The Task Force shall also create recommendations regarding:

1. What facilities and projects listed in § 32.1-102.1:3 of the Code of Virginia should be added to the expedited review process;
2. Criteria that should apply to any project types subject to expedited review; and
3. A framework for the application and approval process of such projects.

Project types for consideration shall include:

1. Increases in inpatient psychiatric beds;
2. Relocation of inpatient psychiatric beds;
3. Introduction of psychiatric services into an existing medical care facility; and
4. Conversion of beds in an existing medical care facility to psychiatric inpatient beds.

Potential Expedited and Psychiatric Process Changes:

Option	How it works now	How it would change	Alternative?	Vote Support, Oppose, No Position, or Undecided
1. Move psychiatric beds from full COPN review to expedited review*	Psychiatric beds are required to be requested using the full 190-day COPN process during the C application cycle.	Psychiatric beds could be requested at any time and would be reviewed during a 45-day review period.	New providers of psych services need to be vetted to determine ability to provide quality services, staff with licensed professionals, meet facility regulations, determine public need,	Oppose (if not existing provider of inpatient psych services)

Submission - Karen Cameron

			etc which requires a full review to complete.	
2. Move the establishment of a psychiatric facility from full COPN review to expedited review*	In order to establish a psychiatric facility, a person is required to apply during the C application cycle for the full 190-day review process.	A person could apply for a COPN for a psychiatric facility at any time and would be reviewed during the 45-day review period.	New providers need to be vetted to determine ability to provide quality services, staff with licensed professionals, meet facility regulations, determine public need, etc which requires a full review to complete.	Oppose
3. Allow facilities that already provide psychiatric services to add beds using the expedited review process*	All facilities, whether they already have psychiatric beds or not, are required to submit an application using the full 190-day COPN process during the C application cycle.	Facilities with psychiatric beds would be able to request beds through the 45-day expedited process.	Support with the caveat that if opposition is filed with DCOPN, it goes to full review and expedited review goes to 90 day batch cycles (see #8 below)	Support (with caveats)
4. Allow facilities to relocate psychiatric beds through the expedited process*	All facilities are required to obtain a COPN through the full 190-day review cycle to relocate beds. If the bed relocation is 10 beds or 10%, whichever is less, and when the cost of relocation is less than $5 million, facilities may apply for a COPN	Facilities could obtain a COPN through the 45-day expedited review process to relocate any number of beds.	Support with the caveat that if opposition is filed with DCOPN, it goes to full review, expedited review goes to 90 day batch cycles (see #8 below) and relocation is within the same P.D.	Support (with caveats)

	through the 45-day expedited review process.			
5. Require facilities to request a COPN in order to convert beds from psychiatric beds to non-psychiatric beds*	Facilities are able to convert psychiatric beds to non-psychiatric beds freely (this does not apply to beds added through the RFA process).	Facilities would be required to request a COPN in order to convert beds from psychiatric beds to non-psychiatric beds.	Without this, the regulations leave a back door way for providers to get additional types of beds that haven't been evaluated for public need.	Highly Support
6. Allow facilities that already provide psychiatric services to establish a new psychiatric facility through the expedited review process*	All projects involving a new psychiatric facility are required to obtain a COPN.	Facilities that already provide psychiatric services would be able to utilize the expedited process in order to establish a new psychiatric facility under its current hospital license.	Support with the caveat that if opposition is filed with DCOPN, it goes to full review, expedited review goes to 90 day batch cycles (see #8 below) and relocation is within the same P.D.	Support (with caveats)
7. Move the addition of psychiatric services from full COPN review to expedited review*	A facility is required to obtain a COPN in order to add new psychiatric services that have not been provided in the previous 12 months.	To add new psychiatric services, a facility would be able to apply at any time and the application would be reviewed during the 45-day review cycle.	New providers of psych services need to be vetted to determine ability to provide quality services, staff with licensed professionals, meet facility regulations, determine public need, etc which requires a full review to complete.	Oppose

8. Extend expedited review from 45 days to 90 days	Expedited review projects adhere to a 45-day review cycle that begins when an application is submitted and ends with a decision from the Commissioner by the 45th day.	Expedited review projects would adhere to a 90-day review cycle that begins when an application is submitted and ends with a decision from the Commissioner by the 90th day.	Have four batching cycles for expedited review of a specific type project with certain type projects in each of the initial three months, ie so public will have reasonable expectation when a project will be filed and can comment. Allows public adequate time to have input and staff adequate time to analyze that input.	Support
9. Require the Commissioner to condition expedited review applications on providing a specified level of charity care*	The Commissioner does not have the authority to condition expedited review projects.	The Commissioner would be required to condition all approved expedited project COPNs on providing a specified level of charity care.	Promotes parity	Support
10. Require the Commissioner to condition psychiatric projects on the acceptance of Temporary Detention Orders (TDOs)*	The Commissioner does not have the authority to condition COPNs on the acceptance of TDOs.	The Commissioner would be required to condition all approved psychiatric project COPNs on the acceptance of TDOs.	Support as an option for the Commissioner, depending on needs	Support
11. Require any project that is	There is no requirement regarding	Any project that is contested by a member		Support

contested to be pulled from expedited review and placed into full review	contested projects in the regulation.	of the public would be pulled out of expedited review and placed into full review.		
12. Allow for members of the public to request a hearing for an expedited project	There is no public participation requirement in the regulation.	Members of the public would be able to request a public hearing for an expedited project to be held during the 45-day review cycle.		Oppose, if all expedited review projects with opposition automatically become full review projects
13. Add the following COPN projects to the expedited review process for existing medical care facilities that already provide the applicable existing service:* • Medical-surgical beds • Hospice beds • Psychiatric beds • Rehabilitation beds • Cardiac catheterization laboratories	Any facility interested in adding any items from the list are required to obtain a COPN through the 190-day process.	Facilities that already provide the applicable services for the corresponding listed items may request a COPN through the expedited review process to add any of the projects listed.		TBD

• Operating rooms • CT machines • MRI machines • PET machines • Linear accelerators				
14.				
15.				

16.				
17.				

*Requires a legislative change

Potential Expedited and Psychiatric Process Changes. ***<u>Options noted with a * please see attached letter to Commissioner</u>***

Option	How it works now	How it would change	Alternative?	Vote Support, Oppose, No Position, or Undecided
1. Move psychiatric beds from full COPN review to expedited review*	Psychiatric beds are required to be requested using the full 190-day COPN process during the C application cycle.	Psychiatric beds could be requested at any time and would be reviewed during a 45-day review period.		**SUPPORT***
2. Move the establishment of a psychiatric facility from full COPN review to expedited review*	In order to establish a psychiatric facility, a person is required to apply during the C application cycle for the full 190-day review process.	A person could apply for a COPN for a psychiatric facility at any time and would be reviewed during the 45-day review period.		**SUPPORT***
3. Allow facilities that already provide psychiatric services to add beds using the expedited review process*	All facilities, whether they already have psychiatric beds or not, are required to submit an application using the full 190-day COPN process during the C application cycle.	Facilities with psychiatric beds would be able to request beds through the 45-day expedited process.		**SUPPORT***
4. Allow facilities to relocate psychiatric beds through the	All facilities are required to obtain a COPN through the full	Facilities could obtain a COPN through the 45-day expedited review		**SUPPORT***

Submission - Keith Berger

expedited process*	190-day review cycle to relocate beds. If the bed relocation is 10 beds or 10%, whichever is less, and when the cost of relocation is less than $5 million, facilities may apply for a COPN through the 45-day expedited review process.	process to relocate any number of beds.		
5. Require facilities to request a COPN in order to convert beds from psychiatric beds to non-psychiatric beds*	Facilities are able to convert psychiatric beds to non-psychiatric beds freely (this does not apply to beds added through the RFA process).	Facilities would be required to request a COPN in order to convert beds from psychiatric beds to non-psychiatric beds.		**OPPOSE**
6. Allow facilities that already provide psychiatric services to establish a new psychiatric facility through the expedited review process*	All projects involving a new psychiatric facility are required to obtain a COPN.	Facilities that already provide psychiatric services would be able to utilize the expedited process in order to establish a new psychiatric facility under its current hospital license.		**SUPPORT***
7. Move the addition of psychiatric services	A facility is required to obtain a COPN in order to add new psychiatric	To add new psychiatric services, a facility would be able to apply		**SUPPORT***

from full COPN review to expedited review*	services that have not been provided in the previous 12 months.	at any time and the application would be reviewed during the 45-day review cycle.		
8. Extend expedited review from 45 days to 90 days	Expedited review projects adhere to a 45-day review cycle that begins when an application is submitted and ends with a decision from the Commissioner by the 45th day.	Expedited review projects would adhere to a 90-day review cycle that begins when an application is submitted and ends with a decision from the Commissioner by the 90th day.		**OPPOSE**
9. Require the Commissioner to condition expedited review applications on providing a specified level of charity care*	The Commissioner does not have the authority to condition expedited review projects.	The Commissioner would be required to condition all approved expedited project COPNs on providing a specified level of charity care.		**UNDECIDED** *
10. Require the Commissioner to condition psychiatric projects on the acceptance of Temporary Detention Orders (TDOs)*	The Commissioner does not have the authority to condition COPNs on the acceptance of TDOs.	The Commissioner would be required to condition all approved psychiatric project COPNs on the acceptance of TDOs.		**UNDECIDED** *
11. Require any project that is contested to be pulled	There is no requirement regarding contested projects in	Any project that is contested by a member of the public would be		**SUPPORT***

from expedited review and placed into full review	the regulation.	pulled out of expedited review and placed into full review.		
12. Allow for members of the public to request a hearing for an expedited project	There is no public participation requirement in the regulation.	Members of the public would be able to request a public hearing for an expedited project to be held during the 45-day review cycle.		**SUPPORT***
13. Add the following COPN projects to the expedited review process for existing medical care facilities that already provide the applicable existing service:* • Medical-surgical beds • Hospice beds • Psychiatric beds • Rehabilitation beds • Cardiac catheterization laboratories	Any facility interested in adding any items from the list are required to obtain a COPN through the 190-day process.	Facilities that already provide the applicable services for the corresponding listed items may request a COPN through the expedited review process to add any of the projects listed.		**SUPPORT***

• Operating rooms • CT machines • MRI machines • PET machines • Linear accelerators				

Analysis on Potential Expedited and Psychiatric Process Changes

Legislative Mandate: Chapter 423 of the 2024 Acts of Assembly mandates the State Health Services Plan Task Force to develop recommendations on expedited review of project types subject to certificate of public need (COPN) requirements that are generally non contested and present limited health planning impacts. The Task Force shall also create recommendations regarding:

1. What facilities and projects listed in § 32.1-102.1:3 of the Code of Virginia should be added to the expedited review process;
2. Criteria that should apply to any project types subject to expedited review; and
3. A framework for the application and approval process of such projects.

Project types for consideration shall include:

1. Increases in inpatient psychiatric beds;
2. Relocation of inpatient psychiatric beds;
3. Introduction of psychiatric services into an existing medical care facility; and
4. Conversion of beds in an existing medical care facility to psychiatric inpatient beds.

Potential Expedited and Psychiatric Process Changes:

Option	How it works now	How it would change	Alternative?	Vote Support, Oppose, No Position, or Undecided
1. Move psychiatric beds from full COPN review to expedited review*	Psychiatric beds are required to be requested using the full 190-day COPN process during the C application cycle.	Psychiatric beds could be requested at any time and would be reviewed during a 45-day review period.		Oppose
2. Move the establishment of a	In order to establish a psychiatric facility, a	A person could apply for a COPN for a		Support

psychiatric facility from full COPN review to expedited review*	person is required to apply during the C application cycle for the full 190-day review process.	psychiatric facility at any time and would be reviewed during the 45-day review period.		
3. Allow facilities that already provide psychiatric services to add beds using the expedited review process*	All facilities, whether they already have psychiatric beds or not, are required to submit an application using the full 190-day COPN process during the C application cycle.	Facilities with psychiatric beds would be able to request beds through the 45-day expedited process.		Support
4. Allow facilities to relocate psychiatric beds through the expedited process*	All facilities are required to obtain a COPN through the full 190-day review cycle to relocate beds. If the bed relocation is 10 beds or 10%, whichever is less, and when the cost of relocation is less than $5 million, facilities may apply for a COPN through the 45-day expedited review process.	Facilities could obtain a COPN through the 45-day expedited review process to relocate any number of beds.		Support but with 90-day review
5. Require facilities to request a COPN in	Facilities are able to convert psychiatric	Facilities would be required to request a		Support

order to convert beds from psychiatric beds to non-psychiatric beds*	beds to non-psychiatric beds freely (this does not apply to beds added through the RFA process).	COPN in order to convert beds from psychiatric beds to non-psychiatric beds.		
6. Allow facilities that already provide psychiatric services to establish a new psychiatric facility through the expedited review process*	All projects involving a new psychiatric facility are required to obtain a COPN.	Facilities that already provide psychiatric services would be able to utilize the expedited process in order to establish a new psychiatric facility under its current hospital license.		Support
7. Move the addition of psychiatric services from full COPN review to expedited review*	A facility is required to obtain a COPN in order to add new psychiatric services that have not been provided in the previous 12 months.	To add new psychiatric services, a facility would be able to apply at any time and the application would be reviewed during the 45-day review cycle.		Oppose. The idea needs more vetting or discussion.
8. Extend expedited review from 45 days to 90 days	Expedited review projects adhere to a 45-day review cycle that begins when an application is submitted and ends with a decision from the Commissioner by the 45th day.	Expedited review projects would adhere to a 90-day review cycle that begins when an application is submitted and ends with a decision from the Commissioner by the 90th day.		Support

9. Require the Commissioner to condition expedited review applications on providing a specified level of charity care*	The Commissioner does not have the authority to condition expedited review projects.	The Commissioner would be required to condition all approved expedited project COPNs on providing a specified level of charity care.		Oppose. Need more information on what qualifies as charity care.
10. Require the Commissioner to condition psychiatric projects on the acceptance of Temporary Detention Orders (TDOs)*	The Commissioner does not have the authority to condition COPNs on the acceptance of TDOs.	The Commissioner would be required to condition all approved psychiatric project COPNs on the acceptance of TDOs.		Support. There needs to be more information on the enforcement of facilities accepting TDO and forensic patients.
11. Require any project that is contested to be pulled from expedited review and placed into full review	There is no requirement regarding contested projects in the regulation.	Any project that is contested by a member of the public would be pulled out of expedited review and placed into full review.		Support. An objection needs to have substantive grounds.
12. Allow for members of the public to request a hearing for an expedited project	There is no public participation requirement in the regulation.	Members of the public would be able to request a public hearing for an expedited project to be held during the 45-day review cycle.		Support.
13. Add the following COPN projects to the expedited review	Any facility interested in adding any items from the list are required to obtain a	Facilities that already provide the applicable services for the corresponding listed		Too many variables so we did not consider this issue today.

process for existing medical care facilities that already provide the applicable existing service:* • Medical-surgical beds • Hospice beds • Psychiatric beds • Rehabilitation beds • Cardiac catheterization laboratories • Operating rooms • CT machines • MRI machines • PET machines • Linear accelerators	COPN through the 190-day process.	items may request a COPN through the expedited review process to add any of the projects listed.		
14.				

15.				
16.				

17.				

*Requires a legislative change

Analysis on Potential Expedited and Psychiatric Process Changes

Legislative Mandate: Chapter 423 of the 2024 Acts of Assembly mandates the State Health Services Plan Task Force to develop recommendations on expedited review of project types subject to certificate of public need (COPN) requirements that are generally non contested and present limited health planning impacts. The Task Force shall also create recommendations regarding:

1. What facilities and projects listed in § 32.1-102.1:3 of the Code of Virginia should be added to the expedited review process;
2. Criteria that should apply to any project types subject to expedited review; and
3. A framework for the application and approval process of such projects.

Project types for consideration shall include:

1. Increases in inpatient psychiatric beds;
2. Relocation of inpatient psychiatric beds;
3. Introduction of psychiatric services into an existing medical care facility; and
4. Conversion of beds in an existing medical care facility to psychiatric inpatient beds.

Potential Expedited and Psychiatric Process Changes:

Option	How it works now	How it would change	Alternative?	Vote Support, Oppose, No Position, or Undecided
1. Move psychiatric beds from full COPN review to expedited review*	Psychiatric beds are required to be requested using the full 190-day COPN process during the C application cycle.	Psychiatric beds could be requested at any time and would be reviewed during a 45-day review period.		Oppose
2. Move the establishment of a	In order to establish a psychiatric facility, a	A person could apply for a COPN for a		Oppose

Submission - Paul Dreyer

psychiatric facility from full COPN review to expedited review*	person is required to apply during the C application cycle for the full 190-day review process.	psychiatric facility at any time and would be reviewed during the 45-day review period.		
3. Allow facilities that already provide psychiatric services to add beds using the expedited review process*	All facilities, whether they already have psychiatric beds or not, are required to submit an application using the full 190-day COPN process during the C application cycle.	Facilities with psychiatric beds would be able to request beds through the 45-day expedited process.		Support, assuming review limited to 10 or 10% of beds, whichever is less
4. Allow facilities to relocate psychiatric beds through the expedited process*	All facilities are required to obtain a COPN through the full 190-day review cycle to relocate beds. If the bed relocation is 10 beds or 10%, whichever is less, and when the cost of relocation is less than $5 million, facilities may apply for a COPN through the 45-day expedited review process.	Facilities could obtain a COPN through the 45-day expedited review process to relocate any number of beds.		Support, assuming review limited to 10 or 10% of beds, whichever is less

5. Require facilities to request a COPN in order to convert beds from psychiatric beds to non-psychiatric beds*	Facilities are able to convert psychiatric beds to non-psychiatric beds freely (this does not apply to beds added through the RFA process).	Facilities would be required to request a COPN in order to convert beds from psychiatric beds to non-psychiatric beds.		Support, assuming review limited to 10 or 10% of beds, whichever is less
6. Allow facilities that already provide psychiatric services to establish a new psychiatric facility through the expedited review process*	All projects involving a new psychiatric facility are required to obtain a COPN.	Facilities that already provide psychiatric services would be able to utilize the expedited process in order to establish a new psychiatric facility under its current hospital license.		Oppose
7. Move the addition of psychiatric services from full COPN review to expedited review*	A facility is required to obtain a COPN in order to add new psychiatric services that have not been provided in the previous 12 months.	To add new psychiatric services, a facility would be able to apply at any time and the application would be reviewed during the 45-day review cycle.		Oppose
8. Extend expedited review from 45 days to 90 days	Expedited review projects adhere to a 45-day review cycle that begins when an application is submitted and ends with a decision from	Expedited review projects would adhere to a 90-day review cycle that begins when an application is submitted and ends with a decision from		Support if combined with 9, 10, 11

	the Commissioner by the 45th day.	the Commissioner by the 90th day.		
9. Require the Commissioner to condition expedited review applications on providing a specified level of charity care*	The Commissioner does not have the authority to condition expedited review projects.	The Commissioner would be required to condition all approved expedited project COPNs on providing a specified level of charity care.		Support
10. Require the Commissioner to condition psychiatric projects on the acceptance of Temporary Detention Orders (TDOs)*	The Commissioner does not have the authority to condition COPNs on the acceptance of TDOs.	The Commissioner would be required to condition all approved psychiatric project COPNs on the acceptance of TDOs.		Support
11. Require any project that is contested to be pulled from expedited review and placed into full review	There is no requirement regarding contested projects in the regulation.	Any project that is contested by a member of the public would be pulled out of expedited review and placed into full review.		Support
12. Allow for members of the public to request a hearing for an expedited project	There is no public participation requirement in the regulation.	Members of the public would be able to request a public hearing for an expedited project to be held during the 45-day review cycle.		No Position

13. Add the following COPN projects to the expedited review process for existing medical care facilities that already provide the applicable existing service:* • Medical-surgical beds • Hospice beds • Psychiatric beds • Rehabilitation beds • Cardiac catheterization laboratories • Operating rooms • CT machines • MRI machines • PET machines • Linear accelerators	Any facility interested in adding any items from the list are required to obtain a COPN through the 190-day process.	Facilities that already provide the applicable services for the corresponding listed items may request a COPN through the expedited review process to add any of the projects listed.		Oppose
14. Expedited Review applications should be	Unclear	Specific start-stop dates throughout the year,		Support

"batched" with specific start-stop dates		occurring every 3-4 months		
15.				
16.				

17.				

*Requires a legislative change

Analysis on Potential Expedited and Psychiatric Process Changes

Legislative Mandate: Chapter 423 of the 2024 Acts of Assembly mandates the State Health Services Plan Task Force to develop recommendations on expedited review of project types subject to certificate of public need (COPN) requirements that are generally non contested and present limited health planning impacts. The Task Force shall also create recommendations regarding:

1. What facilities and projects listed in § 32.1-102.1:3 of the Code of Virginia should be added to the expedited review process;
2. Criteria that should apply to any project types subject to expedited review; and
3. A framework for the application and approval process of such projects.

Project types for consideration shall include:

1. Increases in inpatient psychiatric beds;
2. Relocation of inpatient psychiatric beds;
3. Introduction of psychiatric services into an existing medical care facility; and
4. Conversion of beds in an existing medical care facility to psychiatric inpatient beds.

Potential Expedited and Psychiatric Process Changes:

Option	How it works now	How it would change	Alternative?	Vote Support, Oppose, No Position, or Undecided
1. Move psychiatric beds from full COPN review to expedited review*	Psychiatric beds are required to be requested using the full 190-day COPN process during the C application cycle.	Psychiatric beds could be requested at any time and would be reviewed during a 45-day review period.	Remove from COPN	Support, in lieu of eliminating from COPN
2. Move the establishment of a	In order to establish a psychiatric facility, a	A person could apply for a COPN for a	Remove from COPN	Support in lieu of eliminating from COPN

Submission - Michael Desjadon

psychiatric facility from full COPN review to expedited review*	person is required to apply during the C application cycle for the full 190-day review process.	psychiatric facility at any time and would be reviewed during the 45-day review period.		
3. Allow facilities that already provide psychiatric services to add beds using the expedited review process*	All facilities, whether they already have psychiatric beds or not, are required to submit an application using the full 190-day COPN process during the C application cycle.	Facilities with psychiatric beds would be able to request beds through the 45-day expedited process.	Remove from COPN	Support in lieu of eliminating from COPN
4. Allow facilities to relocate psychiatric beds through the expedited process*	All facilities are required to obtain a COPN through the full 190-day review cycle to relocate beds. If the bed relocation is 10 beds or 10%, whichever is less, and when the cost of relocation is less than $5 million, facilities may apply for a COPN through the 45-day expedited review process.	Facilities could obtain a COPN through the 45-day expedited review process to relocate any number of beds.	Remove from COPN	Support, in lieu of eliminating COPN.
5. Require facilities to request a COPN in	Facilities are able to convert psychiatric	Facilities would be required to request a	Since I support removing psych services from	Support, assuming COPN remains.

order to convert beds from psychiatric beds to non-psychiatric beds*	beds to non-psychiatric beds freely (this does not apply to beds added through the RFA process).	COPN in order to convert beds from psychiatric beds to non-psychiatric beds.	COPN, I would be in favor of adding this provision if that were to happen - as I would want to prevent a loophole that would encourage creating psych beds with the goal of flipping them.	
6. Allow facilities that already provide psychiatric services to establish a new psychiatric facility through the expedited review process*	All projects involving a new psychiatric facility are required to obtain a COPN.	Facilities that already provide psychiatric services would be able to utilize the expedited process in order to establish a new psychiatric facility under its current hospital license.	Eliminate from COPN	Support, in lieu of eliminating COPN
7. Move the addition of psychiatric services from full COPN review to expedited review*	A facility is required to obtain a COPN in order to add new psychiatric services that have not been provided in the previous 12 months.	To add new psychiatric services, a facility would be able to apply at any time and the application would be reviewed during the 45-day review cycle.	eliminate from COPN	Support, in lieu of eliminating COPN
8. Extend expedited review from 45 days to 90 days	Expedited review projects adhere to a 45-day review cycle that begins when an application is submitted and ends with a decision from	Expedited review projects would adhere to a 90-day review cycle that begins when an application is submitted and ends with a decision from		Do not support. 45 days is sufficient time and established precedent. Extending to 90 days (or any other amount) would feel arbitrary.

	the Commissioner by the 45th day.	the Commissioner by the 90th day.		
9. Require the Commissioner to condition expedited review applications on providing a specified level of charity care*	The Commissioner does not have the authority to condition expedited review projects.	The Commissioner would be required to condition all approved expedited project COPNs on providing a specified level of charity care.		Do Not Support. I would need to see what the "specified level" would be, before I supported it. They must already report as part of COPN, and there is no significant difference between for-profit and not-for profit hospitals in % of revenue given to charity care. Not-for-profit organizations are already required to provide charity care in order to maintain their not for profit status.
10. Require the Commissioner to condition psychiatric projects on the acceptance of Temporary Detention Orders (TDOs)*	The Commissioner does not have the authority to condition COPNs on the acceptance of TDOs.	The Commissioner would be required to condition all approved psychiatric project COPNs on the acceptance of TDOs.	Since this change requires legislative action anyway, a more difficult pathway than regulation, I would prefer to see an "incentivization" pathway created by increasing the revenue and/or extending tax benefits to those that do meet a TDO threshold.	Do not support. I do believe we need to bolster the TDO system, but I believe putting an additional requirement on an already strained capacity would send us backward, not forward. I would rather incentivize the acceptance

				of TDOs as opposed to a restrictive requirement.
11. Require any project that is contested to be pulled from expedited review and placed into full review	There is no requirement regarding contested projects in the regulation.	Any project that is contested by a member of the public would be pulled out of expedited review and placed into full review.	An alternative would be to eliminate COPN. A second alternative would be to make all documents and any proceedings public.	Do not support Doing this would effectively negate any action this body recommends to extend expedited review. An organization, such as those that have already lobbied against expedited review before this body, could simply contest and force full COPN and we're back to the beginning. I have every reason to believe this is exactly what would happen.
12. Allow for members of the public to request a hearing for an expedited project	There is no public participation requirement in the regulation.	Members of the public would be able to request a public hearing for an expedited project to be held during the 45-day review cycle.		Do not support I'm not familiar with any other business type that would require a public hearing to slow down its licensure process. I believe doing this would have the same effect as 11.
13. Add the following COPN projects to the expedited review process for existing	Any facility interested in adding any items from the list are required to obtain a	Facilities that already provide the applicable services for the corresponding listed items may request a		Support (though I don't believe this body has discussed and considered these items yet)

medical care facilities that already provide the applicable existing service:* • Medical-surgical beds • Hospice beds • Psychiatric beds • Rehabilitation beds • Cardiac catheterization laboratories • Operating rooms • CT machines • MRI machines • PET machines • Linear accelerators	COPN through the 190-day process.	COPN through the expedited review process to add any of the projects listed.		
14. Change to the review process: Eliminate the full COPN process and				

move it all to expedited review on rolling, planned, 45 day cycles.				
15. Eliminate Psych from COPN requirements				I fully support. COPN laws restrict two things that we are trying to achieve in mental health care: lower cost, and increased access to care. They do this by definition. The proponents of COPN cite quality of care as the primary reason to keep COPN. Minuted conversations of this body have supported this view. These conversations have made three primary points

				during deliberations in support of COPN: 1. Without COPN we would see a string of bad actors enter the commonwealth and we couldn't control for quality. Comment: -this would imply that in the states with no COPN quality is lower, and this is simply not true. There is no correlation between COPN and quality of mental health care (or any other kind of healthcare) in the United States. There is, however, strong correlation between COPN and higher cost, and lower access. A near pier, Pennsylvania, is a state with similar geography, population and demographics but no COPN is ranked in the top-10 for mental health outcomes with Virginia ranked middle of the pack. This state has a larger urban population

				(Pittsburgh, Philadelphia, Scranton, Harrisonburg etc) and a similar rural population. 2. Adding bed capacity would not fix the problem Comment: -there may well be some truth in this, as I do believe there are bigger problems in mental health delivery than inpatient capacity. But even if so, this isn't really an argument for keeping it. -that said, I'm not sure this is true. Despite what seems to be agreement that there exists capacity, my own experience suggests otherwise. Just last weekend a close friend of mine called asking for help, as one of her friends needed to be admitted for mental health, was in crisis and suicidal and she didnt know where to go. She called 3 institutions between

				Richmond and Northern Virginia and the absolute SOONEST a bed was available was 2 weeks. This individual is currently in treatment in Tennessee, as a facility there could take her immediately. I'm not suggesting this is common, or everyone's experience, but this was my experience and it was last week. 3. COPN is working, only 1 application has been denied Comment: this seems a stronger argument to remove it than keep it. That said, I do believe this simply means that COPN is a sufficient deterrent to new entrants fearing the lobbying strength of large incumbent organizations with favorable positions.
16.				

17.				

*Requires a legislative change

Analysis on Potential Expedited and Psychiatric Process Changes

Legislative Mandate: Chapter 423 of the 2024 Acts of Assembly mandates the State Health Services Plan Task Force to develop recommendations on expedited review of project types subject to certificate of public need (COPN) requirements that are generally non contested and present limited health planning impacts. The Task Force shall also create recommendations regarding:

1. What facilities and projects listed in § 32.1-102.1:3 of the Code of Virginia should be added to the expedited review process;
2. Criteria that should apply to any project types subject to expedited review; and
3. A framework for the application and approval process of such projects.

Project types for consideration shall include:

1. Increases in inpatient psychiatric beds;
2. Relocation of inpatient psychiatric beds;
3. Introduction of psychiatric services into an existing medical care facility; and
4. Conversion of beds in an existing medical care facility to psychiatric inpatient beds.

Potential Expedited and Psychiatric Process Changes:

Option	How it works now	How it would change	Alternative?	Vote Support, Oppose, No Position, or Undecided
1. Move psychiatric beds from full COPN review to expedited review*	Psychiatric beds are required to be requested using the full 190-day COPN process during the C application cycle.	Psychiatric beds could be requested at any time and would be reviewed during a 45-day review period.		Oppose
2. Move the establishment of a	In order to establish a psychiatric facility, a person is required to apply during the C application	A person could apply for a COPN for a psychiatric facility at any time and would be reviewed during the 45-day review period.		Oppose

Submission - Amanda Dulin

psychiatric facility from full COPN review to expedited review*	cycle for the full 190-day review process.			
3. Allow facilities that already provide psychiatric services to add beds using the expedited review process*	All facilities, whether they already have psychiatric beds or not, are required to submit an application using the full 190-day COPN process during the C application cycle.	Facilities with psychiatric beds would be able to request beds through the 45-day expedited process.		Qualified Support: with conditions that they meet criteria below, and the loophole is closed
4. Allow facilities to relocate psychiatric beds through the expedited process*	All facilities are required to obtain a COPN through the full 190-day review cycle to relocate beds. If the bed relocation is 10 beds or 10%, whichever is less, and when the cost of relocation is less than $5 million, facilities may apply for a COPN through the 45-day expedited review process.	Facilities could obtain a COPN through the 45-day expedited review process to relocate any number of beds.		Oppose
5. Require facilities to request a COPN in order to convert beds from psychiatric beds to non-psychiatric beds*	Facilities are able to convert psychiatric beds to non-psychiatric beds freely (this does not apply to beds added through the RFA process).	Facilities would be required to request a COPN in order to convert beds from psychiatric beds to non-psychiatric beds.		Fully Support (this is essential)
6. Allow facilities that already provide psychiatric services to establish a new psychiatric facility through the expedited review process*	All projects involving a new psychiatric facility are required to obtain a COPN.	Facilities that already provide psychiatric services would be able to utilize the expedited process in order to establish a new psychiatric facility under its current hospital license.		Oppose

7. Move the addition of psychiatric services from full COPN review to expedited review*	A facility is required to obtain a COPN in order to add new psychiatric services that have not been provided in the previous 12 months.	To add new psychiatric services, a facility would be able to apply at any time and the application would be reviewed during the 45-day review cycle.		Oppose
8. Extend expedited review from 45 days to 90 days	Expedited review projects adhere to a 45-day review cycle that begins when an application is submitted and ends with a decision from the Commissioner by the 45th day.	Expedited review projects would adhere to a 90-day review cycle that begins when an application is submitted and ends with a decision from the Commissioner by the 90th day.		Oppose
9. Require the Commissioner to condition expedited review applications on providing a specified level of charity care*	The Commissioner does not have the authority to condition expedited review projects.	The Commissioner would be required to condition all approved expedited project COPNs on providing a specified level of charity care.		Support (if expedited review is an option)
10. Require the Commissioner to condition psychiatric projects on the acceptance of Temporary Detention Orders (TDOs)*	The Commissioner does not have the authority to condition COPNs on the acceptance of TDOs.	The Commissioner would be required to condition all approved psychiatric project COPNs on the acceptance of TDOs.		Support; but need more information to understand if patient is appropriate for setting
11. Require any project that is contested to be pulled from expedited review and placed into full review	There is no requirement regarding contested projects in the regulation.	Any project that is contested by a member of the public would be pulled out of expedited review and placed into full review.		Support (if expedited review is an option)

Submission - Amanda Dulin

12. Allow for members of the public to request a hearing for an expedited project	There is no public participation requirement in the regulation.	Members of the public would be able to request a public hearing for an expedited project to be held during the 45-day review cycle.		Oppose
13. Add the following COPN projects to the expedited review process for existing medical care facilities that already provide the applicable existing service:* • Medical-surgical beds • Hospice beds • Psychiatric beds • Rehabilitation beds • Cardiac catheterization laboratories • Operating rooms • CT machines • MRI machines • PET machines	Any facility interested in adding any items from the list are required to obtain a COPN through the 190-day process.	Facilities that already provide the applicable services for the corresponding listed items may request a COPN through the expedited review process to add any of the projects listed.	Much more work to be done to evaluate this request	TBD; much more information needed to make a recommendation

• Linear accelerators				
Add: **Close the loophole that allows providers to convert Psych beds to other types without CON**				**Close the loophole that allows providers to convert Psych beds to other types without CON**

Analysis on Potential Expedited and Psychiatric Process Changes

Legislative Mandate: Chapter 423 of the 2024 Acts of Assembly mandates the State Health Services Plan Task Force to develop recommendations on expedited review of project types subject to certificate of public need (COPN) requirements that are generally non contested and present limited health planning impacts. The Task Force shall also create recommendations regarding:

1. What facilities and projects listed in § 32.1-102.1:3 of the Code of Virginia should be added to the expedited review process;
2. Criteria that should apply to any project types subject to expedited review; and
3. A framework for the application and approval process of such projects.

Project types for consideration shall include:

1. Increases in inpatient psychiatric beds;
2. Relocation of inpatient psychiatric beds;
3. Introduction of psychiatric services into an existing medical care facility; and
4. Conversion of beds in an existing medical care facility to psychiatric inpatient beds.

Potential Expedited and Psychiatric Process Changes:

Option	How it works now	How it would change	Alternative?	Vote Support, Oppose, No Position, or Undecided
1. Move psychiatric beds from full COPN review to expedited review*	Psychiatric beds are required to be requested using the full 190-day COPN process during the C application cycle.	Psychiatric beds could be requested at any time and would be reviewed during a 45-day review period.		SUPPORT
2. Move the establishment of a	In order to establish a psychiatric facility, a	A person could apply for a COPN for a		SUPPORT

Submission - Tom Orsini

psychiatric facility from full COPN review to expedited review*	person is required to apply during the C application cycle for the full 190-day review process.	psychiatric facility at any time and would be reviewed during the 45-day review period.		
3. Allow facilities that already provide psychiatric services to add beds using the expedited review process*	All facilities, whether they already have psychiatric beds or not, are required to submit an application using the full 190-day COPN process during the C application cycle.	Facilities with psychiatric beds would be able to request beds through the 45-day expedited process.		SUPPORT
4. Allow facilities to relocate psychiatric beds through the expedited process*	All facilities are required to obtain a COPN through the full 190-day review cycle to relocate beds. If the bed relocation is 10 beds or 10%, whichever is less, and when the cost of relocation is less than $5 million, facilities may apply for a COPN through the 45-day expedited review process.	Facilities could obtain a COPN through the 45-day expedited review process to relocate any number of beds.		SUPPORT
5. Require facilities to request a COPN in	Facilities are able to convert psychiatric	Facilities would be required to request a		SUPPORT

Submission - Tom Orsini

order to convert beds from psychiatric beds to non-psychiatric beds*	beds to non-psychiatric beds freely (this does not apply to beds added through the RFA process).	COPN in order to convert beds from psychiatric beds to non-psychiatric beds.		
6. Allow facilities that already provide psychiatric services to establish a new psychiatric facility through the expedited review process*	All projects involving a new psychiatric facility are required to obtain a COPN.	Facilities that already provide psychiatric services would be able to utilize the expedited process in order to establish a new psychiatric facility under its current hospital license.		SUPPORT
7. Move the addition of psychiatric services from full COPN review to expedited review*	A facility is required to obtain a COPN in order to add new psychiatric services that have not been provided in the previous 12 months.	To add new psychiatric services, a facility would be able to apply at any time and the application would be reviewed during the 45-day review cycle.		OPPOSE
8. Extend expedited review from 45 days to 90 days	Expedited review projects adhere to a 45-day review cycle that begins when an application is submitted and ends with a decision from the Commissioner by the 45th day.	Expedited review projects would adhere to a 90-day review cycle that begins when an application is submitted and ends with a decision from the Commissioner by the 90th day.		OPPOSE
9. Require the	The Commissioner	The Commissioner		UNDECIDED

Submission - Tom Orsini

Commissioner to condition expedited review applications on providing a specified level of charity care*	does not have the authority to condition expedited review projects.	would be required to condition all approved expedited project COPNs on providing a specified level of charity care.		(Need to define "charity care")
10. Require the Commissioner to condition psychiatric projects on the acceptance of Temporary Detention Orders (TDOs)*	The Commissioner does not have the authority to condition COPNs on the acceptance of TDOs.	The Commissioner would be required to condition all approved psychiatric project COPNs on the acceptance of TDOs.	The Commissioner shall have ultimate authority on this matter.	SUPPORT
11. Require any project that is contested to be pulled from expedited review and placed into full review	There is no requirement regarding contested projects in the regulation.	Any project that is contested by a member of the public would be pulled out of expedited review and placed into full review.		UNDECIDED Need to define "Any project" and "member of the public".
12. Allow for members of the public to request a hearing for an expedited project	There is no public participation requirement in the regulation.	Members of the public would be able to request a public hearing for an expedited project to be held during the 45-day review cycle.	The Commissioner shall be required to approve all public hearing requests.	UNDECIDED
13. Add the following COPN projects to the expedited review process for existing	Any facility interested in adding any items from the list are required to obtain a COPN through the	Facilities that already provide the applicable services for the corresponding listed items may request a		SUPPORT

medical care facilities that already provide the applicable existing service:* • Medical-surgical beds • Hospice beds • Psychiatric beds • Rehabilitation beds • Cardiac catheterization laboratories • Operating rooms • CT machines • MRI machines • PET machines • Linear accelerators	190-day process.	COPN through the expedited review process to add any of the projects listed.		
14.				

Submission - Tom Orsini

15.				
16.				
17.				

*Requires a legislative change

Submission - Tom Orsini

Analysis on Potential Expedited and Psychiatric Process Changes

Legislative Mandate: Chapter 423 of the 2024 Acts of Assembly mandates the State Health Services Plan Task Force to develop recommendations on expedited review of project types subject to certificate of public need (COPN) requirements that are generally non contested and present limited health planning impacts. The Task Force shall also create recommendations regarding:

1. What facilities and projects listed in § 32.1-102.1:3 of the Code of Virginia should be added to the expedited review process;
2. Criteria that should apply to any project types subject to expedited review; and
3. A framework for the application and approval process of such projects.

Project types for consideration shall include:

1. Increases in inpatient psychiatric beds;
2. Relocation of inpatient psychiatric beds;
3. Introduction of psychiatric services into an existing medical care facility; and
4. Conversion of beds in an existing medical care facility to psychiatric inpatient beds.

Potential Expedited and Psychiatric Process Changes: IN general, I believe that for the psychiatric facilities and beds COPN is an exercise is wasted time and money. With a 90+% approval rate one wonders why the process. The boards should do their due diligence as to the demand for and cost of any changes. The free market will push all to a level of excellence or they will fail. So far I have seen nothing that leads me to believe otherwise.

Option	How it works now	How it would change	Alternative?	Vote Support, Oppose, No Position, or Undecided
1. Move psychiatric beds from full COPN review to expedited review*	Psychiatric beds are required to be requested using the full 190-day COPN process	Psychiatric beds could be requested at any time and would be reviewed during a 45-day review period.	Prefer no COPN, the BOD should have done their job	Expedited at the most

Submission - Thomas Eppes

	during the C application cycle.			
2. Move the establishment of a psychiatric facility from full COPN review to expedited review*	In order to establish a psychiatric facility, a person is required to apply during the C application cycle for the full 190-day review process.	A person could apply for a COPN for a psychiatric facility at any time and would be reviewed during the 45-day review period.	No COPN review for psychiatric facility establishment, the BOD/investors should have done their job	Support expedited at the most
3. Allow facilities that already provide psychiatric services to add beds using the expedited review process*	All facilities, whether they already have psychiatric beds or not, are required to submit an application using the full 190-day COPN process during the C application cycle.	Facilities with psychiatric beds would be able to request beds through the 45-day expedited process.	No need for COPN, the facility BOD should have done their job	Expidted at the most
4. Allow facilities to relocate psychiatric beds through the expedited process*	All facilities are required to obtain a COPN through the full 190-day review cycle to relocate beds. If the bed relocation is 10 beds or 10%, whichever is less, and when the cost of relocation is less than $5 million, facilities may apply for a COPN through the 45-day	Facilities could obtain a COPN through the 45-day expedited review process to relocate any number of beds.	No need for COPN, should be a facility BOD decision	Expedited at the most

	expedited review process.			
5. Require facilities to request a COPN in order to convert beds from psychiatric beds to non-psychiatric beds*	Facilities are able to convert psychiatric beds to non-psychiatric beds freely (this does not apply to beds added through the RFA process).	Facilities would be required to request a COPN in order to convert beds from psychiatric beds to non-psychiatric beds.	If the BOD feels that this is necessary, so be it	Expedited at the most
6. Allow facilities that already provide psychiatric services to establish a new psychiatric facility through the expedited review process*	All projects involving a new psychiatric facility are required to obtain a COPN.	Facilities that already provide psychiatric services would be able to utilize the expedited process in order to establish a new psychiatric facility under its current hospital license.	No need for a COPN	Expedited at the most
7. Move the addition of psychiatric services from full COPN review to expedited review*	A facility is required to obtain a COPN in order to add new psychiatric services that have not been provided in the previous 12 months.	To add new psychiatric services, a facility would be able to apply at any time and the application would be reviewed during the 45-day review cycle.	No need for a COPN. This is a duplicate question	Expedited at the most
8. Extend expedited review from 45 days to 90 days	Expedited review projects adhere to a 45-day review cycle that begins when an application is submitted and ends	Expedited review projects would adhere to a 90-day review cycle that begins when an application is submitted and ends	For psychiatric facilities and beds remove COPN	oppose

	with a decision from the Commissioner by the 45th day.	with a decision from the Commissioner by the 90th day.		
9. Require the Commissioner to condition expedited review applications on providing a specified level of charity care*	The Commissioner does not have the authority to condition expedited review projects.	The Commissioner would be required to condition all approved expedited project COPNs on providing a specified level of charity care.	This may be the choice of the legislature/commissioner. I would prefer nothing supported by the state paying for the care appropriately.	Expedited not needed as is the commissioner will set the standard
10. Require the Commissioner to condition psychiatric projects on the acceptance of Temporary Detention Orders (TDOs)*	The Commissioner does not have the authority to condition COPNs on the acceptance of TDOs.	The Commissioner would be required to condition all approved psychiatric project COPNs on the acceptance of TDOs.	This may be the choice of the Commissioner/legislature	Up to legislature/commissioner if needed
11. Require any project that is contested to be pulled from expedited review and placed into full review	There is no requirement regarding contested projects in the regulation.	Any project that is contested by a member of the public would be pulled out of expedited review and placed into full review.	No COPN, this contesting is a delaying anti-competitive stance.	Expedited at the most.
12. Allow for members of the public to request a hearing for an expedited project	There is no public participation requirement in the regulation.	Members of the public would be able to request a public hearing for an expedited project to be held during the 45-day review cycle.	Not needed. Who in the public has the knowledge to do this? The BOD's have public members, that should be enough	Expedited at the most

13. Add the following COPN projects to the expedited review process for existing medical care facilities that already provide the applicable existing service:* • Medical-surgical beds • Hospice beds • Psychiatric beds • Rehabilitation beds • Cardiac catheterization laboratories • Operating rooms • CT machines • MRI machines • PET machines • Linear accelerators	Any facility interested in adding any items from the list are required to obtain a COPN through the 190-day process.	Facilities that already provide the applicable services for the corresponding listed items may request a COPN through the expedited review process to add any of the projects listed.	To be discussed	
14.				

15.				
16.				

17.				

*Requires a legislative change

Analysis on Potential Expedited and Psychiatric Process Changes

Legislative Mandate: Chapter 423 of the 2024 Acts of Assembly mandates the State Health Services Plan Task Force to develop recommendations on expedited review of project types subject to certificate of public need (COPN) requirements that are generally non contested and present limited health planning impacts. The Task Force shall also create recommendations regarding:

1. What facilities and projects listed in § 32.1-102.1:3 of the Code of Virginia should be added to the expedited review process;
2. Criteria that should apply to any project types subject to expedited review; and
3. A framework for the application and approval process of such projects.

To consider, Lift / staffing for expedited review
→ would want to define what would be part of expedited review... vs. Full-Review.

Project types for consideration shall include:

1. Increases in inpatient psychiatric beds;
2. Relocation of inpatient psychiatric beds;
3. Introduction of psychiatric services into an existing medical care facility; and
4. Conversion of beds in an existing medical care facility to psychiatric inpatient beds.

Potential Expedited and Psychiatric Process Changes:

Option	How it works now	How it would change	Alternative?	Vote Support, Oppose, No Position, Undecided
1. Move psychiatric beds from full COPN review to expedited review*	Psychiatric beds are required to be requested using the full 190-day COPN process during the C application cycle.	Psychiatric beds could be requested at any time and would be reviewed during a 45-day review period.	? 3 cycles	3 oppose 1 - support NO COPN
2. Move the establishment of a	In order to establish a psychiatric facility, a	A person could apply for a COPN for a		3 oppose 1 - sup. No Copn

psychiatric facility from full COPN review to expedited review*	person is required to apply during the C application cycle for the full 190-day review process.	psychiatric facility at any time and would be reviewed during the 45-day review period.		
3. Allow facilities that already provide psychiatric services to add beds using the expedited review process*	All facilities, whether they already have psychiatric beds or not, are required to submit an application using the full 190-day COPN process during the C application cycle.	Facilities with psychiatric beds would be able to request beds through the 45-day expedited process.	If expand - must not be able to convert	Same
4. Allow facilities to relocate psychiatric beds through the expedited process*	All facilities are required to obtain a COPN through the full 190-day review cycle to relocate beds. If the bed relocation is 10 beds or 10%, whichever is less, and when the cost of relocation is less than $5 million, facilities may apply for a COPN through the 45-day expedited review process.	Facilities could obtain a COPN through the 45-day expedited review process to relocate any number of beds.		~~Same~~ Same
5. Require facilities to request a COPN in	Facilities are able to convert psychiatric	Facilities would be required to request a	Possible safeguards	3 support

1 support NO COPN

order to convert beds from psychiatric beds to non-psychiatric beds*	beds to non-psychiatric beds freely (this does not apply to beds added through the RFA process).	COPN in order to convert beds from psychiatric beds to non-psychiatric beds.		
6. Allow facilities that already provide psychiatric services to establish a new psychiatric facility through the expedited review process*	All projects involving a new psychiatric facility are required to obtain a COPN.	Facilities that already provide psychiatric services would be able to utilize the expedited process in order to establish a new psychiatric facility under its current hospital license.		3 oppose 1 support NO COPN
7. Move the addition of psychiatric services from full COPN review to expedited review*	A facility is required to obtain a COPN in order to add new psychiatric services that have not been provided in the previous 12 months.	To add new psychiatric services, a facility would be able to apply at any time and the application would be reviewed during the 45-day review cycle.		Same
8. Extend expedited review from 45 days to 90 days	Expedited review projects adhere to a 45-day review cycle that begins when an application is submitted and ends with a decision from the Commissioner by the 45th day.	Expedited review projects would adhere to a 90-day review cycle that begins when an application is submitted and ends with a decision from the Commissioner by the 90th day.		Same

9. Require the Commissioner to condition expedited review applications on providing a specified level of charity care*	The Commissioner does not have the authority to condition expedited review projects.	The Commissioner would be required to condition all approved expedited project COPNs on providing a specified level of charity care.		all support -4
10. Require the Commissioner to condition psychiatric projects on the acceptance of Temporary Detention Orders (TDOs)*	The Commissioner does not have the authority to condition COPNs on the acceptance of TDOs.	The Commissioner would be required to condition all approved psychiatric project COPNs on the acceptance of TDOs.		more info needed 4 oppose as is
11. Require any project that is contested to be pulled from expedited review and placed into full review	There is no requirement regarding contested projects in the regulation.	Any project that is contested by a member of the public would be pulled out of expedited review and placed into full review.		1-qualified 2-support 1-support no COPN
12. Allow for members of the public to request a hearing for an expedited project	There is no public participation requirement in the regulation.	Members of the public would be able to request a public hearing for an expedited project to be held during the 45-day review cycle.		Oppose
13. Add the following COPN projects to the expedited review	Any facility interested in adding any items from the list are required to obtain a	Facilities that already provide the applicable services for the corresponding listed		

Submission - Group 2

process for existing medical care facilities that already provide the applicable existing service:* • Medical-surgical beds • Hospice beds • Psychiatric beds • Rehabilitation beds • Cardiac catheterization laboratories • Operating rooms • CT machines • MRI machines • PET machines • Linear accelerators	COPN through the 190-day process.	items may request a COPN through the expedited review process to add any of the projects listed.		Need more info
14. Remove caviat/ability to convert psych beds to med surge w/out COPN			Y	

Submission - Group 2

15.				
16.				

17.				

*Requires a legislative change

Jeanne Adams

Analysis on Potential Expedited and Psychiatric Process Changes

Legislative Mandate: Chapter 423 of the 2024 Acts of Assembly mandates the State Health Services Plan Task Force to develop recommendations on expedited review of project types subject to certificate of public need (COPN) requirements that are generally non contested and present limited health planning impacts. The Task Force shall also create recommendations regarding:

1. What facilities and projects listed in § 32.1-102.1:3 of the Code of Virginia should be added to the expedited review process;
2. Criteria that should apply to any project types subject to expedited review; and
3. A framework for the application and approval process of such projects.

Project types for consideration shall include:

1. Increases in inpatient psychiatric beds;
2. Relocation of inpatient psychiatric beds;
3. Introduction of psychiatric services into an existing medical care facility; and
4. Conversion of beds in an existing medical care facility to psychiatric inpatient beds.

Group 1

Potential Expedited and Psychiatric Process Changes:

Grp 3

Option	How it works now	How it would change	Alternative?	Vote Support, Oppose, No Position, Undecided
1. Move psychiatric beds from full COPN review to expedited review*	Psychiatric beds are required to be requested using the full 190-day COPN process during the C application cycle.	Psychiatric beds could be requested at any time and would be reviewed during a 45-day review period.	Note: Assume this option is equal to making all psych projects subject to expedited review	oppose
2. Move the establishment of a	In order to establish a psychiatric facility, a	A person could apply for a COPN for a		oppose

Approved

Grp 2 option to add a cycle [or make it like NF even other]

oppos

psychiatric facility from full COPN review to expedited review*	person is required to apply during the C application cycle for the full 190-day review process.	psychiatric facility at any time and would be reviewed during the 45-day review period.			
3. Allow facilities that already provide psychiatric services to add beds using the expedited review process*	All facilities, whether they already have psychiatric beds or not, are required to submit an application using the full 190-day COPN process during the C application cycle.	Facilities with psychiatric beds would be able to request beds through the ~~45~~ 90-day expedited process.		Approve w/ no conversion to med surg	
4. Allow facilities to relocate psychiatric beds through the expedited process*	All facilities are required to obtain a required to obtain a COPN through the full 190-day review cycle to relocate beds. If the bed relocation is 10 beds or 10%, whichever is less, and when the cost of relocation is less than $5 million, facilities may apply for a COPN through the 45-day expedited review process.	Facilities could obtain a COPN through the 45-day expedited review process to relocate any number of beds.	Grp 2 Opposed	Approve	Approved same PD
Al 5. Require facilities to request a COPN in	Facilities are able to convert psychiatric	Facilities would be required to request a			

Submission - Jeannie Adams

Group 2 [illegible]

Grup3

order to convert beds from psychiatric beds to non-psychiatric beds*	beds to non-psychiatric beds freely (this does not apply to beds added through the RFA process).	COPN in order to convert beds from psychiatric beds to non-psychiatric beds.	Approve	Approve	Approve
6. Allow facilities that already provide psychiatric services to establish a new psychiatric facility through the expedited review process*	All projects involving a new psychiatric facility are required to obtain a COPN.	Facilities that already provide psychiatric services would be able to utilize the expedited process in order to establish a new psychiatric facility under its current hospital license.	Grp 2 opposed	~~Oppose~~ Approve w/ bracketed language being important	Approve same PD
7. Move the addition of psychiatric services from full COPN review to expedited review*	A facility is required to obtain a COPN in order to add new psychiatric services that have not been provided in the previous 12 months.	To add new psychiatric services, a facility would be able to apply at any time and the application would be reviewed during the 45-day review cycle.		Oppose	No Consensus
8. Extend expedited review from 45 days to 90 days	Expedited review projects adhere to a 45-day review cycle that begins when an application is submitted and ends with a decision from the Commissioner by the 45th day.	Expedited review projects would adhere to a 90-day review cycle that begins when an application is submitted and ends with a decision from the Commissioner by the 90th day.	Grp 2 Opposed	Approve and add batch cycles either 3/yr or every other month	Approve as long as public com

Submission - Jeannie Adams

9. Require the Commissioner to condition expedited review applications on providing a specified level of charity care*	The Commissioner does not have the authority to condition expedited review projects.	The Commissioner would be required to condition all approved expedited project COPNs on providing a specified level of charity care.		Oppose But more info. needed	Approved
10. Require the Commissioner to condition psychiatric projects on the acceptance of Temporary Detention Orders (TDOs)*	The Commissioner does not have the authority to condition COPNs on the acceptance of TDOs.	The Commissioner would be required to condition all approved psychiatric project COPNs on the acceptance of TDOs.	Grp 2 needed more	Approve as an option not mandate worried @ forensic pts	Tabled
ALL 11. Require any project that is contested to be pulled from expedited review and placed into full review	There is no requirement regarding contested projects in the regulation.	Any project that is contested by a member of the public would be pulled out of expedited review and placed into full review.	Grp 2 Gen'l suppt	Yes support if Good cause criteria are met	?
12. Allow for members of the public to request a hearing for an expedited project	There is no public participation requirement in the regulation.	Members of the public would be able to request a public hearing for an expedited project to be held during the 45-day review cycle.	Grp 2 opposed	~~Support~~ Approve	Approve
13. Add the following COPN projects to the expedited review	Any facility interested in adding any items from the list are required to obtain a	Facilities that already provide the applicable services for the corresponding listed			

Submission - Jeannie Adams

process for existing medical care facilities that already provide the applicable existing service:* • Medical-surgical beds • Hospice beds • Psychiatric beds • Rehabilitation beds • Cardiac catheterization laboratories • Operating rooms • CT machines • MRI machines • PET machines • Linear accelerators	COPN through the 190-day process.	items may request a COPN through the expedited review process to add any of the projects listed.		
14.				

yes

worry @ converting to med surg

talk @ batch cycles - designated times

Do all ~~[illegible]~~ review criteria apply

15.				
16.				

17.				

*Requires a legislative change

Center for Health & Cancer Prevention
Keith E. Berger, MD
1301 First Colonial Road Suite 201
Virginia Beach, Virginia 23454

Sunday, June 23 2024

From: Dr. Keith Berger, MD
To: Karen Shelton, MD, State Health Commissioner
Re: Virginia State Health Plan Services Task Force Recommendations on Psychiatric COPN and Expedited Review

Dear Commissioner,

I am writing you as one of the (2) MSV physician representatives appointed to the State Health Services Plan Task Force charged with reforming COPN requirements in Virginia. I will shortly be submitting my 'official' Task Force vote on psychiatric COPN and expedited review proposals under separate cover to the VDH. VDH also requested any additional comments be submitted to VDH for consideration. I would like to take this opportunity to share with you those comments based on my personal and professional experience.

As a physician actively practicing in the state of Virginia continuously for the past 43 years, I have had direct experience with the impact of Virginia COPN on my own practice and the many cases and stories I hear about. For the past 15 years or so, I have made many trips to Richmond attempting to convince legislators of the need to reform COPN. None of these efforts have been successful. When I first opened my practice in 1981, we became the first GI practice in the state of Virginia to offer in-office GI procedures vs. the much costlier hospital-based GI procedures. This resulted saving countless taxpayer dollars and made cancer screening much more accessible for people. Office based endoscopy quickly became the standard of care, the cost of screening was greatly reduced, and many saved lives through improved access to preventive services. Now, after 43 years of operating my office, I find myself less concerned with innovating care, but rather the very survival of my practice. COPN laws have to this point prevented me from being paid by Medicare as a facility for any GI procedure in my office. Together with dropping professional reimbursement, this is greatly impacting the viability of my practice and others like it. Last year, 2023, for the very first time, my practice actually lost money. The result was having to arbitrarily cut back on Medicare patients because of these financial losses. I was forced to reduce my age limit for a portion of my office patients in an attempt to remain viable as a practice. Now those 2-300 patients I used to care for will have to find their GI care somewhere else, but that is going to be difficult since everyone is operating under the same constraints. GI is not the only medical specialty under fire. In part because of the consolidation and monopolization of healthcare, many veteran, highly experienced physicians are leaving practice. This, coupled with the already 35,000 physician shortage, is making healthcare harder and harder to find. Wait times are now ridiculous. People can't even get a primary care physician. I spoke to a PCP in Elizebeth City last week—the earliest she could get a neurologist to evaluate her patient was 12 months (!). People are using the ER as a clinic just to get health care. The ER staff and physicians are stressed out to the max. The situation is not sustainable. In the face of all of this, why are we not *liberalizing* healthcare law in Virginia? During the pandemic, CMS took what was an unusual initiative and lessened their restrictions on telemedicine. This opened up access to services that would have been greatly strained (at least worse than they already were) and is now an established form of healthcare delivery. To the contrary, with COPN restrictions, we are not effectively responding to meet the critical need for services. COPN laws are simply worsening the crisis. Is this the time to 'double down' on old restrictions, when people can't get care? I had understood that the Task Force was initially created to <u>reform</u> COPN laws, presumably for the better. That would be eliminating all or some of them or significantly cutting back on the services requiring COPN. What the Task Force has come up with, in my view is nothing but window dressing—no substantive change. In fact there has been <u>no</u> substantive change in COPD in Virginia for more than 30 years or the 15 years I've been journeying to Richmond in hopes of getting some change. How is it

Center for Health & Cancer Prevention
Keith E. Berger, MD
1301 First Colonial Road Suite 201
Virginia Beach, Virginia 23454

Sunday, June 23 2024

that the hospitals have to this point invariably been successful in beating down consumer interests? I've yet to see (1) substantive change to COPN in my professional lifetime, in my 43 years of GI practice. Right now, my local hospital corporation limits me to (5) outpatient cases per month. The reason, they say, is because they *don't have the resources.* Yet the very same hospital corporation has invariably opposed COPN at every turn. When will VDH and our legislators start to act in the best interests of consumers and patients, rather than special interests?

I'm afraid my 'additional comments' has turned into a tirade, but as our commissioner I am sure you can hear the message. I believe the current proposals (while I did vote for them because the MSV has requested that I do) are inadequate—nothing but 'window dressing' with no substantive reform. My 'personal' vote is to release all psychiatric facilities from COPN. The so-called COPN 'expedited' review is a joke. The existing process has never even been utilized because the requirements are far too onerous. A far more sensible course would be to simply eliminate COPN. The cost to consumers and healthcare is just too high. I believe we are doing <u>nothing</u> to fix a system that doesn't work--and things are getting worse. How much of a crisis will we need to ACT?

Commissioner, thank you for your time and commitment to healthcare. I hope my comments, though somewhat 'unfiltered,' could change some hearts and minds in Richmond. I'm told that 'the people in Richmond really do care about the impact of their actions on people.' I would like this belief to be true.

PS I am sure you are familiar with the numerous academic studies on the impact of COPN laws across the nation and in the Commonwealth. I've taken the liberty of attaching Matt Mitchel's recently published review of the 128 academic studies done on COPN and the repeated conclusion that COPN laws are

Center for Health & Cancer Prevention
Keith E. Berger, MD
1301 First Colonial Road Suite 201
Virginia Beach, Virginia 23454

Sunday, June 23 2024

unequivocally harmful to healthcare. If there is any need to discuss any of my comments I am available most anytime on my cell 757-412-7737. Thank you again for your generous listening.

With Best Regards,

Keith E. Berger, M.D.

Kb/kb

VIRGINIA HOSPITAL
& HEALTHCARE
ASSOCIATION

4200 INNSLAKE DRIVE, SUITE 203, GLEN ALLEN, VIRGINIA 23060-6772
P.O. BOX 31394, RICHMOND, VIRGINIA 23294-1394
(804) 965-1227 FAX (804) 965-0475

SUBMITTED VIA EMAIL AT Allyson.Flinn@vdh.virginia.gov

June 28, 2024

Allyson Flinn
Policy Analyst
Office of Licensure & Certification
Virginia Department of Health
9960 Mayland Drive, Suite 401
Henrico, VA 23233

Re: Evidence-Based Literature on Efficacy of Certificate of Need Laws

Dear Ms. Flinn,

The Chair of the State Health Services Plan Task Force, Dr. Thomas Eppes, notified the Task Force that if any organization has evidence-based papers or publications they would like to be shared with the Task Force to submit them to you for distribution before the July 12, 2024, meeting of the Task Force. This letter and enclosures are submitted in response to that request.

As a preliminary matter, the submission of any evidence-based papers or publications to the Task Force should be used for educational purposes of Task Force members only, not to develop or advance a larger study or analysis by the Task Force regarding the effectiveness of certificate of need laws. Pursuing any such larger study by the Task Force would be wholly outside of the scope and authority of the Task Force created by the legislature. As established in statute at Va. Code. § 32.1-102.2:1, the purpose of the Task Force is "advising the Board on the content of the State Health Services Plan," which is the document that is used to determine need and the basis for approval of applications for all projects regulated under the law. The Task Force is further instructed to provide recommendations related to the State Health Services Plan, specific objective standards of review, project types that are generally noncontested and present limited health planning impacts, whether certain projects should be subject to expedited review, and improvements in the certificate of public need process. It is not granted authority or charged to evaluate the merits of the certificate of need program more generally.

Response to Mercatus Center Materials

With respect to the materials already submitted to the Task Force from the Mercatus Center, it is important to note that these are testimony documents and labeled as "working papers." Such working papers are not typical peer-reviewed academic research publications. Though the Mercatus Center is associated with George Mason University and many of its scholars and other staff teach or attend the university, these publications are not George Mason University publications. Disclosure statements indicate that Mercatus Center working papers present the author's provisional findings and that "upon further consideration and revision" it is expected that the studies will be "republished" in an academic journal. In the state presented, as far as we can ascertain, they have not been accepted for publication in peer-reviewed professional journals.

It is also important to note several limitations raised in the Mercatus Center documents, including statements that findings present *correlations*, but *not causal connections or explanations* of the findings for the hypotheses being examined. Furthermore, as shown in the first article submitted, Mercatus Center authors frequently cite articles by other Mercatus Center authors as support for the article's own findings and conclusions. This is inconsistent with peer-reviewed, evidence-based research publications.

Lastly, with respect to findings by the Mercatus Center that Virginia's certificate of public need (COPN) law results in fewer beds, hospitals, and rural ambulatory surgical centers than states without certificate of need (CON) laws, this completely overlooks data showing that Virginia is well-supplied with an appropriate level of medical facilities and capacity. The ratio of community hospital beds to population has been decreasing nationwide for more than two decades. The U.S. ratio has consistently moved closer to the Virginia ratio (*i.e.*, the higher U.S. ratio has/is falling faster than the Virginia ratio). There is no indication of a need for any additional beds statewide, much less the 10,000 additional beds Mercatus Center argues are needed to improve access. On average, roughly more than 4 out of 10 Virginia hospital beds are unoccupied. It is also worth noting that in the presence of a substantial hospital bed surplus, Virginia hospital use rates have been decreasing for about three decades for a number of reasons unrelated to certificate of need (*e.g.,* shift to outpatient care, healthier population, changing/improving treatment capability and practices).

Similar observations can be made about computed tomography (CT) and magnetic resonance imaging (MRI). Average use of CT scanners regularly falls below the nominal planning standard, less than 6,000 scans per scanner per year. There is substantial unused CT capacity in all regions of the state. The same is true about average use of MRI scanners, which regularly falls below the nominal planning standard, less than 3,500 scans per scanner per year. As with CT scanners, there is substantial unused MRI capacity in all regions of the state.

As it relates to rural ambulatory surgical centers, a review of Virginia COPN records for the last two decades shows that no COPN application for an ambulatory surgical center in a rural area has been recommended for denial by reviewing parties and none has been denied. The relatively low number of ambulatory surgical centers in rural areas is a function of demography and market forces, not regulatory indifference or failure.

Peer-Reviewed Published Literature

There are voluminous studies and peer-reviewed literature by economists and health policy researchers analyzing the effects of certificate of need laws on costs, efficiency, outcomes, and access to care. Generally speaking, the results of this body of work are mixed and the use of these studies is limited because there is insufficient empirical data to produce statistically significant correlations and it is extremely difficult to isolate the effect of other confounding factors present in our health care delivery system.

Below is a sampling of studies that evaluate the effects of CON on charity care, access to care and quality. Reference materials for these studies is enclosed.

Effect on Charity Care

Research supports the rationale that CON laws are needed to allow providers to maintain financial margins so that they can cross-subsidize indigent care.

- Zhang (2008) found that CON laws increased the number and percent of admissions for the uninsured by non-profit hospitals and are significantly positively related to the percent of admissions for the uninsured by for-profit hospitals.
- Campbell and Fournier (1993) found evidence that CON laws have been used to promote internal subsidization of indigent care.

Several studies suggest that specialty service providers and ASCs proliferate in the absence of CON laws, that these providers focus on more profitable services and a more favorable payor mix, and that this may adversely impact the ability of health care providers to sustain levels of charity or indigent care or provide essential health care services.

- Mitchell (2005) found that physician-owned specialty hospitals treated higher percentages of profitable cases, less-severe cases, and had a more favorable payor mix, suggesting that specialty hospitals may adversely impact access to care for indigent patients.
- GAO (2003) found that most specialty hospitals focus on highly profitable services and often are not located in areas of medical need. Available online at https://www.gao.gov/assets/gao-04-167.pdf

Effect on Cross-Subsidization and Essential Health Care Services

There is no definitive research on the effects of deregulation on the ability of hospitals to continue to provide essential health care services through cross-subsidization by more profitable health care services; however, there is evidence that the practice of cross-subsidization exists.

- Guy *et al.* (2014) found support for conjecture that hospitals reduce unprofitable services in response to adverse shocks to profitable services created by single-specialty entrants into the market. Reductions in volume of psychiatric, substance abuse, and to a lesser extent trauma care were greatest among hospital systems most exposed to potential loss in volume of their cardiac services.
- Dobson *et al.* (2006) recognized the integral role of cost-shifting across patient populations and cross-subsidization across service lines.

Effect on Quality

There is robust empirical evidence that concentration of higher procedure volume, a benefit of CON review standards, is strongly associated with better outcomes.

- Conover and Sloan (1998) found more than 100 studies that established a strong association between higher procedure volumes and better outcomes.

To the extent that deregulation leads to the expansion of services with lower procedures volumes, this could lead to an overall decline in the quality of care.

- Vaughan-Sarrazin, et al. (2002) found that unadjusted mortality rates for Medicare patients undergoing CABG surgery was higher in states without CON.
- DiSesa (2006) and Popescu (2006) found that CON regulation had some positive impact on quality for cardiac surgery.
- Ho (2004) found that CON may be marginally effective in improving outcomes for PTCAs.
- Ross *et al.* (2007) found CON regulation of cardiac catheterization was associated with the continued delivery of more appropriate care after admission for AMI and reduced delivery of less appropriate care.
- Cancienne *et al*. (2020) found that the rate of decrease in the incidence of knee arthroscopy was significantly greater in CON states than that in non-CON states, CON states also had significantly lower charges at all time points, and overall, compared with non-CON states. There were significantly more high- and mid-volume facilities in CON states than in non-CON states, and there were significantly more low-volume facilities in non-CON states than in CON states. Finally, there were significantly higher rates of emergency room visits within 30 days and infection within 6 months in non-CON states than in CON states.

Hospital Beds

There is some evidence that CON regulation of hospital beds has had positive effects on efficiency and costs.

- Rosko and Mutter (2014) found that hospitals in states with CON laws that regulate acute care beds were more cost-efficient than hospitals located in other states and suggest that the differences could be driven by greater capital efficiency in CON states. Mean total capital expenses per bed were significantly lower in CON states, coupled with a higher mean occupancy rate in these states.
- Hellinger (2009) found that CON laws have reduced the number of hospital beds by about 10%, which has led to a slight reduction in healthcare expenditures in CON states.

Neonatal Special Care Services

Lorch *et al.* (2012) found that states without CON laws had significantly more hospitals with a NICU compared to other states, with Level III NICUs (specialty and sub-specialty level nurseries) contributing to most of the difference. There were no differences in infant mortality rates, except for CON states with at least one large metropolitan area, which showed significantly lower all-infant mortality rates, suggesting that CON may be an effective tool for encouraging regionalization of neonatal intensive care. Overall, the study concluded CON programs that oversee NICUs are associated with more efficient delivery of neonatal care.

What Happens Without CON - Measuring the Effects of Deregulation in Pennsylvania

While data from states that have eliminated CON has been incorporated into numerous studies and comparison models to determine the effects of deregulation on access to care, supply of services, costs, and quality of care, there is limited empirical data on state-specific effects of deregulation.

Research conducted by state officials in Pennsylvania provides some insight into the effects of deregulation. According to a Pennsylvania Health Care Cost Containment Council (PHC4) report issued in October 2007, a **decline in the number of general acute care hospitals** in the ten years following repeal of CON (1996-2005) was accompanied by a dramatic **increase in the number of ambulatory surgery centers** (ASCs). The number of ASCs quadrupled, growing from 44 to 177. This was twice the rate of growth at the national level. The number of general acute care hospitals fell from 206 to 177, a decline of 14.1%, doubling the rate of decline at the national level (5.0%). This decline in general acute care hospitals included eight closures, twenty-two mergers, and four conversions.

During the same time period, there was **pronounced growth in utilization of outpatient diagnostic and surgical cases**. The growth in cases at ASCs outpaced the growth of cases at outpatient hospital departments, with total growth split evenly between ASCs and outpatient hospital departments. By 2005, one of every four outpatient diagnostic and surgical cases were performed in an ASC with the most common procedures being colonoscopies and eye surgeries.

The PHC4 report also showed that the statewide pre-tax operating margin for ASCs was six times greater than the statewide operating margin for general acute care hospitals. This difference may be attributable in part to a **more favorable payor mix in ASCs**. One in ten (10.3%) of general acute care hospital patients undergoing outpatient diagnostic and surgical cases was a Medicaid recipient, while only 3.1% of ASC patients were covered by Medicaid.

The Pennsylvania Legislative Budget and Finance Committee issued a report conducted as part of a legislative study of the quality of specialized clinical services including cardiac catheterization and open heart surgery. In 2002, one-third (7 of 21) of the **cardiac catheterization programs with open heart surgery that started after the sunset of CON did not meet industry standard minimum proficiency volumes** though all programs approved previously under CON continued to meet or exceed minimum proficiency volumes. Several of these programs not meeting minimum proficiency volumes would have been de-licensed if operating in other states like Massachusetts. The report also showed higher rates of therapeutic catheterizations and **higher mortality rates at facilities that do not meet minimum proficiency volumes**.

<u>Other Evidence in Support of Virginia's Regulatory System</u>

State health care regulatory policies, including certificate of public need, can reduce the cost of delivering health care if they are effectively structured. Virginia's certificate of public need laws are primarily focused on community-wide cost containment and spending, rather than focusing on procedure-by-procedure costs. A recent report by Altarum includes several facts and figures that reflect Virginia's positive health regulatory environment:

- Personal health care spending in the Commonwealth remains below national averages across several measures including total spending as a percent of state gross domestic product (GDP) and per capita health care spending.
- The Altarum report found that "Virginia's total health spending" as a percent of GDP "mainly stayed constant between 2015 and 2020 but has been declining in 2021 and 2022."
- The share of state GDP spent on health care declined from 15.8 percent in the fourth quarter of 2020 to 14.7 percent in the fourth quarter of 2022, reflecting an amount of spending in Virginia that "is the lowest since 2011 and well below the national average."
- In evaluating health care spending, the report notes that "Virginia's estimated health spending per capita in 2022 was over $1,800 less than the national average."
- That includes Virginians spending less than the national average on "professional, physician, and clinical services ($260 less per capita); hospital care ($570 less per capita); nursing home, residential, and home health ($130 less per capita); prescription drugs ($340 less per capita) and other care ($510 less per capita)."

In light of these positive indications, and the experience of deregulating in other states, any changes to Virginia's certificate of public need laws must be carefully considered to avoid any unintended consequences.

Thank you for including this information and enclosures in materials submitted to the Task Force. We hope that this additional information provides value to the SHSP Task Force as it continues its work.

Again, we are grateful for the work that the Task Force are undertaking to improve Virginia's COPN Program. The COPN Program is a critical policy function of the Commonwealth and reforms to modernize this program present a great opportunity to produce greater efficiencies and generate even better outcomes.

Sincerely,

R. Brent Rawlings
Senior Vice President & General Counsel

Enclosures

cc: Dr. Thomas Eppes, Chair, SHSP Task Force
Karen Cameron, Vice Chair, SHSP Task Force

6-25-2008

Uncompensated Care Provision and the Economic Behavior of Hospitals: the Influence of the Regulatory Environment

Lei Zhang
Georgia State University

UNCOMPENSATED CARE PROVISION AND THE ECONOMIC BEHAVIOR OF HOSPITALS: THE INFLUENCE OF THE REGULATORY ENVIRONMENT

A Dissertation
Presented to
The Academic Faculty

by

Lei Zhang

In Partial Fulfillment
of the Requirements for the Degree
Doctor of Philosophy in the
School of Public Policy/Andrew Young School of Policy Studies

Georgia Institute of Technology/Georgia State University
DECEMBER, 2008

UNCOMPENSATED CARE PROVISON AND THE ECONOMIC BEHAVIOR OF HOSPITALS: THE INFLUENCE OF THE REGULATORY ENVIRONMENT

Approved by:

Dr. Paul G. Farnham, Advisor
Andrew Young School of Policy Studies
Georgia State University

Dr. William Custer
Robinson School of Business
Georgia State University

Dr. Shiferaw Gurmu
Andrew Young School of Policy Studies
Georgia State University

Dr. Patricia Ketsche
Robinson School of Business
Georgia State University

Dr. Karen J. Minyard
Andrew Young School of Policy Studies
Georgia State University

Dr. Douglas Noonan
School of Public Policy
Georgia Institute of Technology

Date Approved: 11/11/2008

THIS DISSERTATION IS DEDICATED TO MY FAMILY…

ACKNOWLEDGEMENTS

I am deeply indebted to many people who have offered tremendous help during my doctoral years. I cannot imagine how lonely this long journey would be without their support, both professionally and personally.

I must first express my deepest gratitude to my dissertation committee: Dr. Paul G. Farnham, Dr. Karen Minyard, Dr. Patricia Ketsche, Dr. William Custer, Dr. Shiferaw Gurmu, and Dr. Douglas Noonan. My dissertation chair, Dr. Farnham, deserves special recognition for his guidance, understanding, patience and, most of all, his friendship during my dissertation process. Not only was he readily available to me, but he always read and responded to each draft of my work more quickly and carefully than I could have hoped. Dr. Patricia Ketsche and Dr. William Custer gave me the inspiration to develop this dissertation. Their extensive knowledge, keen insights and commitment to the highest standards motivated me to achieve excellence. Dr. Karen Minyard has assisted me in so many ways during this journey. None of this work would have been possible without her mentorship. Dr. Shiferaw Gurmu, and Dr. Douglas Noonan also contributed invaluably to this work. I deeply appreciate the time they devoted to providing methodological expertise and critical comments in every phase of my work.

I owe a special note of gratitude to Dr. Donald Compton at Centers for Disease Control and Prevention (CDC) for his encouragement and support. I thank the faculty members who provided contributions to my dissertation. In particular, I am extremely grateful for the assistance, generosity, and advice I received from Dr. Greg Lewis. His help made it possible for me to accomplish this endeavor. Additionally, much appreciation goes out to my long-term friends and colleagues: Rayna Stoycheva, Dr. Ignacio Navarro, Dr. Kwaw Adam, Dr. Hai (David) Guo, and Taeyhun Jung for their insights and, more importantly, emotional support. I enjoyed every minute working with them. I extend many thanks to Mei Zhou, Glenn Landers, as well as other friends and colleagues from the Georgia Health Policy Center for their assistance with the data.

I would like to extend special thanks to my parents, Qingyi Zhang and Jinli Liu, for their unending encouragement throughout my life and for being a constant source of support. I would also like to thank my husband, Binjian Sun, for his unwavering love and patience. He helps to keep me optimistic whenever I am faced with great challenges. Without his support, I would never have been able to accomplish as much as I have in my research.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

SUMMARY

This dissertation project examines the effect of various state regulations such as Certificate-of-Need (CON) regulation, uncompensated care pools and community benefit requirement laws on hospital provision of uncompensated care and analyzes both for-profit and non-profit hospitals' responsiveness to the regulatory environment. The analysis of these regulations uses panel data econometric methods for a sample of hospitals in 17 states from 2002 to 2004. This study overcomes the limits of previous research that focused primarily on the effect of a single regulation in a given state. It uses three estimation methods: pooled Ordinary Least Squares (pooled OLS), random effects generalized least squares (GLS) and Hausman Taylor instrumental variable (HTIV) to obtain the parameter estimates. Weighing the advantages and disadvantages of each method, we interpret results based on the cross-validation of the GLS and HTIV estimates. Findings suggest that nonprofit and for-profit hospitals respond to some policy instruments similarly and others differently. For example, both nonprofit and for-profit hospitals respond to CON laws by increasing their uncompensated care provision. However, they respond to policy incentives such as community benefit requirement laws differently. Furthermore, regulatory interactions are found to significantly influence the uncompensated care provision by both nonprofit and for-profit hospitals. The dissertation helps policy makers formulate strategies to create incentives to enhance access to care for the economically disadvantaged. For example, implementing CON and providing public subsidies at the same time may offer better access to care for the uninsured than

implementing either regulation alone. However, community benefit requirement laws do not appear to expand the amount of uncompensated care provided by nonprofit hospitals.

CHAPTER ONE

INTRODUCTION

A continued decline in the share of the population with health insurance coverage combined with movement to decreased reimbursement for hospitals have caused renewed concern about access to health care for the underinsured and uninsured. Hospital uncompensated care, a primary source of care for the indigent, has been declining even though the demand for such care continues to grow. According to a Census Bureau report, the number of uninsured has risen considerably over the years. In less than a decade, the percentage of people without health insurance coverage rose from 14.2 percent in 2000 to 15.8 percent in 2006, that is, 47 million people (DeNavas-Walt, Proctor et al. 2006; Census 2008). This trend has resulted in substantial stress for public and nonprofit teaching hospitals that have played a central role in providing access to care for the indigent. American Hospital Association (AHA) statistics show that hospitals provided almost $29 billion in uncompensated care in 2005, which comprised about six percent of U.S. acute care hospitals' revenue (AHA 2006). In the face of growing fiscal pressures, this burden has started to jeopardize the financial solvency of some hospitals, and has consequently exerted significant impact on access to care for those who need it the most.

Because state regulatory policies have greatly influenced the level of uncompensated care and the ability of hospitals to finance such care, this study examines the impact of such policies on hospital provision of uncompensated care and analyzes hospitals' relative responsiveness to the regulatory environment[*]. Specifically, the study will seek to answer the following research questions: (1) How do regulatory environments affect hospitals that differ by type of ownership? (2) Do regulatory interactions make individual regulations more or less effective?

Answers to these research questions are important because they will help policy makers formulate strategies to improve hospital financing of uncompensated care and create incentives to enhance access to care for the uninsured. For instance, in light of the recent debate over the new Internal Revenue Service (IRS) ruling requiring nonprofit hospitals to report community benefits, it is crucial for the policy makers to understand the intended or unintended consequences of the existing state community benefit requirement laws and whether they influence other similar regulations. In addition, alternative interventions might be developed to protect the safety net hospitals[†], which are often the last resort for care for the uninsured and underinsured, by redistributing the burden of uncompensated care to financially relieve these providers. Furthermore, if regulations are jointly effective in increasing hospital provision of uncompensated care, policy makers targeting at expanding access to care for the uninsured should consider designing more complex regulatory strategies. If interaction among regulations reduces the effectiveness of an individual regulation, the existing regulatory environment should

[*] Note that we are not including federal regulations in the current study due to a lack of variation across states. Our main interest lies in state's regulatory variations.
[†] These are hospitals, either public or private, that have a legal obligation or a commitment to provide direct health care services to the uninsured or underinsured Dalton, et al. (2005). "Survival strategies for Michigan's health care safety net providers." Health Serv Res **40**(3): 923-40..

be carefully examined when new regulations are designed. Thus, the investigation of multiple regulations is crucial to policy design (Antel, Ohsfeldt and Becker, 1995).

We adopt panel data econometric methods for a sample of 2,235 nonprofit and 295 for-profit hospitals in 17 states from 2002 to 2004. This study uses a comprehensive dataset that includes information obtained from three major data sources: the American Hospital Association (AHA) annual survey of hospitals, the Area Resource File (ARF) and the State Inpatient Database (SID) of the Health Care Utilization Project (HCUP). It overcomes the limits of previous research that focused primarily on the effect of a single regulation in a given state. It uses three estimation methods: pooled Ordinary Least Squares (pooled OLS), random effects generalized least squares (GLS) and Hausman Taylor instrumental variable (HTIV) to obtain the parameter estimates. Weighing the advantages and disadvantages of each method, we interpret results based on the cross-validation of the GLS and HTIV estimates.

Our findings suggest that nonprofit and for-profit hospitals respond to some policy instruments similarly and others differently. In addition, we find significant regulatory interactions. Sometimes the effect of a regulation bundle differs from that of individual regulations. This result indicates that previous studies that failed to include regulatory interactions tend to overestimate or misestimate the effect of single regulations. Some important limitations need to be noted. Due to data unavailability, we do not have real changes over time for some key variables that the HTIV model uses to construct robust internal instruments. Additionally, our population adjustment of these variables, though introducing within group variation, creates measurement errors that could bias our estimates. Future research should focus on obtaining more data on these variables so that we could improve the HTIV estimations. Enhanced measures of regulatory intensity using data that include information on primary/preventive care should also be used improve our understanding of the mechanism by which these regulations affect hospital uncompensated care provision.

Scope of the Research

In the current research, we focus on nonfederal, short-term general medical and surgical hospitals. We exclude nursing homes, hospices, and home health care agencies because they compete in a different market and are typically treated separately. We further exclude federal hospitals for similar reasons.

We focus on differences in state regulatory environments for three reasons. First and foremost, states are playing an increasingly significant role in regulating their marketplaces. With the recent shifts toward a more state-centered form of federalism, states have been encouraged to formulate and implement their own regulations to reflect regional dynamics (Turnock and Atchison 2002). Second, failure to recognize regulatory variations among states would lead to an incomplete understanding of regulation's impact on organizational behaviors (Anderson, Heyssel et al. 1993). Third, states have always been an ideal laboratory for "natural experiments". With the variation in the regulatory environment among states, we are able to test theoretical models in a more scientific and rigorous fashion, using a near-natural experiment approach (i.e., comparisons of outcomes under different regulatory environments). To capture a state's regulatory environment, we include in our analysis a much broader scope of regulations than many existing studies. These regulations include Certificate-of-Need (CON) laws, Any-Willing-Provider (AWP) or Freedom-of-Choice (FOC) regulation, rate-setting/uncompensated care pool regulation, state hospital conversion regulation, and community benefit mandates.[‡]

[‡] Due to a lack of variations on AWP/FOC and state hospital conversion regulations in our data sample, we do not empirically test the impact of these two regulations.

Dissertation Overview

This dissertation is organized as follows. Chapter Two first reviews literature on hospital regulation and behavior, as well as hospital provision of uncompensated care. It then summarizes the empirical studies and identifies gaps in the research.

Chapter Three discusses theoretical models of hospital behavior and uncompensated care provision. The first section develops models of hospital behaviors in response to exogenous changes. The next section presents hypotheses to be tested.

Chapter Four presents the methodology, empirical model, and data to be used in the analysis. Chapter Five describes the estimation methodology and presents findings, while Chapter Six concludes, discusses policy implications and study limitations, and suggests directions for future research.

CHAPTER TWO

LITERATURE REVIEW

Previous literature analyzing regulation's impact on uncompensated care provision largely emphasizes the effect of a single regulation without much focus on sectoral differences or policy interactions. This chapter first reviews literature on uncompensated care trends. It then explores motivations for government intervention and the regulation of the hospital industry. This chapter then describes the specific regulations under investigation and reviews relevant empirical studies. It concludes with a summary of the literature and an evaluation of the gaps in prior research.

Trends in Uncompensated Care Provision

Health services researchers have been closely monitoring uncompensated care trends since the early 1980s. They have generally found that between 1980 and 1990, the relative cost of uncompensated care as a percentage of total revenue for all non-federal acute care hospitals increased by about 20 percent, with much of the increase occurring in the first half of the 1980s. The 1990s saw a reversed trend. Despite the fact that the demand for uncompensated care continued to increase, the level of uncompensated care generally declined throughout the 1990s (Atkinson, Helms et al. 1997; Cunningham and Tu 1997; Mann, Melnick et al. 1997; GAO 2006). These studies also find that uncompensated care has not been evenly distributed across hospitals and in fact has been increasingly concentrated among a small number of hospitals. Public and nonprofit teaching hospitals bear much of the uncompensated care burden. Some studies report a lower level of uncompensated care supply by for-profit hospitals when compared with nonprofit and public/nonprofit teaching hospitals (Rosenau 2003). Some others fail to show that there is significant performance difference between for-profit and nonprofit hospitals on this criterion[§] (Rosenau 2003; Rosenau and Linder 2003).

For example, a 2006 General Accounting Office report (GAO 2006) reviewed hospital uncompensated care provision by nonprofit, for-profit and government hospitals in five states (California, Florida, Georgia, Indiana, and Texas). Their statistics show that government hospitals generally devoted the largest share of patient operating expenses to uncompensated care. The nonprofit hospitals' average percentages of uncompensated care expenses were greater than for-profit hospitals in four of the five study states (Florida, Georgia, Texas, and Indiana). In California, the report did not find significant differences among the two hospital groups. In addition, within each hospital group, the uncompensated care burden was generally concentrated in a small number of hospitals. The authors of the report did not, however, control for any hospital or market characteristics that might influence hospital provision of uncompensated care.

Another study released by the Congressional Budget Office (CBO) expands on the GAO's findings (CBO, 2006). Using the same dataset, the CBO adopted multiple regression techniques to adjust the differences between nonprofit and for-profit hospitals

---

[§] The empirical literature examining other performance criteria such as cost, efficiency, diffusion of technology, or quality of care among hospitals of different ownership types is not discussed here. For a systematic evaluation of nonprofit vs. for-profit performance, please see Rosenau, P. V. (2003). "Performance Evaluations of For-profit U.S. Hospitals Since 1980." Nonprofit Management and Leadership **13**(4): 401-423, Rosenau, P. V. and S. H. Linder (2003). "Two Decades of Research Comparing For-profit and Nonprofit Health Provider Performance in the United States." Social Science Quarterly **84**(2): 219-241..

in uncompensated care provision due to hospital and market characteristics. They report an adjusted difference of 0.6 percentage points in uncompensated care as a share of operating expenses, with nonprofit hospitals slightly leading for-profit hospitals.

Schlesinger et al. (1997) used data from a 1987-1988 national survey of 915 psychiatric specialty and general hospitals to examine the impact of hospital ownership and competition, as well as the interaction of these variables on access to hospital care for the uninsured. Results from their Ordinary Least Squares (OLS) regressions show that controlling for some confounding covariates, nonprofit hospitals operating in 1988 provided significantly more uncompensated care than their for-profit counterparts. However, when competition intensifies, such difference in the provision of uncompensated care tends to disappear.

Another study by Norton and Staiger (1994) used the 1981 American Hospital Association (AHA) annual survey of hospitals to compare the volume of uninsured patients treated in nonprofit and for-profit hospitals. Employing an instrumental variable approach, their study failed to find any significant ownership-related difference in the number of uninsured patients served by nonprofit and for-profit hospitals when they are located in the same market. However, they also found that for-profit hospitals often self-select into better-insured markets to avoid those in need of charity care.

Banks, Paterson and Wendel (1997) examined nonprofit vs. for-profit hospital response to exogenous shocks in term of their uncompensated care provision. They used an unbalanced panel of non-Kaiser acute care hospitals in California from 1981-1989 to test the hypotheses that nonprofit and for-profit hospitals react differently to exogenous shocks in the market when they make decisions to supply uncompensated care measured as bad debt and charity care expenditures. The study results show that decreased demand for hospital services is associated with an increase in the for-profit hospital supply of uncompensated care, and a negative but insignificant change in the nonprofit hospital supply of such care. Reduced community expectations as measured by the percent of public hospitals in the market are negatively related to for-profit hospital uncompensated care provision.

Using discharge data from California's short-term acute care hospitals that were operating from 1982-1988, Gruber (1994) investigates the impact of market concentration on hospital provision of uncompensated care measured as bad debt and charity care charges. Results show that hospitals in less concentrated areas reduced their uncompensated care, relative to those in more concentrated areas. However, this study did not directly test whether hospitals of different ownership types respond to market concentration differently in terms of their uncompensated care provision due to limited sample size (398 hospitals including public, for-profits and nonprofits). Instead, the study shows that controlling for market concentration and other covariates, for-profit and nonprofit hospitals' supply of uncompensated care did not differ significantly.

In summary, the literature provides some evidence that nonprofit and for-profit hospitals might behave differently in terms of their uncompensated care provision as well as responses to the exogenous environment. This is relevant to our analysis of regulation because if hospitals of different ownership types respond in different ways with regard to their uncompensated care provision, they ought to be modeled differently and tested in separate equations.

Theory of Regulation

In order to predict hospital responses to regulation or in other words, the impact of regulation on hospital provision of uncompensated care, it is important to understand motivations for states to intervene in private activities. There are mainly three lines of theory that provides reasons for government interventions: the public interest theory, the private interest theory and regulation for taxation.

The prevailing theory of regulation since Adam Smith has been known as the "normative analysis as a positive theory" or NPT (Joskow and Noll 1981). It regarded market failure as the motivating reason for the entry of regulation. Once established, regulatory bodies were supposed to lessen or eliminate the inefficiencies engendered by the market failure (Peltzman 1989). Since this theory is based on traditional welfare economics, it implies that regulations are implemented to serve the public interest. However, the weakness of this theory is its assumption that perfectly informed social welfare maximizers are either managing the regulation or running the regulated organizations (Winston 1993).

Private interest theory of regulation starts with the capture theory or CT. It states that over time regulatory agencies are controlled by the industry pressing to pass supportive regulations (Stigler 1971). In other words, regulation is designed to protect the regulated firms from competition. It was later developed by Pelzman (1976) and Becker (1983) into a general line of theory called the Chicago theory of regulation or the economic theory of regulation (ET). Taken together, the private interest theory implies that members of the regulated industry often form effective advocacy coalitions that are able to influence policy making for their own protection.

The taxation by regulation theory is developed mainly because neither public interest theory or private interest theory is able to adequately explain the deliberate and continued provision of many services by the regulated industry at lower rates and in larger quantities than would be offered in an unregulated competitive or monopolistic market (Posner 1971). This theory hence maintains that regulation is designed to realize cross-subsidization. That is regulatory authorities may use cross-subsidization (or taxation) as a means to regulate the activity of a monopoly by limiting monopoly rents and improving consumer welfare.

Hospital Regulation

Scholars have provided a variety of reasons for government intervention in the hospital industry (Salkever 2000). Early discussion focused on health care market failures. In line with the public interest theory, supporters of this argument posit that regulatory agencies act to improve economic performance of hospitals since the market itself fails to achieve an efficient allocation of resources. Indeed, the hospital industry is replete with market failures. First, consumers typically lack perfect information about the prices and technical aspects of many medical devices. This lack of information places physicians in a strong position to practice opportunistic behavior; second, most health care providers (hospitals, clinics, physicians) face portions of downward sloping demand curves (i.e., they have some degree of monopoly power); third, there is a lack of incentives for both patients and providers to shop around and conserve resources. Particularly, there is a problem of moral hazard as a result of traditional forms of health insurance; fourth, hospitals tend to compete over quality because consumers are less sensitive to prices. It is frequently argued that hospitals often engage in a “medical arms race" and compete through the provision of medically unnecessary services (Feldstein 1971; Robinson and Luft 1987; Kessler and McClellan 2000). However, some scholars argue that correcting market failure and enhancing efficiency as objectives of regulatory agencies are more normative than descriptive. In other words, in principle, government should regulate the hospital industry only because public interventions maximize social welfare. In practice, the entry of government regulations often cannot be solely explained by the public interest theory.

With the development of more positive theories such as private interest theory and taxation by regulation, scholars started to offer additional explanations to hospital regulation. McDonough (1997) examined the regulation and deregulation of hospital rate settings in four states: New York, New Jersey, Massachusetts, and Maryland. He found that key at-stake interest groups were able to manipulate regulation to their own advantage. After investigating the Certificate-of-Need (CON) law in all 50 states, Teske (2004) concluded that CON has increased hospital revenue, evidence of regulation serving the interest of the regulated.

Paralleling the taxation by regulation or consumer subsidy rationales explained by Posner (1971) and others, this line of argument for direct regulation of hospitals posit that public interventions such as rate settings and CON offer some protection to hospitals that provide charity or uncompensated care. For example, Salkever (2000) noted that as managed care plans promote price competition in markets for hospital services, hospital profit margins will be squeezed and the willingness of hospitals to supply charity care will diminish. Price regulation in this case is able to pressure major payers to cover a portion of the hospital's uncompensated care costs.

The next section examines the adoption, implementation and impact of specific regulations such as Certificate-of-Need (CON) laws, Any-Willing-Provider (AWP) or Freedom-of-Choice (FOC) regulation, rate-setting/uncompensated care pool regulation, state hospital conversion regulation, and community benefit mandates which are the focus of this study.

Certificate-of-Need

Certificate-of-Need (CON) laws require that hospitals obtain approval from health planning agencies for investment related to new buildings or expansion of services in excess of certain dollar thresholds. The original rationale of this regulatory intervention, which is to control escalating hospital costs, is embedded in views that hospitals will duplicate services and invest in costly excess capacity because they tend to compete on a non-price basis (Folland, Stano et al. 2004). In the hospital industry, consumers are believed to be largely insensitive to the price of care due to moral hazard resulting from the proliferation of health insurance. Left unchecked, unnecessary duplication of facilities as well as the mere availability of facilities leads to higher cost of care.

CON regulation began when New York became the first state instituting the law in 1964. In 1972, the federal government enacted investment regulation with the passage of Section 1122 of the Social Security Act Amendments. Section 1122 provided for the denial of Medicare and Medicaid cost reimbursement to hospitals expanding capacity without prior approval by local planning agencies. In 1974, the federal government passed the National Health Planning and Resource Development Act (§P.L.93-641) which provided federal funds for states to implement investment laws. As a consequence, CON soon gained in popularity among states. Most states adopted CON regulations in the mid-1970s. By 1980 all 50 states had some form of CON or Section 1122 agreement.

In 1984, Section 1122 expired with the implementation of Medicare's prospective payment system. In 1986, the federal government ended its National Health Planning and Resource Development Act that supported the development of CON programs (Santerre, 2005). Absent federal support, 14 states completely repealed CON regulation. However, six states (Arkansas, Nebraska, Louisiana, Ohio, Oregon, and Wisconsin) retained their CON regulation for nursing homes and long term care services, and as many as 31 states maintained their complete CON laws.

CON laws may improve access to care for the indigent and uninsured in many ways. Regulators may use CON to prevent entry of potential competitors who may "cherry-pick" profitable services, hence undermining the ability of existing providers to sustain money-losing services such as care for the indigent (Alpha-Center, 1999; Conover & Sloan, 2003). CON may also be used to give providers incentives to build facilities in underserved areas that have a greater demand for services such as uncompensated care (Lewin-ICF & Center, 1991). CON is further used to protect safety net providers who form the backbone of uncompensated care provision by increasing their financing margin (Mendelson & Arnold, 1993). CON may explicitly require providers to supply certain level of uncompensated care as a condition of obtaining CON approval. Lastly, some states use CON to encourage development of nonprofit hospitals that are supposed to provide more uncompensated care than for-profit hospitals (Alpha Center, 1999).

Few studies provide a direct link between CON and hospital uncompensated care provision. Mendelson and Arnold (1993) found that regulators in Ohio used CON to protect access to care for the disadvantaged by denying applications that could have adverse effects on the financial viability of safety net hospitals in inner cities. Lewin and Alpha Center's report (1991) to the Ohio Department of Health provided similar evidence. In Pennsylvania, the CON program also tended to reward providers who agreed to supply more uncompensated care (Alpha-Center 1999). However, an evaluation of the CON program in Michigan yielded only minimal support for a moderate beneficial effect of CON on serving the uninsured (Conover and Sloan 2003).

Linkages between CON and uncompensated care were most thoroughly investigated in studies in Florida and California. Using a unique Florida data set on CON rulings from 1983 to 1986, Fournier and Campbell (1997) examined the relationship between CON licenses and uncompensated care provision (measured by the dollar amount of indigent care provided by the hospital and a relative measure constructed by dividing the dollar amount of indigent care by hospital bed size). They found that, controlling for the endogeneity of indigent care, regulators in Florida systematically awarded CON licenses to hospitals providing greater amount of care to the poor. Although the validity of their instrument, hospital teaching status, is questionable, the study offers some evidence of the impact of CON on the provision of indigent hospital care. Similar results were reported in their earlier, more descriptive study of Florida's CON (Campbell and Fournier 1993).

Campbell and Ahern (1993) used two-period California data to explore the effect of CON on uncompensated care provision. Specifically, they run separate multivariate regressions for California hospitals in 1963 and 1987 to examine the determinants of hospital provision of uncompensated care. They found a positive relationship between net profitability of private nonprofit hospitals and the amount of uncompensated care they provide. They argue that this finding suggests government regulators reward heavily burdened uncompensated care providers with profitable CON licenses. Since no CON variables are actually used in estimating the amount of uncompensated care given by providers, this study fails to demonstrate a direct connection between CON activities and actual provision of indigent care (Conover and Sloan 1998).

Any-Willing-Provider and Freedom-of-Choice Law

The Any-Willing-Provider (AWP) law requires that managed care organizations accept any provider willing to abide by the plans' terms and conditions as well as their payment rates. The Freedom-of-Choice (FOC) law requires that a managed care enrollee be reimbursed for health care services outside of the managed care plan networks.

The arguments for the adoption of AWP/FOC are threefold. AWP increases access to care and, at the same time, improves quality of care. Many proponents of AWP believe that AWP promotes health care continuity by allowing patients to maintain relations with providers who have been their regular source of care. These laws also resulted from the negative consumer reactions to the restrictions of managed care although they may increase the costs of health care by relaxing these restrictions.

There are wide variations among states instituting AWP/FOC laws. Some laws affect virtually all providers (e.g., hospitals, physicians, pharmacies) whereas others only restrict pharmacies. As our study examines the effect of regulations on hospitals, we include only AWP/FOC laws relating to hospitals. AWP laws applying to hospitals were enacted as early as 1984 in Georgia. However, since the 1990s, the laws gained popularity from concerns about potential adverse effects of managed care selective contracting. Thirty states had enacted either AWP or FOC, or both, for pharmacies by 1996. Thirteen states have laws relating to hospitals, and 17 have laws covering physician services (Ohsfeldt, Morrisey et al. 1998).

Although there is no direct evidence that AWP/FOC laws influence hospital provision of uncompensated care, some studies argue that such laws stifle competition among hospitals, which may in turn affect their financial ability to provide uncompensated care (Gruber 1994; Hellinger 1995). Gruber (1994) used hospital panel data from 1984 to1988 to examine the effect of managed care selective contracting on uncompensated care provision in California. He found that there was a large fall in net revenue and net income in more competitive hospital markets after the advent of selective contracting by managed care organizations. This result suggests that when competitive pressure from selective contracting increased, uncompensated care to the uninsured declined because hospitals are less capable of cross-subsidizing such care. Since AWP/FOC laws restrict the extent to which managed care organizations selectively contract with hospitals, the competitiveness of hospital markets might have decreased. One plausible explanation is that with AWP/FOC laws, hospitals no longer enjoy guaranteed volume of patients when all hospitals that agree to the terms set by managed care organization are able to contract with them. As a result, hospitals do not have the incentive to lower their cost in order to compete for managed care contracts, and hence lower levels of competition.

Hospital Rate Settings and Uncompensated Care Pools

These two regulations are discussed together because empirical studies of the impact of rate setting programs on uncompensated care focus exclusively on its mandated uncompensated pools.

Rate setting programs were widely believed to be designed to alleviate the perceived problem of rapidly growing hospital expenditures (Cone and Dranove, 1988). New York was the first state to enact a mandatory rate setting law in 1969 (Salkever, 2000). Rate setting soon spread to other states with some variations. However, in a typical rate setting program, a legal authority is established for approving the rates that hospitals charge. With Medicare's shift to a perspective payment system in the early 1980s and the emergence of managed care and capitation as viable cost-control mechanisms in the late 1980s, states started terminating their rate setting programs. In the early 1980s, about 30 states employed some form of hospital rate-setting as a cost-containment device, but today none of these states except Maryland still use hospital rate-setting (McDonough 1997; Volpp, Ketcham et al. 2005).

In the early 1980s, some states started to mandate hospital uncompensated care pools as part of their rate setting programs. Although all but one of these states eliminated their rate setting programs, some kept the uncompensated pools requirement. New mandates replaced the old hospital-specific add-on to rates and applied a uniform surcharge. The resulting funds were then pooled and redistributed to hospitals according to their amounts of uncompensated care. Hospitals with low loads of uncompensated care were net contributors, while those with high levels were net recipients. The goals of pooling were to improve the financial condition of hospitals with high uninsured care loads, more equitably fund uncompensated care, and improve access for the uninsured by removing disincentives for hospitals, particularly private hospitals, to treat uninsured patients (Bovbjerg, Cuellar et al. 2000). In the 1990s, Florida, Indiana, Massachusetts, New Jersey, New York, South Carolina and Virginia all had such pools. Since Maryland still maintains its rate setting system, hospitals are reimbursed for their uncompensated care as part of the rate setting program (Fraser 1990).

Using data from a sample of New Jersey short-term, acute care hospitals from 1979 to 1987, Dunn and Chen (1994) employed a pre- and post-design to assess the impacts of the introduction of uncompensated care payment on the overall level of uncompensated care provision as well as the distribution of uncompensated care across hospitals. Their study shows that hospitals in New Jersey did not significantly increase their uncompensated care after the implementation of this new regulation. However, there is evidence that this regulation has resulted in a more even distribution of uncompensated care burden across hospitals as indicated by a positive effect on the financial condition of hospitals providing a disproportionately larger share of this care.

Using an updated New Jersey data from 1986 to1990, Gaskin (1997) estimated the impact of the uncompensated care pool on both inpatient and outpatient uncompensated care. He further investigated how uncompensated care pools affect hospitals' collection efforts. Evidence from this study suggests that such pools have actually induced hospitals to increase their inpatient uncompensated care by an average of 14.8% and statewide uncompensated care by $360 million during 1987-1990. This study did not find evidence that uncompensated care pools created a moral hazard problem by decreasing the state's collection efforts.

Spencer (1998) examined the redistributive effect of the uncompensated care pool across hospitals in New York. Using data from 1981 to 1987, the author found that such pools did result in routine care being redistributed away from hospitals that traditionally provided a disproportionate share of uncompensated care to the uninsured, whereas highly technological care was not significantly redistributed.

Earlier studies using New York hospital data all found that levels of uncompensated care increased due to changes in regulation. Thorpe (1988) found that during the post-regulation period from 1983 to 1985, uncompensated care increased significantly. Similar results were found in another study by Thorpe and Phelps (1991). However, they further argued that hospitals in New York did not increase charity care in proportion to the amount of the grant received. Thorpe and Spencer (1991) later used a longer panel (1981-1987) and found that pools have led to increased access for the uninsured with public hospitals leading private hospitals in the amount of care provided.

Hospital Conversion Regulations

These state regulations impose state oversight on the process of converting public or non-profit facilities to for-profit status through requiring attorney general approval, advance notification, and community involvement. This state intervention was partly motivated by the concern that conversions from public or non-profit hospitals to for-profit status might harm access to care for the low income uninsured and underinsured population by reducing the amount of charity care provided. Stricter oversight (i.e., state monitoring in addition to federal oversight) might protect the community's charitable interests. As of 1997, 24 states and District of Columbia have enacted such laws to affect conversions from nonprofit/public hospital to for-profit status (GAO 1997).

Little evidence exists concerning the effect of hospital conversion regulation on conversions or uncompensated care, although a number of studies have examined the impact of actual conversions on the provision of uncompensated care. These studies noted either insignificant differences in the level of uncompensated care provision in nonprofit to for-profit conversions (Young, Desai et al. 1997; Needleman, Lamphere et al. 1999; Young and Desai 1999) or significantly less uncompensated care provided to the indigent when such conversions occur (Thorpe, Florence et al. 2000). This literature implies that if the presence of conversion regulations successfully inhibits or stimulates conversion activity, these regulations may have profound impact on hospital provision of uncompensated care.

Community Benefit Mandates

Community benefit mandates require that nonprofit hospitals provide a sufficient amount of community benefit[**] to justify their tax exempt status (Noble, Hyams et al. 1998). Prior to the mid-1980s, most states used a broad community benefit approach in defining tax exempt status for health care providers (Noble, Hyams et al. 1998; Colombo 2006). However, during the 1980s and early 1990s, motivated by the escalating concerns that the line between nonprofit and for-profit was blurring, several states began to question the tax exemption status for nonprofit hospitals (Potter and Longest, 1994; Noble, Hyams, and Kane, 1998). As a result, some states adopted explicit charity care

---

[**] Community benefit commonly include uncompensated care, health promotion services, research and education, open access to services and community health orientation. Please see Ginn, G. O. and C. B. Moseley (2006). "The impact of state community benefit laws on the community health orientation and health promotion services of hospitals." J Health Polit Policy Law **31**(2): 321-44..

tests in defining tax exempt status. In 1993, Texas became the first state to pass legislation that requires hospitals to provide a specific percentage of hospital net patient revenues for charity care and other community benefits. Other states have adopted a broader community benefit test and required public reporting for a variety of community benefits, including charity care (Noble, Hyams, and Kane 1998).

We did not find studies that explicitly examined the effect of these mandates on hospital uncompensated care provision. Only one study indirectly investigated the effect of state community benefit laws and guidelines on community health orientation and the provision of hospital-based health orientation activities including uncompensated care provision. Using a sample that included all not-for-profit and investor-owned acute-care hospitals in the United States during the year 2000, Ginn and Moseley (2006) used multiple regressions to test the effect of community benefit laws and type of ownership while controlling for organizational and environmental variables. The results indicated that, on average, nonprofit hospitals in the ten states with community benefit laws/guidelines reported significantly more community health orientation activities than did nonprofit hospitals in the forty other states. In addition, on average, for-profit hospitals in the ten states with laws/guidelines reported significantly more community health orientation activities than did comparable hospitals in the forty other states. The study also found that community benefit laws had the effect of decreasing ownership-related differences in reported community health orientation activities.

Summary of Literature Review

The literature provides some evidence that nonprofit and for-profit hospitals might behave differently in terms of their uncompensated care provision as well as responses to the exogenous environment. This suggests that they ought to be examined in separate models. Furthermore, much of the research on regulation and hospital provision of uncompensated care has focused on uncompensated care pools (and pools as part of hospital rate setting programs). A majority of studies found that such subsidies have successfully increased the level of uncompensated care provision in the market (Thorpe 1988; Thorpe and Spencer 1991; Gaskin 1997; Spencer 1998). Two other studies provided additional evidence that uncompensated care pools redistributed provision of such care among hospitals (Dunn and Chen 1994; Spencer 1998). However, one of them fails to find that uncompensated care pool increases the level of uncompensated care provided in New Jersey (Dunn and Chen 1994).

Although researchers have also examined the impact of CON on hospital behavior, few studies provide a direct link between CON and hospital uncompensated care provision. Most studies presented descriptive evidence from evaluation reports of state CON programs (Lewin-ICF and Center 1991; Mendelson and Arnold 1993; Alpha-Center 1999; Conover and Sloan 2003). They found that CON has been used by regulators to increase access to care for the vulnerable population. Only two studies provided some limited empirical evidence on this question (Campbell and Ahern 1993; Campbell and Fournier 1993; Fournier and Campbell 1997). Their studies show that in Florida and California, hospitals that provide more uncompensated care are systematically rewarded under CON legislation.

The impact of other regulatory programs on hospital provision of uncompensated care is inadequately explored. Only one study indirectly examined the effect of a community benefit requirement on uncompensated care provision (Ginn and Moseley 2006). Their results supported the hypothesis that nonprofit hospitals offer significantly more community health-oriented services (which include uncompensated care) in the presence of community benefit mandates.

The review of the literature on regulatory environment and hospital supply of uncompensated care also revealed some shortcomings. First, most previous studies have examined hospitals' uncompensated care provision and regulatory environment by focusing on a single regulation such as hospital uncompensated pool or certificate-of-need (CON) regulation. Recent studies have indicated that regulatory programs should be analyzed in the context of the larger regulatory environment (Sloan, Morrisey et al. 1988; Antel, Ohsfeldt et al. 1995). The interplay of incentives offered by different regulatory programs may have resulted in unexpected consequences that cannot be predicted by analyzing a single regulation. In addition, due to interactions among different regulations, the combined effects of a regulation bundle may be different from a regulation acting alone. Evidence from other industry studies further suggest that regulations, particularly of different parts of an industry, should be viewed as a system because, for instance, when regulation controls price, firms will find other ways to compete (i.e., engaging in non-price competition) (Viscusi, Harrington et al. 2005).

Second, early works have predominately used data from a single state (e.g., New Jersey, New York, California or Florida). Although some CON studies have used a dichotomous variable to compare regulatory effects in markets with and without regulation using data from all 50 states, none has investigated the effect of CON on uncompensated care provision using national data. The shortcoming of employing data from a single state is the inability to compare differences in regulations among the states. Further, even if studies have used national data, the comparison states are not completely free of similar regulations if they fail to take into account a broader scope of regulations. Regulations other than the one under investigation might have confounded the results if researchers are not cautious about their comparison groups.

Finally, existing studies need to be updated. An overwhelming number of studies used data in the 1980s and early 1990s, a period which is no longer of current policy interest. There have been dramatic changes in the health care marketplace during the late 1990s and early 2000s (e.g., increased competition and cost control and reduced support for care of the uninsured). These major changes in the health care market may be altering the effectiveness of existing programs. Results obtained from recent data will prove to be more relevant to formulate policies for the current health care system.

CHAPTER THREE

THEORETICAL FRAMEWORK, TYPOLOGY AND HYPOTHESES

Theoretical Framework

As suggested by previous literature, hospitals of different ownership types differ in term of their uncompensated care provision and their different responses might be influenced by the regulatory environment. Theoretical models of hospital uncompensated care supply are useful in examining hospital response to and the impact of different policy options since these frameworks help illuminate determinants of hospital uncompensated care provision.   We draw on the work of Frank and Salkever (1991), Gruber (1994), and Banks, Paterson and Wendel (1997) and simplify their models to investigate equilibrium hospital behavior when the regulatory environment changes.

In these models, nonprofit hospitals are assumed to be concerned about the health of the entire community, including the economically disadvantaged. Their supply of uncompensated care is believed to be socially motivated, subject to financial resource constraints. In contrast, for-profit hospitals are hypothesized to supply uncompensated care to the extent that doing so maximizes profits because they are concerned that they might incur costs if the community perceives that they under-produce uncompensated care. For-profit hospitals' supply of uncompensated care therefore is a business strategy that may enhance a hospital's reputation and reduce the expected penalty of under-producing such care.

Frank and Salkever (1991) focus on the supply of charity services by nonprofit hospitals. They argue that price-taking private nonprofit hospitals seek to maximize utility (U) which is a function[††] of net revenue *R* and unmet indigent care need *N*.

$$U = U\,(R, N) \quad \text{or}$$

$$U = U\,[(QP + rD + E - C(Q + D)), (T\text{-}D\text{-}H\text{-}G)]$$

where

QP = the average revenue for compensated care;

Q = the number of paying patients

r = revenue per indigent patient;

D = the number of indigent patients;

E = sum of endowment income;

C = hospital's cost function

T = total indigent care need;

H = other private hospitals

G = public hospitals

In this model, nonprofit hospitals earn net revenue to subsidize uncompensated care. It also predicts that increases in the supply of charity care by other hospitals in the market crowds out indigent care in the nonprofit hospital. A slight variation, the "impure

[††] It should be noted that the argument *R* in the nonprofit utility function may be viewed as a proxy representing "profits" spent to pursue all objectives perceived by the hospital's managers or trustees other than uncompensated care provision. For example, Newhouse proposed a utility function with quality and quantity as arguments subject to a breakeven constraint (please refer to Newhouse, J. (1970). "Toward a theory of nonprofit institutions: an economic model of a hospital." American Economic Review **60**(1): 64-74.) The model offered by Pauly suggests that hospitals seek to maximize income of physicians or decision makers. The specification of the arguments does not however alter the results (see Pauly, M. V. (1987). "Nonprofit firms in medical markets." American Economic Review **77**(2): 257-262.)

altruism" model (Frank and Salkever 1991), was proposed to account for nonprofit hospital's rivalry motivation, which leads to a potential smaller crowd-out effect by other hospitals in the market. In this model, a third argument (Z) indicating the hospital's performance in supplying charity care relative to its rivals was added to the utility function so that nonprofit hospitals are assumed to compete with other private hospitals by providing uncompensated care.

Gruber (1994) simplified the above model as nonprofit hospitals maximizing a utility function $V[R, U]$, subject to $R = pq - c(q) - U$

where

R = net revenue,

U= uncompensated care,

p = price per unit of service,

q = quantity of services,

$c(q)$ = hospital cost function; $c_q > 0$, $c_{qq} > 0$.

In contrast to Frank and Salkever's framework which takes price as exogenous, this model assumes a monopolistic hospital market, or in other words, prices charged to private paying patients are endogenous. This assumption was supported by literature arguing that the medical market place can be best described as monopolistically competitive, due to the presence of imperfect, costly price and quality information (Dranove, Satterthwaite et al. 1986; Dranove and Satterthwaite 1992). However, the difference in assumptions does not change the predictions drawn from these models.

The model developed by Banks, Paterson and Wendel (1997) was motivated by Gray (1991) to explain uncompensated care provision by for-profit hospitals. This model assumes that for-profit hospitals provide charity care because they are concerned that they might incur costs if the community perceives that they under-produce uncompensated care. These costs might take the form of penalties such as failure to be granted a CON or loss of state Disproportionate Share Hospital (DSH) payments. For-profit hospitals are hence assumed to maximize the profit function[‡‡] (Π) with:

$$\Pi = QP\,(Q;d) - C(Q, U) - F - L(e - U)$$

where

U = uncompensated care;

$QP\,(Q;d)$ = the average revenue for compensated care;

Q = the patient days of compensated care;

d = demand curve shift parameter;

$C\,(Q, U)$ = variable cost of producing Q and U;

F = fixed cost

$L(e - U)$ = expected penalty cost.

Based on previous research and given different motivations between nonprofit and for-profit hospitals, a nonprofit hospital's utility function (*V*) can be mathematically expressed as:

Nonprofit: $V \equiv \max\,[R, U]$; subject to[§§] $R = QP\,(Q;d) + rU - C(Q, U)$

[‡‡] For derivations of the for-profit model, please refer to Banks, et al. (1997). "Uncompensated hospital care: charitable mission or profitable business decision?" Health Econ **6**(2): 133-43..

[§§] Nonprofit organizations face a non-distribution constraint, which means they cannot legally distribute any of their residual earnings to stakeholders. Santerre, R. E. and J. A. Vernon (2006). "The consumer welfare implications of the hospital ownership mix in the US: an exploratory study." Ibid. **15**(11): 1187-99.

To simplify the derivations, we follow Banks et al (1997) and assume a special case where hospitals earn net revenue to subsidize uncompensated care. In other words, we assume that nonprofit hospitals maximize uncompensated care:

$$V' \equiv \max [U]; \text{ subject to } F = QP(Q;d) + rU - C(Q, U) = 0$$

whereas a for-profit hospital's objective is to maximize profit (Π):

For-profit: $\Pi \equiv \max [QP(Q;d) + rU] - C(Q, U) - L(e - U)$

where

R = net revenue

U = uncompensated care;

$QP(Q;d)$ = the average revenue for compensated care;

Q = the patient days of compensated care;

d = demand curve shift parameter such as competition;

r = revenue per indigent care patient[***]

$C(Q, U)$ = variable cost of producing Q and U;

$L(e - U)$ = expected penalty cost.

These theoretical models assume that hospitals are price setters and they exercise control over the amount of uncompensated care supplied. In addition, the medically indigent demand for uncompensated care is assumed to exceed hospital desired supply.

For nonprofit hospitals, solving for their constraint:

$$F = QP(Q;d) + rU - C(Q, U) = 0$$

[***] *r* theoretically is zero for indigent care as this care is uncompensated. However, with various subsidies this care can be compensated at a rate that equals to r ($0 \leqslant r \leqslant p$).

$QP(Q;d)+rU = C(Q, U)$

This equation implies that nonprofit hospitals supply uncompensated care to the point when marginal revenue equals marginal cost (i.e., MR = MC)[†††].

For for-profit hospitals: the first order conditions (FOC) are

$$\pi_Q = QP_Q + P - C_Q = 0$$

$$\pi_U = r - C_U + L' = 0$$

These FOCs imply that for-profit hospitals supply uncompensated care to the point when marginal benefit equals marginal cost (i.e., MB = MC).

Solving for the constraint and the FOCs, we obtain the following comparative statics for nonprofit and for-profit hospitals respectively (Table 1[‡‡‡]).

[†††] Given that net revenue is modeled as a proxy for "activities" that produce utilities/benefits, the marginal revenue really is another way of labeling marginal utility/benefits.

[‡‡‡] D is the determinant of matrix $\begin{vmatrix} \dfrac{\partial \pi_Q}{\partial Q} & \dfrac{\partial \pi_Q}{\partial U} \\ \dfrac{\partial \pi_U}{\partial Q} & \dfrac{\partial \pi_U}{\partial U} \end{vmatrix}$.

.

Table 1: Comparative Static Results for Nonprofit and For-profit Model

Nonprofit		***For-profit***	
$U_d = P_d Q / C_U$	<0	$U_d = [-C_{QU} P_{Qd}]/D$	>0
$U_r = -U/-C_U$	>0	$U_r = -[2P_Q + QP_{QQ} - C_{QQ}]/D$	>0
		$U_e = [(QP_{QQ} + 2P_Q - C_{QQ})(-L'')]/D$	>0

These results delineate the differences between nonprofit and for-profit hospital supply of uncompensated care. Nonprofit hospitals provide uncompensated care because supplying such care increases their utility. They produce uncompensated care to the point where the marginal revenue is balanced by the marginal cost of uncompensated care provision. However, for-profit hospitals provide uncompensated care because they are concerned that they might incur costs if the community perceives that they under-produce uncompensated care. Unlike their nonprofit counterparts, for-profit hospitals treat uncompensated care provision as a profit maximizing strategy. Producing such care does not add utility to for-profit hospitals but it maximizes their profits by lowering their penalty costs. The optimum level of uncompensated care supplied by for-profit hospitals is achieved by equating marginal cost with the hospital's marginal benefit of producing such care.

These differences indicate that nonprofit hospitals and for-profit hospitals would respond to different incentives and environmental changes differently. Nonprofit hospitals respond to a downward shift in demand by reducing the amount of uncompensated care provision because decreased demand for paid care implies decreased profits available for financing uncompensated care. An increase in the marginal revenue that results from an increased number of paying patients will increase supply of uncompensated care. Similarly, an increase in the revenue per indigent patient (usually in the form of subsidies) increases uncompensated care. Nonprofit hospitals will also respond to increased competition by reducing their charity care output. This is because when competition intensifies, the price for paying patients goes down. As a result, nonprofit hospitals have less revenue from the paying patients to cross-subsidize uncompensated care. They therefore have to decrease the amount of uncompensated care in order to survive the fierce competition. On the contrary, for-profit hospitals may increase the supply of uncompensated care when market demand for compensated care decreases since the concurrent decrease in paid care reduces the marginal cost of producing uncompensated care. They would respond to competition by increasing their uncompensated care supply. One explanation is that the price for paying patients decreases as competition increases. Consequently, the decrease in the price of paid care lowers the marginal cost of providing uncompensated care. For-profit hospitals therefore supply more uncompensated care as the marginal cost of providing such care decreases. On the other hand, the for-profit model also predicts that for-profit hospitals will respond to the level of community expectation or will incur penalties resulting from failure to meet community expectation.

Typology

Before we generate any predictions regarding the impact of regulatory environment on hospital's provision of uncompensated care, it is crucial that we develop a typology so that regulations can be grouped and examined in meaningful ways. The comparative static analysis represents a convenient tool for this categorization. The analysis illuminates different mechanisms through which regulations exert an impact on hospital behavior. We hence categorize different regulatory environment on this basis. Since both CON and AWP/FOC affect hospital supply of uncompensated care by either increasing or decreasing competition *d*, we label these regulations as competition regulations. Uncompensated care pools and pools as part of the rate setting programs increase revenue per indigent care patient *r,* and we classify this type of regulation as subsidies. Because states use requirements such as conversion oversight and community benefit requirements to explicitly communicate expectations for community services such as uncompensated care, we categorize these regulations as mandates. This taxonomy provides us a framework to organize seemingly complicated regulatory environments so as to improve our understanding of the different mechanisms through which regulations can affect hospital behavior. The next section uses CON, uncompensated care pool, and community benefit requirement regulations as examples to illustrate how hypotheses can be developed for each type and/or individual regulation.

Hypotheses

Previous research shows that CON, as an entry barrier, has reduced competition by maintaining high levels of industry concentration and restricting supply of services. After analyzing the impact of CON on entry of new firms into the dialysis industry, Ford and Kaserman (1993) found that the presence of CON laws significantly reduced the entry and expansion of dialysis firms. Gruber (1994) studied the effect of competitive pressure on hospital provision of uncompensated care. He found that nonprofit hospitals provide more uncompensated care in more concentrated markets. These findings, in conjunction with predicted effect of competition on hospital provision of uncompensated care discussed in the previous section, led us to conclude that nonprofit hospitals may increase their uncompensated care supply in response to CON laws.

For-profit hospitals may respond to CON by either decreasing or increasing their uncompensated care supply. This is because on the one hand, CON has constrained market competition and promoted profits generated by private paying patients. When paid care becomes more profitable, the opportunity cost of providing uncompensated care (i.e., cost of forgoing paid care) rises. For-profit hospitals therefore would reduce their uncompensated care supply when CON increases industry concentration. On the other hand, for-profit hospitals may also perceive the failure to obtain CON as a profit loss, and hence increase their uncompensated care provision in states with such a regulation. The resulting direction of CON's impact on for-profit hospitals remains undetermined.

H1: ceteris paribus, nonprofit hospitals in states with CON laws will provide more uncompensated care than their counterparts in states without such a regulation.

H2: ceteris paribus, for-profit hospitals in states with CON laws will provide less or more uncompensated care than their counterparts in states without such a regulation.

With increasing direct subsidies such as reimbursement from uncompensated care pools, both nonprofit and for-profit hospitals should increase their uncompensated care supply. Intuitively, this happens because reimbursing hospitals based on their uncompensated care cost increases the revenue per indigent patient. Therefore, we expect to see hospitals increase their uncompensated care supply when provided such a subsidy. Profit maximizing for-profit hospitals might also perceive the loss of pool subsidies as penalties resulting from failure to meet the health care needs of the community. In this case, they will increase their supply of uncompensated care when such subsidies raise their expected penalty cost. Therefore, the direction of the signs on nonprofit and for-profit hospital uncompensated care provision is expected to be the same.

H3: ceteris paribus, both nonprofit and for-profit hospitals in states with uncompensated care pool regulation or subsidy regulation will provide more uncompensated care than their counterparts in states without such regulations.

The responses of nonprofit and for-profit hospitals under community benefit requirement regulations are rather ambiguous. Given the mandate for nonprofit hospitals, we expect that they comply with the regulations by increasing their uncompensated care supply (if they had not provided the desired level). However, if community benefit requirement regulations help to improve the overall health of the community, given that hospitals in states with such laws typically provide better access to primary/preventive care (Ginn and Moseley 2006), we might see a decrease in uncompensated inpatient care as a result of a decline in the demand for inpatient care. We might also see such a negative relationship between community benefit requirement laws and nonprofit hospitals' provision of uncompensated care if the community benefit requirement is set below the level at which hospitals actually provide uncompensated care. These laws could provide a signal to reduce nonprofit hospitals' provision of care by suggesting that their prior levels of such care are above the levels expected by the community.

Although these mandates are not intended to be binding for the for-profit hospitals, they send a signal to health care providers of what is expected by the community. Since for-profit hospitals perceive that they could incur costs if they fail to meet community expectation, we might expect to see a significant increase in the level of uncompensated care provided by for-profit hospitals.

However, there might be a "crowd-out" effect as a result of these mandates as Frank and Salkever (1991) predict. If for-profit hospitals increase their uncompensated care supply, nonprofits serving the same market will tend to reduce their provision of uncompensated care. A number of empirical studies supported this argument (Horwitz 2005; Schlesinger and Gray 2006). The extended "impure altruism" model adds to this prediction by arguing that this effect is likely to be moderate or weak if we further assume that a nonprofit hospital maximizes performance in supplying charity care relative to its rivals. If an increase in for-profit hospital's uncompensated care provision results in a decrease of supply from its rivalry nonprofit hospital, the mandates could lead to a different distribution of uncompensated care supply in the market.

Another piece of evidence complicates this prediction even further. Some studies have shown that in mixed ownership markets, for-profit hospitals provide significantly less charity care when nonprofit hospitals provide high level of uncompensated care (Clement, White et al. 2002). This phenomenon represents a reversed crowd-out effect: for-profit crowd-out by nonprofit hospitals. This means if nonprofit hospitals respond to mandates by increasing their supply of care, for-profit hospitals will decrease their supply. After all, these mandates are not legally intended for for-profit hospitals and might not be binding for them. The final direction of the signs therefore remains an empirical matter.

H4: ceteris paribus, both nonprofit and for-profit hospitals in states with community benefit requirement laws will provide more/less uncompensated care than their counterparts in states without such regulations.

In addition to behavioral differences between hospitals, we are also interested in regulatory interactions. A few studies suggest that regulations working together may in some cases enhance the effectiveness of one another. For example, Antel et al. (1995) examined the effects of various regulation (e.g., rate setting, CON, Medicare perspective payment and Nixon-era Economic Stabilization Program) on hospital costs. Using a two-decade-long panel dataset of the 48 continental states, they found that although few regulations under investigation have had a significant effect on controlling hospital costs, rate regulation, interacting with Medicare perspective payment, has successfully limited the cost increase. We therefore predict that there might be interaction effects in the sense that an individual regulation will be more/less effective in the presence of other regulations.

CON, interacting with uncompensated care pools may complement each other and increase the uncompensated care provision by nonprofit hospitals. This is expected because both CON and pool are predicted to be positively related to nonprofit hospital supply of uncompensated care. CON improves nonprofit hospital's ability to cross-subsidize care for the uninsured. When given extra incentive by public subsidies such as uncompensated care pools, nonprofit hospitals will provide more uncompensated care comparing with comparable hospitals in states that do not have both regulations. For for-profit hospitals, the sign on the interaction term between CON and uncompensated care pool is undetermined. CON is expected to decrease uncompensated care provision by for-profit hospitals since the cost of providing unpaid care increases when CON stifles competition. However, uncompensated care pool gives for-profit hospitals incentive to increase their uncompensated care provision. Which impact dominates when states implement both regulations remains an empirical issue.

The evaluation of interaction effects between CON and community benefit requirement laws is another empirical issue because the impact of community benefit requirement laws can be either positive or negative for both types of hospitals. The sign on the interaction between community benefit requirement and uncompensated care pool as well as the interaction of all three regulations remain uncertain for similar reasons.

CHAPTER FOUR

DATA AND EMPIRICAL MODEL SPECIFICATION

Empirical Specification

Our model specification follows the theoretical framework described in the previous section. A hospital's provision of uncompensated care is influenced by the regulatory environment, institutional/market factors that affect the hospital's capacity to supply uncompensated care, and demand for uncompensated care.

We treat nonfederal, short-term hospitals as our study unit to examine different organizational responses to the regulatory environment and possible policy interactions. A general specification of our empirical model is:

$$UC_{it} = \beta_0 + \beta_1 Hospital_{it} + \beta_2 Market_{it} + \beta_3 Regulation_{it} + \beta_4 Year + \beta_5 State + \varepsilon_{it}$$

where i = 1 to N, t = 1 to T; UC_{it} is our measure for hospital i uncompensated care provision by services in year t; *Hospital* is a vector of hospital organizational characteristics to measure a hospital's capacity to provide uncompensated care; *Market* is a vector of market variables that can affect the supply of, or demand for, uncompensated care in a market; *Regulation*, our key focus, is a vector of regulatory variables that measures states' different regulatory environments; *Year* represents year dummies; *State* represents a vector of states dummies, capturing state specific trends; ε_{it} is a composite error term that can be expressed as $\varepsilon_{it} = \alpha_i + \eta_{it}$, where α_i is a hospital specific error component term; and η_{it} represents the idiosyncratic error term.

Data

We rely on three primary data sources for the period 2002 – 2004 for the current research. (1) The American Hospital Association (AHA) Annual Survey of Hospitals (2002, 2003, and 2004) collects data from all U.S. hospitals and includes a variety of organizational and operational characteristics such as availability of services, utilization, personnel, finances and governance; (2) The Area Resource File (ARF) (2005) contains information on market characteristics as well as community demographics that may affect demand for uncompensated care. Compiled by the Health Resources and Services Administration (HRSA), ARF is a national county-level collection of datasets from more than 50 sources including the Current Population Survey (CPS), InterStudy, and the Bureau of Labor Statistics. It includes information on healthcare professionals, health professions training, health facilities, hospital utilization, hospital expenditures, county population and economics, as well as county-level socioeconomic and geographic codes that allow us to merge these data with other files; (3) The State Inpatient Database (SID) from the Healthcare Cost and Utilization Project (HCUP) (2002, 2003, and 2004) contains detailed information on over 90 percent of inpatient discharges from all community hospitals in 20 states. Since hospital discharge data include zip code information on patient residence, we are able to define markets using patient flows and test if differences in market definition will affect study results.

Construction of the Sample

We used HCUP SID data for seventeen states (AZ, CO, FL, IA, KY, MA, MD, NV, NJ, NY, OR, RI, UT, WA, WV, WI and NC) for information on the total number of admissions and payer types to obtain the percentage of admissions for the uninsured. These states are selected based on their geographical representativeness and diverse regulatory environments.

Geographically, our study states are distributed across the five U.S. regions (as shown by Figure 1): West (WA, OR, NV, UT, CO), Southwest (AZ), Midwest (IA, WI), Southeast (FL, NC, KY, WV), and Northeast (MD, NY, NJ, RI, MA) with Southwest and Midwest slightly under-represented.

When examining individual regulations, we observe some variation except in AWP/FOC laws. Table 2 shows that among all 17 states, five are non-CON states (AZ, CO, OR, UT and WI). Five states have community benefit requirement regulations (MA, MD, NY, RI and UT)[§§§], and eight states fund an uncompensated care pool (AZ, CO, MA, MD, NJ, NV, NY and WV). Additional evidence for variations in policy interactions can be found in Appendix A.

[§§§] NC and NV enacted community benefit requirement laws in 2005.

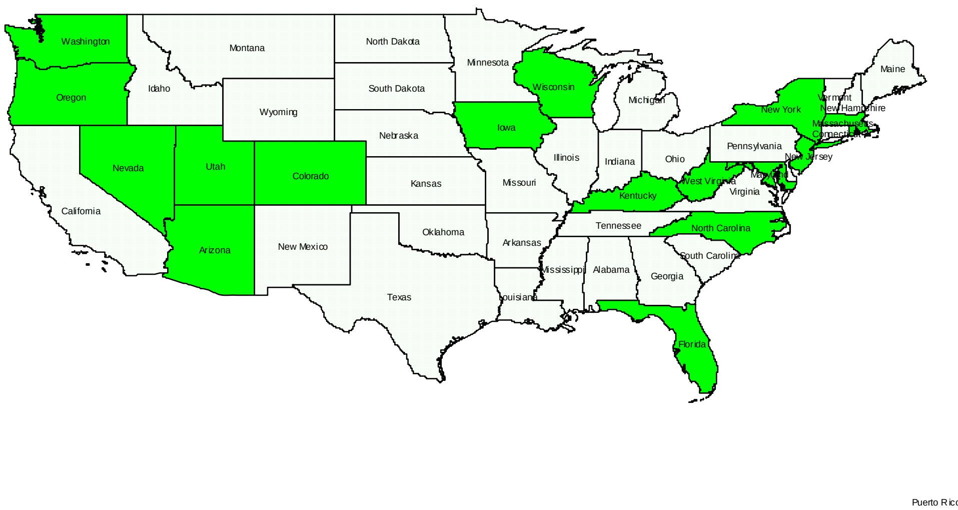


Figure 1: Study States vs. Non-study States

Table 2: Variations of Regulations by Study States

States	*CON*	*REQUIREMENT*	*POOL*	*CONVERSION*	*AWP/FOC*
Arizona			X	X	
Colorado			X	X	
Florida	X				
Iowa	X				
Kentucky	X				X
Maryland	X	X	X	X	
Massachusetts	X	X	X		
Nevada	X	X	X		
New Jersey	X		X		
New York	X	X	X		
North Carolina	X	X			
Oregon†	X			X	
Rhode Island	X	X		X	
Utah		X			
Washington	X			X	
West Virginia	X		X		
Wisconsin†	X				X
Total	12	7	8	6	2

† Long-term care facility only

The HCUP SID data assign a unique data source hospital identifier which can be matched with the AHA identifier provided by a link file in the HCUP SID data. The AHA identifier then serves as the distinguishing identifier in the linked dataset, which uses the AHA data for information on hospital characteristics such as hospital size and ownership status. Data from the Area Resource Files on market and community characteristics are merged using county codes.

The sample for this study consists of hospital-level data for nonfederal, short-term, general hospitals in the 17 states. All specialty, psychiatric, and long-term care hospitals are excluded. The original dataset for analysis comprised 4,324 hospital-years for the study period 2002-2004. This excludes 2004 data for Utah and New York as these states did not report to the HCUP for those years. After hospitals with only one year of observations are excluded, we are left with a study sample of 2,625 nonprofit and 500 for-profit hospital-year observations. In the nonprofit sample, about 78 percent (779 hospitals) have all three years of observations and the remaining 22 percent (204 hospitals) have two years of observations. In the for-profit sample, about 84 percent (148 hospitals) have three years of observations and the remaining 16 percent (28 hospitals) have two years of observations. In addition, we have missing values on two important control variables, the technology intensity variable and the ER variable measuring whether a hospital has an emergency department. We imputed values for the technology intensity variable for 2002, the year we have missing values. Our final sample therefore contains 2,322 nonprofit and 295 for-profit observations. In our final sample, 76 percent (613 nonprofit hospitals) and 24 percent (198 nonprofit hospitals) have three and two years of observations respectively. 48 percent (57 for-profit hospitals) and 52 percent (62 for-profit hospitals) have three and two years of observations respectively.

We carefully examined whether there might be sample selection bias due to our choice of the states as well as to the pattern of the missing values. Since it is reasonable to assume that a state's decision to participate in HCUP reporting during certain time periods is independent of hospital supply of uncompensated care, we are confident that states are excluded randomly.

We also lost a significant number of observations due to missing values on the technology intensity and ER variable. Table 3.1 shows that none of the hospitals in our study states reported on the technology intensity variable in 2002. The remaining states/years have missing values that range from 1% to 42%. In 2003 and 2004, those hospitals that did not respond to the technology intensity variable did not respond to the ER variable, either. Most hospitals reported on the ER variable in 2002 (Table 3.2). In order to utilize the 2002 data, we imputed values for the 2002 technology intensity variable. We replaced missing values on this variable in 2002 by values the same hospitals reported in 2003, assuming that the number of hi-tech services did not change from 2002 to 2003 for these hospitals. Sensitivity analyses are conducted to examine whenever our results are significantly affected by excluding/including these two variables.

Table 3.1: Percent of Missing Values for Technology Intensity by State/Year

State	*2002*	*2003*	*2004*
Arizona	X	26%	24%
Colorado	X	22%	13%
Florida	X	27%	29%
Iowa	X	0	0
Kentucky	X	5%	19%
Maryland	X	0	4%
Massachusetts	X	0	1%
Nevada	X	27%	42%
New Jersey	X	13%	13%
New York	X	24%	N/A
North Carolina	X	15%	14%
Oregon	X	0	0
Rhode Island	X	20%	20%
Utah	X	13%	N/A
Washington	X	15%	22%
West Virginia	X	0	0
Wisconsin	X	2%	7%

Table 3.2: Percent of Missing Values for ER by State/Year

State	*2002*	*2003*	*2004*
Arizona	22%	26%	24%
Colorado	21%	22%	13%
Florida	33%	27%	29%
Iowa	0	0	0
Kentucky	13%	5%	19%
Maryland	9%	0	4%
Massachusetts	1%	0	1%
Nevada	23%	27%	42%
New Jersey	6%	13%	13%
New York	25%	24%	N/A
North Carolina	17%	15%	14%
Oregon	3%	0	0
Rhode Island	10%	20%	20%
Utah	18%	13%	N/A
Washington	12%	15%	22%
West Virginia	0	0	0
Wisconsin	7%	2%	7%

Dependent Variable

Uncompensated care is widely used to capture hospital provision of care to the uninsured. In many prior studies, it is measured as charity care and bad debt. Charity care includes care provided to the indigent who are not expected to pay, whereas bad debt is accrued by someone who is expected to pay but does not pay at all or fails to pay the full amount of their medical bills. There are three problems with this definition. Some scholars argue that including bad debt as part of the measure would overstate a hospital's uncompensated care provision. This is because the amount of bad debt also reflects a hospital's debt collection efforts (Gaskin 1997; Thorpe, Florence et al. 2000; Rosko 2004). For example, Gaskin (1997) argues that the implementation of an uncompensated care pool in Massachusetts could potentially create a moral hazard problem in that the pool reduced the marginal cost of debt collection. As a result, without proper monitoring of the hospitals' debt collection efforts, their bad debt portion of the uncompensated care could increase in response to the Trust Fund. A second disadvantage of lumping charity care and bad debt under the same uncompensated care umbrella is that the distinction between charity care and bad debt is unclear. Some hospitals use a formal process in advance of billing to identify those who are unable to pay, while others use the billing and collection process. Consequently, care delivered to patients may be classified as charity care by one hospital but bad debt by another (AHA 2005). Lastly, using uncompensated care data for comparisons among different types of hospitals or hospitals with mixed payer types can be problematic because uncompensated care data, generally expressed as charges, are usually sensitive to different hospital accounting practices (AHA 2005). Despite these concerns, studies continue to use both charity care and bad debt to measure hospital provision of uncompensated care due to the fact that existing data sets do not make meaningful distinctions between the two concepts (Rundall, Sofaer et al. 1988).

We improve upon measures of uncompensated care used in previous studies by focusing on the actual hospital services delivered to the uninsured. In our analysis, uncompensated care is measured as number/percent of admissions per hospital that are for the uninsured. This dependent variable is constructed as (1) number of all admissions for self-pay/charity patients in a hospital; (2) percent of admissions for self-pay/charity patients by dividing the number of admissions for self-pay and charity patients in a hospital by all the admissions in that hospital. Although this measure could slightly overstate the amount of hospital care that is indeed uncompensated since some of these uninsured patients may pay in-part or in-full and some may qualify for coverage after they have been admitted, this still represents an improvement over previous measures for the following reasons. Our measure directly captures care provided to the uninsured. Therefore, it represents a better indicator of access to care for the uninsured than financial measures of uncompensated care. In addition, it is not influenced by individual hospital accounting practices. As argued by Gruber (1994), changes in uncompensated care measured as charges may not be directly interpretable as changes in the level of care delivered to the uninsured because these changes in charges are likely to reflect shifts in hospital pricing policy and debt collection efforts.

One earlier study that used the same measure to capture hospitals services to the uninsured, Frank and Salkever (1991), developed a theoretical model of indigent care supply by nonprofit hospitals. They tested the model using 40 nonprofit general hospitals in Maryland during the period of 1980-1984. Three regression analyses were conducted with three different dependent variables: the number of equivalent admissions accounted for by uncompensated care in the hospital (calculated by dividing the dollar amount of uncompensated care by the hospital's gross inpatient revenue per admission), the same measure adjusted by case-mix costliness, and number of discharges of inpatients classified at admission as either self-pay or charity cases. Their study found few differences across the three measures, which provides validation for our alternative measure of uncompensated care.

Regulatory Variables

The literature on regulations suggests that variations in regulatory intensity affect the financial resources of hospitals and hence have direct and indirect effects on hospital responses to their regulatory environment (Cook, Shortell et al. 1983). Cook, Shortell et al. (1983) also argue that dimensions of regulations, such as scope, restrictiveness, uncertainty, and duration, need to be considered when examining regulatory impacts. We therefore include these specific dimensions proposed by Cook et al. in our regulatory measures to capture the intensity of the regulations.

Researchers argue that the structure and scope of CON regulations have led to variations in the effectiveness of this program (Salkever 2000). Variables such as dollar thresholds and scope of services are indicative of intensity variations of CON programs with lower dollar thresholds and broader scope of control predictive of stricter regulatory control. We therefore adopt the index developed by the American Health Planning Association (2005) to measure the presence and intensity of CON programs. This index is constructed as a weighted number of covered services, with the weights capturing the review thresholds**** of different CON programs. Specifically, state CON programs are first weighted by their capital, equipment and new service review dollar thresholds. Assigning a weight to each state's CON programs represents a way to reflect the restrictiveness of the program. These weights are then multiplied by the number of services, which captures the scope of the program, to obtain the intensity index. States with a higher index have more restrictive CON control, while states without CON programs are assigned a score of zero. Although this index has been adopted by many earlier studies, it has some limitations. This index does not reflect the duration of the program, which is argued to affect the intensity of the programs. However, this will not affect our estimates because all the study states adopted their CON regulation in the late 1960s or early 1970s. Another problem with this index, as is true with all indices, is the assumption that each unit on the intensity scale exerts the same impact on the dependent variable, which tends to limit our interpretation of marginal effects. However, our ability to determine the direction of the impacts is not compromised by this problem.

POOL is an interval level variable measuring variations of the restrictiveness of state uncompensated care pool regulations. States without a pool regulation are assigned a value of zero, states with a voluntary pool regulation, such as West Virginia and Nevada, are accorded a value of one, and states with mandatory pools are assigned a value of two.

**** Review threshold refers to the threshold for expenditure of the new service/capital/equipment that exceeds certain dollar amount. Hospital expenditures have to be reviewed if they exceed a certain threshold.

REQUIREMENT represents an index that takes values of zero, one, two and three. It captures the duration, restrictiveness and scope of community benefit requirement laws. Duration is measured by the length of time community benefit requirement laws have been in effect. Consistent with Ginn and Moseley (2006) and given our study period, we argue that laws that are proposed and implemented before year 2000 are more mature, have a longer duration and stronger impact than laws that were instituted after year 2000. We measure restrictiveness by whether community benefit requirement laws are mandatory or voluntary. Some states such as Massachusetts have laws that are largely voluntary, making them less restrictive than those that are mandatory. Lastly, we posit that laws that are broader in scope, such as those mandating both public reporting of community benefits and a specific percentage of hospital net patient revenues be devoted to charity care, are more intense than laws that require either public reporting or a proportionate amount of contribution. The index is developed by summing the numbers across three dimensions (see Table 4). States without community benefit requirement laws are assigned a value of zero. By construction, a state with a voluntary community benefit requirement law implemented prior to 2000 and with either public reporting or a percent requirement would also assume a value of zero, which makes it indistinguishable from states without such a regulation. This, however, is not a concern for the current study because none of our study states fits the above profile.

Table 4: Intensity Index: Dimensions for Community Benefit Requirement Laws

Dimensions	*Duration*	*Restrictiveness*	*Scope*
Before 2000	0		
After 2000	1		
Voluntary		0	
Mandatory		1	
Public Reporting OR Percentage Requirement			0
Public Reporting AND Percentage Requirement			1

We also create interactions of regulatory variables to test if there are any interaction effects among different regulatory programs. We test nonprofit and for-profit hospitals in separate models, as suggested by previous literatures as well as the theoretical framework. We exclude AWP/FOC and state conversion laws from our final analysis due to a lack of variation on both regulations. Only two states (KY and WI) have AWP/FOC laws. Although six states have conversion regulations, limited information on regulatory intensity prohibits us from separating the effects of locating in a given state (or states effects) from the effects of state conversion regulations.

Control Variables

We control for a series of hospital characteristics that could affect its capacity to provide uncompensated care. To be consistent with other studies of hospital uncompensated care provision, we controlled for teaching status, the number of high-technology services offered by the hospital, hospital size, public hospital, whether a hospital has an emergency department, and hospital system/network membership. These variables are all extracted from the AHA (2002, 2003, and 2004) data.

We include hospital teaching status coded one as teaching and zero otherwise to capture uncompensated care provision by teaching hospitals. We define a teaching hospital as one approved to participate in residency training by the Accreditation Council for Graduate Medical Education, affiliated with a medical school, or a member of the Council of Teaching Hospitals (COTH). Studies have shown that teaching hospitals bear a disproportionate share of the uncompensated care burden. In their five-state analysis of uncompensated care distribution among U.S. hospitals, the General Accounting Office (GAO) found that major teaching hospitals accounted for a large percentage of the total uncompensated care cost compared with other nonprofit or for-profit hospitals (GAO 2006). We hence expect that hospital teaching status is positively associated with uncompensated care provision.

Following previous studies, we also control for hospital characteristics that would affect the shape of the cost curve. Such measures include technology intensity, hospital size, and whether the hospital has an emergency department. Since larger and more technology-intense hospitals have more capacity to provide uncompensated care, we expect that hospital size (as measured by number of beds), technology intensity (as measured by the number of high-technology services offered by the hospital in the following areas: neonatal intensive care, open heart surgery, cardiac catheterization, CT and Positron Emission Tomography or PET[††††]), are positively related to uncompensated

---

[††††] As suggested by previous studies, Dranove, D. and M. Shanley (1995). "Cost Reductions or Reputation Enhancement as Motives for Mergers: the Logic of Multihospital Systems." Strategic Management Journal **16**(1): 55-74, Davidoff, A. J., A. T. LoSasso, et al. (2000). "The effect of changing state health policy on hospital uncompensated care." Inquiry **37**(3): 253-67, Bazzoli, G. J., R. C. Lindrooth, et al. (2006). "The influence of health policy and market factors on the hospital safety net." Health Serv Res **41**(4 Pt 1): 1159-

care provision. Whether a hospital has an emergency department is a dummy variable measure indicating the presence of an ER. Since hospitals with an ER are more likely to encounter uninsured patients (given that the uninsured often wait to seek care until symptoms worsen), we expect that having an emergency department is also positively associated with uncompensated care provision.

Research suggests that multiunit system affiliations promote hospital provision of community benefits including uncompensated care (Proenca, Rosko et al. 2000; Lee, Alexander et al. 2003). This is because, on the one hand, hospitals belonging to a system/network have more resources or excess capacity to deal with exogenous pressures, such as financial stress from various cost containment efforts, without compromising their community orientation (Cook, Shortell et al. 1983). On the other hand, institutional theory indicates that larger organizations attract more attention and therefore may be under more pressure to conform to community expectations (Rosko 2004). We therefore expect that the network/system affiliation be positively related to hospital uncompensated care provision. Because we have missing values for 51 percent of the hospital-years, we replace the network dummy variable with the prevalence of a network/system (measured as percent of hospitals that belong to a network/system in the market). We hypothesize that this variable will be positively associated with uncompensated care provision, given that network/system hospitals tend to provide more uncompensated care than non-network/system hospitals.

80.), these services tend to require higher technological investment and hence represent a good measure of technological sophistication.

We also control for major market area characteristics that affect hospital provision of uncompensated care. A growing body of literature suggests that the level of hospital competition and health maintenance organization (HMO) penetration greatly influence hospitals' ability to provide uncompensated care (Gruber 1994; Bazzoli, Lindrooth et al. 2006). Price shopping and cost control strategies adopted by managed care organizations have increased price competition among hospitals. As market competition intensifies, nonprofit hospitals' ability to cross-subsidize uncompensated care decreases. However, such care becomes more attractive for for-profit hospitals because the opportunity cost of providing uncompensated care decreases. We therefore expect to see different behavioral responses from hospitals of different ownerships in markets with various levels of HMO penetration and market competition. We also include an interaction term between HMO penetration and market competition to test if there are any interaction effects. As suggested by previous studies, in markets where competition is already intense, HMO penetration could reduce nonprofit hospitals' capacity to provide uncompensated care even further by shrinking their paying patient base (Mann, Melnick et al. 1997; Davidoff, LoSasso et al. 2000). In addition, Davidoff et al. (2000) found that although market competition has no effect on nonprofit hospitals at any level of HMO penetration, for-profit hospitals show a negative effect of competition on uncompensated care at all but the highest level of penetration.

The key issue in measuring market competition and HMO penetration is defining the appropriate hospital market area. Prior research suggests a number of ways to define relevant hospital markets. Some studies choose geographic measures such as counties, Metropolitan Statistical Areas (MSAs), or Health Service Areas (HSAs) (Dranove, Shanley et al. 1992; Gaynor and Vogt 2000). Other studies define a fixed or variable radius from each hospital as the relevant market area (Luft, Robinson et al. 1986; Gresenz, Rogowski et al. 2004). Although these measures have the advantage of computational ease, they are often considered to be arbitrary and sometimes underestimate the amount of competition facing a hospital (Wong, Zhan et al. 2005). Another commonly used method is to examine patient flows and define markets as consisting of geographic areas (typically zip codes) that send a nontrivial number of patients to a given hospital. This approach overcomes the disadvantages inherited in previous measures. However, using patient flows has the potential for endogeneity bias when used to investigate the effects of competition on hospital cost and quality (Wong, Zhan et al. 2005). Given the relative merits and drawbacks of each approach, the current study defines hospital markets using an exogenous measure - counties and a potential endogenous measure - patient flows (please see Appendix B for a detailed account of this construction). We performed a sensitivity analysis to select a superior measure between markets defined by counties and markets defined by patient flows. The test did not, however, reveal significant differences between these two measures (see Appendix C for detailed results from the sensitivity analysis). We therefore use the market measure defined by patient flows in our final analysis to avoid the arbitrariness of the county measure.

Once the relevant geographic market is defined, we are able to control for the market competition by computing a Hirschman-Herfindahl Index (HHI) using hospital market shares. HHI is a commonly used index to measure the degree of competition in a given market area. It is derived by summing the squared market shares of each hospital in the relevant market area:

$$HHI = \sum_{i=1}^{N} S_i^2$$

where S_i is the percentage of hospital beds the i^{th} hospital has. HHI ranges from 0 to 10,000 with 10,000 representing a monopoly and 0 being a hospital in a near perfectly competitive market. As HHI increases, the competitiveness in the market decreases. The U.S. Department of Justice (1992) considers a market with a HHI of less than 1,000 to be a competitive marketplace. This index is calculated for each year, using the full sample of hospitals. It is then rescaled to a range of 0 to 1.

HMO penetration is measured by the percentage of county population enrolled in HMOs in 1998. This measure was extracted from the 2005 ARF data. Unfortunately, this dataset does not give us access to the updated numbers for our study period. Since studies have suggested an increasing trend for managed care enrollment (Bian and Morrisey 2006), we expect that our measure will likely underestimate the effect of managed care organizations on the level of uncompensated care provision.

Socioeconomic characteristics of the surrounding community also affect hospital provision of uncompensated care. The demand for uncompensated care is much greater in communities with a large number of uninsured, lower income individuals and lower percentage of elderly population. We therefore control for insurance coverage, per capita income and percentage of population aged 65 or above. We obtain insurance coverage information from the 2000 Census Small Area Health Insurance Estimates for Counties and States (SAHIE). This measure is calculated as the percentage of county population without health insurance. We generate comparable numbers for markets defined by patient flows. However, with the steadily growing number of uninsured over the years, our year 2000 data will likely understate the demand for uncompensated care due to lack of insurance. Per capita income for county markets is calculated by dividing the total income by county population for each year. The same measure for markets based on patient flows is calculated by adding all the income by market groups and total population by market groups respectively, and then dividing total income by market groups by total population by market groups. We use 2003 per capita income to replace the 2004 numbers as the 2004 data are not available from the 2005 ARF. Percent of population over age 65 is calculated using similar method for both county markets and markets based on patient flows. As we only have the 2002 data on this variable, we use the 2002 numbers for 2003 and 2004. We do expect that percentage of population over 65 is relatively stable over these three years.

We also control for whether a hospital is located in rural or urban areas. We define rural/urban status using the Department of Agriculture's rural-urban continuum codes for metro and non-metro counties provided by the ARF data. These codes range from one to nine, with one representing metro areas with a million population or more and nine being completely rural with less than 2,500 urban population, and not adjacent to a metro area. Appendix D provides a complete list of rural-urban continuum codes.

Tables 5 presents the independent variables and the expected sign of their effects on uncompensated care based on the above discussion.

Table 5: Predicted Effects on Uncompensated Care Provision

	Uncompensated Care	
Variables	**Nonprofit**	**For-profit**
Regulatory Measures		
CON	+	+/-
POOL	+	+
REQUIREMENT	+	+/-
CON*POOL	+	+/-
CON* REQUIREMENT	+/-	+/-
POOL*REQUIREMENT	+/-	+/-
CON*POOL* REQUIREMENT	+/-	+/-
Hospital Characteristics		
Teaching hospital status	+	+
Proportion public hospital	-	-
Technology intensity	+	+
Hospital size	+	+
ER	+	+
Proportion network/system	-	-
Market Characteristics		
HHI	+	-
HMO penetration	-	+
Percentage of population aged 65 or above	-	-
Per capita income	-	-
Percentage of population that are uninsured	+	+
Rural	-	-

Descriptive Statistics

Table 6 defines each variable and Table 7 presents the descriptive statistics for our full sample. These data represent means across three years, treating each hospital-year combination as a separate observation.

Over the three year period, our full sample has 4,324 hospital-year observations, which includes 1,552 hospitals in 2002, 1,508 hospitals in 2003, as well as 1,264 hospitals in 2004. The figures show that, for example, in 2003, there are about 69% nonprofit hospitals in our sample, as compared to 62 percent nationally; 19% public hospitals, as compared to 20% nationally; and 12 percent for-profit hospitals, as compared to 18 percent nationally. We slightly over-sampled nonprofit hospitals and under-sampled for-profit hospitals. For all hospital-year observations, we have about 19 percent public hospitals, 70 percent nonprofits and 11 percent for-profit hospitals, with nonprofit hospitals slightly over-represented. Also note that public hospitals are included in the full sample for the purpose of comparison among different types of hospitals. They are however excluded from the analytical sample because we use percent of public hospitals in the market as a control variable.

Table 6: Variables and Their Definitions

Variables	*Definition*
Dependent Variables	
Selfpay/Charity	Number of admissions that are for self-pay/charity care patients
Percent Selfpay/Charity	Percentage of admissions that are for self-pay/charity care patients
Regulatory Measures	
CON	Certificate of Need
REQUIREMENT	Community benefit requirement
POOL	Uncompensated care pool
Hospital Characteristics	
Teaching hospital status	Dummy variable representing teaching hospital status
Public Hospital_county	Proportion of public hospitals in the market (by counties)
Public Hospital_market	Proportion of public hospitals in the market (by patient flows)
Technology intensity	Number of hi-tech services offered
Hospital size	Hospital bed size
ER	Dummy variable indicating whether a hospital has an Emergency Department
Network/system_county	Proportion of system/network members in markets defined by counties
Network/system_market	Proportion of system/network members in markets defined by patient flows
Market Characteristics	
HHI_county	Herfindahl-Hirschman Index (based on county)
HHI_market	Herfindahl-Hirschman Index (based on patient flows)
HMO penetration_county	Proportion of population in the market (based on county) enrolled in HMO
HMO penetration_market	Proportion of population in the market (based on patient flows)enrolled in HMO
Percentage of population 65+_county	Percentage of population aged 65 or above
Percentage of population 65+_market	Percentage of population aged 65 or above
Per capita income_county	Per capita income (1,000)
Per capita income_market	Per capita income (1,000)
Percent uninsured_county	Percentage of population that are uninsured
Percent uninsured_market	Percentage of population that are uninsured
Rural	Rural/Urban continuum

Table 7: Descriptive Statistics for the Full Sample

Variables	*Obs*	*Mean*	*Std. Dev.*	*Min*	*Max*
Dependent Variables					
Selfpay/Charity	4324	443.37	805.14	0	14215
Percent Selfpay/Charity	4324	5	6	0	100[‡‡‡‡]
Regulatory Measures					
CON	4324	9.31	6.64	0	21.60
REQUIREMENT	4324	0.35	0.75	0	3
POOL	4324	0.70	0.93	0	2
Hospital Characteristics					
Teaching hospital status	4324	0.26	0.44	0	1
Public Hospital_county	4324	3	8	0	29
Public Hospital_market	4324	3	6	0	76
Technology intensity	2385	2.10	1.41	0	5
Hospital size	4324	220.99	265.32	0[§§§§]	2163
ER	3706	0.98	0.13	0	1
Network/system_county	4324	10	39	0	87
Network/system_market	4324	10	30	0	41
Market Characteristics					
HHI_county	4324	0.50	0.35	0	1
HHI_market	4324	0.31	0.29	0.05	1
HMO penetration_county	4324	0.25	0.18	3.8	0.96
HMO penetration_market	4324	0.28	0.17	0	0.96
Percentage of population 65+_county	4324	14	4	6.54	34
Percentage of population 65+_market	4324	13.97	3.94	6.53	34.24
Per capita income_county	4324	29.64	9.51	14.80	84.59
Per capita income_market	4324	30.63	9.03	14.80	84.59
Percent uninsured_county	4324	13.65	4.12	5.4	29.50
Percent uninsured_market	4324	13.44	3.77	13.52	25.70
Rural	4324	3.24	2.41	1	9

[‡‡‡‡] A nonprofit hospital that is excluded later in the analysis because of possible reporting error from the hospital.
[§§§§] A public hospital that reported zero beds. Public hospitals are excluded in the analysis.

The next set of tables (Tables 8.1 – 8.3) report full sample summary statistics by hospital status: public, nonprofit, and for-profit. It shows that on average, a slightly higher percentage (6%) of admissions in public and for-profit hospitals are for the uninsured patients than those in nonprofit hospitals (5%). Figure 2 and 3 further illustrate the distribution of total number of admissions for the uninsured by ownership types in 2002. This pattern remains largely unchanged for 2003 and 2004 (Appendix E). In the aggregate, nonprofit hospitals consistently have the most uninsured admissions (68-70 percent) compared with public (11-14 percent) and for-profit hospitals (16-21 percent). This is partly because the majority of U.S. hospitals are nonprofits.

The summary tables also show that on average, nonprofit hospitals tend to be larger (as measured in number of beds) and are more technologically sophisticated than public or for-profit hospitals.

Table 8.1: Descriptive Statistics for the Full Sample by Hospital Ownership Status (Public)

Variables	*Obs*	*Mean*	*Std. Dev.*	*Min*	*Max*
Number of Self-pay/Charity	826	495.77	1350.11	0	14215
Percent of Self-pay/Charity	826	6	7	0	71
CON	826	9.92	6.21	0	21.6
REQUIREMENT	826	0.16	0.57	0	3
POOL	826	0.42	0.77	0	2
Teaching hospital status	826	0.16	0.37	0	1
Technology intensity	461	1.58	1.27	0	5
Hospital size	826	143.69	224.77	0	1839
ER	715	0.98	0.13	0	1
Network/system_county	826	5	15	0	36
Network/system_market	826	6	21	0	41
HHI_county	826	0.64	0.36	0.05	1
HHI_market	826	0.36	0.33	0.03	1
HMO penetration_county	826	0.13	0.13	0	0.66
HMO penetration_market	826	0.21	0.15	0	0.66
Percentage of population 65+_county	826	15	4	7	30
Percentage of population 65+_market	826	13.92	3.58	6.54	31.58
Per capita income_county	826	26.52	7.71	14.30	84.59
Per capita income_market	826	28.90	8.04	16.05	84.59
Percent uninsured_county	826	14.80	4.54	4.4	26.9
Percent uninsured_market	826	14.11	4.21	5.5	24.76
Rural	826	4.85	2.57	1	9
2002	826	0.35	0.48	0	1
2003	826	0.34	0.47	0	1
2004	826	0.31	0.46	0	1

Table 8.2: Descriptive Statistics for the Full Sample by Hospital Ownership Status (Nonprofit)

Variables	*Obs*	*Mean*	*Std. Dev.*	*Min*	*Max*
Number of Self-pay/Charity	2962	434.68	636.01	0	5844
Percent of Self-pay/Charity	2962	5	5	0	100
CON	2962	9.50	6.81	0	21.6
REQUIREMENT	2962	0.44	0.78	0	3
POOL	2962	0.83	0.97	0	2
Teaching hospital status	2962	0.31	0.46	0	1
Public Hospital_county	2962	1	7	0	29.4
Public Hospital_market	2962	2	6	0	76
Technology intensity	1674	2.26	1.44	0	5
Hospital size	2962	251.38	288.31	6	2163
ER	2634	0.99	0.12	0	1
Network/system_county	2962	13	46	0	87
Network/system_market	2962	12	34	0	41
HHI_county	2962	0.48	0.34	0.05	1
HHI_market	2962	0.30	0.28	0.03	1
HMO penetration_county	2962	0.27	0.18	0	0.96
HMO penetration_market	2962	0.30	0.17	0	0.96
Percentage of population 65+_county	2962	14	4	0.03	0.34
Percentage of population 65+_market	2962	13.69	3.48	7.15	34.24
Per capita income_county	2962	30.64	10.12	14.80	84.59
Per capita income_market	2962	31.35	9.62	14.80	84.59
Percent uninsured_county	2962	13.01	3.97	3.8	29.5
Percent uninsured_market	2962	12.89	3.59	5.4	25.7
Rural	2962	2.94	2.25	1	9
2002	2962	0.37	0.48	0	1
2003	2962	0.35	0.48	0	1
2004	2962	0.28	0.45	0	1

Table 8.3: Descriptive Statistics for the Full Sample by Hospital Ownership Status (For-profit)

Variables	*Obs*	*Mean*	*Std. Dev.*	*Min*	*Max*
Number of Self-pay/Charity	536	410.70	427.47	0	4070
Percent of Self-pay/Charity	536	6	6	0	55
CON	536	7.35	5.95	0	20.7
REQUIREMENT	536	0.19	0.68	0	3
POOL	536	0.44	0.76	0	2
Teaching hospital status	536	0.11	0.32	0	1
Public Hospital_county	536	1	0.02	0	12
Public Hospital_market	536	1	0.02	0	9
Technology intensity	250	2.02	1.19	0	5
Hospital size	536	172.18	118.89	6	655
ER	357	0.96	0.20	0	1
Network/system_county	536	4	0.10	0	84
Network/system_market	536	4	0.07	0	49
HHI_county	536	0.40	0.33	0.05	1
HHI_market	536	0.24	0.24	0.03	1
HMO penetration_county	536	0.29	0.19	0	0.64
HMO penetration_market	536	0.30	0.18	0.01	0.61
Percentage of population 65+_county	536	15	6	4	34
Percentage of population 65+_market	536	15.55	5.97	8.15	34.24
Per capita income_county	536	28.93	7.14	13.52	49.54
Per capita income_market	536	29.28	6.12	17.56	49.54
Percent uninsured_county	536	15.39	3.33	6.5	25.3
Percent uninsured_market	536	15.44	3.16	8.27	24.76
Rural	536	2.43	1.88	1	9
2002	536	0.33	0.47	0	1
2003	536	0.34	0.47	0	1
2004	536	0.34	0.47	0	1

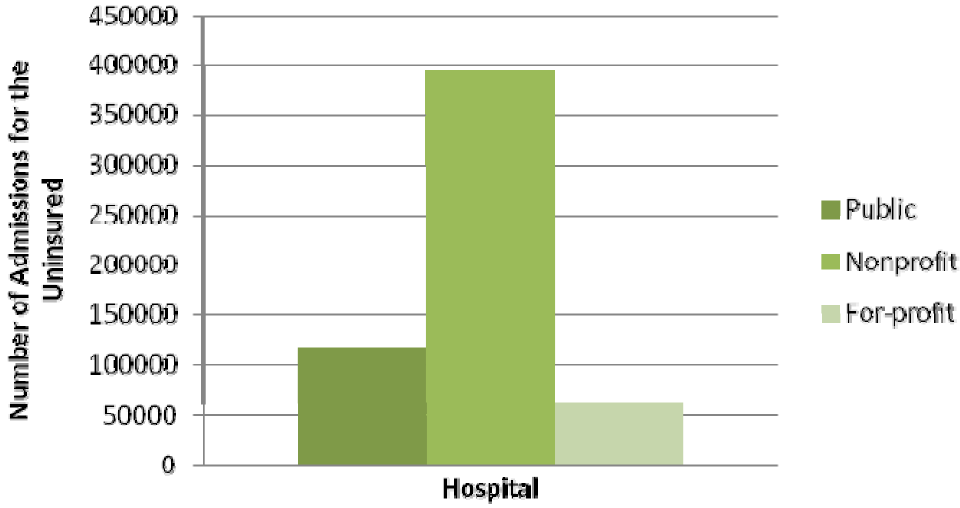


Figure 2: Hospital Provision of Uncompensated Care 2002

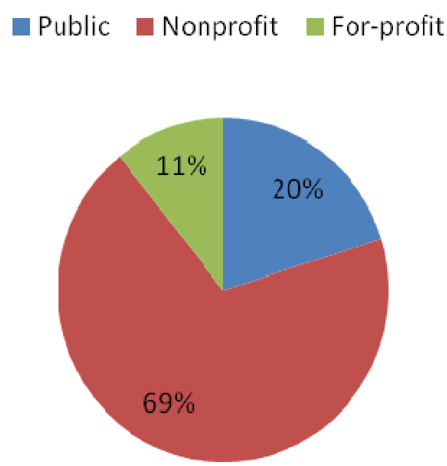


Figure 3: Percent of Uncompensated Care Admissions by Ownership Types 2002

Table 9 presents summary statistics for the final study sample by nonprofit/for-profit status, after all the missing values for technology intensity variable and ER variable are excluded. This sample has 2,235 nonprofit observations and 295 for-profit observations that are representative of nonprofit and for-profit hospitals of all sizes in the U.S. Table 10 compares hospitals in our study sample in 2003 with those nationally with regard to size (as measured in number of beds) and location (as indicated by rural/urban). Our two-sample paired *t* test fails to find any significant differences between the study sample and national statistics, indicating that our nonprofit and for-profit samples mirror the U.S. hospitals of all sizes and in rural/urban areas (test results are reported in Appendix F). Additionally, the summary statistics are not significantly different from the full sample statistics. Nonprofit hospitals are still found to provide, on average, a higher volume of admissions for the uninsured but a slightly lower percentage than their for-profit counterparts. They tend to be larger, more technologically sophisticated and more likely to have an Emergency Department.

We further examined the regulatory variations by ownership status. Tables 11.1 – 11.3 and 12.1 – 12.3 represent intensity variations of each regulation across all hospitals by ownership types. In the nonprofit sample, 28.9 percent of the hospitals are located in non-CON states and the remaining 71.1 percent in states with CON of varying intensities. 74.5 percent of the nonprofit hospitals are in states without a community benefit requirement regulation. More than half of the nonprofit hospitals are found in states that do not have an uncompensated care pool. In the for-profit sample, 20.7 percent of the hospitals are located in non-CON states. 88.1 percent of the for-profit hospitals are in states without a community benefit requirement regulation. 71 percent of the for-profit hospitals are found in states without an uncompensated care pool.

Table 9: Descriptive Statistics for the Final Study Sample by Nonprofit/For-profit Status

	Nonprofit				*For-profit*			
Variables	Mean	Std. Dev.	Min	Max	Mean	Std. Dev.	Min	Max
Number of Self-pay/Charity	476.98	705.25	0	9370	395.11	346.24	0	1613
Percent of Self-pay/Charity	4.62	4.90	0	100	5.19	3.94	0	25.66
CON	8.91	7.01	0	20.7	7.90	6.53	0	20.7
REQUIREMENT	0.39	0.74	0	3	0.26	0.78	0	3
POOL	0.80	0.95	0	2	0.45	0.75	0	2
Teaching hospital status	0.30	0.46	0	1	0.09	0.29	0	1
Public Hospital_county	0.90	2.78	0	19.63	0.75	2.10	0	12.22
Public Hospital_market	1.51	2.61	0	19.63	1.34	2.05	0	8.83
Technology intensity	2.15	1.37	0	5.00	2.11	1.18	0	5.00
Hospital size	216.86	215.09	6	2163	159.02	104.71	6	655
ER	0.99	0.12	0	1	0.97	0.18	0	1
Network/system_county	9.50	15.80	0	109.90	5.21	11.23	0	84.39
Network/system_market	9.36	12.78	0	90.91	4.70	8.12	0	49.07
HHI_county	0.52	0.34	0.05	1	0.44	0.32	0.05	1
HHI_market	0.32	0.30	0.03	1	0.26	0.24	0.03	1
HMO penetration_county	0.26	0.18	0	0.8	0.27	0.19	0.01	0.64
HMO penetration_market	0.29	0.18	0	0.8	0.29	0.18	0.01	0.61
Percentage of population 65+_county	13.84	3.62	3.00	32.02	15.50	6.00	6.40	33.77
Percentage of population 65+_market	13.70	3.34	7.15	34.24	15.94	6.28	8.15	34.24
Per capita income_county	30.26	9.22	14.80	84.59	28.45	6.91	17.56	47.45
Per capita income_market	30.98	8.66	14.80	84.59	28.83	6.05	17.56	44.12
Percent uninsured_county	12.70	3.93	3.8	29.5	14.85	3.11	7.8	23.5
Percent uninsured_market	12.60	3.48	5.4	25.3	14.97	2.98	8.90	23.32
Rural	3.09	2.29	1	9	2.56	1.87	1	9
2002	0.35	0.48	0	1	0.31	0.46	0	1
2003	0.36	0.48	0	1	0.40	0.49	0	1
2004	0.29	0.45	0	1	0.29	0.46	0	1
		2235				295		

Table 10: Comparing Hospitals in Final Study Sample and in U.S. in 2003

			Sample	*U.S.*
Nonprofit	Percent of beds	0-49	17%	23%
		50-99	16%	19%
		100-199	25%	24%
		200-399	27%	25%
		>=400	15%	9%
	Percent of urban		67%	62%
	N		807	2,794
For-profit	Percent of beds	0-49	13%	22%
		50-99	19%	20%
		100-199	36%	34%
		200-399	31%	20%
		>=400	2%	4%
	Percent of urban		74%	73%
	N		118	667

Table 11.1: Nonprofit Hospital Distribution by Regulatory Intensity

Certificate-of-Need (CON)

CON Intensity Index	*Freq.*	*Percent*
0	646	28.9
3.5	21	0.94
4.8	171	7.65
6.3	151	6.76
8.1	170	7.61
12.1	167	7.47
12.8	91	4.07
14.4	128	5.73
15	212	9.49
15.2	23	1.03
16	185	8.28
18.4	177	7.92
20.7	93	4.16
Total	2,235	100

Table 11.2: Community Benefit Requirement

Community Benefit Requirement Intensity Index	*Freq.*	*Percent*
0	1,665	74.5
1	299	13.38
2	235	10.51
3	36	1.61
Total	2,235	100

Table 11.3: Uncompensated Care Pool

Uncompensated Care Pool Intensity Index	*Freq.*	*Percent*
0	1,280	57.27
1	114	5.1
2	841	37.63
Total	2,235	100

Table 12.1: For-profit Hospital Distribution by Regulatory Intensity

Certificate-of-Need (CON)

CON Intensity Index	*Freq.*	*Percent*
0	61	20.68
3.5	9	3.05
4.8	10	3.39
6.3	136	46.1
12.1	3	1.02
12.8	7	2.37
14.4	3	1.02
15	2	0.68
16	21	7.12
18.4	14	4.75
20.7	29	9.83
Total	295	100

Table 12.2: Community Benefit Requirement

Community Benefit Requirement Intensity Index	*Freq.*	*Percent*
0	260	88.14
1	13	4.41
2	2	0.68
3	20	6.78
Total	295	100

Table 12.3: Uncompensated Care Pool

Uncompensated Care Pool Intensity Index	*Freq.*	*Percent*
0	210	71.19
1	38	12.88
2	47	15.93
Total	295	100

CHAPTER FIVE

ESTIMATION AND RESULTS

Estimation

We use panel data for our analysis because they present several advantages over cross section or time series data. Cross section data measure an observation at a point in time and time series data follows an observation across time, while panel data combine cross section and time series data. As a result, our sample size increases because an observation was repeatedly measured at different points in time. Additionally, since we follow the same cross section unit over time, we are able to obtain consistent estimators in the presence of omitted variables using proper panel data techniques.

There is some concern that omitted variables might be a problem because some hospital characteristics might not be observable or measurable. In other words, there is a hospital specific latent variable α_i as defined in the component error term ε_{it} :

$$UC_{it} = \beta_0 + \beta_1 Hospital_{it} + \beta_2 Market_{it} + \beta_3 Regulation_{it} + \beta_4 Year + \beta_5 State + \varepsilon_{it}$$

where $\varepsilon_{it} = \alpha_i + \eta_{it}$. This latent variable can be, for example, the preferences of hospital administrators/boards of trustees towards uncompensated care provision, or hospital managerial quality or structure that tend to be constant over time. Depending on whether this unobserved α_i is correlated with some right-hand side hospital specific explanatory variables such as size, structure (i.e., whether the hospital maintains an emergency department) or technological sophistication, we test different estimation methods: pooled

Ordinary Least Squares or pooled OLS, random effects Generalized Least Squares (GLS), and a Hausman Taylor instrumental variable (HTIV) approach.

Three Estimation Approaches: Pooled OLS, GLS and HTIV

The general form of our empirical model can be expressed as

$$Y_{it} = X_{it}\beta + \varepsilon_{it} \qquad t\text{=1, 2, 3} \qquad (1)$$

$$\varepsilon_{it} = \alpha_i + \eta_{it}$$

ε_{it} is a composite error term which represents the sum of the unobserved effect and an idiosyncratic error. We first estimate our empirical model using a pooled OLS. The pooled OLS estimator requires no correlation between X_{it} and ε_{it} (i.e., $E(X_{it}'\ \varepsilon_{it})$=0 and $E(X_{it}'\alpha_i)$=0) to obtain a consistent estimator of β in model (1). This estimator, however, ignores hospital specific unobserved effects.

We then re-estimate the model using an improved estimation --- random effect GLS that controls for random hospital specific effects using variation over both time and cross sectional units to estimate the parameter β vector. In addition, it exploits the serial correlation in the composite error $\varepsilon_{it} = \alpha_i + \eta_{it}$ to produce more efficient estimators than pooled OLS or fixed effects. Similar to pooled OLS, it also requires orthogonality between α_i and X_{it}. In other words, both pooled OLS and random effects GLS rely on the assumption that unobservable hospital characteristics are not correlated with our right-hand side variables.

However, there is concern that such a correlation might exist. Some evidence suggests that the hospital industry, acting as a powerful interest group, is able to influence state policy making such as the adoption of CON regulations so that the hospitals can preserve a profitable patient mix or volume (Wendling and Werner 1980; Lanning, Morrisey et al. 1991). Although such a concern might be legitimate, there is also evidence suggesting that a state's adoption of such regulations is motivated by its concern over inefficiency or market failure in the system rather than pure interest group transfers (Cone and Dranove, 1986; Morrisey and Ohsfeldt, 1991). As previously discussed in the theory of regulation and hospital regulation in particular (Chapter 2), a state's decision to adopt certain policies can be viewed as in the public interest. For example, CON approval by regulators is made contingent, through formal conditions or informal negotiation, upon the willingness of the hospital to provide services (e.g., uncompensated care) that are perceived by the regulators as in the public interest (Salkever, 2000). Therefore, industry capture might not be a concern if adoption of these policies is intended to amend market failure and is meant to protect the public interest. However, if we allow for the possibility of interest group influence and relax the assumption of strict exogeneity, our regulations will be endogenous as they are correlated with the latent hospital characteristics α_i . In other words, if the industry capture theory holds true, unobserved hospital motivations to lobby for regulations might influence the level of uncompensated care they ultimately provide (by the patient mix/volume they choose).

To allow such a correlation, we re-estimate the empirical model with a Hausman-Taylor instrumental variables procedure (HTIV) that relaxes the independence assumption by allowing unobservable hospital characteristics to be correlated with our right-hand side variables. Some previous studies have used fixed effects to eliminate potential endogeneity resulting from this omitted latent variable problem. However, fixed effects estimation removes time constant variables, such as the regulatory variables in our model. As we only have recent years of hospital discharge data, the lack of variation in the regulatory variables over time will prohibit us from estimating their impact on hospital behaviors with fixed effects estimation. Fortunately, Hausman and Taylor (1981) proposed a model that conveniently solves the potential correlation between omitted variables and the explanatory variables but still allows us to estimate the effects of time constant variables of interest.

In a Hausman-Taylor procedure, the general form of our empirical model can be expressed as:

$$Y_{it} = X_{it}\beta + Z_i\gamma + \varepsilon_{it}, \qquad (1)$$

$$\varepsilon_{it} = \alpha_i + \eta_{it}$$

where i = 1 to N and, t = 1 to T; β and γ are k and g vectors of coefficients associated with time varying (X_{it}) and time-invariant (Z_i) observable variables respectively. In our case, X_{it} will contain variables such as percentage of network/system in the market, percentage of public hospitals in the market, HHI, per capita income, uninsurance rate, teaching status, technology intensity, bed size, ER, HMO penetration, and percentage of population over 65, while matrix Z_i will include regulatory measures and state dummies.

Intuitively the Hausman-Taylor procedure follows an instrumental variable approach. It uses variables in the model as instruments for the endogenous time-invariant variables. This has the advantage over traditional instrumental variables methods in that it does not rely on excluded exogenous instruments which are usually difficult to obtain. However, the Hausman-Taylor procedure does require *a priori* information: the ability to distinguish columns of X and Z which are asymptotically correlated with α_i from those which are not. In our application, we have reason to believe that hospital characteristics such as technology intensity, size, and whether a hospital has an Emergency Department are influenced by the latent individual hospital effect. CON laws may also be correlated if we further assume that unobserved hospital motivation to lobby for CON also influences the level of uncompensated care they ultimately provide (by the patient mix/volume they choose). However, percent of network/system in the market, percent of public hospitals in the market, HHI, percentage of population that are uninsured, other regulations, state dummies, HMO and percent of population over 65 are not correlated.

Once we distinguish the time-varying/time invariant, exogenous/endogenous variables, X_{it} and Z_i can be further partitioned as $X_{it} = (x_{it1}, x_{it2})$ and $Z_i = (z_{i1}, z_{i2})$, where x_{it1} is a $1 \times k_1$ time-varying exogenous vector, x_{it2} a $1 \times k_2$ time-varying endogenous vector, z_{i1} a $1 \times g_1$ time-invariant exogenous vector, and z_{i2} a $1 \times g_2$ time-invariant endogenous vector. A vector of deviations from means averaged over time Q_v was used as part of the instruments to transform equation (1). Thus by construction, Q_v is orthogonal to any time-invariant vector of observations (i.e., $Q_v Z_i = 0$ and $Q_v \alpha_i = 0$). Unfortunately, since Q_v is also orthogonal to Z_i, which violates the requirement that instruments be correlated with all the endogenous variables, Hausman and Taylor (1981) added the columns of x_{it1} and z_{i1} so that we now have the matrix $\left[Q_v \vdots X_{it1} \vdots Z_{i1}\right]$ as instruments. However, one necessary condition for all the parameters in equation (1) to be identified is $k_1 \geq g_2$, Recall that the vector with $1 \times k_1$ time-varying exogenous variables is x_{it1} which includes eight variables (per capita income, percent of network/system in the market, percent of public hospitals in the market, HHI, percentage of population that are uninsured, HMO, teaching, and percent of population over 65). The vector with $1 \times g_2$ time-invariant endogenous variables is z_{i2} that includes seven regulatory variables and their interactions (see Table Z). Thus our model is over-identified ($k_1 > g_2$). However, some of the time varying exogenous variables have low variation across the study period, which prohibits the HTIV model from constructing strong internal instruments. Percent of public hospital and teaching have zero variation for about half of the study sample. In addition, all of the over time variation for variables HMO penetration, percent of population over 65 and percent uninsured comes from population adjustment, which further weakens the identification. Specifically, these variables are constructed in the following ways. For example, for the HMO penetration variable, we take the year when county level data on this variable are available and multiply it by the county population for each year to obtain the number of people enrolled in HMO plans each year. We then sum the total number of enrollees in the market defined by patient flows and divide it by the total population in that market for each study year. As a result, a small amount of within group or over time variation was introduced in the market level HMO penetration variable, which is used in the analysis. Although this is the best we can achieve with the existing county level data to obtain the market level HMO penetration, percent of population over 65, and uninsurance rate, we need to be cautious about the potential problems this manipulation could create. The amount of the variation created by our population adjustment is low and does not represent the true underlying changes in variable trends over time. Even though the real HMO penetration, percent of population over 65, and percent of population uninsured in different years would also reflect population changes, our adjustment yields variations that are not the same as having information on the changes in the real underlying variable. As a result, the Hausman Taylor procedure will still use these variables as instruments despite their low over-time variation, but may not perform well: low variation could result in weak identification, and hence large standard errors. In addition, because not all three variables are affected by population growth trend in the same way, a new bias is introduced and creates a measurement error that may bias the Hausman Taylor estimates.

Table 13: List of Time Varying/Invariant and Endogenous/exogenous Variables

	Endogenous	***Exogenous***
Time Varying Variables (*X*)	Emergency Department	Percent network
	technology intensity	Percent of public hospital
	hospital size	Teaching
		HHI
		HMO penetration*
		Percent over 65*
		Per capita income
		Percent uninsured*
Time Invariant Variables (*Z*)	CON	Rural
	Pool	
	Requirement	
	CON*Pool	
	CON*Requirement	
	Pool*Requirement	
	All three	

*Within group variation represents population weighted averages.

Cluster Correlated Errors

The model is also examined for cluster correlated errors. Clustering can occur when residuals of hospitals within the same state correlate with each other. This intragroup correlation of the errors may create a clustering effect that could produce inconsistent estimates of the covariance matrix. One assumption for the Hausman-Taylor model to produce consistent and efficient parameter estimates is that the idiosyncratic errors are homoskedastic, with zero mean and constant variance across time and individuals (i.e., $\eta_{it} \sim$ iid (0, σ_{η}^{2})). In the presence of clustered errors, the off-diagonal elements of the covariance matrix might not be zero due to potential correlations of the errors among hospitals within the same state. In addition, the diagonal elements might not be identical since the clustering of hospitals by states might lead to different variances along the diagonals of the covariance matrix. As a result, the parameter estimates will be inefficient although they are still consistent.

The Breusch-Pagan (1980) Lagrangian Multiplier (LM) and Cook-Weisberg tests are performed on the pooled cross-sectional final sample to test for state effects in the form of cluster correlated errors. Under the null hypothesis, both tests follow a Chi-square distribution. We should note that the LM test is not designed specifically to test for cluster-correlated errors. It captures other types of heteroskedasticity as well. Table 14 presents the Breusch-Pagan / Cook-Weisberg test statistics. The critical value for the Chi-squared distribution with 30 degrees of freedom is 43.77. The table therefore shows that with a test statistics of 3674.05, there is almost no probability that the distribution is Chi-squared. The null hypothesis of homoskedasticity is rejected, meaning there is some evidence that the errors are correlated or heteroskedastic. A robust cluster estimator of the variance covariance matrix should be used to correct for the estimated residuals.

Table 14: Breusch-Pagan / Cook-Weisberg Test for Heteroskedasticity

	Uncompensated Care
Final Sample	chi2(30) = 3674.05, Prob > chi2 = 0.0000

However, the literature reveals no commonly adopted corrections to obtain robust cluster estimators for the Hausman-Taylor procedure. Thus, the HTIV estimator does not correct for cluster correlated errors. Because such a robust estimator exists in the pooled OLS and the random effects GLS model, we report robust variance matrix estimator for these estimation procedures.

A Test for Endogeneity

The Hausman test is devised for a number of model specifications in econometrics including endogeneity as a result of unobserved individual factors (Hausman 1978). To the extent that unobserved hospital heterogeneity remains an omitted influence on our right hand side variables, we conduct the Hausman test using the property of fixed effects (FE) estimation[*****]. FE will produce consistent parameter estimates in the presence of endogeneity as a result of unobserved hospital effects. However, in the absence of such an endogeneity and/or the presence of cluster correlated

[*****] FE will only be used for the purpose of the specification test and not as part of the estimation procedure because FE does not allow us to estimate the coefficients on the regulatory variables.

errors, such estimates will be asymptotically inefficient. Similar to FE, an HTIV estimator is consistent under both the null and alternative hypothesis. On the other hand, under the hypothesis of no misspecification (i.e., no latent hospital effects), random effect GLS models will yield consistent and asymptotically efficient estimators, where efficiency is defined as attaining the asymptotic Cramer-Rao upper/lower bound. We therefore utilize the properties of these three estimators (FE, HTIV and GLS) to construct several tests of misspecification.

Results

The Hausman test based on the difference between FE and GLS estimates yields χ^2 =45.02 with 12 degrees of freedom which is significant (*p*=0) for the nonprofit hospitals sample (Table 15.1). This rejects the null that there is no correlation between the individual hospital effects and explanatory variables. In other words, there is evidence that latent individual effects exist and GLS will yield inconsistent parameter estimates. The Hausman test based on the difference between FE and HTIV estimator yields χ^2 =1.5 with one degree of freedom which is not significant at the 5% level (*p*=0.22) (Table 15.2). The same tests yield similar results for the for-profit hospital sample. The Hausman test based on the difference between FE and GLS estimates yields χ^2 =35.9 with 11 degrees of freedom which is significant (Table 15.3) and χ^2 =4.26 with two degrees of freedom which is not significant at the 5% level (*p*=0.12) when testing for the difference between FE and HTIV estimators (Table 15.4) Results from the Hausman tests justify the use of the HTIV method.

Table 15.1: Hausman Test for Nonprofit Hospitals: FE vs. GLS

Number of Admissions	*(b)*	*(B)*	*(b-B)*	*sqrt(diag(V_b-V_B))*
	a	b	Difference	S.E.
Technology Intensity	-6.25	18.48	-24.72	13.07
ER	26.53	47.49	-20.95	28.39
Teaching hospital status	-64.72	37.62	-102.34	57.10
Proportion with public owner	-22.53	-38.76	16.23	10.76
Hospital size	0.71	1.68	-0.96	0.25
Proportion network/system member	-1.33	-1.56	0.22	1.23
HHI	191.62	-148.73	340.35	318.43
HMO penetration	-27.63	-3.23	-24.40	43.40
Percentage of population 65+	-0.31	-1.04	0.73	165.34
Per capita income	56.46	-0.63	57.09	12.90
Percent uninsured	-283.09	10.37	-293.46	318.98
Rural	62.61	-21.79	84.41	108.46

b = consistent under Ho and Ha; obtained from xtreg

B = inconsistent under Ha, efficient under Ho; obtained from xtreg

Test: Ho: difference in coefficients not systematic

chi2(12) = (b-B)'[(V_b-V_B)^(-1)](b-B)

= 45.02

Prob>chi2 = 0.0000

Table 15.2: Hausman Test for Nonprofit Hospitals: FE vs. HTIV

Number of Admissions	*(b)*	*(B)*	*(b-B)*	*sqrt(diag(V_b-V_B))*
	a	b	Difference	S.E.
Technology Intensity	-6.25	-2.50	-3.75	4.80
ER	26.53	26.06	0.47	13.92
Teaching hospital status	-64.72	-56.88	-7.84	14.65
Proportion with public owner	-22.53	-19.33	-3.19	3.73
Hospital size	0.71	0.72	-0.01	0.05
Proportion network/system member	-1.33	-1.57	0.23	0.41
HHI	191.62	172.02	19.60	64.69
HMO penetration	-27.63	-18.65	-8.99	31.93
Percentage of population 65+	-0.31	-108.47	108.15	93.76
Per capita income	56.46	54.48	1.98	2.96
Percent uninsured	-283.09	31.11	-314.20	289.77
Rural	62.61	16.60	46.01	48.55

b = consistent under Ho and Ha; obtained from xtreg

B = inconsistent under Ha, efficient under Ho; obtained from xthtaylor

Test: Ho: difference in coefficients not systematic

chi2(1) = (b-B)'[(V_b-V_B)^(-1)](b-B)

= 1.50

Prob>chi2 = 0.2201

Table 15.3: Hausman Test for For-profit Hospitals: FE vs. GLS

Number of Admissions	*(b)*	*(B)*	*(b-B)*	*sqrt(diag(V_b-V_B))*
	a	b	Difference	S.E.
Technology Intensity	-42.28	22.03	-64.31	16.72
ER	-9.16	87.95	-97.11	43.03
Teaching hospital status	-59.30	-64.21	4.91	99.11
Proportion with public owner	-41.11	-14.24	-26.87	38.20
Hospital size	0.04	1.14	-1.10	0.27
Proportion network/system member	-3.09	-1.59	-1.50	5.97
HHI	-131.55	-59.99	-71.56	763.52
HMO penetration	230.54	-0.78	231.32	122.36
Percentage of population 65+	390.48	-1.51	391.99	476.92
Per capita income	25.91	9.88	16.03	22.69
Percent uninsured	91.35	34.12	57.23	416.74

b = consistent under Ho and Ha; obtained from xtreg

B = inconsistent under Ha, efficient under Ho; obtained from xtreg

Test: Ho: difference in coefficients not systematic

chi2(11) = (b-B)'[(V_b-V_B)^(-1)](b-B)

= 35.90

Prob>chi2 = 0.0002

Table 15.4: Hausman Test for For-profit Hospitals: FE vs. HTIV

Number of Admissions	*(b)*	*(B)*	*(b-B)*	*sqrt(diag(V_b-V_B))*
	a	b	Difference	S.E.
Technology Intensity	-42.28	-40.34	-1.94	15.58
ER	-9.16	-10.85	1.69	54.64
Teaching hospital status	-59.30	-53.72	-5.57	74.55
Proportion with public owner	-41.11	-40.04	-1.07	26.43
Hospital size	0.04	0.07	-0.03	0.21
Proportion network/system member	-3.09	-5.17	2.08	4.36
HHI	-131.55	-58.81	-72.74	498.27
HMO penetration	230.54	14.96	215.59	119.85
Percentage of population 65+	390.48	45.95	344.53	471.01
Per capita income	25.91	25.97	-0.06	14.88
Percent uninsured	91.35	98.22	-6.87	393.55

b = consistent under Ho and Ha; obtained from xtreg

B = inconsistent under Ha, efficient under Ho; obtained from xthtaylor

Test: Ho: difference in coefficients not systematic

chi2(2) = (b-B)'[(V_b-V_B)^(-1)](b-B)

= 4.26

Prob>chi2 = 0.1188

However, some important caveats should be noted. First, HTIV estimation has weak identification due to data limitations. Some time-varying exogenous variables which the HTIV procedure uses to construct internal instruments have low variation. In addition, variables such as uninsurance rate, percent of population over 65 and HMO penetration are adjusted by population growth due to lack of data for some study years. Specifically, we computed values for 2003 and 2004 market level variables using the 2002 county level data. As a result, the internal instruments constructed based on these population adjusted variables not reflect the true underlying changes in the HMO penetration, percent over 65, and uninsurance rate. However, these internal instruments are not completely invalid because even real changes in these variables reflect population changes over time to some extent because changes in population could change the percentage of HMO penetration, population that are over 65 or uninsurance rate. However, this manipulation of multiplying all three variables by the same growth trend likely introduces a new measurement bias to the parameter estimates. Second, there may be potential misclassification of endogenous/exogenous variables. Third, comparing FE and HTIV estimators, a few coefficient estimates such as the uninsurance rate in the nonprofit model and the percent of population over 65 in the for-profit model exhibit large differences. However, most of the estimates are similar in both magnitude and sign.

Table 16 and Table 17 present results from the GLS and HTIV estimation respectively. Pooled OLS results are reported in Appendix G. Even though the Hausman specification tests show evidence of inconsistency, the GLS procedure yields meaningful estimates. First, all the significant regulatory variables in the GLS model are of similar signs to those in the HTIV model, which, despite its problems discussed previously, are not significantly different from the consistent but less efficient FE model as shown by the Hausman test. Second, comparing with the HTIV results, endogeneity due to omitted variables or unobserved heterogeneity seems to bias our GLS estimates for the regulatory variables downward for the nonprofit hospital sample. This may suggest that the magnitude of the true regulatory effects might be even larger than what we have estimated using the GLS procedure. Significant variables therefore in our GLS model could be even more significant if the magnitude of the true effects are greater. For the for-profit hospital sample, the comparison of GLS vs. HTIV again shows that GLS tends to underestimate the magnitude of the true regulatory effects but the HTIV estimates are extremely large. It is not clear to us whether the large HTIV estimates for the regulatory variables in the for-profit model result from the problem discussed previously or the limited sample size (*N*=295).

Given the caveats of each model, findings are reported based on the GLS estimation and validated by the HTIV estimates. Even though both the GLS and HTIV methods have their limitations, our cross-validation provides a way to overcome some of the drawbacks. A comparison of the fixed effects estimation with the HTIV using the Hausman test shows that most of the HTIV estimates are consistent despite the problems with identification and measurement. A comparison of the GLS and HTIV estimates gives us some information on the direction of the bias for the GLS model. Results from these analyses should however be interpreted with caution.

Table 16: GLS Results for Hospital Provision of Uncompensated Care

	Nonprofit		*For-profit*	
Variables	Number of Admissions	Percent of Admissions	Number of Admissions	Percent of Admissions
CON	10.73**	0.07**	3.95	0.25***
REQUIREMENT	9.71	-0.63***	-42.34***	0.69***
POOL	51.55*	0.51*	-131.97***	1.14*
CON*REQUIREMENT	-1.91	0.02	-	-
CON*POOL	26.82***	0.14***	18.67***	0.004
POOL*REQUIREMENT	46.33	0.35	231.69***	-0.12
CON*REQUIREMENT*POOL	-20.49***	-0.11	-19.57***	0.03
Technology Intensity	35.57	-0.26**	39.37	-0.36**
ER	19.61	0.28	51.08	0.19
Teaching hospital status	56.27	0.22	-28.81	-0.18
Proportion with public owner	-2383.43***	-7.35	-872.67	-1.66
Hospital size	1.60***	-0.001	0.97***	-0.004***
Proportion network/system member	-191.01	-2.79*	-254.34	-6.12
HHI	-62.6	-0.21	-148.07**	0.31
HMO penetration	-214.63***	-1.68	-123.36	2.87
Percentage of population 65+	-11.23***	-0.06	0.25	-0.08
Per capita income	-2.27	-0.004	8.03**	0.06
Percent uninsured	3.42	0.17	36.24***	0.06
Rural	-0.56	0.02	-19.28	0.67
2003	37.17**	0.07	34.40**	0.34
2004	81.56***	0.18	108.85***	1.07
Constant	123.27	3.78***	-578.55***	-2.48
N	2235		295	

*$p \leq .10$; **$p \leq .05$; ***$p \leq .01$

Table 17: HTIV Results for Hospital Provision of Uncompensated Care

	Nonprofit		*For-profit*	
Variables	Number of Admissions	Percent of Admissions	Number of Admissions	Percent of Admissions
CON	38.87	0.07	738.43	6.90
REQUIREMENT	-77.61	-3.36	3342.12	30.07
POOL	382.01	1.42	5030.90	65.76
CON*REQUIREMENT	15.71	0.17	-	-
CON*POOL	66.32	0.25	-484.41	-5.61
POOL*REQUIREMENT	385.07	3.68	-3231.54	-45.64
CON*REQUIREMENT*POOL	-49.15	-0.21	148.01	1.68
Technology Intensity	-2.50	-0.19	-40.34	-0.45
ER	26.06	0.22	-10.85	-0.19
Teaching hospital status	-56.88	-0.58	-53.72	0.92
Proportion with public owner	-19.33	-0.22	-40.04	-0.40
Hospital size	0.72***	0.85	0.07	0.0016
Proportion network/system member	-1.57**	-0.03	-5.17	-0.06
HHI	172.02	-2.04	-58.81	-2.42
HMO penetration	-18.65	-0.03	14.96	0.76
Percentage of population 65+	-108.47	-0.15	45.95	-0.06
Per capita income	54.48	-0.04	25.97	-0.70*
Percent uninsured	31.11	0.24	98.22	5.33
Rural	16.60	0.0022	359.39	4.34
2003	27.78***	-0.19	66.16***	-1.41***
2004	69.26***	-0.11	138.09***	-0.71***
Constant	-264.45	7.58	-9083.74	-30.29
N	2235		295	

*$p \leq .10$; **$p \leq .05$; ***$p \leq .01$

Regulatory Variables

Results obtained from the GLS procedure show that controlling for other covariates, CON laws, acting individually, have increased both the number and percent of nonprofit hospital admissions for the uninsured. Results obtained from the HTIV procedure yield larger estimates for the CON variable in the number of admissions model and the same estimates in the percent of admissions model, but neither of them is statistically significant at the conventional levels. Although there are limitations with both the GLS and HTIV procedure, the cross validation suggests that the true effects of CON on nonprofit hospital admissions for the uninsured is positive and may be larger than what the GLS model predicts, indicating that nonprofit hospitals are more capable of providing such care in states with CON laws. This finding is consistent with what the model predicts.

Compared to nonprofit hospitals, GLS results did not show that CON laws alone have any effect on for-profit hospital's number of uncompensated care admissions. However, CON laws are significantly positively related to the percent of admissions for the uninsured by for-profit hospitals. The HTIV model yields much larger estimates for the regulatory effects and the signs are consistent with the GLS estimates. The cross-validation shows that CON may have a positive impact on for-profit hospital's percent of uninsured admissions, suggesting that for-profit hospitals in CON states tend to devote a larger share of their resources to provide services to the uninsured. Since for-profit hospitals perceive the failure to obtain CON as a profit loss, they might increase their uncompensated care provision in states with such a regulation. However, given the limited for-profit sample and potential problem of weak identification with the HTIV model, this result deserves further investigation.

Both the GLS and the HTIV estimation report a positive effect of the pool on nonprofit hospitals for the number and percent of admissions for the uninsured, though the HTIV model shows a much greater magnitude. This is consistent with our prediction that uncompensated care pools, acting alone, lead to more nonprofit hospital admissions for the uninsured. It suggests that nonprofit hospitals respond to price subsidies by increasing their uncompensated care provision. For for-profit hospitals, uncompensated care pools are found to be negatively associated with the number of admissions for the uninsured but positively related to the percent of admissions in the GLS model. The HTIV model did not yield consistent results with the GLS estimates. This finding is confounding and needs further investigation given our small for-profit sample size (N=295) and limited number of years (N=3) in the sample.

Community benefit requirement laws are found to have a positive but insignificant impact on the number of uninsured admissions and a significant negative effect on the percent of self-pay/charity admissions for nonprofit hospitals. The HTIV estimation yields a negative yet insignificant impact on both the number and percent of admissions for nonprofit hospitals. The cross-validation suggests that community benefit requirement laws tend to decrease nonprofit hospital's percent of uninsured admissions. There are two possible explanations. First, nonprofit hospitals may decrease their uncompensated care provision as a result of adjusting to the amount required by community benefit requirement laws. If nonprofit hospitals are already providing a higher level of uncompensated care than required by the regulation, community benefit requirement laws may become a non-binding constraint. Since these laws explicitly communicate the amount of uncompensated care nonprofit hospitals should provide, they might send a signal to those hospitals that are already providing a higher level than expected by the community. Consequently, these hospitals decrease their uncompensated care provision because they realize that they are unnecessarily over-producing such care. Second, these laws may have improved preventive/primary care for the uninsured which led to a decrease in the demand for inpatient care. Since community benefit requirement laws typically require that nonprofit hospitals provide health promotion services, research and education, open access to services, and community orientation in addition to uncompensated care (Ginn & Moseley, 2006), it is possible that community benefit requirement laws have enhanced access to preventive/primary care for the community. As a result, there is a decrease in the overall demand for inpatient care, which might lead to a decrease in admissions for the uninsured. Since we only have inpatient care data, we are limited in establishing a causal link between community benefit requirement laws and the decrease in self-pay/charity admissions. However, this remains a possibility.

These laws have led to a different result for for-profit hospitals. The GLS finding shows that community benefit requirement laws are negatively related to the uninsured admissions and positively associated with the percent of admissions for the uninsured among for-profit hospitals, suggesting that the laws may decrease the total number of the admissions but decrease the uninsured admissions less. The HTIV model shows a larger positive effect on the percent of uninsured admissions by for-profit hospitals. The overall evidence indicates that for-profit hospitals devote a larger share of their resources to uncompensated care. It could be that both the overall admissions and the number of self-pay/charity admissions decreased as suggested by reasons such as improved overall preventive/primary care, but for-profit hospitals devote a larger share of their resources to uncompensated care in response to community benefit requirement laws despite such a decrease in demand among the general population. Or as the HTIV results suggest, for-profit increase their uncompensated care provision in response to such laws. This can be explained by reasons suggested by previous literature that for-profit hospitals treat failure to meet community expectations as a cost. Since community benefit requirement laws explicitly express community expectations, it is not surprising that for-profit respond to community expectations by increasing their uncompensated care provision, even though these laws are not intended for them. It is a profit maximizing strategy for for-profit hospitals to increase their uncompensated care provision in the presence of community benefit requirement laws. Again we need to be cautious about these findings given the limitations of both the GLS and HTIV models.

Results from the estimations also show evidence of significant policy interaction effects. The GLS model shows that CON laws and uncompensated care pools have jointly increased nonprofit hospital's uncompensated care provision, indicating that CON laws and uncompensated care pools may have reinforced each other's effectiveness for the nonprofit hospitals. Results from the HTIV estimation provide support for this observation. One possible explanation for this result for nonprofit hospitals is that with CON laws creating a marketplace of less competition, price subsidies may be more effective in encouraging hospitals to increase their provision of services to the uninsured.

We also calculated the total effect of the regulations on uninsured admissions based on the GLS estimates. Tables 18.1-2 present results from this calculation. The green columns provide the parameter estimates for the total effects of the regulations on the number/percent of admissions and the yellow columns present regulatory intensities as discussed previously in the sample construction. For example, in Table 18.1, the first green column represents estimated total effects for CON when states have either both CON and pool or all three regulations and the second column reports estimated total effects of uncompensated care pools when states have either both CON and pool or all three regulations. The different values of CON correspond to the total effects of pool or CON as the intensity of CON increases. Specifically, it shows that as the intensity of CON laws increases on the intensity scale from 8.1 to 15, to 18.4, the total effects of CON on nonprofit hospital uncompensated care provision increase from 521, to 966, to 1184 admissions for states that have both CON laws and mandatory uncompensated care pools (POOL is evaluated at 2 on the intensity scale). For for-profit hospitals, although the GLS estimates yields a positive association between CON laws interacted with uncompensated care pools and number of uninsured admissions, the HTIV estimates give the opposite results. It is possible that this discrepancy is a result of the small for-profit sample since the HTIV procedure is sensitive to sample sizes. The consistent estimates between the GLS and HTIV estimations for the larger nonprofit sample support this possibility. Nevertheless, due to such limitations with our sample and methodology, we do not have sufficient evidence to show that CON laws acting jointly with uncompensated care pools might have a substitution effect on public subsidies.

Results from the GLS suggest that community benefit requirement laws, acting jointly with the uncompensated care pools, have slightly increased the for-profit number of admissions for the uninsured. However, again the HTIV estimates are inconsistent with the GLS results. Although it is likely that the true effects could be larger than what the GLS model predicts, given the tendency of the GLS model to underestimate the regulatory effect, we do not have enough evidence to substantiate this claim. Further investigation is needed to confirm if for-profit hospitals in states with both a mandatory pool and a moderate community benefit requirement regulation tend to have more self-pay/charity care admissions than those in states with only CON regulations.

All three policies working together were found to decrease the number of admissions for the uninsured among nonprofit hospitals, which are supported by both the GLS and HTIV estimates although the latter are not statistically significant. While CON laws and uncompensated care pools have jointly increased the number of admissions for the uninsured, adopting all three policies tends to reduce that number. As a result, the total effect of implementing CON or uncompensated care pool results is a reduction in uncompensated care provided by nonprofit hospitals if states adopt all three policies (Table 18.1). One possible explanation might be that community benefit requirement laws have reduced inpatient admissions and thus reducing nonprofit hospitals' reliance on public subsidies and cross-subsidization of uncompensated care. Another potential explanation would be that if the community benefit requirement is set below the level at which hospitals actually provide uncompensated care, it could provide a signal to reduce their provision of care by suggesting that their prior levels of such care are above the levels expected by the community. We, however, are not able to distinguish the impact of the joint effects on the number or percent of admissions for the uninsured among for-profit hospitals. In our for-profit hospital sample, the interactions of three policies working together happen to be perfectly collinear with the joint variations of CON laws and requirement regulations. The binary interaction was dropped out of the model and consequently we are not able to conclude whether the parameter estimate on the three-way interactions is due to the impact of all three policies working jointly.

Table 18.1: Total effects of Regulations on Nonprofit Hospital Provision of Uncompensated Care (GLS)

Number of Admissions				*Percent of Admissions*	
Estimated Total Effects of CON		Estimated Total Effects of Pool		Estimated Total Effects of CON	
	when POOL=2 and		when POOL=2 and		when POOL=2 and
521.397	CON=8.1	528.836	CON=8.1	0.891	CON=8.1
965.55	CON=15	891.5	CON=15	1.65	CON=15
1184.408	CON=18.4	1070.204	CON=18.4	2.024	CON=18.4
	when POOL=2; REQUIREMENT=3 and		when POOL=2; REQUIREMENT=3 and		
-173.421	CON=8.1	-135.04	when CON=8.1		
-321.15	CON=15	-337.9	when CON=15		
-393.944	CON=18.4	-437.86	when CON=18.4		

Table 18.2: Total effects of Regulations on For-profit Hospital Provision of Uncompensated Care (GLS)

Number of Admissions			
Estimated Total Effects of Community Benefit Requirement		Estimated Total Effects of Pool	
			when POOL=2 and
1263.12	when POOL=2 and REQUIREMENT=3	-28.698	CON=6.3
		508.998	CON=20.7
		1126.2	when POOL=2 and REQUIREMENT=3

To compare our results with previous studies that do not typically control for policy interactions, we also test how our estimation results differ from prior findings. Using the same GLS estimation, Tables 19.1-19.2 show that when CON laws alone are included in the model, there is a positive but insignificant impact on uncompensated care provision by nonprofit hospitals, and a negative but insignificant effect on number of uninsured admissions by for-profit hospitals. Both signs are in the expected direction. In addition, we find a significant positive, yet marginal, effect on the percent of admissions by for-profit hospitals. A one unit increase on the intensity scale is associated with a .19 percent increase in the for-profit hospital admissions for the uninsured. Uncompensated care pools are found to significantly increase both the number and percent of uncompensated care admissions by nonprofit and for-profit hospitals. This finding is consistent with the existing evidence. For community benefit requirement laws, the coefficient on the number of uncompensated care variable for nonprofit hospitals is positive and insignificant and that for for-profit hospital is negative and significant, which is the same with what we find when other policies and their interactions are included. The findings are identical for the percent of uncompensated care admissions variable with or without other policies and their interactions. These results indicate that community benefit requirement laws tend not to be significantly influenced by CON laws or uncompensated care pools regulations. This is reasonable given that hospitals are expected to abide by community benefit requirement laws if they are considered as binding requirements.

Table 19.1: GLS: Comparing Estimates w/ and w/o Other Policy or Interactions (Nonprofit)

	W/O Other Policies or Interactions		***W/ Other Policies or Interactions***	
Variables	Number of Admissions	Percent of Admissions	Number of Admissions	Percent of Admissions
CON	3.26	-0.02	10.73**	0.07**
REQUIREMENT	9.71	-0.63***	9.71	-0.63***
POOL	154.27***	0.88***	51.55*	0.51*
CON*REQUIREMENT	-	-	-1.91	0.02
CON*POOL	-	-	26.82***	0.14***
POOL*REQUIREMENT	-	-	46.33	0.35
CON*REQUIREMENT*POOL	-	-	-20.49***	-0.11

*$p \leq .10$; **$p \leq .05$; ***$p \leq .01$

Table 19.2: GLS: Comparing Estimates w/ and w/o Other Policy or Interactions (For-profit)

	W/O Other Policies or Interactions		***W/ Other Policies or Interactions***	
Variables	Number of Admissions	Percent of Admissions	Number of Admissions	Percent of Admissions
CON	-2.26	0.19*	3.95	0.25***
REQUIREMENT	-42.34***	0.67***	-42.34***	0.69***
POOL	117.82***	2.15**	-131.97***	1.14*
CON*REQUIREMENT	-	-	-	-
CON*POOL	-	-	18.67***	0.004
POOL*REQUIREMENT	-	-	231.69***	-0.12
CON*REQUIREMENT*POOL	-	-	-19.57***	0.03

*$p \leq .10$; **$p \leq .05$; ***$p \leq .01$

Market Characteristics

Our GLS results for the market level characteristics are largely consistent with the previous literature. HMO penetration is found to have a significant negative impact on the number of nonprofit hospital admissions for uninsured patients and a non-significant negative impact on the percent of admissions for uninsured patients. The HTIV results validate this association but the coefficients are statistically insignificant. One reason to explain this negative relationship is that high levels of HMO penetration tend to reduce the price for paying patients, and as a result, nonprofit hospitals have less revenue to cross-subsidize services to the uninsured. At the same time, market penetration by HMOs might also reduce the admissions for the insured patients, which makes the proportion of admissions for the uninsured largely unchanged. Given our relatively small sample size (N=295), we fail to find a significant impact of HMO penetration on the number or percent of admissions for the uninsured among for-profit hospitals in the GLS estimation. The HTIV procedure yields a positive effect of HMO penetration on for-profit hospitals. Although the sign is of the expected direction, the coefficient is not statistically significant.

The GLS results show a negative association between HHI and the for-profit hospital's uncompensated care provision, which is consistent with the HTIV estimate. In other words, in markets with higher HHI, which implies higher industry concentration, for-profit hospitals have fewer uncompensated care admissions. This finding based on the cross-validation of both models is consistent with our prediction that for-profit hospitals respond to higher competition by increasing their uncompensated care provision and react to lower competition by decreasing it. A plausible explanation is higher industry concentration might have made paid care more expensive and hence the cost of uncompensated care is higher. Although we fail to find a significant association between market concentration and nonprofit hospital uncompensated care provision, this is consistent with findings from previous studies that examine the impact of various other regulations on hospital provision of uncompensated care (Bazzoli, Lindrooth et al. 2006).

A higher percentage of uninsured was found to be significantly associated with more admissions for the uninsured for for-profit hospitals in the GLS estimation and insignificant in the HTIV estimation. The percent of population over 65 was negatively related to uncompensated care provision for nonprofit hospitals in both estimation procedures. These results could suggest that in places where health insurance coverage for the non-elderly is low, hospitals face greater demand for uncompensated care. Per capita income is found to be positively related to the number of admissions for the uninsured for for-profit hospitals in the GLS estimation. This finding is contradictory to our prediction and merits further attention. Even though we did not find a significant impact of the percent of uninsured on nonprofit hospital provision of uncompensated care, this finding is consistent with results from prior studies (Bazzoli, Lindrooth et al. 2006).

Hospital Characteristics

Some hospital characteristics have also significantly influenced a hospital's ability to provide uncompensated care. For both nonprofit and for-profit hospitals, technological intensity is found to be negatively related to their percent of uncompensated care admissions in both the GLS and HTIV estimations although the HTIV estimates are insignificant. This cross-validation could mean that hospitals that are more technologically sophisticated have higher number of admissions for paying patients.

One explanation for this result might be that such hospitals may provide better quality of care than hospitals with lower technology intensity and hence attracting more paying patients.

Not surprisingly, for both types of hospitals increasing bed size is associated with an increasing number of admissions that are self-pay or charity. However, among for-profit hospitals, size is negatively related to the percent of admissions for the uninsured in the GLS estimation, while we are unable to detect any effect of bed size on the share of uncompensated admissions among non-profit hospitals. This finding was not validated by the HTIV model and requires further investigation.

The percent of public hospitals in the market is significantly negatively related to the number of admissions for the uninsured among nonprofit hospitals in both GLS and HTIV estimations. This means that public hospitals may have crowded out nonprofit hospitals in terms of their uncompensated care provision. Similarly, we find that the higher the percent of hospitals that belong to a network/system, the lower the percent of uncompensated care admissions by nonprofit hospitals as validated by both the GLS and HTIV procedures. Since research indicates that hospitals within a network/system provide more uncompensated care than those that are not in a network/system (Bazzoli, Lindrooth et al. 2006), it is not surprising that their presence will lead to a crowd-out effect on nonprofit hospital provision of such services. We did not, however, find any significant impact of public hospitals or network/systems hospitals on for-profit hospitals although both GLS and HTIV estimation yield a negative but insignificant association. We might not have enough data to identify the effect given our sample size.

Wrapping up, our findings from the cross-validation of the GLS and HTIV are summarized in Table 20. The strength of the evidence was indicated by three stars (meaning the GLS and HTIV procedures yield consistent results) or no star (meaning the GLS and HTIV model produces inconsistent results). The table also shows whether our results conformed to the hypotheses. Even though both the GLS and HTIV methods have their limitations, our cross-validation provides a way to overcome some of the drawbacks. As can be seen from the table, most of our GLS and HTIV findings are consistent and conform to our predictions. Some of our results however need further investigation because we do not have strong evidence to reach a conclusion.

Table 20: Summary of Effects on Uncompensated Care Provision

	Uncompensated Care					
Variables	**Nonprofit**			**For-profit**		
	Predicted	Found		Predicted	Found	
		Number of Admissions	Percent of Admissions		Number of Admissions	Percent of Admissions
Regulatory Measures						
CON	+	+***	+***	+/-		+***
POOL	+	+***	+***	+	-	+***
REQUIREMENT	+		-***	+/-	-	+***
CON*POOL	+	+***	+***	+/-	+	
CON* REQUIREMENT	+/-			+/-		
POOL*REQUIREMENT	+/-			+/-	+	
CON*POOL* REQUIREMENT	+/-	- ***		+/-	-	
Hospital Characteristics						
Teaching hospital status	+			+		
Percent of public hospital	-	-***		+		
Technology intensity	+		-***	+		
Hospital size	+	+***		+	+***	-
ER	+			+		
Percent of network/system member	-		-***	+		
Market Characteristics						
HHI	+			-	-***	
HMO penetration	-	-***		+		
Percentage of population aged 65 or above	-	-***		-		
Per capita income	-			-	+***	
Percentage of population that are uninsured	+			+	+***	
Rural	-			-		

CHAPTER SIX

CONCLUSION

This chapter presents a summary of the dissertation research. The first section summarizes the results while the second section discusses policy implications. Study limitations and extensions for future research are provided in the last section.

Summary

This dissertation examines the effects of various state regulations on hospital provision of uncompensated care and analyzes both for-profit and nonprofit hospitals' responsiveness to the regulatory environment.

Despite the limitations with our data and methodology, our findings from the cross-validation of the GLS and HTIV models suggest that nonprofit and for-profit hospitals respond to some policy instruments similarly and others differently. For example, our evidence suggests that both nonprofit and for-profit hospitals respond to CON laws by increasing their uncompensated care provision. This may be partially attributed to the fact that nonprofit hospitals behave differently in markets with different levels of industry concentration. As suggested by the literature, nonprofit hospitals increase their uncompensated care provision when industry concentration grows. For-profit hospitals, although responding to CON regulations in similar ways, may view failure to obtain CON regulations as a cost. Their increase in uncompensated care provision is a strategy to maximize profits. Nonprofit and for-profit hospitals also respond to policy incentives such as community benefit requirement laws differently. These laws were found to decrease the uncompensated care provision by nonprofit hospitals, while increasing the provision of such care by for-profit hospitals. This is an interesting finding suggesting that community benefit requirement laws may have sent a signal of overproducing uncompensated care to the nonprofit hospitals that are already providing a higher level of uncompensated care than mandated. They may have also improved preventive/primary care for the uninsured which consequently led to a decrease in demand for inpatient care. However, we lack primary/preventive care data to validate such a connection. The findings also suggest that again for-profit hospitals might consider providing uncompensated care as a profit maximizing strategy and hence respond to community benefit requirement laws by increasing their supply of uncompensated care. It is also plausible that in markets where nonprofit hospitals reduce their uncompensated care provision, for-profit hospitals increase their provision of such care. This is because a decrease in uncompensated care provision increases unmet demand for such care, which in turn increases community expectations regard hospital provision of uncompensated care. Since for-profit hospitals respond to an increase in community expectations by increasing their uncompensated care provision, they might increase such provision when nonprofit hospitals decrease it. However, it is not clear to us if the total market level of uncompensated care has changed as a result of such a shift.

In addition to the above differences between nonprofit and for-profit hospitals, regulations working together can in some cases enhance the effectiveness of one another. For example, uncompensated care pools, when interacted with CON laws, have greatly increased uncompensated care provision by nonprofit hospitals. When the three policies are implemented together, community benefit requirement laws seem to have limited the need for nonprofit hospitals to seek support from the uncompensated care pools or cross-subsidization of services. Specifically, these laws might have improved preventive/primary care for the uninsured so that the demand for the more costly inpatient care is reduced. As a result, nonprofit hospitals could reduce their reliance on uncompensated care pools to reimburse for their free care. Another potential explanation is these laws might have send a signal to nonprofit hospitals already providing a higher level of uncompensated care than required by such a regulation to reduce their care.

Some hospital characteristics also influence uncompensated care provision by nonprofit and for-profit hospitals. Larger hospitals tend to provide more uncompensated care than smaller hospitals, both nonprofit and for-profit. Nonprofit hospitals that are more technologically sophisticated tend to have a lower percentage of uncompensated care. The presence of public hospitals and hospitals that belong to a network/system in a local market lead to lower uncompensated care provision by nonprofit hospitals in that same market.

Both nonprofit and for-profit hospitals respond to the market environment by adjusting their uncompensated care provision. For-profit hospitals decrease their uncompensated care provision when market concentration is high and increase such provisions when uninsured populations increase. Nonprofit hospitals decrease their uncompensated care provision when HMO penetration increases market competition.

Policy Implications

The study results have significant implications for state health policies that aim at improving access to care for the underinsured and uninsured. Reductions in the provision of uncompensated care by hospitals have limited access to care for those who need it most. Further the disproportionate distribution of the uncompensated care burden has started to jeopardize the financial stability of some hospitals, particularly those that are considered as safety-net hospitals for the economically disadvantaged. Understanding the influence of the regulatory environment, especially policy interactions will help policymakers design more complex strategies to address these important issues.

Our study has significant implications for states that do not have CON laws or are reexamining the impact of their existing CON laws on uncompensated care provision. Our findings indicate that both nonprofit and for-profit hospitals respond to CON laws by increasing their uncompensated care provision. As suggested by previous literature, with CON laws creating a marketplace of less competition, nonprofit hospitals have more resources to cross subsidize uncompensated care. For-profit hospitals might perceive the failure to obtain CON as a profit loss and increase their uncompensated care provision in states with such a CON regulation. Therefore, implementing such a policy in either a mixed ownership market or in markets dominated by nonprofit hospitals may be able to increase access to care for the uninsured.

State policies aimed at assisting safety-net hospitals may consider providing public subsidies in combination with regulations that explicitly communicate community expectations. Our evidence suggests that explicit expression of community expectations reduces the provision of uncompensated care by non-profit hospitals and results in greater provision of such care by for-profit hospitals. This result indicates that the new IRS rulings on nonprofit hospital reporting of community benefits may have unintended indirect effects on for-profit hospitals because in mixed ownership markets where community benefit requirement laws are implemented, for-profit hospitals may provide more uncompensated care. In markets dominated by nonprofit hospitals, implementing community benefit requirement regulations may not increase uncompensated care provision by nonprofit hospitals. Such regulations may send a signal to those hospitals that are already providing a higher level of uncompensated care than expected by the community. Consequently, these nonprofit hospitals decrease their uncompensated care provision because they realize that they are unnecessarily over-producing such care. We do not have enough evidence to show, however, if the total market level of uncompensated care has changed as a result of such a shift of uncompensated care provision from nonprofit to for-profit hospitals. The net changes in the amount of uncompensated care at the market level will depend on the magnitude of the decrease by nonprofit hospitals and increase by for-profit hospitals.

Implementing policies that suppress competition (e.g., CON laws) and public subsidies (e.g., uncompensated care pools) together may increase the effectiveness of both types of regulations for nonprofit hospitals. Because nonprofit hospitals largely rely on cross-subsidization of services to provide uncompensated care, a less competitive market will enhance their financial ability to do so. Further incentives from public subsidies will increase their willingness to provide uncompensated care.

Other findings of the study indicate that there is a significant crowd-out effect by public hospitals. Nonprofit hospitals are particularly sensitive to the amount of uncompensated care provided by public hospitals in the same market. They reduce their uncompensated care when there is a large presence of public hospitals in the market. Although public hospitals are not the focus of this study, they play a central role in promoting health in the community. Policy makers need to understand the extent and magnitude of the crowd-out effect in order to write appropriate policy prescriptions to support safety-net hospitals.

Study Limitations and Future Research

The current study benefited from our ability to examine various regulations using comprehensive information on admissions for the uninsured, an improved alternative measure of uncompensated care. However, important limitations must be noted.

First, despite being a powerful technique to correct endogeneity as a result of latent individual effects, the HTIV procedure suffers from weak identification due to our data limitations. Although we cross-validate results using a random effects GLS, future studies will benefit from obtaining data that have more variations for some time-varying variables so as to improve the HTIV estimation.

Second, our measures of the regulatory variables do not capture all the variations of the policies under investigation, so we are unable to completely eliminate the potential confounding factor ---- state effects. In other words, the lack of such a precise measure limits our ability to completely separate the effects of being in a particular state and the effects of the regulations. Future efforts should focus on conducting surveys with the states to collect data on all dimensions of each regulation (e.g., scope, length, restrictiveness and uncertainty). Methods to operationalize these dimensions also deserve further attention.

Another limitation of the study is the lack of hospital discharge data on other non-study states. Although our study represents a comprehensive analysis of these regulations using uncompensated care admission as a measure, we only have data on 17 states. Selection bias remains a potential problem even though we have good reasons to believe that HCUP participating and non-participating states are not systematically different in terms of their uncompensated care provision. In addition, because we worked with only

17 states, the lack of variation on the regulatory measures limits our ability to examine a broader scope of policies such as conversion and AWP-FOC laws. Future studies should identify datasets with information on more states to obtain greater variation on the entire spectrum of policies.

It is also important to note that neither the Hausman-Taylor nor the random effects GLS procedure corrects for the bias as a result of reverse causality if we suspect that such bias indeed exists. In other words, hospitals might have endogenously selected themselves into different programs based on their level of uncompensated care. In such cases, a propensity score matching technique might prove useful. Intuitively, the propensity score matching constructs a control group from the group of untreated individuals and ensures that the control group is as similar as possible as the treatment group with respect to observable characteristics that affect both the outcome and the treatments. Matching has some important advantages over the Hausman-Tayor procedure. As a non-parametric method, matching does not impose any specific linearity assumptions on the evaluated effects that are inherent in regression-based modeling. Furthermore, matching explicitly tries to find for each untreated unit a similar treated unit to evaluate the counterfactual, i.e. what would happen to the treatment group without the treatment. If sample selection remains a concern, additional information on policy adoption needs to be collected. Unfortunately, these data were not available at the time of the study. However, since our unit of analysis is the individual hospital and the adoption of various regulations by the states might be influenced by the magnitude of the uncompensated care at the state level, such endogeneity problems might be mitigated. Another reason to believe that reverse causality will not significantly bias our results is that policy adoptions are unlikely to be correlated with recent level of hospital uncompensated care provision. Most our states adopted these regulations several decades ago. Even if a state's decision to adopt these policies was based on its level of uncompensated care, it is more likely to be determined by the aggregated level of uncompensated care then. In other words, regulations do not correlate with the level of uncompensated care during the same time periods. Nevertheless, future research needs to control for the first stage selection using data containing information that predicts adoption.

Additional concern about endogeneity lies in the potential spillover effects. In other words, states with policies that encourage uncompensated care provision might attract the uninsured from adjacent states with less friendly polices to seek care from their hospitals. As information on patient origin for the self-pay/charity care patients is missing from our data, we are unable to examine the proportion of patients that are from a contiguous state with less generous uncompensated care policies. However, we do not expect that such a spillover, if it indeed exists, will significantly bias our results. The uninsured tend to seek care locally for three main reasons. First and foremost, they typically delay care until symptoms worsen to the point when they end up being admitted into an ER in a local hospital. Second, they lack the information about which hospitals provide charity care, not to mention which states have more uninsured-patients-friendly policies. Third, the uninsured might not be able to afford travelling to another state to seek care, given that they typically have very low income.

Finally, we had access only to inpatient data, which limited our ability to analyze the regulatory effects on primary/preventive care. For example, if a particular bundle of regulations (e.g., community benefit requirements and uncompensated care pools) encourages hospitals to provide primary/preventive care to the underserved population, we were not able to empirically test if the decrease in uncompensated care admissions is due to the effect of that incentive. Future research should focus on incorporating data on primary/preventive care to capture the intermediate effect of these regulations so that we are able to not only assess the full spectrum of the regulatory effects but also improve our understanding of the mechanisms by which each regulation or a bundle of regulations influences uncompensated care provision for the underinsured and uninsured populations.

Future work should focus on obtaining more data on HMO penetration, percent of population over 65, and uninsurance rate so that there will be real changes over time for the HTIV method to yield robust instruments. Furthermore, model identification could also be improved by adopting the county based market measure. Using patient flows to define market has the potential for endogeneity bias when we investigate the effects of competition on hospital cost and outputs (Wong, Zhan et al. 2005). Since our market groups were constructed based on hospital admissions and the dependent variable is also admissions, it is likely that our market level variables are correlated with the random error term. Given that the HTIV procedure is sensitive to endogeniety, we should be able to obtain improved estimates with an exogenous county based market measure. Finally, we should further adjust admissions by case-mix to account for the intensity of resource use so that our measure could better reflect the actual hospital effort for uncompensated care. As suggested by some studies comparing adjusted and unadjusted utilization measures, case mix has significantly affected the level of hospital resource use (Weiner, Starfield et al. 1991; Berlowitz, Ash et al. 1998; Liu, Sales et al. 2003; Lee and Roh

2007). Future work should include in the empirical model a case mix severity measure from the discharge data using the ICD codes.

In conclusion, despite the limitations, our study represents a comprehensive examination of competition (CON), subsidy (uncompensated care pool) and requirement (community benefit requirement) regulations that have the most influence on hospital uncompensated care provision. It overcomes the limits of previous research that focused primarily on the effect of a single regulation in a given state. The current study not only improves generalizability by examining hospitals in 17 U.S. states, it also investigates multiple policy interventions and their interactions, which are argued to be crucial in understanding the impact of the regulatory environment on hospitals provision of uncompensated care. In addition, the current study improves upon measures of uncompensated care using a more direct measure of the actual care delivered to the uninsured --- admissions for self-pay/charity patients. Findings from this study suggest that nonprofit and for-profit hospitals view and respond to policy incentives differently. In addition, regulatory interactions are found to significantly influence the uncompensated care provision by both nonprofit and for-profit hospitals. The study helps improve policy maker’s understanding of the impact of the regulatory environment on nonprofit and for-profit hospital behaviors and their uncompensated care provision. It contributes to the current debate over the new IRS ruling on community benefit reporting for tax exempt nonprofit hospitals.

APPENDIX A

REGULATORY VARIATIONS

The following table presents study regulations for all 48 U.S. states.

Table B.1: Hospital Regulations in 48 U.S. States (by 2007)

States	*CON*	*Duration*	*REQUIREMENT*	*Duration*	*POOL*	*Duration*	*CONVERSION*	*Duration*	*AWP/FOC*	*FOC Duration*	*AWP Duration*
Alabama	X	1979-									
Arizona*		1971-1985			X	1992-	X				
Arkansas†	X	1975-			X				X	1995-	1995-
California		1969-1987	X	1997- effective, passed in 1994	X	1988-	X				
Colorado*		1973-1987			X	1983-The Reform Act for Provision of Care to the Medically Indigent	X				
Connecticut	X	1973-	X	2001-		1991-1994	X				
Delaware	X	1978-									
Florida*	X	1973-				1984-1996					
Georgia	X	1974-			X		X		X		1976-
Idaho		1980-1983	X						X		1994-
Illinois	X	1974-	X						X		1994-
Indiana		1980-1996, 1997-1999	X	1994- reporting	X	HCI			X		1994-
Iowa*	X	1977-									
Kansas		1972-1985									
Kentucky*	X	1972-							X		1994-
Louisiana†	X	1991-					X		X		1995-
Maine*	X	1978-									
Maryland*	X	1968-	X	2001-	X	1974-	X				
Massachusetts*	X	1972-	X	1994-voluntary	X	1985-1988, 1989-1991, 1992-1997, 1998-					
Michigan	X	1972-									
Minnesota		1971-1985	X								
Mississippi	X	1979-							X		1984-
Missouri	X	1979-	X	1994- Access							
Montana	X	1975-									1991-1993
Nebraska†	X	1979-			X		X	1996-			
Nevada*	X	1971-	X	2005-	X	Property tax funded					
New Hampshire	X	1979-	X	2000- effective, passed in 1999			X				
New Jersey*	X	1971-			X	1980-1993, 1993-					
New Mexico		1978-1983			X				X	1979-	
New York*	X	1966-	X	1991- general	X	1974-1997, 1997-					

* Study state
† Long-term care facility only

Appendix B: Continued

States	*CON*	*Duration*	*REQUIREMENT*	*Duration*	*POOL*	*Duration*	*CONVERSION*	*Duration*	*AWP/FOC*	*FOC Duration*	*AWP Duration*
North Carolina*	X	1978-	X	2005-							
North Dakota		1971-1995							X	1985-	
Ohio†	X	1975-			X						
Oklahoma	X	1971-			X				X	1996-	
Oregon†*	X	1971-					X				
Pennsylvania		1979-1996	X	1997-mini	X						
Rhode Island*	X	1968-	X	1999- effective, passed in 1997			X				
South Carolina	X	1971-									
South Dakota		1972-1988									
Tennessee	X	1973-									
Texas		1975-1985	X	1993- mini					X	1975-	1992-
Utah*		1979-1984	X								
Vermont	X	1979-	X								
Virginia	X	1973-			X	SLH 1946-1989, 1989-			X		1983-
Washington*	X	1971-					X				
West Virginia*	X	1977-			X	Property tax funded					
Wisconsin†*	X	1977-1987, 1993-							X	1975-	
Wyoming		1977-1989							X		1990-
Total	34		18		18		12		15		

* Study state

† Long-term care facility only

APPENDIX B

MARKET DEFINITION

To define markets by patient flow, we use the HCUP SID data to implement the following algorism[18]. We first determined patients' origin by their zip code and the county/counties that correspond to that zip code. We then found the hospitals they attended and the county/counties that correspond to those hospitals. We defined markets as county/counties that sent at least 50 percent of its patients to another county. As a result, all counties that share the initial market were grouped.

Counties that do not belong to any markets after the initial grouping were then added to the market groups if a county sent at least 21 percent of its patients to a county that is already in a market. Counties that belong to multiple markets were then placed into the market to which it sent its largest number of patients greater than 21 percent. After all markets were defined, smaller markets were absorbed into larger markets if the combination of the markets was logical in terms of spatial proximity and patient flow.

For example, Maryland has 24 counties with 22 counties that have hospitals in our sample[19]. In the first step, Allegany and Garrett were grouped in the same market since 98 percent of Allegany patients were from Garrett. Baltimore county and Baltimore city were put in the same market as 70 percent of Baltimore county patients were from Baltimore city. After the initial grouping, we have 12 market groups and three counties

[18] We use counties as markets for Nevada, New York, and Rhode Island since either zip code or patient unique identifier/medical records are missing for these three states. For Massachusetts, Maryland, Maine, West Virginia and Utah, we use the first three digits of patients' zip codes to determine the county-to-county patient flow table.
[19] Queen Anne's and Caroline counties do not have hospitals in our sample, so we did not include those counties in our market groups.

(Talbot, Kent and Dochester) that were not assigned to any markets (as shown by the Figure 2). As Kent and Dochester sent most their patients (40 and 55 percent) to Talbot respectively, we grouped them in the same market. Baltimore county belongs to both Baltimore city market and Howard county market, and it sent its largest number of patients greater than 21 percent to its own Baltimore county market. Baltimore city sent 95 percent and Howard County sent 52 percent of their patients to Baltimore county. We therefore group Baltimore county and Baltimore city in the same market. Smaller markets such as Somerset were absorbed into the larger Wicomico/ Worcester market because geographically Somerset borders both counties and it sent a significant number of patients (86 percent) to Wicmico and the remaining 14 percent to Worcester. Calvert was absorbed into the Prince George's market and Howard/Carrol market was absorbed into Baltimore county/Baltimore city market for similar reasons. As a result of all the groupings, we ended up with 10 hospital market groups for Maryland.

APPENDIX C

SENSITIVITY ANALYSIS: MARKET DEFINED BY PATIENT FLOW VS. COUNTY

We performed a sensitivity analysis to test if our results are sensitive to different market measures. Table C.1 defines each market measure. Table C.2 shows that mean market concentration is higher for the county based definition than the patient flow based market definition. Tables C.3-4 represents results from including different HHI measures in otherwise identical hospital uncompensated care admission regressions. The parameter estimates for the regulatory variables are remarkably similar in sign although the level of significance differs slightly. The estimated effects were much lower in absolute value for variables such as CON, CON*POOL and all three variables interacted in the county model than that in the patient flow model, and the magnitude of uncompensated care pool variable is much higher in the county model. In addition, the parameter estimates on the HHI variables were largely similar in sign and magnitude, which is consistent with what Wong et al. (2005) find in their analysis. Their study shows that competition measures based on the geographic boundary definitions and the widely used patient flow definitions yielded the highest correlations with other measures and that empirical studies examining the impact of market competition on hospital costs or outputs are insensitive to the choice of hospital competition measure employed. Lastly, most control variables in both models have the similar signs and effect sizes.

Table C.1: Definition: Herfindahl-Hirschman Index

Variable	*Definition*
HHI_market	Herfindahl-Hirschman Index based on patient flow
HHI_county	Herfindahl-Hirschman Index based on county

Table C.2: Summary Statistics for HHI by Sample and Definition

		Variable	*Obs*	*Mean*	*Std. Dev.*	*Min*	*Max*
Sample w/ Technology Intensity and ER	For-profit	HHI_county	295	4375.01	3154.32	534.05	10000
		HHI_market	295	2571.69	2430.33	316.95	10000
	Nonprofit	HHI_county	2235	5233.36	3425.55	513.36	10000
		HHI_market	2235	3176.62	2953.97	316.95	10000
Sample w/o Technology Intensity and ER	For-profit	HHI_county	500	4099.15	3304.05	513.36	10000
		HHI_market	500	2460.18	2433.56	316.95	10000
	Nonprofit	HHI_county	2625	5091.12	3421.31	513.36	10000
		HHI_market	2625	3165.10	2930.38	316.95	10000

Table C.3: GLS Results for Hospital Provision of Uncompensated Care (Patient Flows)

	Nonprofit		*For-profit*	
Variables	Number of Admissions	Percent of Admissions	Number of Admissions	Percent of Admissions
CON	10.73**	0.07**	3.95	0.25***
REQUIREMENT	9.71	-0.63***	-42.34***	0.69***
POOL	51.55*	0.51*	-131.97***	1.14*
CON*REQUIREMENT	-1.91	0.02	-	-
CON*POOL	26.82***	0.14***	18.67***	0.004
POOL*REQUIREMENT	46.33	0.35	231.69***	-0.12
CON*REQUIREMENT* POOL	-20.49***	-0.11	-19.57***	0.03
Technology Intensity	35.57	-0.26**	39.37	-0.36**
ER	19.61	0.28	51.08	0.19
Teaching hospital status	56.27	0.22	-28.81	-0.18
Proportion with public owner	-2383.43***	-7.35	-872.67	-1.66
Hospital size	1.60***	-0.001	0.97***	-0.004***
Proportion network/system member	-191.01	-2.79*	-254.34	-6.12
HHI	-0.01	-0.00002	-0.01**	0.00003
HMO penetration	-214.63***	-1.68	-123.36	2.87
Percentage of population 65+	-11.23***	-0.06	0.25	-0.08
Per capita income	-2.27	-0.004	8.03**	0.06
Percent uninsured	3.42	0.17	36.24***	0.06
Rural	-0.56	0.02	-19.28	0.67
2003	37.17**	0.07	34.40**	0.34
2004	81.56***	0.18	108.85***	1.07
Constant	123.27	3.78***	-578.55***	-2.48
N	2235		295	

Table C.4: GLS Results for Hospital Provision of Uncompensated Care Controlling for Technology Intensity and ER (County)

	Nonprofit		*For-profit*	
Variables	Number of Admissions	Percent of Admissions	Number of Admissions	Percent of Admissions
CON	7.97	0.06**	1.77	0.22***
REQUIREMENT	-14.96	-0.86***	-24.49*	0.77***
POOL	85.60**	0.40	34.93	1.80***
CON*REQUIREMENT	0.07	0.03	-	-
CON*POOL	23.91***	0.14***	-1.99	-0.05
POOL*REQUIREMENT	-35.59	0.16	49.93	-1.09
CON*REQUIREMENT*POOL	-15.46***	-0.10**	-3.30	0.10*
Technology Intensity	37.00	-0.27**	39.05	-0.38**
ER	18.36	0.28	52.02	0.21
Teaching hospital status	40.47	0.09	-33.88	-0.13
Proportion with public owner	-1447.31**	-7.85	-370.30	-6.91
Hospital size	1.56***	-0.001*	1.00***	-0.004***
Proportion network/system member	-13.26	-1.21	-168.69***	-2.64
HHI	-0.01	-0.0001	0.01	0.0002***
HMO penetration	-163.94*	-1.96	-89.19	-0.50
Percentage of population 65+	-1393.22***	-10.50	-445.78**	-10.33***
Per capita income	-3.26	-0.01	10.41***	0.08
Percent uninsured	6.58	0.18	26.35	0.02
Rural	0.77	-0.004	-26.03	0.52
2003	38.86*	0.06	32.57**	0.33
2004	82.59***	0.17	109.14**	1.07
Constant	165.35	4.97	-548.45**	-1.55
N	2235		295	

APPENDIX D

THE RURAL/URBAN CONTINUUM CODES

The Rural/Urban Continuum Codes are defined as follows:

CODE	METROPOLITAN COUNTIES (1-3)
01	Counties of metro areas of 1 million population or more
02	Counties in metro areas of 250,000 - 1,000,000 population
03	Counties in metro areas of fewer than 250,000 population
	NONMETROPOLITAN COUNTIES (4-9)
04	Urban population of 20,000 or more, adjacent to a metro area
05	Urban population of 20,000 or more, not adjacent to a metro area
06	Urban population of 2,500-19,999, adjacent to a metro area
07	Urban population of 2,500-19,999, not adjacent to a metro area
08	Completely rural or less than 2,500 urban population, adjacent to a metro area
09	Completely rural or less than 2,500 urban population, not adjacent to a metro area
99	Missing Value

APPENDIX E

DISTRIBUTION OF HOSPITALS BY OWERSHIP TYPES

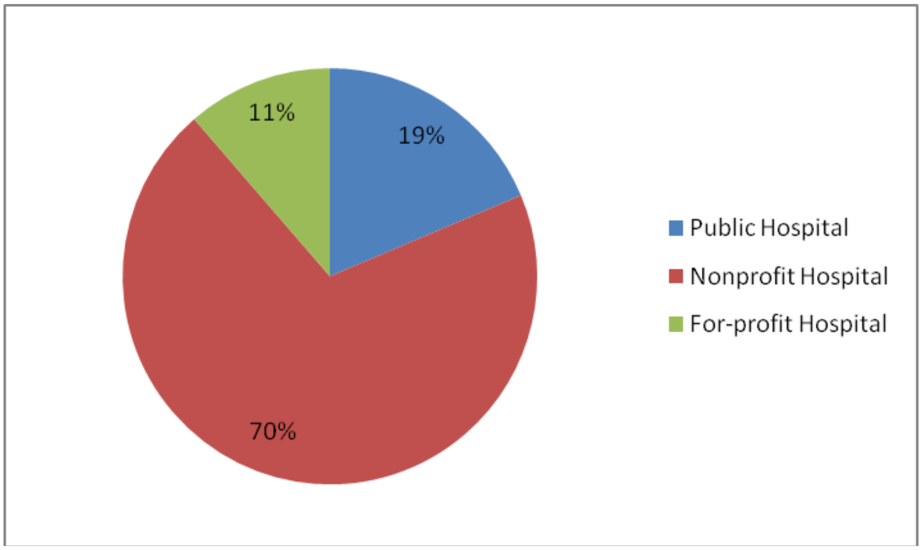


Figure E.1: Percent of Hospitals by Ownership Types 2002

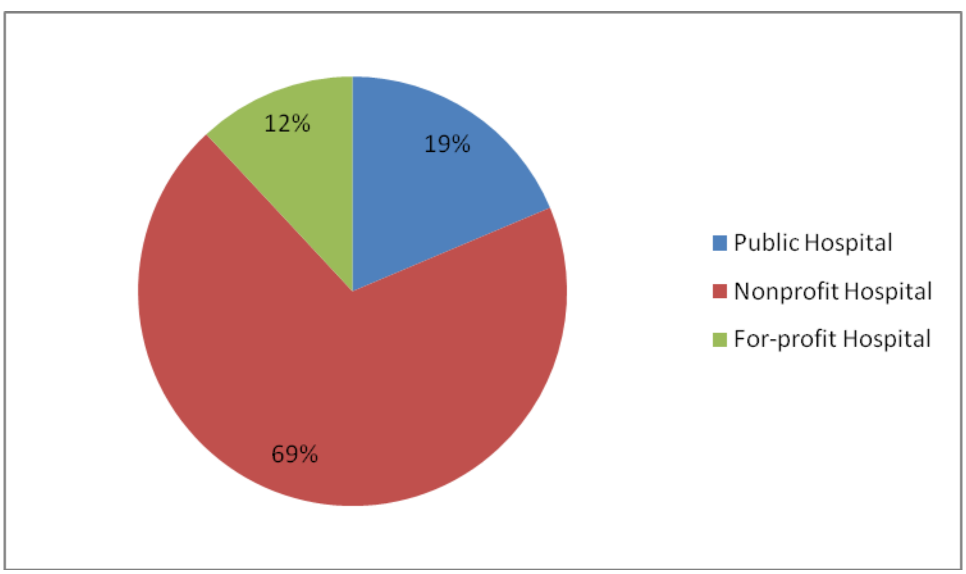


Figure E.2: Percent of Hospitals by Ownership Types 2003

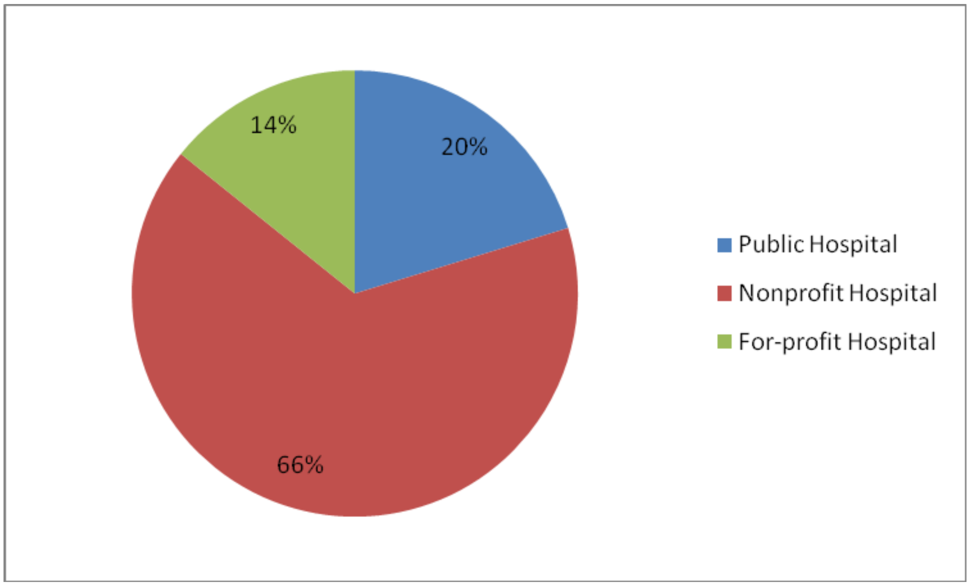


Figure E.3: Percent of Hospitals by Ownership Types 2004

APPENDIX F

COMPARING SAMPLE WITH U.S. STATISTICS

Table F.1: Two Sample *t* Test --- Nonprofit Hospitals

Variable	*Obs*	*Mean*	*Std. Err.*	*Std. Dev.*	*[95% Conf.*	*Interval]*
Sample	5	0.2	0.0249	0.055678	0.130867	0.269133
U.S.	5	0.2	0.029326	0.065574	0.118579	0.281421
diff	5	2.98E-09	0.020736	0.046368	-0.05757	0.057574

mean(diff) = mean(var1 - var2) t = 0.0000

Ho: mean(diff) = 0 degrees of freedom = 4

Ha: mean(diff) < 0 Ha: mean(diff) != 0 Ha: mean(diff) > 0

Pr(T < t) = 0.5000 Pr(|T| > |t|) = 1.0000 Pr(T > t) = 0.5000

Table F.2: Two Sample *t* Test --- For-profit Hospitals

Variable	*Obs*	*Mean*	*Std. Err.*	*Std. Dev.*	*[95% Conf.*	*Interval]*
var1	5	0.202	0.06127	0.137004	0.031888	0.372113
var2	5	0.2	0.047749	0.106771	0.067427	0.332573
diff	5	0.002	0.032465	0.072595	-0.08814	0.092138

mean(diff) = mean(var1 - var2) t = 0.0616

Ho: mean(diff) = 0 degrees of freedom = 4

Ha: mean(diff) < 0 Ha: mean(diff) != 0 Ha: mean(diff) > 0

Pr(T < t) = 0.5231 Pr(|T| > |t|) = 0.9538 Pr(T > t) = 0.4769

APPENDIX G

Table I.1: Hospital Provision of Uncompensated Care by Type of Ownership (Pooled OLS)

	Nonprofit		*For-profit*	
Variables	Number of Admissions	Percent of Admissions	Number of Admissions	Percent of Admissions
CON	4.939*	0.047*	6.58	0.33***
REQUIREMENT	2.295	-0.627**	-29.71	0.44
POOL	102.322***	0.426	-162.14**	1.50*
CON*REQUIREMENT	-0.598	0.030	-	-
CON*POOL	27.864***	0.212***	23.59***	-0.06
POOL*REQUIREMENT	-4.547	0.655	246.09	-1.46
CON*REQUIREMENT*POOL	-18.596***	-0.153***	-27.84**	0.09
Teaching hospital status	114.729***	0.102	-187.14***	-1.27**
Proportion with public owner	-1421.311***	4.517	-2128.67***	-6.68
Hospital size	1.904***	-0.002***	1.83***	-0.005***
Proportion network/system member	-316.237**	-4.582***	-48.57	-0.42
HHI	-0.007	-0.0001	-0.03***	-0.0000003
HMO penetration	-293.959***	-2.148***	-105.19	5.97***
Percentage of population 65+	-7.761**	-0.038	-0.32	-0.14***
Per capita income	-4.156***	-0.021	7.79**	0.06
Percent uninsured	9.870**	0.169***	38.51***	-0.07
Rural	-3.997	0.058	-18.41	0.82***
2003	40.473*	-0.042	41.01	0.38
2004	84.793***	0.205	106.42***	1.08**
Constant	144.676	4.127***	-566.86***	-2.00
N	2322		295	

REFERENCES

(1992). Horizontal Merger Guidelines. 1.51. U. S. D. o. J. a. T. F. T. Commission.

(2005). National Directory of Health Planning, Policy and Regulatory Agencies, American Health Planning Association.

AHA (2005). Uncompensated Hospital Care Cost: Fact Sheet, American Hospital Association.

AHA (2006). Uncompensated Hospital Care Cost, American Hospital Association.

Alpha-Center (1999). Effects of Certificate of Need and Its Possible Repeal, State of Washington Joint Legislative Audit and Review Committee.

Anderson, G., R. Heyssel, et al. (1993). "Competition versus regulation: its effect on hospitals." Health Aff (Millwood) **12**(1): 70-80.

Antel, J. J., R. L. Ohsfeldt, et al. (1995). "State Regulation and Hospital Costs." Review of Economics and Statistics **77**(3): 416-22.

Atkinson, G., W. D. Helms, et al. (1997). "State trends in hospital uncompensated care." Health Aff (Millwood) **16**(4): 233-41.

Banks, D. A., M. Paterson, et al. (1997). "Uncompensated hospital care: charitable mission or profitable business decision?" Health Econ **6**(2): 133-43.

Bazzoli, G. J., R. C. Lindrooth, et al. (2006). "The influence of health policy and market factors on the hospital safety net." Health Serv Res **41**(4 Pt 1): 1159-80.

Becker, G. (1983). "A theory of competition among pressure groups for polical influence." Quarterly Journal of Economics **96**: 371-400.

Berlowitz, D. R., A. S. Ash, et al. (1998). "Profiling outcomes of ambulatory care: casemix affects perceived performance." Med Care **36**(6): 928-33.

Bian, J. and M. A. Morrisey (2006). "HMO penetration, hospital competition, and growth of ambulatory surgery centers." Health Care Financ Rev **27**(4): 111-22.

Bovbjerg, R. R., A. E. Cuellar, et al. (2000). Market Competition and Uncompensated Care Pools, The Urban Institute.

Breusch, T. S. and A. R. Pagan (1980). "The Lagrange Multiplier Test and Its Applications to Model Specification in Econometrics." Review of Economic Studies **47**: 239-253.

Campbell, E. S. and M. W. Ahern (1993). "Have procompetitive changes altered hospital provision of indigent care?" Health Econ **2**(3): 281-9.

Campbell, E. S. and G. M. Fournier (1993). "Certificate-of-need deregulation and indigent hospital care." J Health Polit Policy Law **18**(4): 905-25.

Campbell, H. S. and M. W. Ahern (1993). "Have Procompetitive Change Altered Hospital Provision of Indigent Care." Health Economics **2**.

Census (2008). Health Insurance Coverage: 2006.

Clement, J. P., K. R. White, et al. (2002). "Charity care: do not-for-profits influence for-profits?" Med Care Res Rev **59**(1): 59-78.

Colombo, J. D. (2006). "The role of tax exemption in a competitive health care market." J Health Polit Policy Law **31**(3): 623-42.

Conover, C. J. and F. A. Sloan (1998). "Does removing certificate-of-need regulations lead to a surge in health care spending?" J Health Polit Policy Law **23**(3): 455-81.

Conover, C. J. and F. A. Sloan (2003). Evaluation of Certificate of Need in Michigan, Duke University, Center for Health Policy, Law, and Management

Cook, K., S. M. Shortell, et al. (1983). "A Theory of Organizational Response to Regulation - the Case of Hospitals." Academy of Management Review **8**(2): 193-205.

Cunningham, P. J. and H. T. Tu (1997). "A changing picture of uncompensated care." Health Aff (Millwood) **16**(4): 167-75.

Davidoff, A. J., A. T. LoSasso, et al. (2000). "The effect of changing state health policy on hospital uncompensated care." Inquiry **37**(3): 253-67.

DeNavas-Walt, C., B. D. Proctor, et al. (2006). Income, Poverty, and Health Insurance Coverage in the United States: 2005. Washington, DC, U.S. Census Bureau**:** 60-231.

Dranove, D., M. Satterthwaite, et al. (1986). "The effect of injecting price competition into the hospital market: the case of preferred provider organizations." Inquiry **23**(4): 419-31.

Dranove, D. and M. A. Satterthwaite (1992). "Monopolistic Competition when Price and Quality are Imperfectly Observable " The Rand Journal of Economics **23**(4): 518-534.

Dranove, D. and M. Shanley (1995). "Cost Reductions or Reputation Enhancement as Motives for Mergers: the Logic of Multihosipital Systems." Strategic Management Journal **16**(1): 55-74.

Dranove, D., M. Shanley, et al. (1992). "Is Hospital Competition Wasteful? ." The Rand Journal of Economics **23**(2): 247-262.

Dunn, D. L. and M. Chen (1994). "Uncompensated hospital care payment and access for the uninsured: evidence from New Jersey." Health Serv Res **29**(1): 113-30.

Feldstein, M. S. (1971). "Hospital Cost Inflation: A Study of Nonprofit Price Dynamics." The American Economic Review **61**(5): 853-872.

Folland, S., M. Stano, et al. (2004). The economics of health and health care. Upper Saddle River, NJ, Pearson Prentice Hall.

Ford, J. M. and D. L. Kaserman (1993). "Certificate-of-Need Regulation and Entry: Evidence from the Dialysis Industry." Southern Economics Journal **59**: 783-791.

Fournier, G. M. and E. S. Campbell (1997). Indigent Care as Quid Pro Quo in Hospital Regulation. **79:** 669-673.

Frank, R. G. and D. S. Salkever (1991). "The supply of charity services by nonprofit hospitals: motives and market structure." Rand J Econ **22**(3): 430-45.

Fraser, I. (1990). Direct Financing of Uncompensated care: Critical Questions in the Use and Evaluation of Uncompensated Care Pools and Other Provider Focused Approaches, American Hopsital Association.

GAO (1997). Not-for-profit: Conversion Issues Prompt Increased State Oversight. Washington D.C. , United States General Accounting Office.

GAO (2006). Not-for-profit, For-profit, and Government Hospitals: Uncompensated Care and Other Community Benefits. Washington D.C. , United States General Accounting Office.

Gaskin, D. J. (1997). "Altruism or moral hazard: the impact of hospital uncompensated care pools." J Health Econ **16**(4): 397-416.

Gaynor, M. and W. Vogt (2000). Antitrust and Competition in Health Care Markets. Handbook of Health Economics. J. Newhouse and A. Culyer. Amsterdam, Elsevier. **1B:** 1405-1487.

Ginn, G. O. and C. B. Moseley (2006). "The impact of state community benefit laws on the community health orientation and health promotion services of hospitals." J Health Polit Policy Law **31**(2): 321-44.

Gray, B. H. (1991). The profit motive and patient care : the changing accountability of doctors and hospitals. Cambridge, Mass., Harvard University Press.

Gresenz, C. R., J. Rogowski, et al. (2004). "Updated variable-radius measures of hospital competition." Health Serv Res **39**(2): 417-30.

Gruber, J. (1994). "The Effect of Competitive Pressure on Charity: Hospital Response to Price Shopping in California." Journal of Health Economics **38**: 163-212.

Hausman, J. A. (1978). "Specification Tests in Econometrics." Econometrica **46**(6): 1251-1271.

Hausman, J. A. and W. E. Taylor (1981). "Panel data and unobservable individual effects." Econometrica **49**(6): 1377-1398.

Hellinger, F. J. (1995). "Any-willing-provider and freedom-of-choice laws: an economic assessment." Health Aff (Millwood) **14**(4): 297-302.

Horwitz, J. R. (2005). "Making profits and providing care: comparing nonprofit, for-profit, and government hospitals." Health Aff (Millwood) **24**(3): 790-801.

Jacobson, P. D., V. K. Dalton, et al. (2005). "Survival strategies for Michigan's health care safety net providers." Health Serv Res **40**(3): 923-40.

Joskow, P. L. and R. G. Noll (1981). Regulation in Theory and Practice: An Overview. Studies in public regulation. G. Fromm. Cambridge, Mass., MIT Press.

Kessler, D. P. and M. B. McClellan (2000). "Is Hospital Competition Socially Wasteful." The Quarterly Journal of Economics **May**: 577-615.

Lanning, J. A., M. A. Morrisey, et al. (1991). "Endogenous hospital regulation and its effects on hospital and non-hospital expenditures " Journal of Regulatory Economics **3**(2): 137-154.

Lee, K. H. and M. P. Roh (2007). "The impact of payer-specific hospital case mix on hospital costs and revenues for third-party patients." J Med Syst **31**(1): 1-7.

Lee, S. Y., J. A. Alexander, et al. (2003). "Whom do they serve? Community responsiveness among hospitals affiliated with health systems and networks." Med Care **41**(1): 165-79.

Lewin-ICF and A. Center (1991). Evaluation of the Ohio Certificate of Need Program, Ohio Department of Health.

Liu, C. F., A. E. Sales, et al. (2003). "Case-mix adjusting performance measures in a veteran population: pharmacy- and diagnosis-based approaches." Health Serv Res **38**(5): 1319-37.

Luft, H. S., J. C. Robinson, et al. (1986). "The role of specialized clinical services in competition among hospitals." Inquiry **23**(1): 83-94.

Mann, J. M., G. A. Melnick, et al. (1997). "A profile of uncompensated hospital care, 1983-1995." Health Aff (Millwood) **16**(4): 223-32.

McDonough, J. (1997). "Tracking The Demise Of State Hospital Rate Setting." Health Affairs **16**(1): 142-149.

Mendelson, D. N. and J. Arnold (1993). "Certificate of Need revisited." Spectrum **66**(1): 36-44.

Needleman, J., J. Lamphere, et al. (1999). "Uncompensated care and hospital conversions in Florida." Health Aff (Millwood) **18**(4): 125-33.

Newhouse, J. (1970). "Toward a theory of nonprofit institutions: an economic model of a hospital." American Economic Review **60**(1): 64-74.

Noble, A., A., A. Hyams, L., et al. (1998). "Charitable hospital accountability: A review and analysis of legal and policy initiatives." The Journal of Law, Medicine & Ethics **26**(2): 116.

Norton, E. C. and D. O. Staiger (1994). "How hospital ownership affects access to care for the uninsured." Rand J Econ **25**(1): 171-85.

Ohsfeldt, R. L., M. A. Morrisey, et al. (1998). "The spread of state any willing provider laws." Health Serv Res **33**(5 Pt 2): 1537-62.

Pauly, M. V. (1987). "Nonprofit firms in medical markets." American Economic Review **77**(2): 257-262.

Peltzman, S. P. (1976). "Toward a more general theory of regulation." Journal of Law and Economics **19**(211-240).

Peltzman, S. P. (1989). "The Economic Theory of Regulation after a Decade of Deregulation." Brookings Papers on Economic Activity **1989**: 1-59.

Posner, R. A. (1971). "Taxation by Regulation." The Bell Journal of Economics and Management Science **2**(1): 22-50.

Proenca, E. J., M. D. Rosko, et al. (2000). "Community orientation in hospitals: an institutional and resource dependence perspective." Health Serv Res **35**(5 Pt 1): 1011-35.

Robinson, J. C. and H. S. Luft (1987). "Competition and the cost of hospital care, 1972 to 1982." Jama **257**(23): 3241-5.

Rosenau, P. V. (2003). "Performance Evaluations of For-profit U.S. Hospitals Since 1980." Nonprofit Management and Leadership **13**(4): 401-423.

Rosenau, P. V. and S. H. Linder (2003). "Two Decades of Research Comparing For-profit and Nonprofit Health Provider Performance in the United States." Social Science Quarterly **84**(2): 219-241.

Rosko, M. D. (2004). "The supply of uncompensated care in Pennsylvania hospitals: motives and financial consequences." Health Care Manage Rev **29**(3): 229-39.

Rundall, T. G., S. Sofaer, et al. (1988). "Uncompensated hospital care in California: private and public hospital responses to competitive market forces." Adv Health Econ Health Serv Res **9**: 113-33.

Salkever, D. S. (2000). Regulation of Prices and Investment in Hospitals in the United States. Handbook of Health Economics. A. J. Culyer and J. P. Newhouse, Elsevier Science. **1:** 1490-1532.

Santerre, R. E. and J. A. Vernon (2006). "The consumer welfare implications of the hospital ownership mix in the US: an exploratory study." Health Econ **15**(11): 1187-99.

Schlesinger, M., R. Dorwart, et al. (1997). "Competition, ownership, and access to hospital services. Evidence from psychiatric hospitals." Med Care **35**(9): 974-92.

Schlesinger, M. and B. H. Gray (2006). "How nonprofits matter in American medicine, and what to do about it." Health Aff (Millwood) **25**(4): W287-303.

Sloan, F. A., M. A. Morrisey, et al. (1988). "Effects of the Medicare prospective payment system on hospital cost containment: an early appraisal." Milbank Q **66**(2): 191-220.

Spencer, C. S. (1998). "Do uncompensated care pools change the distribution of hospital care to the uninsured?" Journal of Health Politics, Policy and Law **23**(1): 53.

Spencer, C. S. (1998). "Do uncompensated care pools change the distribution of hospital care to the uninsured?" J Health Polit Policy Law **23**(1): 53-73.

Stigler, G. J. (1971). "The Theory of Economic Regulation." The Bell Journal of Economics and Management Science **2**(1): 3-21.

Teske, P. E. (2004). Regulation in the states. Washington, D.C., Brookings Institution Press.

Thorpe, K. E. (1988). "Uncompensated care pools and care to the uninsured: lessons from the New York Prospective Hospital Reimbursement Methodology." Inquiry **25**(3): 344-53.

Thorpe, K. E., C. S. Florence, et al. (2000). "Hospital conversions, margins, and the provision of uncompensated care." Health Aff (Millwood) **19**(6): 187-94.

Thorpe, K. E. and C. E. Phelps (1991). "The Social Role of Not-for-Profit Organizations: Hospital Provision of Charity Care." Economic Inquiry **29**(3): 472.

Thorpe, K. E. and C. Spencer (1991). "How do uncompensated care pools affect the level and type of care? Results from New York State." J Health Polit Policy Law **16**(2): 363-81.

Turnock, B. J. and C. Atchison (2002). "Governmental public health in the United States: the implications of federalism." Health Aff (Millwood) **21**(6): 68-78.

Viscusi, W. K., J. E. Harrington, et al. (2005). Economics of regulation and antitrust. Cambridge, Mass., MIT Press.

Volpp, K. G. M., J. D. Ketcham, et al. (2005). "The Effects of Price Competition and Reduced Subsidies for Uncompensated Care on Hospital Mortality." Health services research **40**(4): 1056-1077.

Weiner, J. P., B. H. Starfield, et al. (1991). "Development and application of a population-oriented measure of ambulatory care case-mix." Med Care **29**(5): 452-72.

Wendling, W. and J. Werner (1980). "Nonprofit firms and the economic theory of regulation." Quarterly Review of Economics and Business **Autumn**: 6-18.

Winston, C. (1993). "Economic Deregulation: Days of Reckoning for Microeconomists." Journal of Economic Literature **31**(3): 1263-1289.

Wong, H. S., C. Zhan, et al. (2005). "Do Different Measures of Hospital Competition Matter in Empirical Investigations of Hospital Behavior?" Review of Industrial Organization **26**: 61-87.

Young, G. J. and K. R. Desai (1999). "Nonprofit hospital conversions and community benefits: new evidence from three states." Health Aff (Millwood) **18**(5): 146-55.

Young, G. J., K. R. Desai, et al. (1997). "Does the sale of nonprofit hospitals threaten health care for the poor?" Health Aff (Millwood) **16**(1): 137-41.

VITA

LEI ZHANG

Lei Zhang was born in Huhhot, Inner Mongolia, China. She received a B.A. in English from Shanghai International Studies University in China in 1999 and an M.P.A. from Ohio University in Athens, Ohio, in 2003 before coming to Georgia State University/ Georgia Institute of Technology to pursue a joint doctorate in Public Policy. Her research interest spans health policy analysis, public health research as well as program evaluation.

While pursuing her Ph.D. degree, Zhang worked as a Graduate Research Assistant at the Georgia Health Policy Center for three years. From 2006-2008, she was a research fellow with the Centers for Disease Control and Prevention (CDC), Atlanta, Georgia. Her research involves designing and conducting professional program evaluations as well as qualitative and quantitative data analysis.

Zhang is a member of several professional associations including the Atlanta Area Evaluation Association, American Evaluation Association, Academy Health, and AcademyHealth Health Economics Interest Group.

FULL TEXT LINKS

DUKE UNIVERSITY PRESS JHPPL

> J Health Polit Policy Law. 1993 Winter;18(4):905-25. doi: 10.1215/03616878-18-4-905.

Certificate-of-need deregulation and indigent hospital care

E S Campbell [1], G M Fournier

Affiliations
PMID: 8120351 DOI: 10.1215/03616878-18-4-905

Abstract

For almost twenty years certificate-of-need (CON) regulations have protected existing hospitals from unrestricted competition in services. Although the explicit purpose of CON regulation was to prevent hospitals from duplicating services and investing in costly excess capacity, it has been unsuccessful in accomplishing this goal. On the other hand, CON policies have, we suggest, been pursued with the implicit aim of "cross subsidization," that is, regulators have used their power to issue licenses and restrict competition in order to create an incentive to hospitals to provide high levels of care to the indigent population. Posner (1971) has noted that to achieve cross subsidization, entry into lucrative services must be restricted. We present evidence that CON licenses have been used to promote the internal subsidization of indigent care in probit analysis, based on data from Florida spanning the period 1983-89. While this method of financing indigent care may be preferred by legislators who do not want to face the political consequences of raising taxes to pay for the service, it has troubling implications for the hospital provision of indigent care, especially in an era of CON deregulation.

Comment in

New wine in old bottles: certificate of need enters the 1990s.
Hackey RB.
J Health Polit Policy Law. 1993 Winter;18(4):927-35. doi: 10.1215/03616878-18-4-927.
PMID: 8120352

LinkOut - more resources

Full Text Sources

Silverchair Information Systems

WEB EXCLUSIVES

HEALTH AFFAIRS > VOL. 24, NO. SUPPL1: WEB EXCLUSIVES

Effects Of Physician-Owned Limited-Service Hospitals:Evidence From Arizona

Jean M. Mitchell

AFFILIATIONS

Jean Mitchell (mitchejm@georgetown.edu) is a professor of public policy in the Georgetown Public Policy Institute, Georgetown University, in Washington, D.C.

PUBLISHED: 2005 No Access https://doi.org/10.1377/hlthaff.w5.481

View Article

Abstract

ABSTRACT:

In recent years physician ownership of so-called limited-service hospitals has become commonplace in many states lacking certificate-of-need regulations. Empirical evidence documenting the effects of these facilities is sparse. This study compares practice patterns of physician-owners of limited-service cardiac hospitals and physician-nonowners who treat cardiac patients at competing full-service community hospitals. Analyses of six years of Arizona inpatient discharge data show that physician-owners

TOPICS

DIAGNOSIS-RELATED GROUPS | HOSPITALS | PHYSICIAN OWNERSHIP | COMORBIDITY | PATIENT CARE | MARKETS | MEDICARE | PAYMENT | CASE MIX | FEE-FOR-SERVICE

Loading Comments...

1220 19th Street, NW, Suite 800

Washington, DC 20036

T 202 408 6801

F 301 654 2845

customerservice@healthaffairs.org

Journal of Health Economics 37 (2014) 198–218

Contents lists available at ScienceDirect

Journal of Health Economics

journal homepage: www.elsevier.com/locate/econbase

Do hospitals cross-subsidize?

Guy David[a], Richard C. Lindrooth[b,*], Lorens A. Helmchen[c], Lawton R. Burns[a]

[a] University of Pennsylvania, United States
[b] University of Colorado Anschutz Medical Campus, United States
[c] George Mason University, United States

ARTICLE INFO

Article history:
Received 7 May 2012
Received in revised form 24 March 2014
Accepted 2 June 2014
Available online 19 June 2014

JEL classification:
I11
L1
L33

Keywords:
Hospital markets
Cross-subsidies
Specialty hospitals

ABSTRACT

Despite its salience as a regulatory tool to ensure the delivery of unprofitable medical services, cross-subsidization of services within hospital systems has been notoriously difficult to detect and quantify. We use repeated shocks to a profitable service in the market for hospital-based medical care to test for cross-subsidization of unprofitable services. Using patient-level data from general short-term hospitals in Arizona and Colorado before and after entry by cardiac specialty hospitals, we study how incumbent hospitals adjusted their provision of three uncontested services that are widely considered to be unprofitable. We estimate that the hospitals most exposed to entry reduced their provision of psychiatric, substance-abuse, and trauma care services at a rate of about one uncontested-service admission for every four cardiac admissions they stood to lose. Although entry by single-specialty hospitals may adversely affect the provision of unprofitable uncontested services, these findings warrant further evaluation of service-line cross-subsidization as a means to finance them.

1. Introduction

Mechanisms internal to the firm are often promoted to achieve social goals. In health care markets, cross-subsidies are often considered the principal mechanism[1] through which hospitals provide otherwise unprofitable care (Phelps, 1986; Norton and Staiger, 1994; Banks et al., 1997, 1999; Horwitz, 2005; David and Helmchen, 2006; Vladeck, 2006; Chen et al., 2009). While there is evidence of regulation-driven cross-subsidization of otherwise unprofitable services in the transportation and telecommunications industries (Brennan, 1990; Banks et al., 1999; Nicolas, 1991; Chevalier, 2004), evidence of cross-subsidization in the hospital industry remains largely anecdotal and its extent is not well documented.

Cross-subsidization of individually unprofitable service lines within hospitals is not transparent from an accounting perspective, and therefore direct observation of this practice and its extent is not possible. In this paper, we explore a novel approach to test empirically whether hospitals cross-subsidize purportedly unprofitable services. Specifically, we study shocks that affected only hospitals' profitable services and identify the presence and magnitude of cross-subsidization through their effect on unprofitable services.[2] We use single-specialty hospitals' entry in the market for select procedures as a shock that affects incumbent hospitals' profits[3,4] and argue that unprofitable services offered by incumbent hospitals will be affected if they rely financially on the profitable services contested by the entrant. In fact, the potentially adverse effects on general hospitals' ability to cross-subsidize unprofitable care led Congress to institute a moratorium in November 2003 that halted the construction of new single-specialty hospitals.[5]

* Corresponding author. Tel.: +1 303 724 5165; fax: +1 303 724 4620.
E-mail address: richard.lindrooth@ucdenver.edu (R.C. Lindrooth).

[1] Other mechanisms include DSH payments, bailouts, uncompensated care pools, tax exemptions, and donations. We examine each of these in the Discussion section.

[2] Unprofitable care, also referred to as *under-* and *uncompensated care*, includes free or discounted care, care that hospitals charge for but do not realistically expect to be reimbursed for (expected bad debt), as well as shortfalls from Medicare, Medicaid and other insurance. While U.S. hospitals provide approximately $30 billion in unpaid care annually, the practice of financing unprofitable care is not well understood (Nicholson et al., 2000; Vladeck, 2006).

[3] The federal law defines a specialty hospital as one that is "primarily engaged in the care and treatment of cardiac, orthopedic, or surgical patients" (MedPAC, 2005), omitting from this definition psychiatric, and long-term acute hospitals that also are all single-specialty hospitals.

[4] Reports by the Medicare Payment Advisory Committee (MedPAC) and the Government Accountability Office (GAO) found conflicting results on the effect of entry by specialty hospitals on community hospitals' revenues (MedPAC, 2005; GAO, 2003).

[5] While the moratorium ended in August 2006, no specialty hospitals entered the markets we study after this date.

http://dx.doi.org/10.1016/j.jhealeco.2014.06.007
0167-6296/

The success of single-specialty entrants relies on their ability to attract the most profitable components of the demand for the services they offer. To do so, single-specialty entrants carefully consider their potential competitors' provision of the contested services before entry. At the same time, these entrants are unlikely to consider explicitly the incumbents' provision of uncontested unprofitable services, as there is no evidence that these services help predict how an incumbent might respond to entry (Burns et al., 2011). Therefore, we posit that entry into a specific set of profitable services directly affects incumbents' profits but does not affect the incumbents' provision of unprofitable services except through the shock to profits.

Although the possibility of entry by specialty hospitals can challenge the financial resilience and mission-fulfillment capability of incumbent general hospitals, it is not clear if and how general hospitals reconfigure the scope, quantity, and quality of their uncontested service lines in response to entry.

The conditions for cross-subsidization across different service lines arise in part because reimbursement for Medicare fee-for-service and Medicaid admissions is based on administered prices set by the Federal and state governments. While private payers continuously adjust their reimbursement levels to changing supply and demand conditions, public payers seek to mimic these adjustments periodically. As a result, cross-subsidization is more likely to emerge in markets where public payers are the dominant form of insurance and price distortions may persist longer, allowing service lines to remain profitable or unprofitable before reimbursement levels are corrected. Variability in the generosity of reimbursement across service lines also exists in the private market because prices are a function of the ex-ante demand for services by the members of private health plans (Capps et al., 2003). To make their health plans more attractive to firms and their employees, insurers will pay a premium to ensure broad access for the treatment of common and predictable conditions.

Federal regulations also play a role in the persistence of profitable and unprofitable service lines. The Emergency Medical Treatment and Active Labor Act (EMTALA) limits hospitals' ability to discriminate among patients admitted via the Emergency Department based on patients' ability to pay. These patients must be stabilized before discharge regardless of payer. Thus, service lines that tend to attract a large number of underinsured or uninsured patients admitted via the Emergency Department tend to be less profitable. No such restrictions are placed on elective or urgent care if the patient is otherwise stable.

Hospitals (and their admitting physicians) may give preferential treatment to patients based on expected reimbursement, which could lead to higher average reimbursement for scheduled patients, as these patients are more likely to carry generous insurance coverage than emergently admitted patients. In addition, scheduled admissions may be less severe than emergent admissions, for which waiting was not a viable option. Moreover, hospitals that offer only scheduled services do not need to maintain costly surge capacity, which by definition is used only rarely. Finally, patients who can afford to schedule their surgery in advance are typically healthier and not as acutely ill as emergently admitted patients. Thus, hospitals offering only scheduled services will tend to attract patients with fewer comorbidities and a lower risk of complications, which are costly to manage during hospitalization. For these reasons, providers specializing in procedures that are scheduled in advance may realize cost savings that are not available to providers allowing emergent admissions.

We study the effect of entry by specialty cardiac hospitals in Arizona on the provision of psychiatric, trauma, and substance-abuse care by incumbent general hospitals.[6] These uncontested services are considered to be unprofitable (Horwitz, 2005; Vladeck, 2006; Chen et al., 2009; Huckman and Kolstad, 2011). We also test the effect of entry on incumbents' provision of neurosurgery, an uncontested but profitable service (Resnick et al., 2005; Lindrooth et al., 2013). The response by incumbent hospitals to a negative profitability shock allows us to study the reliance of select uncontested services on cross-subsidization. We study Arizona because entry occurred in two markets that are geographically well-delineated. In addition, entry was limited to cardiac specialty hospitals over a relatively short period of time, allowing us to use longer time series for the pre- and post-entry periods.

We find evidence that is broadly consistent with system-level cross-subsidization of services considered unprofitable. The evidence is robust to different specification and samples. In Section 2, we discuss our strategy for identifying cross-subsidization. Section 3 presents the methodology used for measuring hospitals' exposure to entry and its effect on the provision of unprofitable services. Section 4 describes the data. The results are discussed in Section 5. Section 6 concludes.

2. Entry by single-specialty hospitals

2.1. The entry decision by a single-specialty competitor

Most stand-alone specialty hospitals are for-profit entities (Hadley and Zuckerman, 2005; Guterman, 2006)[7] and many are at least partially owned by physicians (Cromwell et al., 2005; McClellan, 2005).[8] They enter when they expect to make a profit and aim to attract patients suited for standard, low-risk procedures that can be delivered profitably, leaving incumbent hospitals to treat disproportionately many high-risk patients with complex care requirements.[9] Consistent with this prediction, specialty hospitals have been found to be more profitable than general community hospitals when all payer types are considered (GAO, 2003; Iglehart, 2005), in part because specialty hospitals treat a lower percentage of severely ill patients than community hospitals (GAO, 2003; MedPAC, 2005; Barro et al., 2006; Mitchell, 2005; Cromwell et al., 2005; Greenwald et al., 2006; Cram et al., 2005).

Forward-looking potential entrants evaluate very carefully and strategically their prospects of success before they decide to offer services in a given location. A potential entrant will consider the likely demand for its services in the context of the competitiveness of hospitals that supply contested services near its preferred

---

[6] Tucson Heart Hospital entered Tucson in 1998 and was fully operational in 1999, Arizona Heart Hospital entered Phoenix in 1999, and Banner Baywood Heart Hospital entered Mesa in 2001.

[7] The Centers for Medicare and Medicaid Services define a specialty hospital as either: (1) a hospital where more than two-thirds of Medicare inpatients fall into no more than two Major Diagnostic Categories, which encompass a range of similar Diagnosis-Related Groups (DRGs), or (2) a hospital where two thirds or more of Medicare claims are from surgical DRGs (McClellan, 2005). The Government Accountability Office (GAO, 2003) identified nearly 100 stand-alone specialty hospitals in three major categories: cardiac (17 hospitals), orthopedic (36), surgical (22). Women's hospitals and other types of specialty hospitals made up the remainder.

[8] Physician ownership of specialty hospitals poses a particular organizational and financial challenge for general hospitals that compete in the same market. Physician-owners have a stake in the clinical and financial performance of the hospital and are a major source of patient referrals. Cardiac specialty hospitals in particular have a higher percentage of physician ownership on average than other types of specialty hospitals.

[9] Specialty hospitals tend to be concentrated in states that lack certificate-of-need (CON) laws; all specialty hospitals are located in 28 states, with two-thirds located in just 7 states (GAO, 2003). In addition, specialty hospitals tend to be located in high-growth metropolitan areas that lack a dominant community hospital, and that have a large, single-specialty physician practice group (Casalino et al., 2003).

location. This decision is based on characteristics of the suppliers of contested services but unlikely to be influenced by the market for uncontested services. Markets will not be selected for entry if incumbent hospitals are expected to succeed in deterring entry, for instance by allocating more resources to retain physicians attractive to single-specialty competitors (Dafny, 2005; Dobson and Haught, 2005; Berenson et al., 2007; Burns et al., 2011).

2.2. The response to entry by incumbents

Entry of specialty hospitals into a profitable service line will reduce incumbents' profits and thereby may compromise the ability of incumbent general hospitals to cross-subsidize unprofitable services (Shactman, 2005; Berenson et al., 2006; Schneider et al., 2007, 2008; Tynan et al., 2009; Al-Amin et al., 2010; Burns et al., 2011; Steinbuch, 2010). For instance, entry by single-specialty competitors will raise the bargaining power of physicians who provide the contested services if they can credibly threaten the incumbent hospitals with defecting to the entering specialty facilities.

To the extent that entry raises the number of competing providers in a market, it will tend to lower the time price of reaching the nearest provider and possibly lower fees and health insurance premia. For this reason, entry may adversely affect the provision of uncontested services if it constrains incumbent hospitals' ability to cross-subsidize less profitable or unprofitable services. For instance, cardiology and cardiovascular surgery diagnosis-related groups (DRGs) account for 25–40 percent of the average community hospital's net revenue (Casalino et al., 2003); entry by an aggressive competitor will put this revenue, and thus the incumbent's overall financial viability, at risk.

The incumbent's response to entry will depend on whether the fixed cost of changing its policies and service offerings is offset by improved future cash flows. Thus the effect of the shock on incumbents' uncontested services will be nonlinear in that only the hospitals and systems most affected will pursue the discrete changes necessary to scale back unprofitable admissions. Potential changes include reducing the admitting privileges of specialists in uncontested and unprofitable services; reducing the number of beds available for specific service lines; or even closing a service line altogether (Horwitz, 2005).

3. Methods

The econometric approach consists of two stages. First, we estimate the exposure of incumbent hospitals to single-specialty hospital entry into contested services. This variable, *exposure*, is calculated in three steps:

(1) estimate a model of patient choice of hospital for an admission,
(2) predict the annual number of admissions with and without the specialty hospital as an option, and
(3) calculate *exposure* using the difference in predicted annual admissions with and without specialty hospital entry. If multiple hospitals within a market were owned by the same hospital system, then *exposure* is aggregated to the system level by calculating the sum of each individual hospital's exposure within each system.

The specification of patient choice of hospital is based on a random-utility model and implemented using McFadden's conditional logit specification (McFadden, 1974). Our measure of exposure is an application of techniques originally developed to measure changes in admissions related to hospital closure in Capps et al. (2010).

The effect of *exposure* on utilization of uncontested services is estimated in the second stage. Utilization is modeled as a function of exposure using two dependent variables:

(1) the patient's choice of hospital for an admission requiring an uncontested service and
(2) the number of admissions for uncontested services.

The patient's choice of hospital is modeled using a conditional logit specification and the number of admissions is modeled using a generalized negative binomial count data model. The coefficients of the conditional logit specification are identified based on alternative-specific variation, in other words variation across hospitals within the patient's choice set. Patients value alternative-specific characteristics more or less depending on their location and diagnosis. In contrast the generalized negative binomial count data model uses within market variation between hospitals and over time. The unit of observation is the hospital and it collapses to a hospital choice model if one assumes that patients within each market are identical.[10]

The estimated coefficients of *exposure* measure how the utilization of uncontested services changed with the loss of profits on the part of the incumbent hospital, expressed as the estimated annual number of cardiac admissions that the incumbent would have lost to the entrant had it remained passive in the face of entry. *Exposure* can be interpreted as the degree of overlap between the incumbent and specialty hospital's service offerings and location in each time period. *Exposure* equals zero prior to entry and increases with the overlap between a specialty hospital's and the incumbent hospital's service offerings and catchment area. *Exposure* is lower for hospitals that did not offer the same services as specialty hospitals, even if their locations were proximate to one another. It also declines as the geographic distance between the incumbent hospital and the specialty hospital increases. The analysis also includes a control group that consists of hospitals that were not exposed because of their location, because they did not offer enough contested services, or both.[11]

3.1. Provision of contested services

A patient's choice of hospital for an admission is based on a random utility model of the utility of an admission to hospital h in year t:

$$U_{hit}(H_{h,pre}, T_{hi}, X_{it}, D_{it}, S_{h,pre}, \gamma_h) = \beta_1 H_{h,pre} + \tau_1 T_{hi} + \tau_2 T_{hi} \cdot X_{it} + \beta_2 D_{it} \cdot H_{h,pre} + \beta_3 D_{it} \cdot S_{h,pre} + \tau_3 T_{hi} \cdot \gamma_h + \varepsilon_{hit} \quad (1)$$

where U_{hit} is patient i's utility of receiving care at hospital h in year t, $H_{h,pre}$ is a vector of cardiac service offerings at hospital h prior to entry or in the case of single-specialty hospitals upon entry; T_{hi} is the approximate travel time from the zip code of patient i's residence to hospital h; X_{it} is a column vector reflecting patient characteristics and clinical attributes that affect hospital choice; D_{it}

[10] Guimarães and Lindrooth (2007) describe the link between individual choices based on a random utility model and a (conditional) fixed effect negative binomial count data model when patient can be grouped by common characteristics. In the current paper, the negative binomial count data model is estimated at the hospital level and thus ignores all within-market variation in patient characteristics including location and diagnosis group.

[11] All hospitals admitted cardiac patients. However several hospitals did not offer cardiac surgery which significantly lowered their degree of exposure, as admissions to specialty hospitals are predominantly surgical.

is a column vector reflecting the patient's diagnosis related group (DRG); $S_{h,pre}$ is a vector of cardiac service offerings at the system that owns hospital h, and γ_h is a hospital fixed effect.[12] The interactions between $H_{h,pre}$ and D_{it} control for access to surgical services relative to the patient's diagnosis and $S_{h,pre}$ and D_{it} control for access to surgical services at other locations within the hospital's system. This is necessary because within-system transfers and referrals will influence where a patient is admitted.

We deliberately hold general hospital and system-wide service offerings fixed over the entire sample period because our objective is to estimate the effect of entry by comparing estimates of the number of admissions with and without specialty hospital entry. We posit that, after adjusting for changes in patient characteristics, hospitals that dropped cardiac services did so in response to entry; therefore, we hold their service offerings constant at their pre-entry level. If we included contemporaneous service offerings, our estimate of the effect of entry would be biased substantially downward for hospitals that dropped services.

Under the logit demand assumption, the predicted probability s of a patient with characteristics (T_{hi}, X_{it}, D_{it}) of choosing a given hospital h from a set of G hospitals available at time t, is

$$s(G_t, X_{it}, D_{it}, T_{hi}) = \frac{\exp[U(H_{h,pre}, T_{hi}, X_{it}, D_{it}, S_{h,pre}, \gamma_h)]}{\sum_{g \in G_t} \exp[U(H_{g,pre}, T_{gi}, X_{it}, D_{it}, S_{g,pre}, \gamma_g)]} \tag{2}$$

The parameter estimates from Eq. (2) are used to calculate the expected number of cardiac admissions in each year over the entire sample period at the system and individual hospital levels, denoted $E(Admissions^{entry}_{st})$ and $E(Admissions^{entry}_{ht})$ respectively. This is done by summing the predicted probabilities over all the hospitals in a system or individual hospitals, respectively. We follow Capps et al. (2010) and simulate the number of system and individual hospital cardiac admissions had entry not occurred, denoted $E(Admissions^{no\ entry}_{st})$ and $E(Admissions^{no\ entry}_{ht})$. This is done by eliminating the single-specialty hospital from the choice set G and re-normalizing the predicted probabilities in Eq. (2) so that they sum to one. For each provider p (individual hospital or system), the estimated change in admissions resulting from entry is[13]:

$$\Delta Admissions_{pt} = Exposure_{pt} = Admissions^{Entry}_{pt} - Admissions^{No\ entry}_{pt} \tag{3}$$

Eq. (3) is the estimated change in incumbents' admissions for the contested service that is attributable to entry. Under this definition, the more closely prospective patients view the entering competitor's services as substitutes for the incumbent's, the more exposed the incumbent will be to entry. Accordingly, we model the response to entry such that an incumbent hospital will respond to entry only when $\Delta Admissions_{pt}$ is large enough to warrant the fixed costs of changing service offerings. We set $Exposure_{pt}$ equal to one if the absolute value of the estimated change in admissions is greater than a response threshold and zero otherwise[14]:

$$Exposure^{Threshold\%}_{pt} = \begin{cases} 1 & \text{if } |\Delta Admissions_{pt}| > \Delta Admissions^{Threshold\%} \\ 0 & \text{otherwise} \end{cases} \tag{4}$$

The estimate of *Exposure* is related to the well-known independence of irrelevant alternatives (IIA) assumption that underlies logit demand models in that a patient's ranking of two incumbent hospitals is unchanged by the addition or removal of a third hospital, including a single-specialty entrant.[15] The simulation without specialty hospitals allocates all specialty-hospital admissions to the incumbent hospitals. As a result, exposure reflects a decline in market share due to entry. If incumbents and specialty hospitals have similar propensities to admit and perform procedures on patients, as found by Stensland and Winter (2006), then this assumption is reasonable. However, if specialty hospitals perform surgeries and admit patients that would not have occurred in absence of the specialty hospital then we would over-estimate exposure. Even so, the ordering of hospitals would be unlikely to change because an increase in the total number of admissions related to entry will affect both $\Delta Admissions^{Threshold}$ and $\Delta Admissions_{ht}$ leaving the providers satisfying the threshold unchanged. For hospitals in systems, $\Delta Admissions^{Threshold}$ is based on the system-level exposure whereas the exposure of independent hospitals is measured using a threshold based on hospital-level exposure.

Entry will also affect the prices that hospitals charge private payers for the contested service. While we do not observe these prices, the effect of entry on private prices could be estimated by calculating the value of a given hospital to an insurance network with and without entry following the approach used by Capps et al. (2003) to measure the effect of hospital mergers on prices. This measure is highly correlated with estimates of the change in admissions due to entry, as both are based on the same parameters from a logit demand model. For this reason, it is not possible to identify price and quantity effects of entry separately. Thus, we make the simplifying assumption that the effect of entry on incumbent hospitals is proportional to the change in the number of admissions. This approach is bolstered by the fact that entry will have no direct or immediate effect on the reimbursement rates for services provided to Medicare and Medicaid beneficiaries.

We estimate Eq. (2) separately for the Denver, Phoenix, and Tucson markets using five years of admissions that span the pre- and post-entry periods. We also report results that use all years of data. We split the sample into surgical and medical admissions. Patients' choice sets are smaller for surgical admissions because surgeries are more invasive and require specialized skills and equipment. Thus fewer hospitals invest in the capability to perform cardiac surgeries than minimally invasive medical admissions. Another reason why we stratify between surgical and medical admissions is that surgical admissions constitute a relatively large share of admissions at specialty hospitals and thus the degree of service

[12] A patient/admission fixed effect could be included to represent an idiosyncratic error related to the patient's utility. However, a patient-specific idiosyncratic error does not vary by hospital in the choice set and is irrelevant to the predicted probability of admission (see McFadden, 1974 or Train, 2003). Empirically, a patient/admission fixed effect is included in the conditional logit specification of a McFadden choice model. The dataset used to estimate a conditional logit model is organized such that one observation reflects the characteristics of a hospital in the patient's choice set. As a result, there are H observations related to each admission, where H denotes the number of hospitals in the patient's choice set. The patient/admission fixed effect represents the node for each decision.

[13] For the single-specialty entrant $E(Admissions^{no\ entry})$ will equal zero.

[14] We used three response thresholds which correspond to the top 25th, 50th, and 75th percent of exposure.

[15] This assumption is reasonable in our specification because, as is described below, we stratified the sample by diagnosis and estimated the model for medical and for surgical admissions separately. Furthermore, within these diagnosis and procedure categories we interacted the clinical supply characteristics of each hospital with the clinical diagnosis characteristics of each patient and also control for travel time from the patient's zip code to each hospital in the choice set. Patients reach each diagnosis node, not by choice, but by nature of their illness. Clearly if specialty hospitals induce demand for more intensive services then our specification that limits the IIA assumption to within diagnosis cells would lead to higher estimates of exposure. However, it would not affect our analysis of uncontested services because the system ranking of exposure would be unchanged.

overlap is greater for hospitals that offer cardiac surgery. If we pooled each type of admission then we would underestimate the exposure of hospitals that offer cardiac surgery and overestimate it at hospitals that only offer medical services.

We control for the hospital and system supply of cardiac catheterizations and open-heart surgery interacted with a patient's diagnosis in the choice model. Thus, if a patient has a diagnosis that requires heart surgery the interaction will control for hospitals that offer heart surgery and zero otherwise. We also control for whether the patient had HMO coverage because this may affect travel patterns and other patient characteristics. All patient characteristics are interacted with the natural log of drive time which serves to incorporate variation in patients' preferences across hospitals in the choice set. Variation in the estimate of *exposure* is in large part due to overlap in services offerings with the new entrant as well as proximity to the new entrant. Eq. (2) is estimated using a grouped conditional logit model in which the data are aggregated to groups of patients that share zip codes and the other patient characteristics in order to speed computation (Guimarães et al., 2003).

3.2. Provision of uncontested services

Utilization of uncontested services is also based on a random utility model where the utility patient i receives from an admission to hospital h in time t is:

$$U_{hit}(Exposure_{ht}, \gamma_h, X_i, T_{hi}) = \beta_1 Exposure_{ht} + \tau_1 T_{hi} + \tau_2 T_{hi} \cdot X_i + \tau_3 T_{hi} \cdot \gamma_h + \varepsilon_{hit} \quad (5)$$

where $Exposure_{ht}$ is a dichotomous variable that measures whether incumbent hospital h is exposed to entry at time t calculated using Eqs. (3) and (4); T_{hi} is the approximate travel time from patient i's residence's zip code to hospital h. X_i is a vector of patient characteristics and clinical attributes that affect demand for inpatient services and γ_h is a hospital fixed effect. The final term in (4), ε_{hit}, represents the personal and idiosyncratic component of patient i's utility of admission to hospital h at time t.

There are a number of ways exposed hospitals can reduce the supply of unprofitable uncontested services. They could reduce the number of beds available for those services, limit admitting privileges of physicians in uncontested specialties, or completely close the service line. Each of these will decrease the attractiveness of a hospital relative to its competitors and thus reduce the expected utility and likelihood of an admission to the exposed hospital. An additional mechanism lies in patients' idiosyncratic valuation of a hospital. As is common in hospital choice models, we treat a patient's choice of a physician as occurring in tandem with the choice of a hospital. Put differently, we assume that the attractiveness of individual physicians to the patient is encompassed in the patient's valuation of a hospital's idiosyncratic attributes. Thus if exposed hospitals reduce the supply of uncontested services by limiting the admitting privileges of specialists, the expected utility of an admission to an exposed hospital will also be lowered relative to its competitors.

Under the logit demand assumption, the predicted probability of a patient with characteristics (X_i, T_{hi}) of choosing a given hospital h from a set of G hospitals available at time t, is

$$\tilde{s}(G_t, X_i, T_{hi}, Exposure_{ht}, \gamma_h) = \frac{\exp[U(Exposure_{ht}, \gamma_h, X_i, T_{hi})]}{\sum_{g \in G_t} \exp[U(Exposure_{gt}, \gamma_g, X_i, T_{gi})]} \quad (6)$$

The parameter associated with $Exposure_{ht}$ measures the effect of entry in contested services on the probability a patient will be admitted to hospital h for an uncontested service. As we described above, $Exposure_{ht}$ equals one if hospital h is above the exposure threshold described in Eq. (3) in year t and zero otherwise.

Recall that the estimate of latent exposure to entry is a function of a hospital or system's exogenous supply of cardiac catheterizations and open-heart surgery. The provision of cardiac services prior to entry is unlikely to independently affect the provision of uncontested services, except through incumbent hospitals' exposure to entry and thus specialty service offerings function as an instrument for our estimate of the true, unmeasured effect of entry. Thus the coefficient on $Exposure_{ht}$ reflects variation in exposure due to overlap in services offerings with the new entrant as well as proximity to the new entrant within the market. To minimize any potential omitted-variable bias, we also instrument for the proximity of the incumbent hospital to the new entrant with measures of the demand for cardiac services in each hospital's catchment area in addition to service offerings as instruments. The results are similar to those presented here and are reported in David et al. (2011).

The specification in Eq. (6) is more parsimonious than the one used for cardiac services. We do not control for specialty service offerings that vary over time because hospital administrators may add or drop these services in response to entry and the inclusion of these changes over time would yield inconsistent estimates of the effect of exposure on the provision of uncontested services. As a result, our estimates capture all changes in specialty services offerings at more exposed hospitals relative to less exposed ones.

We estimate Eq. (6) using a conditional logit model and calculate standard errors with patient/admission-level clustering. The observations in the conditional logit model are nested around each admission (or choice) such that there is an observation for each hospital in the choice set for each admission but only one hospital is selected. The standard errors within each nest (i.e. admission) are naturally clustered because they reflect the same decision and if one hospital is selected than the other hospitals are not selected by definition. Our specification is analogous to a difference-in-differences approach where the sample consists of admissions pre- and post-entry, the treatment is exposure to entry if the hospital is exposed in the post-entry period, and the outcome is the probability of an admission. The control group consists of hospitals located in Arizona (Phoenix or Tucson) that were least exposed to entry, i.e. whose predicted change in admissions for the contested service did not cross the threshold, as well as hospitals located in Colorado, which did not experience entry during the study period.[16]

While the patient-level specification takes advantage of information about the location of each patient's residence and condition in relation to each hospital in the market, it does not allow us to examine whether the absolute number of admissions declined at specific exposed hospitals or in the market as a whole. In other words, the specification does not measure the effect of exposure on the probability of admission to *any* hospital and does not yield insight into whether access to uncontested services was reduced and fewer patients were admitted in the market. To examine whether the absolute number of admissions was affected we estimate a hospital-level specification in which the annual number of admissions for each uncontested service is modeled as a function of the degree of exposure after entry using generalized negative binomial regression with market and year fixed effects and other control variables.[17] This model is estimated using the measure of exposure described above. The hospital-level analysis also enables us to

[16] Overall the results are robust to excluding Colorado and thus do not reflect unusual trends in Colorado. The inclusion of Colorado does increase efficiency.

[17] Specification tests revealed that the data exhibited over-dispersion and that the degree of over-dispersion was a function of the market and a fixed indicator of whether the hospital was ever exposed to entry. Therefore we use a generalized

model alternative specifications for contemporaneous trends that are not feasible in the admission-level analysis. We estimate a variety of specifications of market-specific trends in the annual number of admissions including: market-year dummy variables; market-specific linear trends; market-specific linear trends plus a separate trend for exposed hospitals; and market-specific quadratic trends. We treat the specification with market-year dummy variables as the primary specification because it is most consistent with the patient-level choice model. Alternative specifications of trend are not possible in the conditional logit model because the formulation of the random utility model relies solely on alternative-specific variation at the time of the admission and thus controls for all characteristics that do not vary across hospitals in a patient's choice set.

We also estimate models that control for consolidations that occurred during the sample period. There were several changes in system ownership between the pre and post periods of our sample. These changes occurred in both Arizona and Colorado and affected both exposed and unexposed hospitals. It is not clear whether the system acquisitions during the time period were related to entry of the specialty hospitals. For example, Banner Health System acquired hospitals in other markets in both Arizona and Colorado that were not exposed to entry, possibly implying that it was system-wide decision. The system itself was formed by combining Lutheran and Samaritan Health Systems. It is not possible to conclusively determine whether Banner Health System's acquisitions or any of the other system acquisitions were due to specialty hospital entry. On the one hand, exposed hospitals may be candidates for an acquisition if the acquirer feels it can increase efficiency by realigning service lines and increasing value by reducing unprofitable services. On the other hand, increased market power through consolidation may reduce the strain of entry on profits through increased private prices. Thus it may either facilitate the reduction of uncontested service volume or, in the case of higher prices, lessen the need to reduce volume in uncontested services. Thus we control for system consolidations and test whether there was a differential response among exposed and unexposed systems that acquired new hospitals.

To provide context and an understanding of the contemporaneous trends we also estimate a linear model of hospital admissions with hospital fixed effects. The results of this specification provide the adjusted mean number admissions and trends. Finally, we estimate the model of hospital admissions using a coarse market-level measure of exposure that equals one if the market experienced entry and zero otherwise. The market-level measure compares the difference in admissions pre and post entry in markets with entry to markets that did not experience entry.

4. Data

Our primary dataset is the Healthcare Cost and Utilization Project (HCUP) State Inpatient Database (SID) compiled by the Agency for Healthcare Research and Quality (2006). The HCUP-SID includes the inpatient discharge abstracts from virtually all non-federal general and all specialty cardiac hospitals in Arizona and Colorado of all patients discharged between 1997 and 2007. The patient's choice set of hospitals was defined in the Phoenix, Tucson, and Colorado's front range (including Boulder, Colorado Springs, and Denver) markets based on hospitals that provided contested and uncontested services. Colorado borders Arizona to the northeast, and the front range of Colorado is similar to the Phoenix and Tucson markets in a number of ways. Both states have major population centers that are well delineated by geography from surrounding areas. The front range of Colorado is bordered by the Rocky Mountains to the west and semi-arid grasslands to the east. Similarly, Phoenix and Tucson are surrounded by the Sonoran Desert to the south and west and mountains to the north. These markets have a comparable presence of large local and national systems, reflecting similar regulatory environments. In addition, and perhaps most importantly, there was no specialty cardiac hospital entry in Colorado during the time period we study.

In our preferred specification, we limit the sample to a pre-period 1997–1998 and a three-year post-period 2005–2007 in order to allow for an adjustment period related to the shock. We exclude the adjustment period in 1999–2004 because specialty hospitals gradually increased their admissions and market share over time and because the adjustment process at incumbent hospitals is also likely to be slow. We also estimate the models using the entire 1997–2007 sample and include the results for comparison. However, we treat the pre–post sample as our primary specification because it allows for a lag between entry and the subsequent effect on hospitals' profits and thereby decisions regarding service offerings.

In addition, it took several years before the growth in specialty hospital admissions leveled off. Out of the three entrants, Tucson Heart Hospital opened in Tucson in 1998 and Arizona Heart Hospital opened in Phoenix in 1999. Both experienced rapid growth in 1999–2000 that leveled off after 2000. Banner Baywood Heart Hospital (originally known as Lutheran Heart Hospital) opened in the Phoenix suburb of Mesa in 2001. Banner Baywood Heart's admissions stabilized in 2003 after two years of rapid growth. Tucson and Arizona Heart Hospitals were opened by Medcath, Inc., a national specialty hospital chain. Tucson Heart Hospital was purchased by Carondelet Health System in 2006. In addition, several hospitals were purchased by systems between 1999 and 2003, possibly reflecting realignment to adapt to the new market structure.[18]

Our exposure measure is based on actual system ownership during the 2005–2007 period, since by construction the exposure measures for the pre-entry years 1997–1998 were zero. We use ownership in 2005–2007 because it corresponds to the time period when the adjustment to entry into cardiac services was complete. The estimate of exposure is stable for 2005–2007 such that the group of hospitals and systems in the top 25, 50, and 75 percent of exposure is stable. This may lead to an overestimate of exposure at hospital systems that acquired hospitals with cardiac units after cardiac admissions were reduced. Such acquisitions may also further reduce the impact through increased prices. Both of these will bias our estimates toward zero. As mentioned, we also estimate the models using data from the entire sample period and report these coefficients for comparison. However, the preferred specification excludes 1999–2004 because hospital ownership, and also the estimated level of exposure, was relatively stable during the 2005–2007 period.

version of the negative binomial regression and explicitly model the degree of overdispersion.

[18] Several health systems in Arizona are affected by using 2005–2007 ownership for the entire time period: Banner Baywood Health System; Carondelet; Triad; Tucson Medical Center Healthcare and Vanguard Health System. Banner Baywood Health System was created through the merger of Lutheran Health Systems and Samaritan Health System. Thus Lutheran and Samaritan Health System hospitals are treated as though they were both owned by Banner Baywood during the entire time period. Tucson Medical Center purchased El Dorado Hospital in 2003 and closed the hospital in 2005. Finally, Vanguard Health System, a for-profit hospital chain, entered the Phoenix market through the purchase of the nonprofit Baptist Health System; a former Samaritan hospital; a for-profit hospital previously owned by Triad; and the for-profit Phoenix Memorial Hospital between 1999 and 2001. These hospitals are treated as though they were owned by Vanguard Health System throughout the time period.

Admissions for a contested service are defined as an admission in the Circulatory System Major Diagnostic Category (MDC 5). We examine the following uncontested services: psychiatry (MDC 19); substance abuse treatment (MDC 20); and trauma (MDC 24), all commonly considered to be unprofitable services (Horwitz, 2005; Vladeck, 2006; Chen et al., 2009). We also estimate the models for neurosurgery admissions (defined using surgical diagnosis-related groups [DRGs]).[19] In contrast to psychiatric, substance-abuse, and trauma services, neurosurgery has been shown to be profitable throughout the time period (Lindrooth et al., 2013). As neither market in Arizona experienced entry into neurosurgery, we predict that those incumbents most exposed to entry raised, rather than reduced, the number of neurosurgery discharges.[20] We restricted the sample to persons who were admitted within their state of residence to a hospital with at least 36 admissions for diagnoses in the respective service line in at least one of the sample years. Thus admissions at hospitals with relatively few admissions in all sample years were excluded but admissions at hospitals that grew or reduced service line admissions are included in the sample. As would be expected, the results using a more inclusive restriction of at least 24 admissions are quantitatively smaller than the results presented here but are of similar statistical significance.

Emergency admissions are identified using the admission type associated with the discharge. We do not distinguish between admissions from each payer because several hospitals, and importantly one cardiac specialty hospital, did not consistently report payer type in the HCUP-SID data during the sample period. However, the potential bias from excluding payer type is minimized because the majority of admissions for cardiac care are either Medicare or private and Medicaid and self-pay admissions for cardiac care are relatively rare. We did, however, include a dummy variable that indicates if the payer was in a Medicare, Medicaid or private health maintenance organization (HMO) to control for the fact that HMOs use selective contracting which could result in idiosyncratic differences in travel patterns for these patients.

Travel times from the centroid of each patient zip code to the address of the closest hospital-based service are calculated using data from Mapquest, Inc. (Mapquest, 2010). In the psychiatry sample we included the drive time to closest private specialty psychiatric hospital as a covariate to control for secular variation in access to substitutes to general hospital psychiatric admissions because the HCUP does not include discharges from specialty psychiatric hospitals. Three private psychiatric specialty hospitals closed during the sample period due largely to the bankruptcy of Charter Corporation, a national psychiatric-care chain.[21] By including drive times to psychiatric specialty hospitals, we control for the exit of these hospitals. As a result, our estimates reflect the adjustments in admissions for psychiatric care by incumbent hospitals once the profit-increasing impact of exit by psychiatric specialty hospitals is accounted for.

We link the SID files to data from the American Hospital Association (AHA) Annual Survey of Hospitals and the Centers for Medicare and Medicaid Services (CMS) Hospital Cost Report and Information Reporting System (HCRIS) to include additional hospital covariates. System membership, the existence of a cardiac catheterization lab, and open-heart surgery capability are also drawn from the AHA data. Net revenue per discharge and operating margins are from the HCRIS data. We also add median income at the ZIP-code level from the U.S. Census Bureau Population Estimates. Summary statistics for the patient and hospital covariates included in each uncontested service specification and the specification of neurosurgery falsification test are shown in Table 1. The top 25th percent of exposure corresponds to an estimated reduction of more than 786 system-wide admissions for hospitals in systems or 393 hospital admissions for independent hospitals. Similarly, the top 50 and 75 percent of exposure correspond to a reduction of more than 665 and 236 system-wide admissions for system hospitals, respectively and a reduction of 210 and 87 hospital admissions for independent hospitals, respectively. The average number of cardiac admissions of systems (hospitals) in the top 25 percent of exposure was 4530 (2427); systems (hospitals) in the top 50 percent of exposure averaged 3821 (1719) cardiac admissions and systems (hospitals) in the top 75 percent of exposure average 4041 (1703) cardiac admissions. Thus the percent of the potential reduction in cardiac admissions ranged from about 20 percent in the top 25 percent of exposure to about 5 percent in the top 75 percent of exposure. The percent thresholds were calculated using system and hospital as the respective unit of observation.

5. Results

Table 2 shows the pre–post admission-weighted mean of net income from services to patients; net revenue per hospital discharge; operating margin and the number of admissions for hospitals in our sample by the estimated degree of exposure to specialty hospital entry. The table shows that the mean net income of hospitals that were not exposed increased between the pre and post periods whereas it decreased at hospitals that were exposed. The pre and post values of net revenue per hospital discharge and operating margin exhibit trends where the values are consistent with improved financial condition at unexposed hospital versus a worsening financial condition at exposed hospitals. The pre–post trend of net revenue per discharge is similar to the change in the share of cardiac patients. The exposure thresholds capture all hospitals above each threshold and thus the samples are not mutually exclusive. There was a larger pre–post difference in the average number of admissions for psychiatric, substance abuse, and trauma services at hospitals that were not exposed compared to hospitals in the top 25 and 50 percent of exposure. There was a pre–post increase in neurosurgery admissions at exposed hospitals and a decrease at hospitals that were not exposed.

Fig. 1 displays trends in median net revenue per discharge and operating profits between 1997 and 2007. For comparison over time the sample is limited to the subset of hospitals that report data in every year. The unadjusted trends are consistent with a revenue and profit shock at exposed hospitals and a subsequent adjustment period within which exposed hospitals shifted away from uncontested and relatively unprofitable services. Both exposed and unexposed hospitals experienced declining net revenue per discharge and operating margins between 1997 and 2000. This contemporaneous negative trend at unexposed hospitals is consistent with the reductions in Medicare reimbursement related to the Balanced Budget Amendment (BBA) of 1997. The reductions in net revenue per discharge and operating margins leveled off by 2000

[19] Neurosurgery admissions are defined as admissions with surgical DRGs that are part of the Nervous System Major Diagnostic Category. The category includes Craniotomy (DRG 1–3; 484, 543); Carpal Tunnel Release (DRG 6); Peripheral and Cranial Nerve and other Nervous System Procedures (DRG 7–8); Intracranial Vascular Procedure (DRG 528); Ventricular Shunt Procedures (DRG 529–530); Spinal Procedures (DRG 4; 531–532); and Extracranial Vascular Procedures (DRG 5, 533–534).

[20] This prediction relies on the assumption that hospitals chose their pre-entry mix of profitable services optimally and were operating at capacity. If entry by specialty cardiac hospitals reduced cardiac admissions, space and time would be freed up to provide other services that require similar facilities and personnel.

[21] The exit of these hospitals occurred prior to entry of the cardiac specialty hospitals. The bankruptcy of Charter was unrelated to market-specific trends and likely reflective of national trends in psychiatric care. Nevertheless, the fact that these hospitals were closed rather than acquired could be reflective of local market conditions.

Table 1
Summary statistics by major diagnostic category.

Major Diagnostic Category:	Psychiatric	Substance abuse	Trauma	Neurosurgery
Patient characteristics				
Emergency admission	0.398	0.597	0.666	0.229
	(0.490)	(0.490)	(0.472)	(0.420)
HMO primary payer	0.174	0.206	0.221	0.308
	(0.379)	(0.404)	(0.415)	(0.462)
Age 50–74 years	0.221	0.283	0.287	0.482
	(0.415)	(0.451)	(0.452)	(0.500)
Age >74 years	0.129	0.0457	0.113	0.245
	(0.335)	(0.209)	(0.317)	(0.430)
Drive time (minutes)	21.08	19.27	28.14	35.88
	(29.08)	(27.67)	(46.67)	(50.28)
ICD9 procedures per admission	0.275	0.685	1.593	2.510
	(0.730)	(0.872)	(2.002)	(1.650)
ICD9 diagnoses per admission	4.998	5.681	6.130	5.426
	(2.327)	(2.133)	(2.098)	(2.387)
Admissions	51,489	16,875	50,249	26,035
Hospital characteristics[a]				
Phoenix market	0.402	0.476	0.642	0.595
	(0.490)	(0.499)	(0.479)	(0.491)
Tucson market	0.351	0.219	0.182	0.197
	(0.477)	(0.414)	(0.386)	(0.398)
System exposure level				
Top 25 percent[b]	0.0856	0.177	0.299	0.364
	(0.280)	(0.382)	(0.458)	(0.481)
Top 50 percent[c]	0.153	0.239	0.401	0.405
	(0.360)	(0.426)	(0.490)	(0.491)
Top 75 percent[d]	0.280	0.347	0.554	0.589
	(0.449)	(0.476)	(0.497)	(0.492)
Partial-year data	0.00171	0.00142	0.00203	0.000346
	(0.0413)	(0.0377)	(0.0450)	(0.0186)
Number of hospitals	38	34	53	38

Standard deviations in parentheses.
[a] Proportions weighted by admissions.
[b] System-wide reduction > 786 (system hospitals) or hospital reduction > 393 (independent hospitals).
[c] System-wide reduction > 665 (system hospitals) or hospital reduction > 210 (independent hospitals).
[d] System-wide reduction > 236 (system hospitals) or hospital reduction > 87 (independent hospitals).

Table 2
Hospital financial performance measures and admissions before and after entry, by exposure level, per hospital and year.

	No exposure		Exposure level					
	Pre	Post	Top 25 percent[a]		Top 50 percent[a]		Top 75 percent[a]	
			Pre	Post	Pre	Post	Pre	Post
Net income from service to patients (1000s)[b]	2087.92	7996.68	2077.44	921.56	253.49	−2818.06	−1604.14	−2260.07
	(16326.96)	(15599.34)	(10805.25)	(15053.50)	(12997.46)	(31021.47)	(12213.98)	(26105.65)
Net revenue per hospital discharge[b]	6395.00	6536.80	7773.52	6222.94**	7401.75	6118.30**	7000.00	5933.66
	(1654.80)	(1408.70)	(3134.81)	(1659.11)	(2981.93)	(1549.56)	(2703.32)	(1417.52)
Operating margin[b,c]	0.005	0.03	0.02	−0.002	0.01	−0.01	−0.005	−0.014
	(0.105)	(0.08)	(0.08)	(0.101)	(0.10)	(0.16)	(0.094)	(0.143)
Share of cardiac admissions[d]	0.146	0.144	0.151	0.138	0.152	0.134	0.168	0.146
	(0.029)	(0.035)	(0.023)	(0.051)	(0.038)	(0.050)	(0.051)	(0.055)
Psychiatric admissions	387.52	488.76	94.48	109.86	144.88	137.63	116.69	230.31
	(350.27)	(463.71)	(88.14)	(110.38)	(140.41)	(185.97)	(126.65)	(332.18)
Substance abuse admissions	96.33	195.52***	57.47	69.58	60.54	74.60	53.45	84.42
	(74.09)	(155.75)	(77.94)	(33.91)	(71.01)	(49.92)	(59.87)	(56.36)
Trauma admissions	233.50	359.73*	233.85	303.74	241.75	324.11	228.04	317.49
	(175.87)	(327.54)	(154.10)	(226.60)	(161.37)	(238.98)	(147.75)	(215.56)
Neurosurgery admissions	157.23	142.08	171.39	197.51	161.55	185.16	172.51	199.26
	(69.33)	(94.55)	(181.00)	(336.74)	(167.74)	(310.53)	(150.13)	(263.31)
Total admissions (1000s)	10.665	13.362	11.630	13.724	11.528	13.445	10.930	14.411
	(9.200)	(11.832)	(6.294)	(9.153)	(6.506)	(9.219)	(6.870)	(9.538)

*** $p < 0.01$ based on a hypothesis test that the pre and post difference in unweighted mean (or proportion) is zero.
** $p < 0.05$ based on a hypothesis test that the pre and post difference in unweighted mean (or proportion) is zero.
* $p < 0.1$ based on a hypothesis test that the pre and post difference in unweighted mean (or proportion) is zero.
[a] See Table 1 notes and text for definition. Mean with Standard Deviations in parentheses, weighted by total admissions.
[b] Healthcare Cost Report Information System (HCRIS), Centers for Medicare and Medicaid Services, March 2012 update. Sample limited to hospitals that reported net income from patient care to HCRIS. Converted to 1997 US$ using US hospital net revenue inflation rate.
[c] Operating margin calculated using net income from service to patients divided by net patient revenue.
[d] Share of cardiac admissions measured at hospital level for independent hospitals and the system level for system admissions.

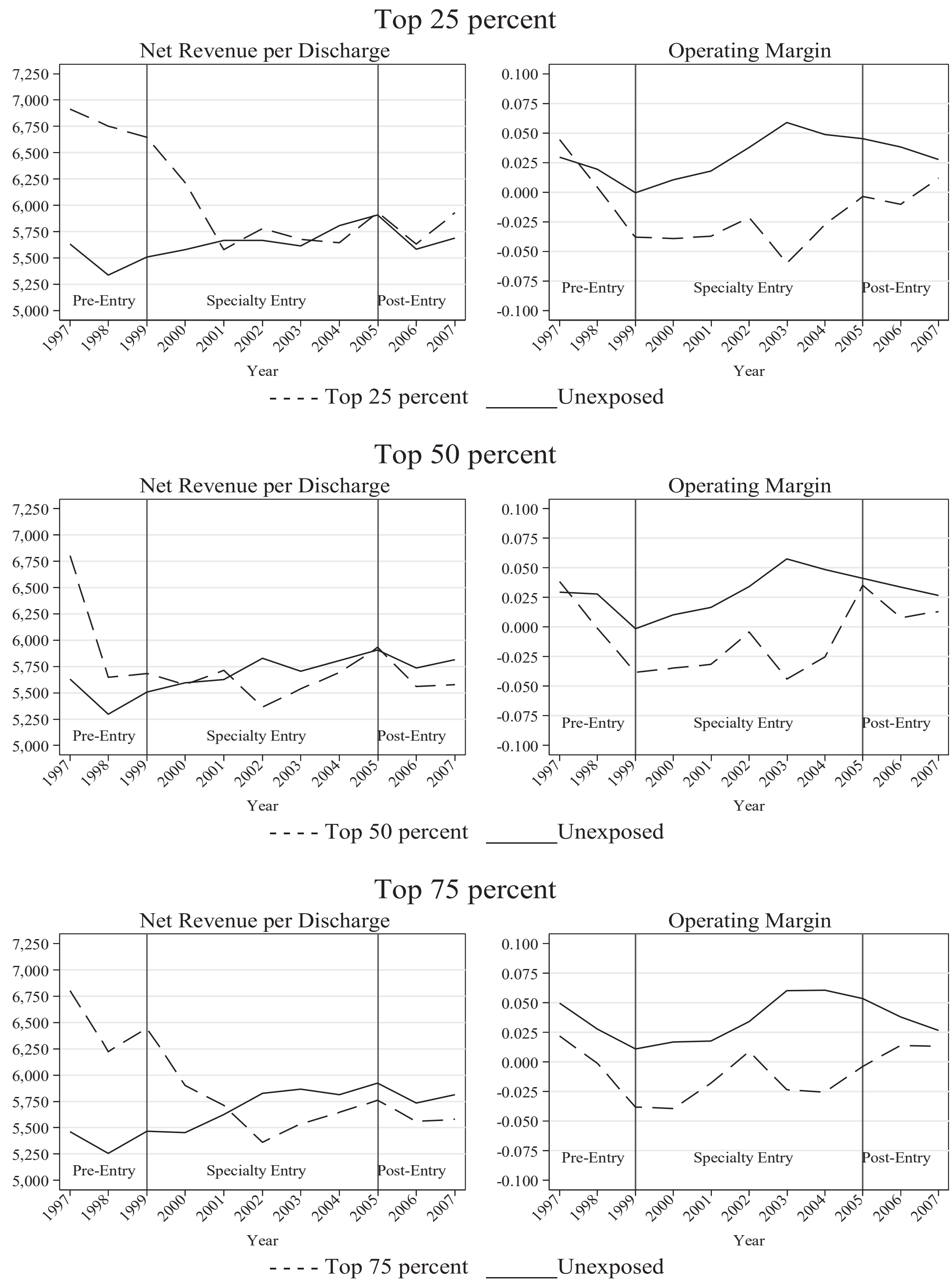


Fig. 1. Median net revenue and margin, by exposure level. *Notes*: Median-band plot using Stata 12.0. Sample limited to hospitals that report in every year.

at unexposed hospitals consistent as would be expected given that the BBA-related cuts were subsequently lessened by the Balanced Budget Refinement Act of 1999 and the Benefits Improvement and Protection Act of 2000 (Bazzoli et al., 2004). Despites these revisions to the BBA-related cuts, net revenue per discharge continued its downward trajectory at exposed hospitals, not leveling until 2002–2003. Operating margins recovered sooner and mirror the trends at the control hospitals more closely.

Covariate-adjusted admissions for uncontested services are shown in Table 3, which includes the parameter estimates of an ordinary least squares regression of admissions on exposure as well as year and hospital fixed effects. Admissions increased between 1997 and 2007 with the exception of neurosurgery in 2007. The constant reflects the adjusted average number of admissions for each service line in 1997. Relative to the controls, psychiatric admissions at exposed hospitals declined by an additional

Table 3
Fixed effect estimates of the effect of exposure and trends in admissions.

	Psychiatry	Substance abuse	Trauma	Neurosurgery
Top 25 percent[a]				
Exposure	−86.20*	−101.2*	−22.31	4.823
	(47.19)	(52.69)	(25.09)	(39.11)
1998	16.60	5.759	2.497	6.737
	(15.89)	(4.956)	(3.095)	(4.786)
2005	137.0***	94.63***	98.18***	48.20**
	(46.33)	(19.11)	(21.53)	(17.88)
2006	142.2***	89.55***	99.41***	39.44**
	(48.85)	(19.47)	(19.55)	(17.70)
2007	90.25*	64.25***	58.91***	1.969
	(49.43)	(17.79)	(15.51)	(12.84)
Constant	250.5***	112.1**	160.9***	161.3***
	(48.66)	(47.00)	(21.74)	(16.77)
Top 50 percent[a]				
Exposure	−96.39	−86.96*	−8.898	1.156
	(59.87)	(44.85)	(25.82)	(33.54)
1998	16.58	5.626	2.509	6.740
	(15.95)	(4.945)	(3.089)	(4.792)
2005	144.8***	95.89***	95.11***	49.38**
	(47.75)	(19.79)	(22.87)	(18.67)
2006	149.9***	90.71***	96.34***	40.63**
	(50.98)	(19.99)	(20.54)	(18.62)
2007	98.23*	65.30***	55.80***	3.143
	(48.94)	(18.06)	(16.81)	(13.55)
Constant	250.3***	109.7**	161.3***	161.5***
	(47.49)	(47.86)	(21.77)	(16.79)
Top 75 percent[a]				
Exposure	−84.50	−84.30**	12.76	16.08
	(62.45)	(40.89)	(27.18)	(23.08)
1998	16.85	6.311	2.506	6.706
	(15.85)	(5.063)	(3.104)	(4.753)
2005	152.3**	112.5***	85.40***	40.17*
	(56.84)	(27.51)	(26.61)	(23.13)
2006	157.6**	107.8***	86.63***	31.34
	(60.46)	(28.25)	(23.61)	(22.70)
2007	106.2*	83.34***	46.00**	−6.004
	(58.19)	(27.29)	(19.49)	(17.34)
Constant	253.5***	122.3**	161.2***	159.4***
	(47.17)	(52.53)	(20.98)	(16.86)
Hospital-years	190	170	265	190

Separate models were estimated for each level of exposure and major diagnostic category. Robust standard errors with hospital-level clustering in parentheses. Controls for hospital fixed effects; percent emergency admissions and partial year reporting by one hospital. Psychiatric specification controls for system-level agreements with psychiatric specialty hospital (Banner in 2007 and Tucson Medical Center after 2005). Sample years: 1997–1998 and 2005–2007.

*** $p < 0.01$.
** $p < 0.05$.
* $p < 0.1$.
[a] See Table 1 notes or text for definition.

84–96 admissions (33–38 percent). Admissions for substance abuse declined by 84–101 admissions (68–82 percent). Trauma admissions were not significantly affected. Admissions for neurology increased at exposed hospitals but the coefficient estimate is not statistically significant.

The results of a specification that uses a market-level measure of exposure where all hospitals in Tucson and Phoenix are treated as exposed in the post period are reported in Table A1 of the Appendix. The estimates based on the market level are not statistically significant and smaller in magnitude than the results based on the hospital-specific measures of exposure. This result is consistent with uncontested admissions being shifted from exposed to unexposed hospitals and demonstrates the importance of the within market variation used to identify the effect of exposure.

The coefficients of the generalized negative binomial count data model of the number of hospital admissions for each of the three uncontested services: inpatient psychiatric services, substance-abuse treatment, and trauma care are reported in Table 4. The models were estimated using the pre–post sample and the sample that includes the entire period. The thresholds are the same in each specification. The estimates using the entire sample are consistently smaller when the top 25 and 50 percent of exposure threshold is used, regardless of the service. However, the coefficient estimates are larger for trauma services using the top 75 percent exposure threshold. Overall the results are consistent with cross-subsidization of psychiatric and substance abuse services, regardless of the sample and specification of time and market fixed effects.

Table 5 reports the marginal effects from the analysis of the number of hospital admissions. For each service and level of exposure, the results are based on three separate specifications that differ only in the way system consolidations are modeled. The first specification is based on the market-year fixed effect parameters reported in Table 4. For inpatient psychiatric services, hospitals in more exposed systems had fewer yearly admissions post entry, even after we control for hospital consolidations. The magnitude of the decrease ranges between 100 and 200 fewer psychiatric admissions, depending on the level of exposure. The hospitals that

Table 4
Coefficient estimates from generalized negative binomial regression of number of admissions.

Service line	Psychiatric				Substance abuse				Trauma			
Exposure level: top 25 percent[a]												
Exposed	−0.680**	−0.660**	0.377	0.468	0.325	0.378	0.549**	0.554**	0.0444	0.117	0.534*	0.536*
	(0.280)	(0.274)	(0.354)	(0.347)	(0.378)	(0.392)	(0.263)	(0.259)	(0.326)	(0.369)	(0.277)	(0.276)
Exposed*post	−0.723**	−0.758	−0.259	−0.382**	−0.770*	−0.833**	−0.534**	−0.568**	−0.104	−0.215	−0.0337	−0.0398
	(0.327)	(0.480)	(0.192)	(0.188)	(0.418)	(0.406)	(0.268)	(0.259)	(0.224)	(0.349)	(0.124)	(0.141)
Exposure level: top 50 percent[a]												
Exposed	−0.456*	−0.377	0.418	0.479	0.376	0.440	0.700***	0.682***	0.110	0.198	0.947***	0.961***
	(0.268)	(0.266)	(0.426)	(0.415)	(0.462)	(0.466)	(0.231)	(0.229)	(0.294)	(0.374)	(0.302)	(0.300)
Exposed*post	−0.826***	−0.951**	−0.536***	−0.585***	−0.650*	−0.738**	−0.226	−0.216	−0.0867	−0.216	−0.0771	−0.0879
	(0.312)	(0.447)	(0.161)	(0.189)	(0.368)	(0.374)	(0.215)	(0.219)	(0.215)	(0.400)	(0.196)	(0.215)
Exposure level: top 75 percent[a]												
Exposed	−0.780***	−0.672**	−0.339	−0.200	−0.0811	−0.0209	0.777***	0.901***	−0.0288	0.0257	1.913***	1.979***
	(0.282)	(0.283)	(0.445)	(0.361)	(0.321)	(0.326)	(0.232)	(0.155)	(0.309)	(0.433)	(0.216)	(0.207)
Exposed*post	−0.609**	−0.778*	−0.712***	−0.815***	−0.602**	−0.687***	−0.320**	−0.255**	0.0506	−0.0302	−0.234	−0.298**
	(0.297)	(0.428)	(0.208)	(0.264)	(0.289)	(0.264)	(0.129)	(0.124)	(0.214)	(0.563)	(0.165)	(0.152)
Fixed effect	Year, market	Market*year	Year, market	Market*year	Year, market	Market*year	Year, market	Market*year	Year, market	Market*year	Year, market	Market*year
Sample	1997–98; 2005–07		1997–2007		1997–98; 2005–07		1997–2007		1997–98; 2005–07		1997–2007	
Sample size[b]	190		398		170		377		265		542	

Separate models were estimated for each level of exposure and diagnosis. All specifications include hospital percent emergency admissions; and a dummy variable indicating a partial year report of one hospital. Psychiatric specification controls for system-level agreements with psychiatric specialty hospitals (Banner in 2007 and Tucson Medical Center after 2005). Likelihood-ratio test for over dispersion parameter $a = 0$: probability $\geq x^2$ yielded $p < 0.001$ in all specifications. The natural log of the over-dispersion parameter is modeled as a function of market dummies and a constant dummy variable indicating that the hospital was exposed. The constant is significant with a $p < 0.001$ in all specifications.

*** $p < 0.01$.
** $p < 0.05$.
* $p < 0.1$.
[a] See Table 1 notes or text for definition of thresholds. Robust standard errors with system/hospital clustering in parentheses.

were exposed and were involved in system consolidation experienced the largest reduction. There were also statistically significant decreases in substance abuse admissions at exposed hospitals, ranging from 52 to 61 admissions. However, the reduction in admissions at exposed hospitals undergoing system consolidations was smaller, although the coefficient estimate for the interaction of the post-entry indicator, system-consolidation indicator, and exposure measure was not statistically significant. Similar results are obtained for trauma care, although the results are not statistically significant. The underlying coefficient estimates including the market-year fixed effects of selected specifications are reported in Table A2 of the Appendix.

Table 6 reports the coefficient estimates from the conditional logit model of the probability of being admitted to each hospital within the market. As in Table 4 the models were estimated using the pre–post sample and the full sample. The probability of an admission at hospitals in the top 25 and 50 percent of exposed for psychiatric, substance abuse, and to a lesser extent trauma services declined significantly, regardless of the sample. The results are largely consistent with those presented in Table 4 for psychiatric and substance abuse services. The effect of exposure on trauma admission market share is negative and significant in the conditional logit specification. Overall, the likelihood of receiving care (for any of the three uncontested services) in hospitals that were in the top 25 and 50 percent of exposure was significantly lower and there was not a meaningful difference in the estimates if drive-time hospital fixed effects were included in the model. For substance abuse and trauma, as the definition of exposure is expanded to include all hospitals in the top 50 and 75 percent of exposure, the estimates become smaller in magnitude. For psychiatric services, attenuation is seen between the top 50 and 75 percent of exposure. The results with hospital fixed effect and drive time interactions were consistently smaller when analyzing the full sample.

The specification used to estimate the parameters reported in Table 7 includes controls for system consolidation interacted with the pre and post dummy variable. The reduction in the probability of admissions to an exposed hospital tends to be larger after we control for system consolidation.

Table 8 shows the results of a falsification test in which we model admissions for neurosurgery, an uncontested service generally considered to be highly profitable. The top set of results shows the marginal effects from the hospital-level generalized negative binomial regression model (analogous to Table 5) and the bottom set of results shows the coefficient estimates from the conditional logit model without drive time and hospital fixed effect interactions (analogous to those reported in Table 6 column 2 and Table 7 column 2). The change in admissions of neurosurgery patients to hospitals exposed to entry is statistically indistinguishable from zero, regardless of the level of exposure. The estimate becomes positive and larger in magnitude but remains statistically indistinguishable from zero when the bottom-quartile cutoff is used. This result is identical in direction but weaker in magnitude and statistical robustness than the result we obtain from the conditional logit analysis, where the probability of a neurosurgery admission to hospitals in the top 75 percent of exposure increased significantly.

Appendix Table A5 reports the results of the alternative specification of the contemporaneous trends in the hospital level models of the number of admissions, for the pre–post sample and the full sample. The magnitude of the coefficients is similar across specifications, although the statistical significance varies. The largest difference in the coefficients and statistical significance occurs in specification that includes both market- and exposure-specific trends and the pre–post sample because the effect of exposure is likely picked up by the trend variables. When the full sample is used the results with market- and exposure-specific trends are closer to the baseline estimates. The results using the 1997–2007 time period mirror the results reported in Table 4 closely. The results are generally robust to alternative specifications of contemporaneous trends lending credence to a causal interpretation.

We also report the results of a continuous measure of exposure which is the change in cardiac admissions denominated in 1000s. Note that a decline cardiac admissions (i.e. increase in exposure)

Table 5
Marginal effects from generalized negative binomial regression of number of admissions.

	Psychiatric (N = 190)			Substance abuse (N = 170)			Trauma (N = 265)		
Exposure level: top 25 percent[a]									
Exposed	−121.9**	−114.1**	−136.7***	37.03	40.88	56.94	22.06	−0.813	26.39
	(55.11)	(49.85)	(48.59)	(42.49)	(39.72)	(55.89)	(70.90)	(62.78)	(99.55)
Consolidated		26.80	−18.37		7.991	21.86		−83.76	−52.34
		(38.76)	(100.5)		(25.10)	(36.23)		(70.72)	(99.41)
Exposed*consolidated			68.96			−38.01			−53.47
			(94.55)			(56.21)			(110.1)
Post interactions									
Exposed	−127.7*	−144.0**	−59.65	−55.95***	−55.84***	−61.16**	−36.82	−53.78	−36.07
	(74.60)	(66.65)	(50.05)	(21.11)	(18.11)	(26.08)	(55.06)	(48.41)	(38.82)
Consolidated		−56.62	123.2		0.677	−8.157		−32.26	−23.25
		(67.40)	(166.8)		(23.14)	(28.03)		(55.46)	(68.72)
Exposed*consolidated			−147.3**			30.47			−41.73
			(59.27)			(87.68)			(67.52)
Exposure level: top 50 percent[a]									
Exposed	−75.12	−72.62*	−97.85	42.89	51.55	99.17	37.32	1.378	96.44
	(52.24)	(43.23)	(65.76)	(50.80)	(55.86)	(63.73)	(73.31)	(71.27)	(115.5)
Consolidated		1.711	−35.05		12.25	53.64*		−96.52	−6.371
		(50.63)	(112.3)		(31.28)	(32.09)		(80.34)	(112.0)
Exposed*consolidated			57.34			−97.51**			−150.4
			(102.2)			(46.17)			(123.1)
Post interactions									
Exposed	−155.1**	−201.6***	−77.81	−52.50**	−53.09**	−56.68**	−37.19	−46.77	−50.10
	(67.47)	(71.33)	(71.03)	(21.19)	(22.35)	(26.34)	(64.64)	(62.17)	(39.70)
Consolidated		−130.9	112.1		−2.640	−7.075		−28.48	−38.32
		(90.05)	(171.7)		(31.46)	(27.14)		(56.22)	(62.61)
Exposed*consolidated			−173.7***			0.594			−1.287
			(47.41)			(51.54)			(64.03)
Exposure level: top 75 percent[a]									
Exposed	−136.5**	−163.8***	−229.9	−1.841	−0.717	20.73	4.706	−49.61	−25.49
	(57.55)	(52.00)	(144.2)	(28.73)	(28.35)	(43.15)	(79.36)	(88.42)	(171.4)
Consolidated		−50.28	−113.9		0.803	21.03		−107.0	−78.44
		(53.56)	(126.0)		(21.51)	(37.15)		(72.71)	(157.8)
Exposed*consolidated			91.44			−29.03			−30.94
			(135.2)			(44.03)			(152.7)
Post interactions									
Exposed	−137.5*	−203.9***	−92.07	−53.18***	−57.41***	−65.47***	−5.512	−46.78	−18.74
	(72.85)	(72.15)	(104.6)	(19.03)	(19.91)	(24.02)	(102.0)	(85.69)	(99.82)
Consolidated		−106.9*	49.71		−11.22	−19.99		−38.52	−22.41
		(57.93)	(149.9)		(17.84)	(16.85)		(49.81)	(71.22)
Exposed*consolidated			−143.5**			15.59			−41.73
			(68.87)			(39.29)			(68.20)

Marginal effects evaluated at the mean values. Separate models were estimated for each level of exposure and diagnosis. Controls for year*market fixed effects; hospital percent emergency admissions; and a dummy variable indicating a partial year report of one hospital. Psychiatric specification controls for system-level agreements with psychiatric specialty hospitals (Banner in 2007 and Tucson Medical Center after 2005). Likelihood-ratio test of $a = 0$: probability $\geq x^2$ yielded $p < 0.001$ in all specifications. The natural log of the over-dispersion parameter is modeled as a function of market dummies and a constant dummy variable indicating that the hospital was exposed. The constant is significant with a $p < 0.001$ in all specifications. Sample years: 1997–1998 and 2005–2007. Standard errors in parentheses.

*** $p < 0.01$.
** $p < 0.05$.
* $p < 0.1$.
[a] See Table 1 notes or text for definition.

is negative. The specifications are otherwise equivalent to the first column of the psychiatric, substance abuse, and trauma results reported in Table 6 and the first column of the neurosurgery results reported in Table 8. The estimates are the partial derivatives of the number of admissions with respect to a change in cardiac admissions denominated in 1000s at the average hospital. Generally the magnitude is within the range of the results reported using the thresholds. Fig. 2 includes the predicted change in admissions from the conditional logit model of patient's choice of hospital. We first predict the number of admissions using the observed exposure level and then use the coefficients to predict the number of admissions after setting the level of exposure equal to zero. The graphs report this measure plotted against the actual level of exposure using the pre–post sample. The results echo those presented in previous tables. We do not estimate consistently significant declines for psychiatric admissions until exposure declines below −600. The decline trauma admissions and the increase in neurosurgery admissions are smaller in magnitude than the declines in psychiatric and substance abuse admissions. Note that the measure of exposure does not differentiate between hospital and system exposure.

We also test whether the reaction to exposure differed by ownership status. These results should be interpreted with caution and should not be interpreted as representative of for-profit ownership as a whole. While all of the markets include both for-profit and non-profit hospitals, the system consolidations that occurred among exposed hospitals all involved for-profit systems. In addition, the only hospitals that changed from not-for-profit to for-profit status were part of a consolidation with an exposed system. As a result, we are unable to separately identify the effects of exposure on consolidated entities versus for-profit entities. The table reveals a number of anomalies captured by the for-profit interactions. Non-profit entities in the top 25 percent of exposure decrease psychiatric admissions relative to unexposed non-profit hospitals, whereas

Table 6
Effect of entry on probability of admission, by exposure level and diagnosis, by sample.

Service line	Psychiatric				Substance abuse				Trauma			
Exposure level: top 25 percent[a]												
Exposed	−1.098***	−1.597***	0.282***	0.128***	0.451***	0.200*	0.866***	0.787***	0.0629***	0.277***	0.482***	0.572***
	(0.0287)	(0.0652)	(0.00851)	(0.0273)	(0.0389)	(0.107)	(0.0159)	(0.0523)	(0.0221)	(0.0415)	(0.00895)	(0.0270)
Exposed*post	−0.246***	−0.155***	−0.248***	−0.0362***	−1.338***	−1.298***	−0.644***	−0.526***	−0.278***	−0.190***	−0.0750***	−0.0478***
	(0.0362)	(0.0344)	(0.0108)	(0.0135)	(0.0515)	(0.0513)	(0.0185)	(0.0196)	(0.0266)	(0.0244)	(0.0108)	(0.0115)
Exposure level: top 50 percent												
Exposed	−0.669***	−1.158***	0.564***	−0.310***	0.402***	0.518***	1.278***	1.368***	0.280***	0.393***	1.032***	0.890***
	(0.0227)	(0.0572)	(0.00971)	(0.0341)	(0.0383)	(0.104)	(0.0203)	(0.0653)	(0.0205)	(0.0409)	(0.0111)	(0.0352)
Exposed*post	−0.307***	−0.262***	−0.453***	−0.0901***	−1.114***	−1.145***	−0.571***	−0.383***	−0.213***	−0.158***	−0.184***	−0.0681***
	(0.0283)	(0.0277)	(0.00995)	(0.0104)	(0.0475)	(0.0487)	(0.0162)	(0.0169)	(0.0247)	(0.0238)	(0.0100)	(0.0101)
Exposure level: top 75 percent												
Exposed	−1.189***	−2.057***	−0.136***	−1.467***	−0.0471	−0.233***	1.524***	1.059***	0.154***	0.103**	2.096***	2.277***
	(0.0209)	(0.0484)	(0.0144)	(0.0491)	(0.0403)	(0.0893)	(0.0309)	(0.100)	(0.0215)	(0.0423)	(0.0249)	(0.0603)
Exposed*post	0.00688	−0.0437	−0.381***	−0.00674	−0.840***	−0.731***	−0.858***	−0.373***	−0.077***	−0.0225	−0.0502***	−0.0268**
	(0.0265)	(0.0271)	(0.0105)	(0.0109)	(0.0490)	(0.0449)	(0.0183)	(0.0177)	(0.0258)	(0.0248)	(0.00928)	(0.0107)
Hospital FE & drive-time interactions?	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes
Sample	1997–98; 2005–07		1997–2007		1997–98; 2005–07		1997–2007		1997–98; 2005–07		1997–2007	
Sample size[b]	685,820		1,719,964		221,029		602,070		1,197,047		2,696,151	

Notes. Choice sets are defined for the Tucson, Phoenix & Colorado market areas. Separate models were estimated for each level of exposure and diagnosis. Conditional logit specification includes drive time interacted with the patient characteristics listed in Table 1 and a dummy variable indicating a partial year report of one hospital. Psychiatric specification controls for system-level agreements with psychiatric specialty hospital (Banner in 2007 and Tucson Medical Center after 2005).

*** $p < 0.01$.
** $p < 0.05$.
* $p < 0.1$.
[a] See Table 1 notes or text for definition. Robust standard errors with patient/admission clustering in parentheses.
[b] The sample size is the number of admissions times the number of hospitals in the patient's choice set.

Table 7
Effect of entry and consolidation on probability of admission, by exposure level and diagnosis.

Service line	Psychiatric		Substance abuse		Trauma	
Exposure level: top 25 percent[a]						
Exposed	−1.043***	−1.621***	0.517***	0.284**	0.0465**	0.241***
	(0.0286)	(0.0662)	(0.0380)	(0.120)	(0.0221)	(0.0440)
Consolidated	0.190***	−0.138***	0.171***	0.191*	−0.0823***	−0.148***
	(0.0195)	(0.0468)	(0.0344)	(0.100)	(0.0186)	(0.0430)
Exposed*post	−0.254***	−0.252***	−1.260***	−1.314***	−0.269***	−0.224***
	(0.0361)	(0.0358)	(0.0510)	(0.0594)	(0.0265)	(0.0266)
Consolidated*post	0.0103	−0.227***	0.294***	−0.0226	0.00461	−0.0887***
	(0.0240)	(0.0239)	(0.0419)	(0.0503)	(0.0223)	(0.0252)
Exposure level: top 50 percent						
Exposed	−0.606***	−1.253***	0.461***	0.710***	0.282***	0.368***
	(0.0225)	(0.0614)	(0.0363)	(0.124)	(0.0207)	(0.0453)
Consolidated	0.261***	−0.228***	0.162***	0.339***	−0.0777***	−0.0741*
	(0.0190)	(0.0483)	(0.0337)	(0.108)	(0.0187)	(0.0450)
Exposed*post	−0.319***	−0.402***	−1.007***	−1.209***	−0.217***	−0.204***
	(0.0279)	(0.0299)	(0.0454)	(0.0593)	(0.0248)	(0.0268)
Consolidated*post	−0.0104	−0.301***	0.304***	−0.102*	0.00312	−0.101***
	(0.0231)	(0.0247)	(0.0410)	(0.0532)	(0.0224)	(0.0261)
Exposure level: top 75 percent						
Exposed	−1.155***	−2.329***	−0.0499	−0.402***	0.147***	−0.0596
	(0.0210)	(0.0525)	(0.0446)	(0.111)	(0.0209)	(0.0544)
Consolidated	0.139***	−0.671***	−0.00485	−0.290***	−0.0637***	−0.258***
	(0.0184)	(0.0489)	(0.0399)	(0.112)	(0.0179)	(0.0517)
Exposed*post	−0.0306	−0.312***	−0.677***	−0.653***	−0.0842***	−0.0462
	(0.0263)	(0.0314)	(0.0549)	(0.0550)	(0.0247)	(0.0321)
Consolidated*post	−0.145***	−0.385***	0.269***	0.128**	−0.00149	−0.0368
	(0.0225)	(0.0264)	(0.0486)	(0.0524)	(0.0213)	(0.0298)
Hospital FE & drive-time interactions?	No	Yes	No	Yes	No	Yes
Sample size[b]	685,820 (discharges = 51,489)		221,029 (discharges = 16,875)		1,197,047 (discharges = 50,249)	

Notes. Choice sets are defined for the Tucson, Phoenix & Colorado markets. Separate models were estimated for each level of exposure and diagnosis. Conditional logit specification includes drive time interacted with the patient characteristics listed in Table 1 and a dummy variable indicating a partial year report of one hospital. Psychiatric specification controls for system-level agreements with psychiatric specialty hospital (Banner in 2007 and Tucson Medical Center after 2005). Sample years: 1997–1998 and 2005–2007. Robust standard errors with patient/admission clustering in parentheses.

*** $p < 0.01$.
** $p < 0.05$.
* $p < 0.1$.
[a] See Table 1 notes or text for definition.
[b] The sample size is the number of admissions times the number of hospitals in the patient's choice set.

Table 8
Analysis of neurosurgery utilization.

Exposure level	Top 25 percent		Top 50 percent		Top 75 percent	
Number of admissions[a]						
Exposed	34.56	−21.21	17.98	−31.97	−5.815	−69.34
	(62.97)	(45.20)	(54.30)	(34.66)	(46.33)	(47.83)
Consolidation		−98.89**		−105.0**		−105.9**
		(39.07)		(42.54)		(41.43)
Exposed*post	−1.184	−20.73	−1.481	−8.544	32.55	5.381
	(57.81)	(53.09)	(45.95)	(45.83)	(60.83)	(61.89)
Consolidation*post		−14.89		−11.33		−9.793
		(29.13)		(30.65)		(28.91)
Probability of admission[b]						
Exposed	0.269***	0.207***	0.157***	0.0911***	−0.0905***	−0.320***
	(0.0251)	(0.0233)	(0.0241)	(0.0229)	(0.0256)	(0.0266)
Consolidation		−0.349***		−0.366***		−0.503***
		(0.0218)		(0.0221)		(0.0244)
Exposed*post	0.0415	0.0249	0.0502	0.0303	0.291***	0.192***
	(0.0316)	(0.0292)	(0.0306)	(0.0290)	(0.0336)	(0.0336)
Consolidation*post		−0.295***		−0.291***		−0.217***
		(0.0277)		(0.0282)		(0.0300)

[a] Generalized negative binomial regression specification includes year*market fixed effects; hospital percent of emergency admissions; and a dummy variable indicating a partial year report of one hospital. Marginal Effects with unconditional standard errors.
[b] Conditional logit specification includes drive time interacted with the patient characteristics listed in Table 1 and a dummy variable indicating a partial year report of one hospital. Robust standard errors with patient/admission clustering in parentheses.
*** $p < 0.01$.
** $p < 0.05$.

for-profits increase admissions relative to unexposed for-profits. However, at the top 50 percent and 75 percent exposed for-profits decrease admissions relative to unexposed for-profits as well as exposed non-profits. This difference is due to the fact that the only one for-profit entity is included in the top 25 percent threshold. The results for substance abuse reveal consistent reductions at exposed non-profits and to a greater extent at for-profits. In contrast, the results for trauma reveal an increase at admissions at exposed for-profits relative to non-profits. Finally, neurosurgery admissions increased at exposed non-profits whereas they decreased at exposed for-profits. The results are suggestive of a differential response by ownership but should be treated with caution because they reflect the response of only a few entities depending upon the level of exposure and are not generalizable (Appendix Tables A6 and A7).

6. Discussion

Despite its salience as a regulatory tool to ensure the delivery of unprofitable services, cross-subsidization of services within firms has been notoriously difficult to detect and quantify. We use repeated shocks to a profitable service in the market for

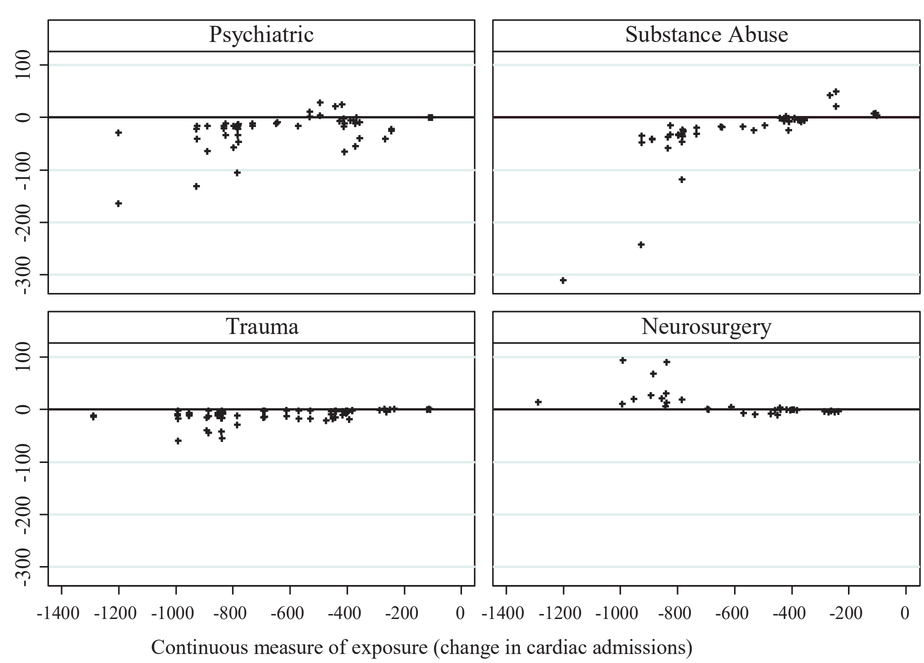


Fig. 2. Predicted change in uncontested admissions due to exposure. *Notes*: Predictions of conditional logit model of patient's choice of hospital with hospital*drive time fixed effects; drive time interacted with the patient characteristics listed in Table 1 and a dummy variable indicating a partial year report of one hospital. Cubic specification of exposure in psychiatry, trauma, and neurosurgery samples and a quadratic specification is used for substance abuse. Parameter estimates in Table A3.

hospital-based medical care to uncover evidence of cross-subsidization of unprofitable services. We find that hospital systems adjusted their uncontested service offerings in the face of entry by single-specialty competitors. Consistent with cross-subsidization, reductions in the volume of psychiatric, substance abuse, and to a lesser extent trauma care were greatest among the hospital systems most exposed to a potential loss in volume of their cardiac services.

Hospitals can react to an erosion of profits on a large number of margins (Bazzoli et al., 2007). For example they could lower discretionary quality (Dor and Farley, 1996), although it is unclear why under prospective payment they would not have reduced the discretionary quality of uncontested services already to a minimum even before single-specialty hospitals began contesting profitable service lines (Lindrooth et al., 2007). They could also increase efficiency by realigning services within a system or by offering new, profitable services such as ambulatory surgery. To the extent that hospitals responded to an erosion of profits in ways other than reducing admissions for unprofitable uncontested service lines, our results understate the extent to which hospitals adjusted their operations.

We focus on cross-subsidization across service lines, but there are several other mechanisms to support the provision of unprofitable care, regardless of a patient's diagnosis. Traditionally, governments have provided additional funding to hospitals treating a disproportionate number of low-income and uninsured patients through the Disproportionate Share Hospital (DSH) programs at the federal level and direct transfers at the state and local levels (Duggan, 2000). The United States Affordable Care Act includes a provision to phase out DSH payments because the offset was deemed unnecessary as the number of patients without health insurance is expected to decline. Another approach used in several states is to cross-subsidize unprofitable care across hospital systems using uncompensated care pools (Anderson et al., 2009; Bovbjerg et al., 2000). The transfers related to DSH payments and uncompensated care pools lessen the cost of cross-subsidizing the care of those without insurance or Medicaid regardless of their condition. Even in the presence of these indirect subsidies we find evidence of cross-subsidization of services that are less generously reimbursed overall. As specialty hospitals aim to treat generously covered patients for conditions that are generously reimbursed, they are unlikely to affect either the DSH payments received by incumbent hospitals or the size of the uncompensated care pool. Furthermore, it is not uncommon for communities to bail out hospitals at risk of bankruptcy and closure that are considered to provide community benefits (Capps et al., 2010). Such subsidies are more likely if a hospital provides unprofitable services that are in short supply. Sole providers of unprofitable services in a community may be in a position to extract a subsidy from local governments in order to keep a service line open.[22]

While we find evidence that the incumbent hospitals most exposed to a loss in profits from contested service lines modified their offerings of uncontested services in the expected direction, the estimates vary in magnitude and in some instances statistically indistinguishable from zero. There are a number of potential reasons why our estimates should be interpreted as conservative. First, as discussed above, hospitals could have lessened the adverse impact on profits by adopting other responses unrelated to the provision of psychiatric or substance abuse care. Second, there were contemporaneous closures of specialty psychiatric hospitals that were unrelated to cardiac hospital entry but could have led to an increase in demand for general hospital beds for psychiatric care. Third, because the moratorium on specialty hospitals was lifted in 2006, the post-entry period of our data (2005–2007) spans two regulatory regimes. Thus, while it is certain that in 2005–2006 no incumbent hospitals were exposed to the threat of entry by specialty hospitals, it is possible that in 2007 some incumbent hospitals were exposed to the threat of entry but successfully deterred actual entry. Any resources that exposed incumbent hospitals expended to deter entry would have reduced their profits and thus raised their likelihood of reducing the provision of unprofitable services. For these reasons, our estimates may understate the impact of specialty entry on the provision of uncontested unprofitable services.

On balance, our results might prompt a reassessment of the prevalence and practical importance of cross-subsidization as a means to finance unprofitable services. In this sense, our results call into question to what extent regulators should continue to rely on hospitals' assumed ability to cross-subsidize unprofitable, yet socially desirable services.

Cross-subsidization of unprofitable services by general hospitals is not necessarily an efficient way to achieve social goals such as supporting access to services or serving indigent patients. Others have shown that direct lump-sum transfers to maintain access to unprofitable hospitals likely decrease welfare (David and Helmchen, 2006; Capps et al., 2010, 2011; Lindrooth et al., 2003). Rather, because reimbursement for a large share of unprofitable patients is set by fiat it would seem advisable to set reimbursement at a level that preserves access to services deemed socially vital. Our findings support the conjecture that hospitals adjust downward their offerings of unprofitable services in response to an adverse shock to services that were profitable enough to encourage entry by single-specialty hospitals. In light of these findings, a comprehensive welfare analysis of entry by single-specialty hospitals should include their market-wide effects, however slight and uneven, not only on contested services but also on uncontested services that are cross-subsidized by incumbent hospitals.

Acknowledgements

This research was supported by grants from the Agency for Healthcare Research and Quality (2RO1 HS010730), the National Institute of Mental Health (R01 MH0745151), and the Center for Health Management Research (CHMR).

Appendix.

See Tables A1–A7.

[22] Similarly, nonprofit hospitals receive tax exemptions and can use the retained tax payments for this purpose, and a number of states have introduced explicit charity care mandates (Ginn and Moseley, 2006; Noble et al., 1998). Additionally, nonprofit hospitals may rely on unrelated business activity (Riley, 2007) and donations (Okten and Weisbrod, 2000; Leone and Van Horn, 2005) to finance care. Incumbent hospitals might also react to entry by declaring bankruptcy or merging.

Table A1
Generalized negative binomial regression estimates of the market-level effect of entry on admissions, by diagnosis.

	Psychiatric	Substance abuse	Trauma	Neurosurgery
Post-entry	77.20*	46.68**	85.85***	28.92
	(41.73)	(18.19)	(16.37)	(26.67)
Arizona*post-entry	−62.70	−37.73	33.58	5.866
	(63.97)	(35.70)	(27.75)	(25.84)
Constant	323.3***	155.1*	129.4***	156.4***
	(103.9)	(79.37)	(32.90)	(22.30)
Observations	190	170	265	190

Robust standard errors with hospital level clustering in parentheses. Separate models were estimated for each diagnosis. Controls for percent emergency admissions and partial year reporting by one hospital. Psychiatric specification controls for system-level agreements with psychiatric specialty hospital (Banner in 2007 and Tucson Medical Center after 2005), Sample 1997–1998 and 2005–2007.

*** $p < 0.01$.
** $p < 0.05$.
* $p < 0.1$.

Table A2
Selected coefficient estimates of the effect of exposure with market*year fixed effects, generalized negative binomial count data model.

	Psychiatry			Substance abuse			Trauma			Neurosurgery		
	25th percentile	50th percentile	75th percentile	25th percentile	50th percentile	75th percentile	25th percentile	50th percentile	75th percentile	25th percentile	50th percentile	75th percentile
Exposure	−0.660**	−0.377	−0.672**	0.378	0.440	−0.0209	0.117	0.198	0.0257	0.248	0.133	−0.0435
	(0.274)	(0.266)	(0.283)	(0.392)	(0.466)	(0.326)	(0.369)	(0.374)	(0.433)	(0.405)	(0.378)	(0.351)
Exposure*post	−0.758	−0.951**	−0.778*	−0.833**	−0.738**	−0.687***	−0.215	−0.216	−0.0302	−0.00893	−0.0112	0.234
	(0.480)	(0.447)	(0.428)	(0.406)	(0.374)	(0.264)	(0.349)	(0.400)	(0.563)	(0.438)	(0.348)	(0.425)
Phoenix*1998	−0.0898	−0.0751	−0.0778	0.131	0.133	0.120	0.0214	0.0216	0.0215	0.127***	0.128***	0.127***
	(0.102)	(0.0983)	(0.0989)	(0.134)	(0.141)	(0.131)	(0.0446)	(0.0456)	(0.0452)	(0.0403)	(0.0405)	(0.0403)
Phoenix*2005	1.028**	1.177***	1.152***	1.329***	1.333***	1.302***	0.354***	0.353***	0.354***	0.259*	0.263*	0.258*
	(0.404)	(0.422)	(0.417)	(0.438)	(0.459)	(0.414)	(0.107)	(0.107)	(0.107)	(0.142)	(0.144)	(0.143)
Phoenix*2006	0.599	0.664	0.652	0.977***	0.980***	0.956***	0.383***	0.383***	0.383***	0.212*	0.212*	0.211*
	(0.386)	(0.415)	(0.410)	(0.365)	(0.376)	(0.351)	(0.0908)	(0.0910)	(0.0910)	(0.109)	(0.111)	(0.108)
Phoenix*2007	0.828**	0.973**	0.947**	1.102***	1.108***	1.068***	0.354***	0.350***	0.352***	0.0835	0.0895	0.0826
	(0.359)	(0.379)	(0.373)	(0.353)	(0.376)	(0.346)	(0.118)	(0.118)	(0.116)	(0.136)	(0.141)	(0.139)
Tucson*1997	−0.262	−0.380	−0.0461	−0.0234	−0.103	0.142	0.138	0.0943	0.179	0.0346	0.0896	0.189
	(0.516)	(0.527)	(0.508)	(0.411)	(0.431)	(0.440)	(0.415)	(0.423)	(0.487)	(0.262)	(0.253)	(0.238)
Tucson*1998	−0.132	−0.0846	0.169	0.0815	0.000496	0.257	0.145	0.100	0.182	0.0465	0.114	0.219
	(0.508)	(0.505)	(0.495)	(0.400)	(0.415)	(0.429)	(0.431)	(0.446)	(0.506)	(0.272)	(0.251)	(0.255)
Tucson*2005	0.905	1.106*	1.410**	1.162***	1.155***	1.472***	0.767*	0.749*	0.741	0.335	0.399	0.314
	(0.620)	(0.597)	(0.574)	(0.420)	(0.421)	(0.421)	(0.429)	(0.420)	(0.517)	(0.284)	(0.278)	(0.391)
Tucson*2006	0.833	1.011*	1.309**	1.206***	1.197***	1.476***	0.777*	0.762*	0.754	0.272	0.336	0.228
	(0.632)	(0.609)	(0.580)	(0.428)	(0.441)	(0.406)	(0.408)	(0.395)	(0.495)	(0.289)	(0.293)	(0.374)
Tucson*2007	0.493	0.970	1.168*	0.903**	0.922**	1.213***	0.571	0.553	0.548	0.00508	0.0725	−0.0188
	(0.653)	(0.663)	(0.617)	(0.448)	(0.455)	(0.409)	(0.414)	(0.399)	(0.499)	(0.280)	(0.285)	(0.388)
Colorado*1997	1.285***	1.259***	1.216**	0.721*	0.700	0.758*	0.274	0.164	0.253	0.468	0.489	0.528*
	(0.482)	(0.479)	(0.509)	(0.432)	(0.504)	(0.405)	(0.398)	(0.390)	(0.453)	(0.305)	(0.298)	(0.277)
Colorado*1998	1.328***	1.301***	1.242**	0.698*	0.662	0.733*	0.270	0.163	0.243	0.486	0.503*	0.552**
	(0.492)	(0.475)	(0.506)	(0.423)	(0.454)	(0.380)	(0.393)	(0.391)	(0.450)	(0.309)	(0.303)	(0.260)
Colorado*2005	2.527***	2.362***	2.507***	1.331***	1.310***	1.510***	0.581	0.492	0.516	0.599***	0.614***	0.504*
	(0.663)	(0.701)	(0.659)	(0.435)	(0.469)	(0.383)	(0.482)	(0.459)	(0.544)	(0.218)	(0.228)	(0.288)
Colorado*2006	2.737***	2.661***	2.693***	1.558***	1.533***	1.689***	0.675	0.583	0.598	0.520**	0.541**	0.458
	(0.619)	(0.654)	(0.627)	(0.474)	(0.526)	(0.409)	(0.509)	(0.481)	(0.550)	(0.247)	(0.252)	(0.348)
Colorado*2007	2.527***	2.407***	2.334***	1.316***	1.311**	1.472***	0.475	0.384	0.393	0.234	0.258	0.148
	(0.638)	(0.678)	(0.653)	(0.464)	(0.521)	(0.393)	(0.491)	(0.465)	(0.530)	(0.237)	(0.242)	(0.298)
Constant	5.801***	5.958***	5.931***	4.654***	4.658***	4.630***	4.576***	4.561***	4.567***	4.680***	4.693***	4.678***
	(0.435)	(0.453)	(0.448)	(0.348)	(0.367)	(0.343)	(0.275)	(0.272)	(0.265)	(0.219)	(0.227)	(0.229)

Robust standard errors with System/Hospital clustering in parentheses. Coefficients are the basis for the marginal effects in Table 4, columns 2, 5 and 8 for psychiatric, substance abuse and trauma admissions, respectively and Table 6, columns 2, 4, and 6 for neurology admissions.

*** $p < 0.01$.
** $p < 0.05$.
* $p < 0.1$.

Table A3
Estimates of the effect of exposure on the probability of uncontested admission.

	Psychiatric	Substance abuse	Trauma	Neurosurgery
Exposure	0.408***	0.818***	0.127***	−0.207***
	(0.0304)	(0.0311)	(0.0294)	(0.0415)
Exposure-squared	−0.246***	−0.659***	−0.0123	0.0541
	(0.0284)	(0.0298)	(0.0240)	(0.0347)
Exposure-cubed	−0.113***		−0.0214	0.0705**
	(0.0225)		(0.0212)	(0.0307)

Conditional logit specification includes drive time interacted with the patient characteristics listed in Table 1 and a dummy variable indicating a partial year report of one hospital. Psychiatric specification controls for system-level agreements with psychiatric specialty hospital (Banner in 2007 and Tucson Medical Center after 2005). Robust standard errors with patient/admission clustering in parentheses. Separate models were estimated for each diagnosis. Sample 1997–1998 and 2005–2007.
*** $p < 0.01$.
** $p < 0.05$.

Table A4
Results of conditional logit analysis cardiac admissions.

Market:	Phoenix		Tucson		Denver	
Service:	Surgical	Medical	Surgical	Medical	Surgical	Medical
Teaching hospital	0.483***	1.101***	−1.298***	−1.038***	0.557**	−0.0962
	(0.0334)	(0.0293)	(0.0548)	(0.0447)	(0.268)	(0.283)
Cardiac catheterization	0.488***	−0.483***	0.468*	0.118**	−1.774***	−0.325***
	(0.0367)	(0.0216)	(0.263)	(0.0574)	(0.0921)	(0.0497)
Open-heart surgery	0.839***	0.823***	1.097***	1.080***	1.890***	0.572***
	(0.0250)	(0.0170)	(0.0940)	(0.0503)	(0.0869)	(0.0476)
ln(drive time)	−1.063***	−1.500***	−0.0256	−0.504***	−1.121***	−0.997***
	(0.0331)	(0.0231)	(0.0788)	(0.0441)	(0.0993)	(0.0762)
ln(drive time) interacted with						
Emergency admission	−0.941***	−0.824***	−0.875***	−0.517***	−0.425***	0.0167
	(0.0125)	(0.00946)	(0.0295)	(0.0178)	(0.0420)	(0.0299)
Median income	−1.14e−05***	−9.68e−06***	−2.34e−05***	−2.70e−05***	−2.31e−05***	−3.21e−05***
	(4.86e−07)	(3.74e−07)	(1.25e−06)	(8.50e−07)	(1.56e−06)	(1.31e−06)
Age 50–74	−0.184***	−0.166***	−0.0715	−0.0765***	−0.319***	−0.167***
	(0.0175)	(0.0131)	(0.0451)	(0.0263)	(0.0460)	(0.0388)
Age ≥75	−0.314***	−0.323***	−0.192***	−0.155***	−0.466***	−0.216***
	(0.0194)	(0.0137)	(0.0495)	(0.0268)	(0.0586)	(0.0435)
# Procedures	−0.0418***	0.0973***	−0.279***	−0.0632***	0.175***	0.494***
	(0.00322)	(0.00249)	(0.0340)	(0.0201)	(0.0396)	(0.0336)
# Diagnoses	0.0185***	0.0167***	0.0320***	0.162***	−0.0168**	0.100***
	(0.00253)	(0.00191)	(0.00798)	(0.00461)	(0.00700)	(0.00585)
HMO payer	−0.0688***	0.00490	−0.0168***	0.0134***	0.00784	−0.0323***
	(0.0122)	(0.00942)	(0.00636)	(0.00351)	(0.00806)	(0.00619)
Patient diagnosis–hospital service offerings interactions						
Cardiac catheterization	1.049***		3.343***		−0.127*	
	(0.0520)		(1.039)		(0.0749)	
Stent*open heart surgery	0.611***		0.884***		0.397***	
	(0.0240)		(0.0733)		(0.147)	
Open heart surgery	1.830***		0.961***		0.0753	
	(0.0336)		(0.0847)		(0.0613)	
Patient diagnosis–system service offerings interactions						
Cardiac catheterization	0.0265***		0.0225*		−0.0626***	
	(0.00457)		(0.0132)		(0.0104)	
Stent*open heart surgery	−0.0317***		0.0374**		−0.0838***	
	(0.00492)		(0.0154)		(0.0233)	
Open heart surgery	0.0141***		−0.341***		−0.00977	
	(0.00545)		(0.0191)		(0.0216)	
*Hospital fixed effects*ln(drive time)*						
Hospital 2	−0.0102*	−0.0646***	−0.0243***	−0.194***	−0.375***	−0.273***
	(0.00605)	(0.00554)	(0.00645)	(0.00553)	(0.0146)	(0.0117)
Hospital 3	−0.102***	−0.0529***	−0.0210	0.0254	−0.218***	−0.393***
	(0.00862)	(0.00691)	(0.0266)	(0.0161)	(0.0145)	(0.0164)
Hospital 4	0.221***	0.0211***	−1.625***	−1.462***	−0.0466***	−0.186***
	(0.00607)	(0.00543)	(0.0799)	(0.0830)	(0.0121)	(0.0120)
Hospital 5	−0.281***	0.103***	−0.240***	−0.431***	−0.193***	−0.254***
	(0.0193)	(0.00801)	(0.00788)	(0.0233)	(0.0138)	(0.0133)
Hospital 6	0.104***	0.0244***	−0.189***	−0.145***	0.0750***	−0.935***
	(0.00624)	(0.00621)	(0.00741)	(0.0158)	(0.00941)	(0.0301)
Hospital 7	−0.225***	−0.164***	−0.0919***	−0.192***	−0.338***	0.0215***
	(0.00956)	(0.00793)	(0.0307)	(0.0195)	(0.0152)	(0.00701)

Table A4 (*Continued*)

Market:	Phoenix		Tucson		Denver	
Service:	Surgical	Medical	Surgical	Medical	Surgical	Medical
*Hospital fixed effects*ln(drive time)*						
Hospital 8	−0.0756***	−0.116***	0.272***	−0.208***	−0.221***	−0.401***
	(0.00790)	(0.00658)	(0.0154)	(0.00555)	(0.0140)	(0.0151)
Hospital 9	−0.310***	−0.0319***	−0.112***	−0.00896**	−0.216***	−0.286***
	(0.0108)	(0.00676)	(0.00614)	(0.00454)	(0.0124)	(0.0128)
Hospital 10	−0.00463	0.0541***		−0.131***	−0.287***	−0.264***
	(0.00738)	(0.0116)		(0.0192)	(0.0139)	(0.0119)
Hospital 11	0.0363***	−0.206***		0.194***	−0.259***	−0.318***
	(0.00854)	(0.00727)		(0.0140)	(0.0619)	(0.0133)
Hospital 12	0.0687***	−0.181***		−0.0967***	−0.327***	−0.164**
	(0.0143)	(0.00730)		(0.00501)	(0.0167)	(0.0664)
Hospital 13	−0.261***	−0.295***		−0.308***	0.0866***	−0.346***
	(0.00820)	(0.0152)		(0.0220)	(0.0109)	(0.0144)
Hospital 14	0.222***	−0.0570***			−0.400***	0.0753***
	(0.00693)	(0.00813)			(0.0185)	(0.00965)
Hospital 15	0.117***	−0.153***			−0.830***	−0.267***
	(0.0103)	(0.0109)			(0.0434)	(0.0138)
Hospital 16	−0.122***	−0.315***				−0.544***
	(0.00747)	(0.00712)				(0.0203)
Hospital 17	−0.151***	0.0176**				
	(0.0160)	(0.00683)				
Hospital 18	−0.0162	−0.154***				
	(0.0121)	(0.00997)				
Hospital 19	0.125***	−0.115***				
	(0.00777)	(0.00609)				
Hospital 20	−0.243***	−0.328***				
	(0.0124)	(0.0128)				
*Hospital fixed effects*ln(drive time)*						
Hospital 21	0.0110	−0.00662				
	(0.00733)	(0.00880)				
Hospital 22	−0.287***	−0.350***				
	(0.0162)	(0.00853)				
Hospital 23	−0.307***	−0.438***				
	(0.0174)	(0.0111)				
Hospital 24	−0.256***	−0.224***				
	(0.00807)	(0.00731)				
Hospital 25	−0.0553***	−0.224***				
	(0.00707)	(0.0105)				
Hospital 26	0.0194***	−0.157***				
	(0.00667)	(0.0103)				
Hospital 27	−0.530***	−0.250***				
	(0.0324)	(0.00655)				
Hospital 28	−0.00371	−0.0398***				
	(0.00668)	(0.00573)				
Hospital 29	−0.309***	0.00656				
	(0.0180)	(0.00519)				
Hospital 30		−0.313***				
		(0.00990)				
Hospital 31		0.00817				
		(0.00548)				
Hospital 32		−0.112***				
		(0.0102)				
Observations	2,234,621	2,376,325	195,349	415,210	332,565	341,968

Standard errors in parentheses. Separate models were estimated for each market and diagnosis type.

*** $p < 0.01$.
** $p < 0.05$.
* $p < 0.1$.

Table A5
Parameter estimates using alternative specifications of trends by exposure level.

	Psychiatry				Substance abuse			
Top 25 percent								
Exposure	−0.502*	−0.659**	0.318	0.424	0.502	0.378	0.651**	0.553**
	(0.283)	(0.274)	(0.338)	(0.347)	(0.435)	(0.393)	(0.279)	(0.266)
Exposure*post	0.142	−0.764	−0.280	−0.333*	−0.136	−0.834**	−0.530**	−0.537**
	(0.782)	(0.477)	(0.210)	(0.183)	(0.752)	(0.410)	(0.249)	(0.257)
Top 50 percent								
Exposure	−0.448*	−0.365	0.394	0.446	0.507	0.439	0.876**	0.691***
	(0.240)	(0.275)	(0.365)	(0.421)	(0.561)	(0.468)	(0.363)	(0.227)
Exposure*post	−1.388	−0.979**	−0.554***	−0.547***	−0.335	−0.741**	−0.197	−0.209
	(1.175)	(0.446)	(0.162)	(0.170)	(0.756)	(0.376)	(0.173)	(0.206)
Top 75 percent								
Exposure	−0.576*	−0.661**	0.413	−0.261	0.0870	−0.0251	1.011***	0.768***
	(0.335)	(0.288)	(0.620)	(0.405)	(0.416)	(0.326)	(0.370)	(0.211)
Exposure*post	−0.302	−0.805*	−0.693***	−0.727***	−0.0778	−0.683***	−0.295***	−0.294**
	(1.220)	(0.424)	(0.200)	(0.213)	(0.694)	(0.262)	(0.111)	(0.119)
	Trauma				**Neurosurgery**			
Top 25 percent								
Exposure	0.145	0.111	0.639**	0.533*	0.267	0.237	0.336	0.0544
	(0.371)	(0.366)	(0.295)	(0.276)	(0.406)	(0.399)	(0.228)	(0.205)
Exposure*post	0.0214	−0.206	−0.0194	−0.0356	0.193	0.00923	0.146	0.114
	(0.250)	(0.345)	(0.130)	(0.131)	(0.347)	(0.432)	(0.107)	(0.140)
Top 50 percent								
Exposure	0.214	0.191	1.151***	0.955***	0.214	0.121	0.442	0.247
	(0.383)	(0.370)	(0.271)	(0.299)	(0.392)	(0.371)	(0.329)	(0.351)
Exposure*post	−0.0302	−0.207	−0.0614	−0.0850	0.523	0.00589	−0.0501	−0.0385
	(0.304)	(0.394)	(0.188)	(0.203)	(0.409)	(0.343)	(0.132)	(0.134)
Top 75 percent								
Exposure	0.0808	0.0144	2.077***	1.964***	0.0174	−0.0529	0.395	0.541
	(0.465)	(0.423)	(0.376)	(0.207)	(0.372)	(0.349)	(0.302)	(0.391)
Exposure*post	0.383	−0.0134	−0.261*	−0.283*	0.635*	0.249	−0.0118	0.0195
	(0.296)	(0.546)	(0.139)	(0.148)	(0.361)	(0.425)	(0.138)	(0.165)
Trend	Market and exposure-specific	Market-specific quadratic	Market and exposure-specific	Market-specific quadratic	Market and exposure-specific	Market-specific quadratic	Market and exposure-specific	Market-specific quadratic
Sample	1997–98 & 2005–07		1997–2007		1997–98 & 2005–07		1997–2007	

Estimated using a generalized negative binomial regression model, see Table 4 notes for details. All specifications include market and year fixed effects. Robust standard errors with system level clustering in parentheses.
*** $p < 0.01$.
** $p < 0.05$.
* $p < 0.1$.

Table A6
Analysis of number of admissions with continuous measure of exposure.

	Psychiatry		Substance abuse	
Exposure[a]	1.151***	0.670***	0.427***	0.243*
	(0.255)	(0.208)	(0.0826)	(0.125)
Marginal effect of exposure[b]	259.0***	168.6**	37.85***	24.71*
	(79.49)	(74.44)	(7.324)	(13.02)
	Trauma		**Neurosurgery**	
Exposure[a]	0.311*	0.116	−0.0699	−0.0567
	(0.173)	(0.181)	(0.151)	(0.122)
Marginal effect of exposure[b]	58.52*	22.85	−9.246	−7.882
	(31.39)	(36.45)	(21.14)	(17.52)
Sample	1997–98 & 2005–07	1997–2007	1997–98 & 2005–07	1997–2007

All specifications include market and year fixed effects.
[a] Robust standard errors with system level clustering in parentheses.
[b] Calculated at sample means, unconditional standard errors calculated for marginal effects.
*** $p < 0.01$.
** $p < 0.05$.
* $p < 0.1$.

Table A7
Effect of entry and for-profit ownership on probability of admission, by exposure level and diagnosis.

Exposure level	Psychiatry			Substance abuse		
	25 percent	50 percent	75 percent	25 percent	50 percent	75 percent
Exposed*post	−0.323***	−0.0138	0.0661**	−0.305***	−0.350***	−0.232***
	(0.0469)	(0.0349)	(0.0322)	(0.0733)	(0.0657)	(0.0624)
Exposed*for-profit*post	0.963***	−0.293***	−0.190***	−1.789***	−1.486***	−0.350***
	(0.0813)	(0.0610)	(0.0568)	(0.140)	(0.121)	(0.0953)
For-profit*post	−0.979***	−0.597***	−0.696***	−0.473***	−0.598***	−1.350***
	(0.0366)	(0.0367)	(0.0347)	(0.0914)	(0.0911)	(0.0928)
Exposure level	Trauma			Neurosurgery		
	25 percent	50 percent	75 percent	25 percent	50 percent	75 percent
Exposed*post	−0.218***	−0.300***	−0.0482	0.140***	0.103***	0.418***
	(0.0304)	(0.0290)	(0.0299)	(0.0362)	(0.0363)	(0.0401)
Exposed*for-profit*post	0.197***	0.587***	0.147***	−0.662***	−0.262***	−0.350***
	(0.0664)	(0.0558)	(0.0529)	(0.0864)	(0.0697)	(0.0633)
For-profit*post	−0.401***	−0.662***	−0.417***	−0.256***	−0.428***	−0.328***
	(0.0443)	(0.0445)	(0.0465)	(0.0563)	(0.0534)	(0.0555)

Conditional logit specification includes drive time interacted with the patient characteristics listed in Table 1 and a dummy variable indicating a partial year report of one hospital. Also includes a dummy indicating any exposure; a dummy for for-profit ownership and an interaction between any exposure and for-profit ownership. Psychiatric specification controls for system-level agreements with psychiatric specialty hospital (Banner in 2007 and Tucson Medical Center after 2005). All specifications include hospital*drive time fixed effects. Sample: 1987–88 and 2005–07. Robust standard errors with patient/admission clustering in parentheses.

*** $p < 0.01$.

** $p < 0.05$.

References

Agency for Healthcare Research Quality (AHRQ), 2006. Introduction to the HCUP State Inpatient Databases (SID).

Al-Amin, M., Zinn, J., Rosko, M.D., Aaronson, W., 2010. Specialty hospital market proliferation: strategic implications for general hospitals. Health Care Management Review 35 (4), 294–300.

American Hospital Association, various. Annual Survey of Hospitals Database.

Anderson, R., Cunningham, P., Hofmann, P., Lerner, W., Seitz, K., McPherson, B., 2009. Dialogue: protecting the hospital safety net. Inquiry 46, 7–16.

Banks, D.A., Foreman, S., Keeler, T., 1999. Cross-subsidization in hospital care: some lessons from the law and economics of regulation. Health Matrix 9 (1), 1–35.

Banks, D.A., Paterson, M., Wendel, J., 1997. Uncompensated hospital care: charitable mission or profitable business decision? Health Economics 6 (2), 133–143.

Barro, J.R., Huckman, R.S., Kessler, D.P., 2006. The effects of cardiac specialty hospitals on the cost and quality of medical care. Journal of Health Economics 25 (4), 702–721.

Bazzoli, G.J., Lindrooth, R.C., Hasnain-Wynia, R., Needleman, J., 2004. The balanced budget act of 1997 and U.S. hospital operations. Inquiry 41 (4), 401–417.

Bazzoli, G.J., Clement, J.P., Lindrooth, R.C., Chen, H.F., Aydede, S.K., Braun, B.I., Loeb, J.M., 2007. Hospital financial condition and operational decisions related to the quality of hospital care. Medical Care Research and Review 64 (2), 148–168.

Berenson, R.A., Ginsburg, P.B., May, J.H., 2007. Hospital–physicians relations: cooperation, competition, or separation? Health Affairs 26 (1), w31–w43.

Berenson, R.A., Bazzoli, G.J., Au, M., 2006. Do specialty hospitals promote price competition? Issue Brief Center for Studying Health System Change 103 (January), 1–4.

Bovbjerg, R.R., Cuellar, A.E., Holahan, J., 2000. Market Competition and Uncompensated Care Pools. The Urban Institute, Washington, DC, Assessing the New Federalism Occasional Paper No. 35. http://newfederalism.urban.org/html/op35/occa35.html

Brennan, J.T., 1990. Cross-subsidization and cost misallocation by regulated monopolists. Journal of Regulatory Economics 2 (1), 37–51.

Burns, L.R., David, G., Helmchen, L.A., 2011. Strategic response by providers to specialty hospitals, ambulatory surgery centers, and retail clinics. Population Health Management 14 (2), 69–77.

Capps, C., Carlton, D., David, G., 2011. Antitrust Treatment of Nonprofits: Should Hospitals Receive Special Care? Working paper.

Capps, C., Dranove, D., Satterthwaite, M., 2003. Competition and market power in option demand markets. Rand Journal of Economics 34, 737–763.

Capps, C., Dranove, D., Lindrooth, R., 2010. Hospital closure and economic efficiency. Journal of Health Economics 29 (1), 87–109.

Casalino, L.P., Devers, K.J., Brewster, L.R., 2003. Focused factories? Physician-owned specialty facilities. Health Affairs 22 (November–December (6)), 56–67.

Chevalier, J., 2004. What do we know about cross-subsidization? Evidence from merging firms. Advances in Economic Analysis & Policy 4 (1), Article 3.

Cram, P., Rosenthal, G.E., Vaughan-Sarrazin, M.S., 2005. Cardiac revascularization in specialty and general hospitals. New England Journal of Medicine 352 (April (14)), 1454–1462.

Cromwell, J., Adamache, W., Bernard, S., Greenwald, L., Drozd, E., Root, E., Kane, N., Devers, K., 2005, September. Specialty Hospital Evaluation, Final Report to the CMS. RTI, Waltham, MA.

Nicolas, C., 1991. The theory and measure of cross-subsidies: an application to the telecommunications industry. International Journal of Industrial Organization 9, 73–108.

Dafny, L.S., 2005. Games hospitals play: entry deterrence in hospital procedure markets. Journal of Economics and Management Strategy 14 (3), 513–542.

David, G., Helmchen, L., 2006. An uncertain prescription – are tax exemptions for nonprofit hospitals an efficient way to fund indigent care? Regulation 29 (2), 14–16.

David, G., Lindrooth, R., Helmchen, L., Burns, L., 2011. Do Hospitals Cross-Subsidize? NBER Working Paper #14300.

Dobson, A., Haught, R., 2005. The rise of the entrepreneurial physician. Health Affairs (Millwood), W5-494-7.

Dor, A., Farley, D.E., 1996. Payment source and the cost of hospital care: inferences on quality from a multiproduct cost function. Journal of Health Economics 15 (1).

Duggan, M., 2000. Hospital ownership and public medical spending. The Quarterly Journal of Economics 115 (4), 1343–1373.

Ginn, G.O., Moseley, C.B., 2006. The impact of state community benefit laws on the community health orientation and health promotion services of hospitals. Journal of Health Politics, Policy and Law 31 (2), 321–344.

Greenwald, L., Cromwell, J., Adamache, W., Bernard, S., Drozd, E., Root, E., Devers, K., 2006. Specialty versus community hospitals: referrals, quality, and community benefits. Health Affairs 25 (1), 106–118.

Guimarães, P., Figueirdo, O., Woodward, D., 2003. A tractable approach to the firm location decision problem. The Review of Economics and Statistics 85 (1), 201–204.

Guimarães, P., Lindrooth, R.C., 2007. Controlling for overdispersion in grouped conditional logit models: a computationally simple application of Dirichlet-multinomial regression. The Econometric Journal 10 (2), 439–452.

Guterman, S., 2006. Specialty hospitals: a problem or a symptom? Health Affairs 25 (January–February (1)), 95.

Hadley, J., Zuckerman, S., 2005. Physician-owned specialty hospitals: a market signal for Medicare payment revisions. Health Affairs (web exclusive) W5 (October), 491–493.

Horwitz, J.R., 2005. Making profits and providing care: comparing nonprofit, for-profit, and government hospitals. Health Affairs 24 (3), 790–801.

Chen, H.-F., Bazzoli, G.J., Hsieh, H.-M., 2009. Hospital financial conditions and the provision of unprofitable services. Atlantic Economic Journal 37, 259–277.

Huckman, R.S., Kolstad, J.T., 2011. Fight or Flight: The Threat of Specialty Competition and the Service Offerings of General Hospitals. Working paper.

Iglehart, J.K., 2005. The emergence of physician-owned specialty hospitals. New England Journal of Medicine 352 (January (1)), 78–84.

Leone, A.J., Van Horn, R.L., 2005. How do nonprofit hospitals manage earnings? Journal of Health Economics 24, 815–837.

Lindrooth, R.C., Bazzoli, G.J., Clement, J., 2007. The effect of reimbursement on the intensity of hospital services. Southern Economic Journal 73 (3), 575–587.

Lindrooth, R., Lo Sasso, A., Bazzoli, G., 2003. The effect of urban hospital closure on markets. Journal of Health Economics 22 (5), 691–712.

Lindrooth, R.C., Konetzka, R.T., Navathe, A.S., Zhu, J., Chen, W., Volpp, K., 2013. The impact of profitability of hospital admissions on mortality. Health Services Research 48 (2), 792–809.

Mapquest, 2010. Directions. MapQuest, Inc., Denver, CO, Available at http://www.mapquest.com/directions (accessed 18.02.10).

McClellan, M.B., 2005, May. Specialty Hospitals: Assessing their Role in the Delivery of Quality Health Care, Testimony before the House Committee on Energy and Commerce.

McFadden, D., 1974. Conditional logit analysis of qualitative choice behavior. In: Zarembka, P. (Ed.), Frontiers in Econometrics, 105–142.

Medicare Payment Advisory Commission, 2005, March. Report to the Congress: Physician-Owned Specialty Hospitals, Washington, DC.

Mitchell, J.M., 2005. Effects of physician-owned limited-service hospitals: evidence from Arizona. Health Affairs (web exclusive) W5 (October), 481–490.

Nicholson, S., Pauly, M.V., Burns, L.R., Baumritter, A., Asch, D.A., 2000. Measuring community benefits provided by for-profit and nonprofit hospitals. Health Affairs (November/December), 168–177.

Noble, A.A., Hyams, A.L., Kane, N.M., 1998. Charitable hospital accountability: A review and analysis of legal and policy initiatives. The Journal of Law, Medicine & Ethics 26, 116–137, http://dx.doi.org/10.1111/j.1748-720X.1998.tb01668.x.

Norton, E.C., Staiger, D.O., 1994. How hospital ownership affects access to care for the uninsured. Rand Journal of Economics 25 (1), 171–185.

Okten, C., Weisbrod, B.A., 2000. Determinants of donations in private nonprofit markets. Journal of Public Economics 75 (2), 255–272.

Phelps, E.C., 1986. Cross-subsidies and charge-shifting in American hospitals. In: Sloan, F.A., et al. (Eds.), Uncompensated Health Care: Rights and Responsibilities. , pp. 108–125.

Resnick, A.S., Corrigan, D., Mullen, J.L., et al., 2005. Surgeon contribution to hospital bottom line: not all are created equal. Annals of Surgery 242 (4), 530–539.

Riley, M., 2007. Unrelated business income tax returns, 2003: financial highlights and a special analysis of a nonprofit charitable organization's revenue and taxable income. Statistics of Income Bulletin 26, 88–115.

Shactman, D., 2005. Specialty hospitals, ambulatory surgery centers, and general hospitals: charting a wise public policy course. Health Affairs (Millwood) 24 (May–June (3)), 868–873.

Schneider, J.E., Ohsfeldt, R.L., Morrisey, M.A., Li, P., Miller, T.R., Zelner, B.A., 2007. Effects of specialty hospitals on the financial performance of general hospitals, 1997–2004. Inquiry 44 (Fall (3)), 321–334.

Schneider, J.E., Miller, T.R., Ohsfeldt, R.L., Morrisey, M.A., Zelner, B.A., Li, P., 2008. The economics of specialty hospitals. Medical Care Research and Review 65 (October (5)), 531–553, discussion 554-63.

Steinbuch, R., 2010. Healthy competition: getting the best hospital care for patients. Journal of the National Medical Association 102 (June (6)), 491–492.

Stensland, J., Winter, A., 2006. Do physician-owned cardiac hospitals increase utilization? Health Affairs 25 (January–February (1)), 119–129.

Train, K., 2003. Discrete Choice Methods with Simulation. Cambridge University Press.

Tynan, A., November, E., Lauer, J., Pham, H.H., Cram, P., 2009. General hospitals, specialty hospitals and financially vulnerable patients. Research Brief 11 (April), 1–8.

U.S. Government Accountability Office, 2003, October. Specialty Hospitals: Geographic Location, Services Provided, and Financial Performance., pp. 1–41, Washington, DC (GAO-04-167).

Vladeck, C.B., 2006. Paying for hospitals' community service. Health Affairs 25 (1), 34–43.

FULL TEXT LINKS

HA

Health Aff (Millwood). 2006 Jan-Feb;25(1):22-33. doi: 10.1377/hlthaff.25.1.22.

The cost-shift payment 'hydraulic': foundation, history, and implications

Allen Dobson [1], Joan Davanzo, Namrata Sen

Affiliations
PMID: 16403741 DOI: 10.1377/hlthaff.25.1.22

Abstract

The cost-shift payment "hydraulic" is an integral component of the fragmented U.S. health care financing system. If private payers' acceptance of the cost-shifting burden were to erode, our system of health care financing could become unstable. This is especially true for the hospital industry. In this paper we provide a series of examples of cost shifting and a historical profile of the cost shift in the hospital industry since 1980, noting that cost-shifting pressures seem to fluctuate over time and across health care markets. Cost shifting need not be dollar per dollar, as hospitals can absorb some degree of cost-shifting pressure through increased efficiency and decreases in service provision.

LinkOut - more resources

Full Text Sources

Atypon

Does Removing Certificate-of-Need Regulations Lead to a Surge in Health Care Spending?

Christopher J. Conover and Frank A. Sloan
Duke University

Abstract This study assesses the impact of certificate-of-need (CON) regulation for hospitals on various measures of health spending per capita, hospital supply, diffusion of technology, and hospital industry organization. Using a time series cross-sectional methodology, we estimate the net impact of CON policies on costs, supply, technology diffusion, and industry organization, controlling for area characteristics, the presence of other forms of regulation, such as hospital rate-setting, and competition. Mature CON programs are associated with a modest (5 percent) long-term reduction in acute care spending per capita, but not with a significant reduction in total per capita spending. There is no evidence of a surge in acquisition of facilities or in costs following removal of CON regulations. Mature CON programs also result in a slight (2 percent) reduction in bed supply but higher costs per day and per admission, along with higher hospital profits. CON regulations generally have no detectable effect on diffusion of various hospital-based technologies. It is doubtful that CON regulations have had much effect on quality of care, positive or negative. Such regulations may have improved access, but there is little empirical evidence to document this.

For more than two decades, health care cost containment has been at the forefront of the health policy agenda. However, the approaches used to achieve cost containment have changed. One of the first policies adopted by states (and that for a time was required by federal statute) was certificate-of-need laws (CON). Such laws, which focused on hospitals and nursing homes, were adopted to curb needless duplication of ser-

The authors would like to acknowledge capable research assistance by Shin Yi Chou and Marc Spooner. This research was supported in part by a contract with the Delaware Health Planning Commission.

Journal of Health Politics, Policy and Law, Vol. 23, No. 3, June 1998.

vices and consequent excess capacity. At the time, retrospective reimbursement provided guaranteed reimbursement even if facilities operated at well below capacity. Also, given nearly complete insurance coverage for hospitals, competition for patients occurred on a nonprice basis (Robinson and Luft 1987; Dranove, Shanley, and Simon 1992). The hospitals that could offer the most sophisticated range of services and equipment were most attractive to patients and their physicians. The price of such care did not matter, or at least it mattered much less. Competition by service expansion and proliferation of new technology has been termed the "medical arms race." At least in principle, CON regulations could control the medical arms race by requiring that organizations demonstrate need for a facility, service, or equipment before investing in them. Also, in the 1980s, some states expanded CON regulations to control the proliferation of ambulatory care providers that was occurring (Finkler 1985). Other perhaps secondary objectives of CON regulations were to promote access and to promote quality. A less charitable view is that CON regulations sought to establish entry barriers to protect the income of existing providers, especially hospitals (Feldstein 1988; Wendling and Werner 1980).

Several developments have occurred since the late 1960s and early 1970s that have lessened the popularity of CON regulations, especially as they affect hospital care. First, other regulatory mechanisms thought to be more effective in cost containment have been adopted. Primary among these is Medicare's Prospective Payment System (PPS), but some states implemented various forms of regulation of hospital rates and revenue. Although PPS is still in effect, hospital rate-setting remains in only one state.[1] Second, there has been substantial growth in various forms of managed care, stimulated in part by legislation, such as selective contracting laws. Although specific incentives differ, managed care provides incentives for hospitals to be concerned about cost. In this context, there is a perception that CON regulations may not be needed as much as they were previously to control hospital cost growth. As a result of managed care plan growth as well as implementation of PPS, demand for inpatient hospital care has decreased appreciably. Third, as discussed later, a substantial amount of empirical evidence accumulated by the early 1980s indicating that CON regulations were ineffective in cost containment. Research findings per se did not contribute to the demise of CON laws, but such findings probably coincided with

1. At various times, six different states had adopted this approach, with New York being the most recent to abandon it (on 30 June 1996).

experience-based impressions of policy makers and experts in the field. Fourth, the federal law requiring states to have CON regulations expired in 1986. Since then, fifteen states have dropped CON regulations for hospital services; about half of these have retained CON regulations for nursing homes.

Policy makers in many other states have been reluctant to drop CON laws because of a concern that removing them would lead to a surge in health care spending, including both capital expenditures (initially, subsequent to removal of CON laws) followed by increased operating expenses. Some largely anecdotal accounts of surges following removal of CON laws were reported (Simpson 1986; Lewin-ICF 1992b). Although PPS and managed care have changed incentives, these forces may be insufficient to offset the other inflationary factors that preceded these more recent developments. Second, there is concern that without restraint by CON regulations, market forces will exacerbate an existing maldistribution of facilities, thus placing a greater burden on the disadvantaged. Some observers are also worried that for-profit providers would benefit disproportionately from removal of CON regulations. Some view this as troublesome since for-profit facilities may be less willing to provide uncompensated care. Some studies have shown this to be so (see references in Kuttner 1996), but other studies indicate that the contribution to uncompensated or indigent care is about equal, whether measured in terms of the self-pay share of patients, the bad debt–charity care share of charges, or the share of revenue accounted for by Medicaid (see Sloan's 1988 review). Proliferation of low-volume facilities also is a concern on the grounds that high volume is associated with higher quality of care, at least for some procedures (Luft et al. 1990).

Absent from these policy discussions to date has been systematic empirical evidence of the experiences in states that have lifted CON regulations. Did a surge in spending occur? If so, for which types of facilities and services did the surge occur? Did removal of CON regulations open the doors to the for-profits? Conversely, did removal of CON regulations have beneficial effects, such as increasing price competition through promoting growth of managed care, which may have been restrained previously because of CON entry barriers? Compared with other approaches to cost containment, how well do CON regulations perform? This is an old question, but the track record for comparing alternative approaches to cost containment is now far longer than when most studies were conducted during the 1970s and 1980s. Furthermore, it is now possible to follow the experience of states that dropped CON instead of simply comparing states with CON to those that had not yet adopted it. Finally, for the first time, a fourteen-year, continuous time series of state per capita health spending data has become available from the U.S. Health Care Financing Administration (HCFA).[2]

This article provides new empirical evidence about these issues with regard to acute care services. In focusing on acute care services, we exclude nursing homes, hospices, and home health care, but we do include ambulatory surgery and visits to physicians' offices as well as to hospitals. Using a state time series of cross-sections, we assess the effects of lifting CON through 1993. The success of CON in cost containment is compared with other approaches. We show that mature CON programs are associated with a modest (5 percent) long-term reduction in acute care spending per capita, but with no significant reduction in total per capita spending. We also found no evidence of a surge in acquisition of facilities or in costs following removal of CON.

Our empirical specification is followed by a discussion of findings on CON, other regulatory programs, competition, control variables on expenditures on acute care services, hospital beds, service intensity, and profitability, diffusion of technology, and industry organization. We then evaluate our results, compare our findings with those from previous studies, and discuss previous research on effects of CON on quality and access. Although we do not present any new direct evidence about quality and access, these issues are clearly germane to states' decisions about whether CON should be retained.

Empirical Specification

Dependent Variables

We specified equations for the following dependent variables. To measure the effects of CON and other factors on per capita health spending, we defined dependent variables for (1) total expenditures on personal health care services; (2) total acute care expenditures (defined as total spending minus nursing and home health expenditures); (3) expenditures on hospital care; and (4) expenditures on physicians' services per person

2. These data have not been published, but can be obtained by sending a blank diskette to Anna Long in the Health Care Financing Administration's Office of National Health Statistics, Office of the Actuary, Room N3-02-02, 7500 Security Boulevard, Baltimore, MD 21244-1805.

for a state's resident population. We also obtained estimates of Medicare spending per elderly enrollee, including total Medicare expenses and Part A and Part B expenditures.[3] Unpublished estimates of personal health care expenditures by state and year in total and by component were obtained from HCFA for 1980–1993.[4] We also analyzed Medicare expenditures for 1980–1993. All monetarily expressed variables were deflated by the all-items Consumer Price Index.

Dependent variables for hospital supply were beds per 1,000 state residents; for service intensity, the dependent variables were expense per adjusted (for outpatient volume) patient day and per adjusted admission; the dependent variable for hospital profits was the ratio of total revenue to total expense. The revenue measure was for funds actually received by hospitals during the fiscal year, not for hospital charges. Data for these dependent variables for 1976–1993 came from the American Hospital Association's *Hospital Statistics* (AHA 1977–1994).

To measure the influence of CON and other factors on the variable diffusion of technology, we defined dependent variables for (1) the number of hospitals with open-heart surgery units (1980–1993), (2) for hospitals with organ transplant units (1980–1993), (3) for hospitals with ambulatory surgery units (1983–1993), and (4) for all ambulatory surgery units, including freestanding facilities, per one million state residents (1983–1993). The different time periods we studied were dictated

3. Our figure for total Medicare per elderly enrollee equals the sum of the per enrollee estimates for Part A and Part B. Given that not all Part A eligibles receive Part B, our figure is slightly different from the HCFA-reported state level estimates of total spending per enrollee who was eligible for either Part A or Part B during the year. This latter figure will fluctuate based on changes in the mix of Part A and Part B eligibles, so we sought a slightly more stable measure that can be interpreted as estimated spending for an elderly enrollee who had enrolled in both Part A and Part B.

4. Most readers may be aware that these HCFA estimates measure spending by place of service, so our measure of spending per state resident is not intended to be an accurate measure of resource consumption by residents in that state, given that many residents may cross state borders to seek care. HCFA is still working on the development of residence-adjusted per capita spending figures. However, even if these were available, we believe they would not have been appropriate for our analysis insofar as the impact of a state's CON should be reflected in all spending within its own borders, not just that of its own citizens. Given that our method in essence measures the influence of various factors on year-to-year changes in per capita spending, the measure we have chosen would be unsuitable only if there were large year-to-year variations in the extent of border-crossing, which seems improbable. On the other hand, we also recognize that if CON regulations had the effect of driving citizens to neighboring states to seek care, our analysis of HCFA data would not be able to detect it. Part of our motivation in also analyzing Medicare spending per eligible person—which is a residence-adjusted measure of spending—was to see whether we got consistent results using both place-of-service and place-of-residence measures of per capita spending.

by data availability.[5] Information on the first three variables came from the *Hospital Statistics* (AHA 1977–1994). Data for the fourth came from the SMG Marketing Group (1984–1995). For the variable industry organization, we defined dependent variables for the for-profit share of hospital beds[6] for 1976–1993 based on *Hospital Statistics* and the HMO enrollments as a fraction of the state population, information taken from the Group Health Association of America's *National Directory of HMOs* (GHAA 1977–1994). We used data for 1976–1993 in our analysis of HMO market share.

Examining Certificate-of-Need Laws

Four binary variables represented certificate-of-need laws: pre-CON—the year before and the first year CON was implemented; young CON—the first two years postimplementation; mature CON—the remaining years CON was in effect; and CON lifted—the first three years after the CON law was dropped. Pre-CON was included to capture anticipatory effects of CON. There is some empirical evidence that hospitals began some capital projects in anticipation of CON (Sloan and Steinwald 1980a). Once enacted, CON laws plausibly had greater effects after they had been in place for a number of years. The variable CON lifted was included to determine whether there was a surge in hospital investment (and consequently in hospital costliness) immediately after CON laws were dropped.

If CON laws constrain hospital investment and cost, the savings may be offset by greater expenditures in other parts of the health care sector, as others have argued (see e.g., Finkler 1987). By including analysis of the ambulatory sector and of total health care expenditures, we were able to examine this possibility.

Program age is only one aspect of CON programs that is heterogeneous. Programs also logically differ in *stringency*, which reflects the scope of coverage and the difficulty applicants have in securing certificates of need. In an alternative specification, we used a CON stringency

5. Because our observational unit was the state, our diffusion measures were based on counts of the number of facilities offering a particular service. At a lower level of aggregation, it would be useful to study whether additional units opened where existing units were, or where the facility was the first of its kind in the area.

6. We recognize that our results might have been somewhat different if we had measured the for-profit share as a percentage of revenues or admissions. Our convention here is typical of previous analyses of CON regulations using state or regional data (see Noether 1988; Lanning, Morrisey, and Ohsfeldt 1991).

measure originally developed by Lewin-ICF (1992a).[7] These measures took account of dollar thresholds used to determine whether a project was subject to CON review, in terms of the scope of specific categories of services subject to review. This produced a continuous numerical score that Lewin-ICF used to categorize states into three mutually exclusive categories: 1 = limited; 2 = moderate; 3 = stringent. These categorical scores were used in our analysis.[8]

Finally, for most of the observational period, states could adopt section 1122 programs at their option. Unlike CON, section 1122 allowed hospitals to make unapproved investments in plant, equipment, and services, but unless approved, there was no Medicare or Medicaid reimbursement for the capital expenditures associated with the projects. The section 1122 variable measured the fraction of hospital revenues from Medicare and Medicaid by state and year, only for the years that section 1122 was in effect in a given state.

Hospital Rate-Setting

An explanatory variable for Medicare Prospective Payment measured the fraction of hospital revenues covered by PPS by state and year. The variable accounts for the years the program was phased in (1984–1987) as well as the fraction of hospital revenue from Medicare by state and year. We also measured the fraction of hospital revenue covered by mandatory rate-setting programs.[9] Following previous work by one of the authors (Sloan 1981), we distinguished between young rate-setting —the first three years of implementation—and mature rate-setting, the remaining years that CON laws were in effect. The variables were defined to reflect the fraction of revenue covered by the program.

7. More recent data for this measure are reported in Lewin-VHI (1995).

8. The Lewin-ICF methodology was not explained in enough detail to replicate the continuous scoring system. Because we had to interpolate figures for 1991 (based on reported figures for 1990 and 1992) and extrapolate to 1993 based on other available information about changes in thresholds, we were able to do so more reliably with the categorical data (whose values tended to be stable over time for any given state) than if we had attempted to replicate the continuous scoring system.

9. Previous work by Sloan (1981) examined a wider range of hospital rate-setting programs, including voluntary and advisory programs. Both theory and most evidence suggest that mandatory prospective rate-setting is the most effective form of hospital rate regulation (Biles, Shramm, and Atkinson 1980; Morrisey, Sloan, and Mitchell 1983; Sloan 1983; Rosko 1989).

Reimbursement

Explanatory variables were included to represent the fractions of hospital revenue that came from Medicare and from Medicaid programs, respectively.

Price Competition

The HMO share—calculated by dividing HMO enrollment by resident population on 1 July of each year—was used to represent the influence of managed care on hospital costs.[10] These data were obtained from GHAA's *National Directory of HMOs*.

Area Characteristics

We controlled for other factors likely to affect the dependent variables: income per capita population (Bureau of Economic Analysis estimates); the ratio of general practitioners to all physicians; the fraction of population over age sixty-five (Bureau of the Census); the population density (Bureau of the Census); and the weekly wage paid to service workers (Bureau of Labor Statistics [BLS] 1976–1994).

Other Explanatory Variables

To capture omitted cross-sectional and intertemporal influences, we included state binary variables and a time trend. To conserve space, coefficients and standard errors on the intercept, state binary variables, and the Voluntary Effort (only included in analysis that spanned the 1970s but not presented because it is no longer of policy interest) are not presented in the tables shown here.[11] To allow us to distinguish between short- and long-run influences on explanatory variables, we included

10. Unfortunately, analogous data on PPO enrollments were not sufficiently reliable to use in our analysis because of changes in definitions over time. HMO share is not a perfect measure of price competition insofar as it does not take into account the nature of plans offered (e.g., group model versus independent practice association) or the aggressiveness of purchasers in the market, which strongly influences the degree to which HMO presence actually affects competition and hospital costs (Robinson 1995; Zwanziger and Melnick 1996). Despite its limitations, HMO share has been shown to be related to price (premium) levels in two different studies (Wholey, Feldman, and Christianson 1995; Feldstein and Wickizer 1995), so in the absence of a better measure, we feel justified in using it.

11. The Voluntary Effort was a voluntary cost-containment effort promoted by the American Hospital Association to diminish support for President Carter's proposed price controls on hospitals. This effort began in December 1977 and lasted until about 1980 (Sloan 1983).

lagged dependent variables. The coefficient on the dependent variable is interpretable as one minus the fraction of the gap between the actual and the equilibrium value of the dependent variable that is closed in a year (λ). Thus, if the coefficient were .8, .2 of the gap would be closed annually. To obtain the long-run influence, the coefficient on an explanatory variable is divided by λ.

Functional Form

With the exception of the HMO share equation, all dependent variables were expressed in natural logarithm form, as were the variables in the other explanatory variables category; all other explanatory variables were entered linearly. Since there were an appreciable number of observations with no HMOs (about one hundred), we estimated the HMO share equation in linear form.

Results

Effects of Certificate-of-Need Laws

Certificate-of-need laws had no effect on total personal health expenditures per capita or on per capita spending on physicians' services (Table 1). For spending on acute care, mature CON had a negative impact that was statistically significant at the five percent level. The long-run effect of mature CON was an almost five-percent reduction in per capita acute care expenditures, which includes ambulatory care as well as hospital expenditures. However, we were unable to detect a statistically significant effect of removing CON on these same expenditures. Surprisingly, in view of this finding, mature CON did not have a statistically significant effect in reducing hospital spending, and in this regression, the coefficient on the variable CON lifted has a negative sign (statistically significant at the 10 percent level).

For Medicare expenditures, the only statistically significant CON coefficients have positive signs. A positive sign on CON lifted suggests a surge in Part A (i.e., hospital expenses), but the positive sign on mature CON in the Part B regression suggests that physicians' services may have substituted for hospital care when the latter was constrained.

On the whole, the section 1122 program seems to have been effective in containing costs. Negative and statistically significant coefficients were obtained in most regressions, but strangely, not in the regression

Table 1 Expenditures on Acute Care Services

	Medical Spending/Pop. (HCFA)				Spending Per Medicare Eligible Age 65+		
	Total Spending	Acute Spending	Hospital Spending	Physician Spending	Total Medicare	Part A	Part B
CERTIFICATE-OF-NEED REGULATION							
Section 1122	–.012[b]	–.018[b]	–.001	–.029[c]	–.049[c]	–.090[b]	.053
	(.005)	(.007)	(.010)	(.015)	(.029)	(.045)	(.063)
Young CON	.006	.001	.0002	–.0001	.002	–.013	.041
	(.006)	(.007)	(.010)	(.015)	(.029)	(.045)	(.064)
Mature CON	–.004	–.009[b]	–.005	.004	.029[c]	–.008	.163[a]
	(.003)	(.004)	(.006)	(.009)	(.017)	(.027)	(.038)
CON Lifted	–.004	–.006[c]	–.010[c]	.003	.032[c]	.017	.143[a]
	(.003)	(.004)	(.006)	(.009)	(.017)	(.026)	(.038)
HOSPITAL RATE-SETTING							
Prospective Payment System (PPS)	.042[a]	.018	.091[a]	.103[b]	–.254[a]	–.401[a]	.169
	(.016)	(.022)	(.031)	(.045)	(.083)	(.128)	(.182)
Young Mandatory Prospective	–.038[b]	–.036[c]	–.063[b]	–.065[c]	.051	–.024	.253
	(.015)	(.021)	(.029)	(.043)	(.082)	(.126)	(.178)
Old Mandatory Prospective	–.011[c]	–.017[c]	–.022[c]	–.027[c]	–.073[b]	–.101[c]	–.052
	(.006)	(.009)	(.012)	(.018)	(.034)	(.053)	(.075)
REIMBURSEMENT							
Medicaid Share	.059[a]	.082[a]	.153[a]	–.039	.125	.330[c]	–.322
	(.022)	(.030)	(.042)	(.063)	(.120)	(.185)	(.261)
Medicare Share	–.179[a]	–.204[a]	–.330[a]	–.092[b]	.008	.124	–.246
	(.017)	(.023)	(.033)	(.047)	(.089)	(.139)	(.193)
COMPETITION							
HMO Market Shares	.033	.011	.041	.031	–.178	–.330[c]	–.420
	(.025)	(.034)	(.049)	(.072)	(.137)	(.208)	(.295)

Table 1 Continued

	Medical Spending/Pop. (HCFA)				Spending Per Medicare Eligible Age 65+		
	Total Spending	Acute Spending	Hospital Spending	Physician Spending	Total Medicare	Part A	Part B
AREA CHARACTERISTICS							
Income Per Capita	.006	–.002	.011	.071[b]	–.249[a]	–.168[c]	–.513[a]
	(.012)	(.016)	(.023)	(.034)	(.065)	(.099)	(.141)
General Practitioner	.061[a]	.089[a]	.088[a]	.019	.442[a]	.521[a]	.599[a]
	(.016)	(.021)	(.030)	(.044)	(.084)	(.129)	(.183)
All Physicians	–.008	-.001	.069[c]	.135[b]	.412[a]	.334[c]	1.081[a]
	(.026)	(.033)	(.046)	(.067)	(.128)	(.197)	(.272)
Elderly	.065[a]	.100[a]	.051	.054	–.085	–.163	.207
	(.021)	(.028)	(.039)	(.059)	(.112)	(.172)	(.243)
Density	–.087[a]	–.127[a]	–.079[a]	.003	–.087	–.112	–.171
	(.016)	(.021)	(.030)	(.045)	(.085)	(.131)	(.186)
Service Wage	.046[a]	.045[b]	–.122[a]	.218[a]	.101[c]	.230[b]	–.053
	(.013)	(.018)	(.025)	(.038)	(.070)	(.108)	(.152)
OTHER							
Lagged Dependent	.847[a]	.815[a]	.732[a]	.508[a]	.458[a]	.358[a]	.105[b]
	(.022)	(.026)	(.030)	(.036)	(.034)	(.044)	(.042)
Time	.008[a]	.012[a]	.016[a]	.034[a]	.035[a]	.041[a]	.068[a]
	(.002)	(.002)	(.003)	(.003)	(.004)	(.006)	(.009)
R^2	.998	.997	.993	.989	.993	.985	.970
$R^2(C)$	.998	.997	.992	.988	.993	.983	.967
F	4547	2693	1136	770	1259	536	275
N	623	623	623	623	623	623	623

[a] Significant at the 1 percent level (two-tail test).
[b] Significant at the 5 percent level (two-tail test).
[c] Significant at the 10 percent level (two-tail test).

for total hospital spending. The largest negative effect was for Medicare Part A, which was directly affected by section 1122 controls.

Mature CON reduced bed supply by two percent (long-run effect). However, it raised hospital expense per adjusted patient day and per admission, and also increased hospital profitability (Table 2). Lifting CON had no impact on any of these dependent variables. Section 1122 lowered hospital profits, but the magnitude of this effect appears to be implausibly large.

Mature CON or its removal had no effect on diffusion of technology such as open-heart surgery units, organ transplant units, or ambulatory surgery units (Table 3). Availability of organ transplant units rose immediately after the implementation of CON, but this result could reflect the low number of such units in most states. Pre-CON was not included in any of the technology regressions, and young CON was not included in the regressions for ambulatory surgery, because there were no "young" programs during the observational periods for this analysis.

Both mature CON and CON lifted had positive influences on the for-profit share of the hospital market (Table 4). If a policy objective of retaining CON is to keep the for-profit market share in check, the empirical evidence, if anything, suggests that CON has the opposite effect.

Holding other factors constant, none of the CON variables affected HMO market share; however, the signs on the statistically insignificant coefficients are negative, suggesting that CON may have impeded HMO growth. Section 1122 had significantly positive effects on the for-profit share and a positive but insignificant effect on the HMO share.

In an alternative specification of CON, not shown, we examined whether our findings would persist once we had accounted for differences in stringency of CON across different states. The simplest way of measuring stringency is in terms of thresholds for coverage. States with high thresholds have less stringent programs insofar as fewer projects would qualify for review. We analyzed thresholds for capital and major medical equipment separately, and found very few instances in which these had an impact on the many measures examined. States with high capital thresholds (i.e., with less stringent CON) had lower Part B Medicare spending than did states with no CON.

When stringency was defined in terms of the Lewin-ICF categories described earlier, we found that states with limited CON had worse results than states with no CON. Limited CON states had higher hospital spending per capita and higher Medicare Part B spending per person over age sixty-five. For stringent CON, the effect on hospital spending was not observed. However, in these states too, Part B spending was comparatively high.

Hospital Rate-Setting

Young state hospital rate-setting programs reduced the rate of growth in hospital expenditures overall, and thereby lowered growth rates in both acute care spending and total spending on personal health care services as well (Table 1). The magnitude of effects was lower for the mature programs. There were no statistically significant effects on expenditures for physicians' services. For Medicare, the mature programs had a stronger effect on hospital spending and on total spending. State rate-setting had no statistically significant effects on hospital bed supply, intensity, hospital profitability (Table 2), or on diffusion of technology with the exception of organ transplant units (Table 3).

Although PPS reduced Medicare expenditures through its effect on Part A expenditures, it seems to have had a positive effect on spending overall. These effects are not attributable to a secular trend in expenditures since we included a time trend as a separate explanatory variable. In contrast to state hospital rate-setting, PPS was negatively related to expense per adjusted admission, to expense per patient day, and to for-profit hospital market share, but was positively related to the HMO market share (Table 4).

Price Competition

Holding other factors constant, the HMO market share was associated with lower hospital bed supply, lower expense per adjusted admission, and lower diffusion of open-heart surgery units, but with greater diffusion of organ transplant units. For expenditures, only the effect of HMO share on Part A expenditures is negative and statistically significant at the 10 percent level or better. We split the sample between the periods 1988 and before and 1989 and after (results not presented). The negative effects of HMO share on Part A Medicare, on diffusion of open heart units, and on the number of hospital beds were statistically significant for the earlier but not for the later period. The HMO coefficient on profit was negative and statistically significant at the 10 percent level for the earlier period, but was insignificant for the latter.

Table 2 Hospital Beds, "Intensity," and Profitability

		Intensity		
	Beds per 1,000 Population	Expense per Adjusted Patient Day	Expense per Adjusted Admission	Hospital Profits
CERTIFICATE-OF-NEED REGULATION				
Section 1122	–.0004	–.007	–.002	–.272[b]
	(.008)	(.012)	(.009)	(.130)
Pre-CON	–.002	.007	.003	.263[a]
	(.006)	(.009)	(.007)	(.101)
Young CON	–.007	.006	.007	.256[a]
	(.006)	(.008)	(.006)	(.093)
Mature CON	–.008[c]	.011[c]	.010[b]	.153[b]
	(.004)	(.006)	(.005)	(.069)
CON Lifted	.002	–.001	.004	.018
	(.005)	(.008)	(.006)	(.085)
HOSPITAL RATE-SETTING				
Prospective Payment System (PPS)	–.095[a]	–.125[a]	–.105[a]	–.395
	(.025)	(.035)	(.027)	(.400)
Young Mandatory Prospective	–.005	.027	.038[c]	–.130
	(.018)	(.026)	(.020)	(.382)
Old Mandatory Prospective	.006	–.003	.005	.157
	(.010)	(.014)	(.011)	(.173)
REIMBURSEMENT				
Medicaid Share	.129[a]	.081[c]	.176[a]	–.689
	(.037)	(.053)	(.041)	(.613)
Medicare Share	–.003	.171[a]	.049[c]	2.020[a]
	(.023)	(.034)	(.026)	(.388)
COMPETITION				
HMO Market Shares	–.111[a]	–.003	–.186[a]	–.897[c]
	(.041)	(.054)	(.045)	(.604)
AREA CHARACTERISTICS				
Income Per Capita	–.044[b]	.021	.004	–.019
	(.018)	(.025)	(.019)	(.306)
General Practitioner	.042[b]	.032	.026	–.062
	(.017)	(.024)	(.019)	(.290)
All Physicians	.215[a]	–.002	.097[a]	–1.096[b]
	(.029)	(.044)	(.033)	(.469)
Elderly	.100[a]	–.019	–.070[b]	–.268
	(.026)	(.036)	(.028)	(.414)

Table 2 Continued

		Intensity		
	Beds per 1,000 Population	Expense per Adjusted Patient Day	Expense per Adjusted Admission	Hospital Profits
Density	−.024	−.005	.066[a]	−.125
	(.020)	(.029)	(.022)	(.312)
Service Wage	−.032[c]	.124[a]	.032[c]	1.175[a]
	(.020)	(.028)	(.022)	(.320)
OTHER				
Lagged Dependent	.616[a]	.803[a]	.801[a]	.318[a]
	(.021)	(.023)	(.021)	(.033)
Time	−.007[a]	.009[a]	.006[a]	.075[a]
	(.001)	(.002)	(.001)	(.017)
R^2	.986	.986	.990	.621
R^2(C)	.985	.984	.989	.586
F	818	802	1178	18
N	863	863	863	818

[a] Significant at the 1 percent level (two-tail test).
[b] Significant at the 5 percent level (two-tail test).
[c] Significant at the 10 percent level (two-tail test).

Discussion

The major findings about CON can be summarized as follows: first, we found no surge in expenditures after CON was lifted; second, despite a statistically significant reduction by mature programs on acute spending per capita, there was no corresponding reduction in total per capita spending (apparently due to offsetting expenditures on nonhospital services).

Empirical analysis of CON is an old topic. What is new or relatively new about our analysis is the research on the effects of lifting CON, the broad range of cost-related outcomes of CON studied, and the analysis of CON and other factors on a recently released data base of personal health care expenditures and their components. Particularly given the long history of empirical analysis of CON, it is important to review our evidence in the context of past research. A scorecard of previous studies of the effects of CON is shown in Table 5. Overall, the record for CON as a cost-containment mechanism appears to be mixed at best. If anything, our results provide slight optimism for CON's cost-containing potential relative to some other studies.

To date, only one other study has used the HCFA per capita spending

Table 3 Diffusion of Technology

	Open Heart Units/ Million	Organ Transplant Units/Million	Hospital-based Units/ Million	Total Units/ Million
CERTIFICATE-OF-NEED REGULATION				
Section 1122	–.069[c]	–.084	.001	.005
	(.046)	(.128)	(.022)	(.025)
Young CON	–.005	.235[c]	(—)	(—)
	(.046)	(.141)	(—)	(—)
Mature CON	–.009	–.071	.007	.012
	(.027)	(.078)	(.015)	(.017)
CON Lifted	.022	.019	.007	.021
	(.027)	(.074)	(.012)	(.013)
HOSPITAL RATE-SETTING				
Prospective Payment System (PPS)	.405[a]	–.278	.206[a]	.155[c]
	(.140)	(.407)	(.073)	(.081)
Young Mandatory Prospective	–.082	–1.427[a]	.009	.085
	(.128)	(.345)	(.095)	(.106)
Old Mandatory Prospective	–.031	.050	.022	.034
	(.054)	(.146)	(.028)	(.031)
REIMBURSEMENT				
Medicaid Share	.181	–1.22[b]	–.063	–.003
	(.190)	(.556)	(.102)	(.113)
Medicare Share	–.334[b]	.669	–.022	.023
	(.146)	(.418)	(.095)	(.105)
COMPETITION				
HMO Market Shares	–.495[b]	2.351[a]	–.050	.149
	(.228)	(.645)	(.118)	(.128)
AREA CHARACTERISTICS				
Income Per Capita	.044	.144	–.136[b]	–.113[c]
	(.101)	(.300)	(.056)	(.062)
General Practitioner	.339[b]	.071	.025	–.109
	(.133)	(.469)	(.078)	(.087)
All Physicians	.299[c]	.236	–.043	–.025
	(.197)	(.615)	(.099)	(.109)
Elderly	–.023	.416	.278[a]	–.001
	(.174)	(.560)	(.099)	(.108)
Density	–.117	–.253	–.216[a]	.066
	(.133)	(.416)	(.070)	(.076)
Service Wage	.060	–.755[b]	.041	.080
	(.113)	(.345)	(.059)	(.065)

Table 3 Continued

	Open Heart Units/ Million	Organ Transplant Units/Million	Hospital-based Units/ Million	Total Units/ Million
OTHER				
Lagged Dependent	.543[a]	.409[a]	.477[a]	.639[a]
	(.036)	(.039)	(.043)	(.038)
Time	.006	.036[b]	–.012[a]	.00001
	(.006)	(.017)	(.003)	(.003)
R^2	.931	.750	.988	.981
R^2(C)	.922	.716	.986	.979
F	112	22	532	337
N	617	541	479	479

[a] Significant at the 1 percent level (two-tail test).
[b] Significant at the 5 percent level (two-tail test).
[c] Significant at the 10 percent level (two-tail test).

data to assess the impact of CON. Examining data through 1982, Lanning, Morrisey, and Ohsfeldt (1991) found that after controlling for the fact that per capita spending was significantly different in states which adopted CON early, CON was associated with a 20.6 percent *increase* in hospital spending and a nine percent increase in spending on other health care. The net impact was a 13.6 percent increase in per capita spending on personal health care services. Using data derived from the annual *Hospital Statistics* on per capita hospital spending through 1990 (AHA 1977–1994) and a method that accounted for endogeneity of CON, Antel, Ohsfeldt, and Becker (1995) reported that CON had no impact on this form of spending, although they found that section 1122 reduced hospital spending. Without controlling for the endogeneity of CON, the coefficient on the CON variable was negative but very small, with a t-ratio of –.47. Taking account of endogeneity, the coefficient on CON became positive and statistically significant at the 10 percent level. It is noteworthy that explicitly accounting for CON's endogeneity made it appear to perform *less* well. Salkever and Bice (1976) found no impact of CON on total hospital operating costs per capita. Likewise, an earlier study by the Federal Trade Commission found that CON had no impact on hospital costs, but also found that section 1122 had a negative influence (Sherman 1988). By contrast, in our study, neither mature CON nor section 1122 had an impact on this type of expenditure, although both were associated with lower growth in acute care spending.

Table 4 Industry Organization

	For-Profit Share of Beds	HMO Market Share
CERTIFICATE-OF-NEED REGULATION		
Section 1122	.211[b]	.436
	(.101)	(.364)
Pre-CON	.121	−.279
	(.115)	(.312)
Young CON	.149	−.176
	(.108)	(.285)
Mature CON	.120[c]	−.155
	(.064)	(.213)
CON Lifted	.139[b]	−.335
	(.059)	(.234)
HOSPITAL RATE-SETTING		
Prospective Payment System (PPS)	−.800[b]	1.357
	(.364)	(1.154)
Young Mandatory Prospective	.369	.971
	(.578)	(.875)
Old Mandatory Prospective	−.195	.341
	(.157)	(.444)
REIMBURSEMENT		
Medicaid Share	.329	.938
	(.420)	(1.575)
Medicare Share	.513[c]	3.837[a]
	(.320)	(1.008)
COMPETITION		
HMO Market Shares	.255	(—)
	(.589)	(—)
AREA CHARACTERISTICS		
Income Per Capita	.289	.0001[c]
	(.243)	(.0001)
General Practitioner	.751[a]	−.075[a]
	(.263)	(.024)
All Physicians	.016	−1.247[a]
	(.370)	(.311)
Elderly	−.684[c]	.035[a]
	(.352)	(.053)
Density	.003	−.0002
	(.248)	(.0006)
Service Wage	−.700[b]	.012[a]
	(.294)	(.004)

Table 4 Continued

	For-Profit Share of Beds	HMO Market Share
OTHER		
Lagged Dependent	.585[a]	.879[a]
	(.039)	(.019)
Time	.016	.038
	(.013)	(.028)
R^2	.961	.976
$R^2(C)$	.955	.974
F	154	463
N	456	815

[a] Significant at the 1 percent level (two-tail test).
[b] Significant at the 5 percent level (two-tail test).
[c] Significant at the 10 percent level (two-tail test).

In our analysis, adoption of CON was certainly exogenous, but eliminating CON may have been endogenous; that is, it was more likely to have occurred in states where legislatures perceived that cost increases were under control without relying on CON. To ascertain whether this was so, we specified CON lifted and the lagged dependent variable as endogenous variables. Instrumental variables excluded from the main equations were the Blue Cross–Blue Shield market share; share of government hospital beds; population; and values of these variables lagged one year. CON lifted, specified as a endogenous variable, had either no effect or a more negative impact on cost than when the variable was assumed to be exogenous. If the above argument held, one would have expected CON lifted to have had a more positive effect on cost when CON lifted was specified to be endogenous.

Further, in analysis not presented, we used a method developed by Hatanaka (1974) to correct for autocorrelated error terms in a pooled time series cross-section. We found some autocorrelation, both negative and positive, but the correction had only minor effects on our results.

Two newer studies by Lewin-ICF (Lewin-ICF and Alpha Center 1991; Lewin-ICF 1992a) took account of differences in CON stringency and found that CON had a negative impact on hospital costs. This evidence conflicts with ours, since, after accounting for stringency, we did not find that CON had a greater cost-constraining influence. On balance, we believe our results merit more confidence since we controlled for many more influences other than CON.

We found that mature CON reduced hospital bed supply per capita

Table 5 Empirical Studies of the Impact of CON on Hospital Costs

	Number of Studies Showing:		
Major Impact	Decrease	No Effect	Increase
Health Spending			
Spending per capita	0	0	1
Hospital expenses per resident	0	3	2
Total hospital costs	2	1	0
Supply/Utilization			
Hospital capital expenditures	2	5	2
Hospital bed supply	2	3	1
Admissions per 1,000	0	2	0
Intensity			
Cost per patient day	2	1	2
Average length of stay	0	2	0
Cost per admission	0	2	6
Resource Mix			
Assets per bed	0	3	1
Labor use per bed	0	1	1
Market Structure			
For-profit share of beds	1	3	1
Public share of beds	1	0	0

population, but could detect no increase in bed supply following removal of CON. The magnitude of the reduction we detected was small—two percent from mature CON. Using an estimate from Ginsburg and Koretz (1983) that a 1 percent reduction in bed supply results in a .4 percent decline in admissions (the predicted reduction in admissions), the 2 percent reduction in supply translates into less than a 1 percent reduction in admissions. For this reason, it may not be surprising that we show only a minor (statistically insignificant) decline in hospital spending.

One of the earliest studies of CON found that CON reduced hospital bed supply, but also led to increased investment per bed (Salkever and Bice 1976, 1979). The result was no net saving on capital expenditures overall—simply a diversion of spending away from beds into other types of capital equipment that, due to less precise standards for judging need, was less well controlled. Sloan and Steinwald (1980b) also found a compensatory response to CON regulation, but it took the form of higher spending on labor rather than greater investment in other forms of capital. Since then, most studies have found that CON had no detectable impact on hospital bed supply (Eastaugh 1982; Ashby 1984; Lewin-VHI 1995) or on hospital capital spending (PAI-US 1980; Eastaugh 1982; Begley, Schoeman, and Traxler 1982; Ashby 1984; Wedig, Hassan, and Sloan 1989). In fact, only two studies since the landmark study by Salkever and Bice (1976) found evidence that CON reduces bed supply (Joskow 1980; Begley, Schoeman, and Traxler 1982). Whether the true effect of CON is slightly negative or not, there are certainly better ways to control hospital bed supply, in particular by promoting HMO growth. The effect of HMO share on bed supply in our analysis was over ten times that of mature CON.

We found that mature CON increased cost per adjusted patient day and per admission. The mechanism is presumably that cost-increasing investments are unconstrained or, as Sloan and Steinwald found, there is a compensatory response in use of labor, and as a consequence there is an increase in operating costs. Many previous studies have reported results consistent with ours (Salkever and Bice 1979; Sloan and Steinwald 1980a; Sloan 1981; Farley and Kelly 1985; Noether 1988; Anderson et al. 1989; Lewin-ICF and Alpha Center 1991; and Antel, Ohsfeldt, and Becker 1995). Fewer have found no impact (Sloan 1983; Lewin-VHI 1995).

In this study, the now-defunct section 1122 program had no effect on either cost measure, a result consistent with Antel, Ohsfeldt, and Becker 1995; however, Noether (1988) reported that section 1122 reduced cost per admission by seven percent.

We reviewed eight previous studies that examined the impact of CON on diffusion of technology. In nearly seventy separate tests of the relationship between CON and the rate or extent of diffusion contained in these studies, only about one-third found that CON retards diffusion; a few, like our result for organ transplant units, found that CON accelerates diffusion, but the majority found no effect in either direction. None dealt with ambulatory surgery units; we found that CON had no effect on their diffusion.

Taken at face value, these studies suggest that CON appears to have slowed diffusion of the following technologies: hospital-based cardiac catheterization units, CAT-scan units, and MRI units (Lewin-ICF and Alpha Center 1991); open-heart surgery units (Russell 1979; Lewin-ICF and Alpha Center 1991); hip arthroplasty and morbid obesity surgery (Sloan et al. 1986); cobalt therapy (Russell 1979); and nonhospital-based renal dialysis (Ford and Kaserman 1993).

Yet, for the following reasons, even these favorable findings do not provide unambiguous support for the view that CON retards diffusion of expensive technologies. First, there are conflicting results. For example, although Lewin-ICF (1992a and Lewin-ICF and Alpha Center 1991) found that CON reduced diffusion of MRIs. Teplensky et al. (1995) reported that more stringent CON policies caused an increase in diffusion of such units. Second, some results are counterintuitive. For example, Sloan et al. (1986) reported that CON had no impact on diffusion of coronary bypass graft surgery (CABG) units, a result consistent with the findings reported here. However, the same analysis showed that CON slowed diffusion of hip arthroplasty and morbid obesity surgery. The latter procedures were not subject to CON review, whereas CABG is subject to review in the vast majority of states with CON. Further, explicit guidelines for review had been developed by the agency responsible for federal oversight of state CON programs. No such guidelines existed for the other types of surgery.

There has been comparatively little research on the effect of CON on market structure. Concerns have been expressed that, absent CON, there will be a flood of for-profit entrants. However, the limited empirical evidence suggests no differential effect of CON on for-profit hospitals (Sloan and Steinwald 1980b). Using a time series of state cross-sections, Wedig, Hassan, and Sloan (1989) showed that the for-profit market share was unrelated to CON. In the current study, we found that mature CON stimulated growth of the for-profit hospital market share, and holding other factors constant, that the share was higher during the immediate period after CON was lifted. Rather than confirming the fears of those who favor retaining CON, our result for CON lifted could reflect a spillover from mature CON. This explanation seems especially likely, given the result for mature CON.

Our finding that CON had negative, albeit insignificant effects on HMO market penetration could reflect endogeneity, although this should have been handled by our fixed-effects analysis. That is, states with low HMO market shares may be reluctant to lift CON. We examined HMO market shares in the year that states lifted CON. They ranged from a high of 24.0 percent for California to lows of 1 percent or less for Idaho, New Mexico, South Dakota, and Wyoming. Preferred provider organization (PPO) penetration was also very low in these states (unpublished data from the American Medical Care and Review Association). Clearly, these states had something other than the presence of high HMO or PPO penetration in mind when they dropped CON. In many of the states that lifted CON, the HMO market share was below the national mean. In all of the states, there has been appreciable growth in managed care since they dropped CON.

Unlike research in many areas of health policy, research into CON effects on acute care costs provides a rather clear answer. CON has not succeeded in cost containment. Other cost-containment programs appear to work better, but even they appear to have lost their effectiveness as they matured. Certainly, from the regression results presented here and from the descriptive evidence we analyzed but have not reported, there is no reason to fear an expenditure surge after CON laws were lifted. But might CON laws be retained for other reasons?

Might CON improve quality of care? It might do this in at least two ways—first, by assuring adequate patient volume and second, by denying entry to facilities that lack the capacity to deliver high-quality care. There is substantial evidence for one aspect of the former, but no "hard" information on the latter.

Luft et al. (1990) compiled an extensive review of the literature on the volume-outcome relationship that we supplemented with our own review of research published in the 1990s. More than one hundred studies have examined the relationship between hospital volume and outcomes, either mortality or complication rates (e.g., infection rates, rates of reoperation), excessive lengths of stay, or other indicators of patient health status. Although the underlying mechanism is not understood, most studies show higher rates of good outcomes in higher volume facilities. By contrast, there are far fewer studies of the relationship between physician volume and outcomes, and for reasons that are also not well understood, the link between volume and outcomes is less clear.

If the relationship between hospital volume and outcomes is accepted as valid, the question remains whether or not CON increases volume. Only one study has assessed the effect of CON on outcomes directly. Analyzing data from nearly 1,000 hospitals, Shortell and Hughes (1988) found that states with more stringent CON policies or more stringent hospital rate-setting experienced higher mortality rates. Although this analysis would suggest that lifting CON may result in favorable effects on mortality, such an inference would be having it both ways. Given that there appears to be no surge in costs following removal of CON, nor much if any effect of mature or stringent CON on hospital costs, nor much if any effect on diffusion of technology, why CON should have an *adverse* impact on mortality defies explanation.

Finally, there is the potential impact of CON on access. The 1974 National Health Planning and Resources Development Act, which mandated that states have CON, contained several provisions designed to promote better access to care. For example, consumer members were required to outnumber provider members on local planning boards (Sloan 1988). Also, any Health Systems Agency plan that failed to address needs of low-income persons was subject to challenge at a public hearing.

There is a paucity of empirical studies of effects of CON on access to acute care services. One study conducted in Florida reported that a hospital's success in obtaining CON approval was consistently related to the amount of indigent care that it provided (Campbell and Fournier 1993). A study of California hospitals found evidence consistent with the hypothesis that hospital regulators reward large uncompensated care providers with profitable CON licenses, although no CON variables were actually used in estimating the amount of uncompensated care given by providers (Campbell and Ahern 1993).

Even though this information is suggestive, it is difficult to use it as a basis for continuing to support CON. First, it only applies to two states. Second, there must be more efficient ways to promote access than conferring monopoly franchises on facilities. Efforts to promote access are likely to be more productive if they are focused on primary care providers. Lack of adequate and timely primary care has been found to lead to a significant number of avoidable hospitalizations (Billings et al. 1993)

Earlier studies were more favorable than ours to other regulatory programs such as PPS and state hospital rate-setting relative to CON. It is not that CON has become more effective, but rather that the other programs became worse performers in terms of cost containment as the provider community became more familiar with them.

Conclusion

Our empirical analysis of effects of CON on costs revealed that, at best, CON has had a modest cost-containing influence on hospital and other acute care services. We found no evidence for a surge in acquisition of new facilities or in costs following removal of CON. States that lifted CON did not experience a rise in spending on hospital and physicians' services relative to those that retained it. The conclusion of lack of surge even holds for facilities such as ambulatory surgery units that have experienced substantial growth in recent years. It is doubtful that CON has had much of a positive or negative influence on quality of care. CON may have improved access, but the empirical evidence for this is quite meager.

References

American Hospital Association (AHA). 1977–1994. *Hospital Statistics* (annual). Chicago: AHA.

Anderson, Gerard F., Judith R. Lave, Catherine M. Russe, and Patricia Neumann. 1989. *Providing Hospital Services: The Changing Financial Environment*. Baltimore, MD: Johns Hopkins University Press.

Antel, John J., Robert L. Ohsfeldt, and Edmund R. Becker. 1995. State Regulation and Hospital Costs. *Review of Economics and Statistics* 77(3):416–422.

Ashby, John L. 1984. The Impact of Hospital Regulatory Programs on per Capita Costs, Utilization, and Capital Investment. *Inquiry* 21(1):45–59.

Begley, Charles E., Milton Schoeman, and Herbert Traxler. 1982. Factors That May Explain Interstate Differences in Certificate-of-Need Decisions. *Health Care Financing Review* 3(4):87–94.

Biles, Brian, Carl Shramm, and J. Graham Atkinson. 1980. Hospital Cost Inflation under State Rate-Setting Programs. *New England Journal of Medicine* 303(12): 664–668.

Billings, John, Lisa Zeitel, Joanne Lukomnik, Timothy S. Carey, Arthur E. Blank, and Laurie Newman. 1993. Impact of Socioeconomic Status on Hospital Use in New York City. *Health Affairs* 12(1):162–173.

Bureau of Labor Statistics (BLS). 1976–1994. *Employment and Earnings* (monthly). Washington, DC: Government Printing Office.

Campbell, Ellen S., and Melissa W. Ahern. 1993. Have Procompetitive Changes Altered Hospital Provision of Indigent Care? *Health Economics* 2(3):281–289.

Campbell, Ellen S., and Gary M. Fournier. 1993. Certificate-of-Need Deregulation and Indigent Hospital Care. *Journal of Health Politics, Policy and Law* 18(4):905–925.

Dranove, David, Mark Shanley, and Carol Simon. 1992. Is Hospital Competition Wasteful? *Rand Journal of Economics* 23(2):247–261.

Eastaugh, Steven R. 1982. The Effectiveness of Community-Based Hospital Planning: Some Recent Evidence. *Applied Economics* 14(5):475–490.

Farley, Dean E., and Joyce V. Kelly. 1985. *The Determinants of Hospitals' Financial Positions*. Rockville, MD: National Center for Health Services Research.

Feldstein, Paul J. 1988. *Health Care Economics*. 3d ed. New York: Wiley.

Feldstein, Paul J., and Thomas M. Wickizer. 1995. Analysis of Private Health Insurance Premium Growth Rates: 1982–1992. *Medical Care* 33(10):1035–1050.

Finkler, Merton D. 1985. Changes in Certificate-of-Need Laws: Read the Fine Print. In *Incentive versus Controls in Health Policy: Broadening the Debate*, ed. Jack A. Meyer. Washington, DC: American Enterprise Institute.

———. 1987. State Rate Setting Revisited. *Health Affairs* 6(4):82–89.

Ford, Jon M., and David L. Kaserman. 1993. Certificate-of-Need Regulation and Entry: Evidence from the Dialysis Industry. *Southern Economic Journal* 59(4): 783–791.

Ginsburg, Paul B., and Daniel M. Koretz. 1983. Bed Availability and Hospital Utilization: Estimates of the Roemer Effect. *Health Care Financial Review* 5(1):87–92.

Group Health Association of America (GHAA). 1977–1994. *National Directory of HMOS* (annual). Washington, DC: GHAA.

Hatanaka, Michio. 1974. An Efficient Estimator for the Dynamic Adjustment Model with Autocorrelated Errors. *Journal of Econometrics* 2(3):99–220.

Joskow, Paul L. 1980. The Effects of Competition and Regulation on Hospital Bed Supply and the Reservation Quality of the Hospital. *Bell Journal of Economics* 11(2):421–444.

Kuttner, Robert. 1996. Columbia/HCA and the Resurgence of the For-Profit Hospital Business. *New England Journal of Medicine* 335(5):362–367.

Lanning, Joyce A., Michael Morrisey, and Robert L. Ohsfeldt. 1991. Endogenous Hospital Regulation and Its Effects on Hospital and Nonhospital Expenditures. *Journal of Regulatory Economics* 3(2):137–154.

Lewin-ICF. 1992a. *Appendix I: Econometric Analysis of CON in Pennsylvania*, by Judith Arnold and Daniel Mendelson. Washington, DC: Lewin-ICF.

Lewin-ICF. 1992b. *Evaluation of the Pennsylvania Certificate-of-Need Program*, by Judith Arnold and Daniel Mendelson. Washington, DC: Lewin-ICF.

Lewin-ICF and Alpha Center. 1991. *Evaluation of the Ohio Certificate-of-Need Program*. Washington, DC: Lewin-ICF.

Lewin-VHI, Inc. 1995. *Potential Cost Shifting under Proposed Funding Reductions for Medicare and Medicaid: Final Report Prepared for the National Leadership Coalition on Health Care*, by John F. Sheils and David J. Ricks. Washington, DC: Lewin-VHI.

Luft, Harold S., Deborah W. Garnick, David H. Mark, and Stephen J. McPhee. 1990. *Hospital Volume and Patient Outcomes: Assessing the Evidence*. Ann Arbor, MI: Health Administration.

Morrisey, Michael A., Frank A. Sloan, and Samuel A. Mitchell. 1983. State Rate Setting: An Analysis of Some Unresolved Issues. *Health Affairs* 2(2):36–47.

Noether, Monica. 1988. Competition among Hospitals. *Journal of Health Economics* 7(3):259–284.

Policy Analysis, Inc., and Urban Systems Research and Engineering, Inc. (PAI-US). 1980. *Evaluation of the Effects of Certificate-of-Need Programs*. Vol. 1, *Executive Summary*. Washington, DC: U.S. Department of Health and Human Services, Health Resources Administration, Bureau of Health Planning and Resources Development.

Robinson, James C. 1995. Health Care Purchasing and Market Changes in California. *Health Affairs* 14(4):118–130.

Robinson, James, and Harold Luft. 1987. Competition and the Cost of Hospital Care, 1972–1982. *Journal of the American Medical Association* 257(23):3241–3245.

Rosko, Michael D. 1989. A Comparison of Hospital Performance under the Partial-Payer Medicare PPS and State All-Payer Rate-Setting Systems. *Inquiry* 26(1): 48–61.

Russell, Louise B. 1979. Regulating the Diffusion of Hospital Technologies. *Law and Contemporary Problems* 43(1):26–42.

Salkever, David S., and Thomas W. Bice. 1976. The Impact of Certificate-of-Need Controls on Hospital Investment. *Milbank Quarterly* 54(2):185–214.

———. 1979. *Hospital Certificate-of-Need Controls: Impact on Investments, Costs, and Use*. Washington, DC: American Enterprise Institute for Public Policy Research.

Sherman, Daniel. 1988. *The Effect of State Certificate-of-Need Laws on Hospital Costs: An Economic Policy Analysis*. Washington, DC: U.S. Federal Trade Commission, Bureau of Economics.

Shortell, Stephen M., and Edward F. X. Hughes. 1988. The Effects of Regulation, Competition, and Ownership on Mortality Rates among Hospital Inpatients. *New England Journal of Medicine* 318(17):1100–1107.

Simpson, James B. 1986. Full Circle: The Return of Certificate-of-Need Regulation of Health Facilities to State Control. *Indiana Law Review* 19(4):1025–1127.

Sloan, Frank A. 1981. Regulation and the Rising Cost of Hospital Care. *Review of Economics and Statistics* 63(4):479–487.

———. 1983. Rate Regulation as a Strategy for Hospital Cost Control: Evidence from the Last Decade. *Milbank Quarterly* 61(2):195–221.

———. 1988. Property Rights in the Hospital Industry. In *Health Care in America: The Political Economy of Hospitals*, ed. Harold E. Frech, III. San Francisco: Pacific Research Institute for Public Policy.

Sloan, Frank A., and Bruce Steinwald. 1980a. Effects of Regulation on Hospital Costs and Input Use. *Journal of Law and Economics* 23(1):81–109.

———. 1980b. *Insurance, Regulation, and Hospital Costs*. Lexington, MA: D. C. Heath.

Sloan, Frank A., Joseph Valvona, James M. Perrin, and Killard W. Adamache. 1986. Diffusion of Surgical Technology: An Exploratory Study. *Journal of Health Economics* 5(1):31–61.

SMG Marketing Group. 1984–1995. *Freestanding Outpatient Surgery Centers: Report and Directory* (annual). Chicago: SMG Marketing Group.

Teplensky, Jill D., Mark V. Pauly, John R. Kimberly, Alan L. Hillman, and J. Sanford Schwartz. 1995. Hospital Adoption of Medical Technology: An Empirical Test of Alternative Models. *Health Services Research* 30(3):437–465.

Wedig, Gerard, Mahmud Hassan, and Frank Sloan. 1989. Hospital Investment Decisions and the Cost of Capital. *Journal of Business* 62(4):517–536.

Wendling, Wayne, and Jack Werner. 1980. Nonprofit Firms and the Economic Theory of Regulation. *Quarterly Review of Economics and Business* 20(3):6–18.

Wholey, Douglas, Roger Feldman, and Jon B. Christianson. 1995. The Effect of Market Structure on HMO Premiums. *Journal of Health Economics* 14(1):81–105.

Zwanziger, Jack, and Glenn A. Melnick. 1996. Can Managed Care Plans Control Health Care Costs? *Health Affairs* 15(2):186–199.

Mortality in Medicare Beneficiaries Following Coronary Artery Bypass Graft Surgery in States With and Without Certificate of Need Regulation

Mary S. Vaughan-Sarrazin, PhD
Edward L. Hannan, PhD
Carol J. Gormley, MA
Gary E. Rosenthal, MD

Context Certificate of need regulation was designed to control health care costs by preventing health care facilities from expanding unnecessarily. While there have been several studies investigating whether these regulations have affected health care investment, few have evaluated the relationship between certificate of need regulation and quality of care.

Objective To compare risk-adjusted mortality and hospital volumes for coronary artery bypass graft (CABG) surgery in states with and without certificate of need regulation.

Design, Setting, and Participants Retrospective cohort study of 911407 Medicare beneficiaries aged 65 years or older, who underwent CABG surgery between 1994 and 1999 in 1063 US hospitals.

Main Outcome Measures States (and the District of Columbia) with continuous (n=27), none (n=18), or intermittent (n=6) certificate of need regulation; mortality (in-hospital or within 30 days of CABG surgery) rates; and mean annual hospital volumes for CABG surgery.

Results Unadjusted mortality was 5.1% in states without certificate of need regulation compared with 4.4% in states with continuous regulation, and 4.3% in states with intermittent certificate of need regulation ($P<.001$ for each comparison). Adjusting for demographic and clinical factors, mortality remained higher in states without certificate of need regulation compared with states with continuous certificate of need regulation (odds ratio [OR], 1.22; 95% confidence interval [CI], 1.15-1.28; $P<.001$). Using the same groups for comparison, the mean annual hospital volume for CABG surgery was 84% lower in states without certificate of need regulation (104 vs 191; $P<.001$) and more patients underwent CABG surgery in low-volume hospitals (<100 procedures annually) (30% vs 10% for states with continuous certificate of need programs; $P<.001$). Following the repeal of certificate of need regulation in states categorized as intermittent, the percentage of patients undergoing CABG surgery in low-volume hospitals tripled.

Conclusions Mortality rates for Medicare patients undergoing CABG surgery were higher in states without certificate of need regulation. Repeal of certificate of need regulations during the study period was associated with declines in hospital volume for CABG surgery.

JAMA. 2002;288:1859-1866 www.jama.com

CERTIFICATE OF NEED REGULATION began in 1974 under federal guidelines that were designed to control health care costs by preventing health care facilities from expanding unnecessarily. Certificate of need laws also were intended to ensure quality of care and clinical proficiency by limiting the number of health care facilities performing complex medical procedures. However, opponents of certificate of need regulation argued that it may limit competition and give unfair economic advantage to established facilities. In 1984, opponents to certificate of need regulation successfully worked to enact legislation that abolished the federal government's role. This legislation allowed each state to determine whether to have certificate of need regulation.[1] With the enactment of public policies in the mid-1980s to deregulate many sectors of the economy and the emergence of competition in health care, many states, in turn, have significantly reduced certificate of need regulation or eliminated it altogether.

At the heart of the certificate of need regulation debate are concerns about whether elimination of the regulation may adversely affect the quality of care or result in excess use of services. While

Author Affiliations: Division of General Internal Medicine, Department of Medicine, VA Medical Center and University of Iowa College of Medicine, Iowa City (Drs Vaughan-Sarrazin and Rosenthal); School of Public Health, State University of New York, Albany (Dr Hannan); and Florida Hospital Association, Tallahassee (Ms Gormley).
Corresponding Author and Reprints: Gary E. Rosenthal, MD, Division of General Internal Medicine, University of Iowa Hospitals and Clinics, SE618 GH, 200 Hawkins Dr, Iowa City, IA 52242 (e-mail: gary-rosenthal@uiowa.edu).

there have been several studies investigating whether certificate of need regulation has affected health care investment,[2-5] few studies have evaluated the relationship of certificate of need regulation with quality of care.[6,7]

Our study examines associations between state certificate of need regulation and outcomes of patients undergoing coronary artery bypass graft (CABG) surgery. The analysis used claims data for Medicare beneficiaries from all 50 states for a 6-year period (1994-1999) to compare risk-adjusted hospital mortality rates and the proportions of patients undergoing CABG surgery in low-volume hospitals in states with and without certificate of need regulation. Although the validity of using Medicare claims data to adjust for case-mix and severity of illness has been questioned in analyses of hospital mortality, it is likely that state-level differences in patient-mix are less than hospital-level differences. Moreover, Medicare data are available for all states, making it feasible to compare outcomes across states with and without certificate of need regulation.

While the cross-sectional design of the analysis may limit the ability to infer a causal relationship between the repeal of certificate of need regulations and patient outcomes, we nonetheless hypothesized that states without certificate of need regulation would have more low-volume hospitals and higher proportions of patients receiving CABG surgery at low-volume hospitals. We further hypothesized that states without certificate of need regulation would have higher mortality rates.

METHODS

Data

The study used Medicare Provider Analysis and Review Part A public use data files, which were purchased from the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration). The Part A files contain data available on the UB-92 hospital discharge abstract for a 100% sample of Medicare patients discharged from acute care hospitals and have been extensively used in health services research.[8] Data elements include demographic information; patients' state of residence; primary and secondary diagnoses and procedures (classified by the *International Classification of Diseases, Ninth Revision, Clinical Modification* system); the diagnosis related group; admission source (eg, transfer from another hospital, emergency department); admission and discharge dates; disposition at the time of hospital discharge; and a 6-digit unique hospital identifier. In addition, Part A files are matched quarterly to the Medicare Enrollment database to obtain dates of death for Medicare beneficiaries who died after hospital discharge.

Patients who underwent CABG surgery between 1994 and 1999, and who were 65 years or older were identified (N=911 740) on the basis of specific diagnosis related groups (106, 107, and 109). The 109 group became effective in October 1998. Patients discharged from hospitals with 5 or fewer CABG surgery procedures in the Medicare Provider Analysis and Review data (n=333; 0.04% of total cases) were assumed to represent procedure coding errors and were excluded from the analysis, leaving a final sample of 911 407 patients in 1063 US hospitals. Analyses including these patients yielded nearly identical findings.

Information on the number of Medicare beneficiaries aged 65 years or older with either Medicare hospital or supplemental insurance in each state was obtained from the Centers for Medicare and Medicaid Services Web site at http://www.hcfa.gov/stats/. Information regarding the percentage of the population aged 65 to 74 years, 75 to 84 years, and 85 years or older by sex was obtained from the US Census 2000 Summary File at http://factfinder.census.gov.

Information about states' certificate of need regulation was obtained from the American Health Planning Association's National Directory of Health Planning, Policy, and Regulatory Agencies for 1993 through 2000.[9] Individual states (and the District of Columbia) were categorized according to whether they had certificate of need regulation regarding open heart surgery in effect from 1994 through 1999. Three certificate of need categories were defined. Twenty-seven states had *continuous* certificate of need regulations for open heart surgery from 1994 through 1999. Eighteen states terminated certificate of need regulation for open heart surgery prior to 1994 and had *no* (without) regulation during the study period. Six states had terminated and/or reinstated certificate of need regulation for open heart surgery between 1994 and 1999 and had *intermittent* regulation during the study period. Of the states in the no regulation category, 8 states had regulation for services other than open heart surgery (Arkansas, Indiana, Louisiana, Minnesota, Montana, Oklahoma, Oregon, and Wisconsin) from 1994 through 1999, and 10 states had no regulation for any services (Arizona, California, Colorado, Idaho, Kansas, New Mexico, South Dakota, Texas, Utah, and Wyoming). Of the states in the intermittent category, Pennsylvania repealed regulations in 1996; Nebraska, Nevada, North Dakota, and Delaware repealed regulations in 1997; and Ohio repealed regulations in 1998.

Analysis

Demographic variables and primary and secondary diagnosis and procedure codes that represented potential patient risk factors were identified in the Medicare Provider Analysis and Review data. These variables included race, sex, age, admission type, and several comorbid conditions previously identified by Hannan et al[10,11] as risk factors for post-CABG surgery mortality using administrative data. The prevalence of demographic variables and clinical risk factors, mean predicted risk of death, and mortality rates of patients in states in all 3 certificate of need regulation categories were compared using analysis of variance or the χ^2 test. Mortality was defined as deaths that occurred within 30 days of CABG surgery or during hospitalization for CABG surgery.

A risk-adjustment model was developed by entering candidate variables associated ($P<.05$) with mortality in bivariate analyses into a stepwise logistic regression. Variables independently related to mortality were identified using a statistical criterion of $P<.01$. In the risk-adjustment model, age was expressed as 1 of 5 indicator variables (70-74 years, 75-79 years, 80-84 years, 85-89 years, or $\geq$90 years), with a referent category of 65 to 69 years. Race was expressed using 2 indicator variables for patients who were classified in the database as either having black or other nonwhite race. Surgical priority was expressed using 2 indicator variables for emergent and urgent admissions, relative to elective admissions. Admission source was expressed as indicator variables for patients transferred to the hospital from another acute care facility and patients admitted through the emergency department, with a referent category that primarily included patients referred by a physician.

Model discrimination was evaluated using the c statistic,[12] and calibration was assessed using the goodness of fit statistic.[13] The coefficients from the risk adjustment model were then used to determine a predicted risk of death (0%-100%) for each patient as a measure of overall patient severity.

Differences in risk-adjusted mortality were determined by including 2 indicator variables for CABG procedures performed in states with intermittent or without certificate of need regulations in the patient-level multivariable risk-adjustment model that also included patient-specific risk factors. The regression coefficients were exponentiated to provide the adjusted odds of death of patients in these 2 groups, relative to patients in states with continous certificate of need regulations. This analysis was then repeated using an indicator variable for each state without or with intermittent certificate of need regulations to determine the odds of death for individual states, relative to all states with continuous certificate of need regulations. To account for the clusters of patients within hospitals and for heterogeneity in the odds of death across individual states in each group, robust methods of determining the 95% confidence intervals (CIs) around the odds ratios (ORs) were used.[14,15]

Mean age-adjusted CABG surgery rates and annual hospital CABG surgery volumes in states with continuous, intermittent, and without certificate of need regulations were compared using analysis of variance. Surgery rates for each state were standardized directly by determining the observed rate in each age-sex stratum and then applying those rates to a standard distribution of patients (ie, the age-sex distribution of the entire sample).[16] In addition, the proportion of low-volume hospitals and the proportions of patients undergoing CABG surgery in low-volume hospitals were compared using the χ^2 statistic. These analyses used the following thresholds to define low-volume hospitals: less than 50 procedures performed for Medicare patients per year or less than 100.

Analyses were performed using SAS statistical sofware (Version 8.0; SAS Institute, Cary, NC), except for the logistic regression analysis with robust variance estimates, which was performed using STATA statistical sofware (Version 7; STATA Corp, College Station, Tex).

RESULTS

The mean (SD) age of patients was 73 (5.3) years and was nearly identical in all 3 certificate of need categories (continuous, intermittent, and none) (TABLE 1). Of 911 407 Medicare patients, 34.8% were women and 93.0% were white. The 3 certificate of need categories varied ($P<.001$) according to sex and race, although the magnitude of the differences was relatively small. Patients in states without certificate of need regulations had a somewhat lower prevalence of diabetes, chronic obstructive lung disease, congestive heart failure, cerebrovascular disease, and peripheral vascular disease compared with patients in states with continuous or intermittent certificate of need regulations. Although patients in states without regulations were less likely ($P<.001$) to be classified as undergoing emergent procedures, they were more likely ($P<.001$) to undergo CABG surgery on the same day as a cardiac catheterization or on the same day as a percutaneous transluminal coronary angioplasty (PTCA). Patients in states without regulations were less likely ($P<.001$) to be transferred from another acute care hospital.

Unadjusted 30-day or in-hospital mortality rates in states without certificate of need regulations were higher than in states with either continuous or intermittent certificate of need regulations (5.1% vs 4.4% and 4.3%, respectively; $P<.001$ for each pairwise comparison). Differences in mortality were similar in analyses limited to just in-hospital mortality (4.2% vs 3.6% and 3.6%, respectively; $P<.001$) or to just 30-day mortality (5.0% vs 4.2% and 4.2%, respectively; $P<.001$). These differences were consistent across individual years (data not shown).

Risk-Adjusted Mortality

Fourteen risk factors met criteria for inclusion in the multivariable risk-adjustment model: age (expressed as 5 indicator variables); female sex; race (expressed as 2 indicator variables); primary diagnosis of acute myocardial infarction; secondary diagnoses of congestive heart failure, cerebrovascular disease, diabetes mellitus, peripheral vascular disease, or chronic obstructive pulmonary disease; surgical priority (expressed as 2 indicator variables); admission source (expressed as 2 indicator variables); PTCA on the same day as CABG surgery; cardiac catheterization on the same day as CABG surgery; and use of an intra-aortic balloon pump prior to CABG surgery. The ORs associated with each risk factor are shown in TABLE 2. The c statistic of the model was 0.72. The proportion of patients with a predicted risk of death of less than 2% (based on the risk-adjustment model) was somewhat higher ($P<.001$) in states without certificate of need regulations (Table 1).

Using the multivariable model, the odds of death was 22% higher for patients in states without certificate of need regulations for open heart surgery, relative to patients in states with continuous certificate of need regulations (OR, 1.22; 95% CI, 1.15-1.28; *P*<.001) during the entire 6-year period of analysis. Results were similar in analyses limited to deaths within 30 days (OR, 1.23; 95% CI, 1.17-1.30; *P*<.001) and in-hospital deaths (OR, 1.20; 95% CI, 1.13-1.27; *P*<.001). Results were similar in an analysis that examined the odds of death separately for the 10 states without certificate of need regulations for any clinical service relative to states with continuous regulations (OR, 1.23; 95% CI, 1.15-1.31; *P*<.001). Results were also similar in an analysis of the 8 states with intermittent certificate of need regulations for some services, but not open heart surgery (OR, 1.20; 95% CI, 1.12-1.27; *P*<.001). The odds of death for patients receiving CABG surgery in states with intermittent certificate of need regulations were similar to states with continuous regulations (OR, 0.99; 95% CI, 0.92-1.07; *P*=.78).

Further analyses (FIGURE 1) found that the adjusted odds of death of patients in states without certificate of need regulations were higher in each of the 6 years, when examined individually, ranging from 16% to 26%. Differences in risk-adjusted odds of death in states with intermittent certificate of need regulations were generally similar to states with continuous regulations, with the exception of 1994, during which mortality was higher in states with intermittent regulations (OR, 1.14; 95% CI, 1.02-1.28; *P*=.02).

The odds of death of patients in individual states without or with intermittent certificate of need regulations for open heart surgery were also determined, relative to patients in states with continuous regulations. These analyses found a higher (*P*<.05) odds of death for 10 of 18 states without regulations: Arizona (OR, 1.56; 95% CI, 1.39-1.76); Arkansas (OR, 1.22; 95% CI, 1.06-1.40); Colorado (OR, 1.18; 95% CI, 1.04-1.35); Idaho (OR, 1.42; 95% CI, 1.07-1.89); Indiana (OR, 1.14; 95% CI, 1.04-1.23); Louisiana (OR, 1.36; 95% CI, 1.16-1.59); Oklahoma (OR, 1.26; 95% CI, 1.11-1.43); Oregon (OR, 1.10; 95% CI, 1.02-1.19); Texas (OR, 1.45; 95% CI, 1.35-1.57); and Wisconsin (OR, 1.14; 95% CI, 1.01-1.29). South Dakota, which had no certificate of need regulation, had lower odds of death (OR, 0.64; 95% CI, 0.55-0.74). Of the 6 states with inter-

Table 1. Patient Characteristics According to State Certificate of Need Regulation Status

	State Certificate of Need Regulation Status, %			
	Continuous (n = 509 679)	None (n = 278 611)	Intermittent (n = 123 117)	*P* Value*
Women	35.0	33.8	36.2	<.001
Age, mean (SD), y	73 (5.35)	73 (5.38)	73 (5.25)	<.001
65-69	29.0	29.2	28.6	<.001
70-74	32.4	32.3	33.0	
75-79	25.1	24.9	25.7	
80-84	10.9	10.9	10.4	
85-89	2.4	2.4	2.1	
≥90	0.2	0.3	0.2	
Race				
White	93.0	91.8	95.1	<.001
Black	4.4	2.8	3.1	
Other	2.6	5.4	1.8	
Surgical priority				
Emergent admission	30.1	22.5	32.0	<.001
Urgent	31.3	35.6	28.3	<.001
Elective	38.2	41.6	39.1	<.001
Admission source				
Transferred from other facility	22.1	14.4	23.4	<.001
Emergency department	19.0	19.7	17.4	<.001
Comorbid conditions				
Diabetes mellitus	10.6	9.4	10.1	<.001
Chronic obstructive lung disease	14.3	14.0	14.5	.003
Congestive heart failure	19.3	18.3	19.3	<.001
Cerebrovascular disease	10.2	9.5	10.2	<.001
Peripheral vascular disease	8.6	8.0	8.7	<.001
High-risk clinical conditions				
Primary diagnosis of acute myocardial infarction	20.4	20.0	20.2	<.001
Cardiac catheterization on same day as coronary artery bypass graft (CABG) surgery	7.8	9.6	7.8	<.001
Percutaneous transluminal coronary angioplasty on same day as CABG surgery	1.2	1.7	1.2	<.001
Intra-aortic balloon pump prior to day of CABG surgery	3.4	3.1	3.2	<.001
Predicted risk of death, %				
Mean (SD)	4.7 (4.1)	4.5 (4.0)	4.6 (4.0)	<.001
<2	15.9	16.8	16.2	<.001
2-5	55.5	56.0	55.3	
5-10	20.9	20.0	21.0	
>10	7.8	7.3	7.5	
Observed deaths				
30-day or in-hospital	4.4	5.1	4.3	<.001
30-day only	4.2	5.0	4.2	<.001
In-hospital only	3.6	4.2	3.6	<.001

*The *P* value tests the null hypothesis that the 3 groups are equivalent.

mittent certificate of need regulations, the odds of death were higher for Nebraska (OR, 1.28; 95% CI, 1.04-1.59) and Nevada (OR, 1.57; 95% CI, 1.37-1.81); and lower for Pennsylvania (OR, 0.87; 95% CI, 0.80-0.95) and Delaware (OR, 0.92; 95% CI, 0.88-0.96).

Table 2. Risk Factors Included in the Logistic Regression Risk-Adjustment Model*

Risk Factor	Unadjusted Mortality, %†	OR (95% CI)	*P* Value
All	4.6		
Women	5.7	1.27 (1.23-1.28)	<.001
Age, y‡			
70-74	4.0	1.22 (1.18-1.25)	<.001
75-79	5.3	1.55 (1.50-1.60)	<.001
80-84	7.2	2.04 (1.97-2.11)	<.001
85-89	9.4	2.56 (2.42-2.70)	<.001
≥90	12.7	3.39 (2.95-3.90)	<.001
Race§			
Black	5.6	1.18 (1.11-1.25)	<.001
Other nonwhite	5.0	1.15 (1.08-1.23)	<.001
Comorbid conditions			
Diabetes mellitus	5.4	1.10 (1.06-1.14)	.003
Chronic obstructive pulmonary disease	5.8	1.24 (1.20-1.28)	<.001
Congestive heart failure	9.0	2.14 (2.08-2.19)	<.001
Cerebral vascular disease	9.2	2.31 (2.24-2.39)	<.001
Peripheral vascular disease	6.4	1.41 (1.36-1.46)	<.001
Surgical priority‖			
Emergent procedure	6.0	1.17 (1.12-1.23)	<.001
Urgent procedure	4.8	1.12 (1.07-1.17)	<.001
High-risk clinical conditions			
Primary diagnosis of acute myocardial infarction	7.1	1.33 (1.30-1.37)	<.001
Cardiac catheterization on same day as coronary artery bypass graft (CABG) surgery	7.8	1.64 (1.58-1.71)	<.001
Percutaneous transluminal coronary angioplasty on same day as CABG surgery	12.4	2.61 (2.46-2.77)	<.001
Intra-aortic balloon pump prior to day of CABG surgery	15.0	3.05 (2.86-3.24)	<.001
Admission source			
Transferred from other facility	5.5	1.12 (1.07-1.16)	<.001
Emergency department	6.4	1.13 (1.08-1.18)	<.001

*OR indicates odds ratio; CI, confidence interval.
†The unadjusted mortality rate was higher (*P*<.001) for patients with each of the variables listed than in patients without the variable or included in the referent group.
‡The ORs are relative to patients aged 65 to 69 years.
§The ORs are relative to white patients.
‖The ORs are relative to elective procedures.

Hospital Volume

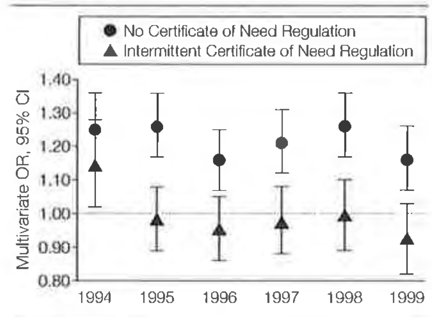
The mean (SD) annual hospital volume for Medicare beneficiaries in states with continuous certificate of need regulations was 84% higher than in states without regulations (191 [155] vs 104 [97]; *P*<.001), but was similar (*P*=.16) to the mean (SD) annual hospital volume in states with intermittent regulations (173 [130]). However, mean annual hospital volume in states with intermittent regulations (ie, states that repealed certificate of need regulations during the study period) decreased by 23% from 201 to 154 between 1994 and 1999, while mean volumes decreased only by 1% from 191 to 189 for states with continuous regulation and 7% from 105 to 98 for states without regulations. Additionally, the number of hospitals performing CABG surgeries increased 22% in states with intermittent certificate of need regulations, while the increase was 4% both in states with continuous and without regulations.

Higher proportions (*P*<.001) of hospitals performing CABG surgeries in states without certificate of need regulations were classified as being of lower volume than in states with continuous or intermittent regulations (FIGURE 2). For example, 32% of the 474 hospitals that performed CABG surgeries in states without regulations had mean annual volumes for Medicare beneficiaries of 50 or less, while 62% of hospitals had mean annual volumes of 100 or less. In contrast, 12% and 33% of hospitals in states with continuous certificate of need regulations had mean annual volumes of 50 or less and 100 or less, respectively, and 10% and 40% of hospitals in states with intermittent regulations had mean annual volumes of 50 or less and 100 or less, respectively.

Similarly, proportions of patients undergoing CABG surgery in low-volume hospitals were higher (*P*<.001) in states without certificate of need regulations (Figure 2). In states without regulation, 9% of CABG surgeries occurred in hospitals that performed 50 or fewer procedures and 30% of CABG surgeries occurred in hospitals that performed 100 or fewer procedures annually. In contrast, in states with continuous certificate of need regulations, the respective percentages were 2% and 10%.

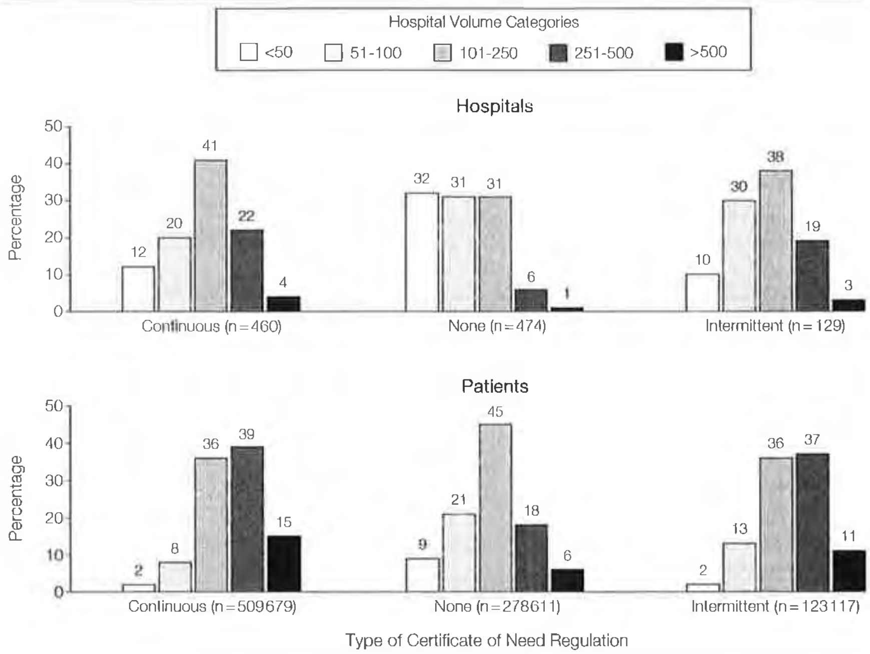
For states with intermittent regulations, the proportion of patients treated at low-volume hospitals increased during the study period to a greater degree than in states with either continuous or intermittent certificate of need regulations (particularly after 1996, which was the first year during the study period in which a repeal occurred). For example, the proportion of patients treated in hospitals that performed fewer than

Figure 1. Risk-Adjusted Odds of Death



Reference group is states with continuous certificate of need regulations (dotted line). OR indicates odds ratio; CI, confidence interval.

Figure 2. Differences in the Distributions of Mean Annual Hospital Volumes and in the Proportions of Patients Undergoing CABG Surgery Between 1994 and 1999



Volumes reflect procedures performed in Medicare beneficiaries aged 65 years or older. CABG indicates coronary artery bypass graft.

100 procedures annually increased 3-fold from 6% in 1996 to 19% in 1999.

CABG Surgery Use

Overall age and sex-adjusted use was lower in states without certificate of need regulations (4.23 procedures/1000 Medicare beneficiaries aged ≥65 years) compared with states with continuous (4.75 procedures/1000 Medicare beneficiaries aged ≥65 years) and intermittent (4.97 procedures/1000 beneficiaries) regulations. Results were similar in analyses that only included patients who had CABG surgery performed in hospitals in their state of residence (use rates of 3.83 procedures/1000 Medicare beneficiaries for states without regulations, 4.16 procedures/1000 Medicare beneficiaries for continuous regulations, and 4.59 procedures/1000 Medicare beneficiaries for intermittent regulations). Differences in CABG surgery use were smaller when the age- and sex-adjusted use rates in individual states were averaged (4.66 procedures/1000 Medicare beneficiaries for states without regulations, 4.57 procedures/1000 Medicare beneficiaries for continuous regulations, and 4.84 procedures/1000 Medicare beneficiaries for intermittent regulations). This largely reflected the lower use rate in California (3.20 procedures/1000 Medicare beneficiaries), which is a state without a certificate of need regulation, and the "unweighting" of the state's large CABG surgery volume in the latter calculation.

COMMENT

This analysis represents the first large-scale evaluation of the potential impact of certificate of need regulation on hospital outcomes and use of CABG surgery in the United States. Using Medicare claims data for patients undergoing CABG surgery during 1994 to 1999, a period in which US health care delivery experienced substantial change, the study found that risk-adjusted mortality was 22% higher in the 18 states that had no certificate of need regulation for open heart surgery than in the 26 states and the District of Columbia that had continuous certificate of need regulations. The higher mortality in states without a certificate of need regulation was observed in all 6 years of the study period. In addition, mean patient volume in states with continuous certificate of need regulations was 84% higher than in states without regulation. A substantially higher proportion of patients in states without a certificate of need regulation underwent CABG surgery in low-volume hospitals.

These findings confirm our a priori hypotheses that the absence of certificate of need regulations would be associated with higher mortality and more low-volume hospitals providing CABG surgery. While factors other than certificate of need status may explain the differences in hospital volume (eg, differences in population density or managed care penetration), the higher proportions of patients treated at low-volume hospitals in states without certificate of need regulation provides a plausible explanation for the higher risk-adjusted mortality in such states, given the well-documented relationship between hospital volume and mortality for CABG surgery and other surgical procedures.[17-20]

While mortality was similar in states with continuous and intermittent certificate of need regulations, the number of hospitals performing CABG surgery in states that repealed regulations (intermittent) increased to a greater degree than in states with continuous regulations, as did the proportion of patients undergoing CABG surgery in low-volume hospitals.

The study also found that somewhat higher proportions of patients undergoing CABG surgery in states without certificate of need regulations (vs continuous or intermittent regulations) underwent cardiac catheterization or PTCA on the same day as surgery. Since cardiac catheterization and PTCA are also generally regulated in states that have certificate of need regulations for open heart surgery, outcomes of these procedures in states without certificate of need regulations may be worse for the same reasons that outcomes of CABG surgery are worse in states without regulations. The higher incidence of cardiac catheterization and PTCA on the same day as CABG surgery may reflect higher complication rates for those procedures, rather than greater patient presurgical risk. If this is the case, then use of these variables as risk factors in the mortality model biases results in favor of states without certificate of need regulations. When these variables were not included in the mortality risk-adjustment models, the relative odds of death increased slightly to 1.24 in states without regulations.

Last, CABG surgery use was somewhat lower in states without certificate of need regulations when compared with states with either continuous or intermittent regulations. While this finding was somewhat unexpected, most of the lower use was explained by the low rates of CABG surgery in California, a state with a high presence of managed care and with low use of hospital services and other surgical procedures.[21]

Taken together, these findings suggest that repeal of certificate of need regulations may have adverse effects on patient outcomes and may promote the development of low-volume surgical programs. Although underlying factors responsible for the direct relationship between volume and outcomes in CABG surgery (eg, better presurgical evaluations, anesthesia practices, surgeon skill, postoperative care, nursing care) have yet to be elucidated, surgical volume has become an important proxy for quality in recent initiatives to measure quality and reward high-quality clinicians.[22]

However, in interpreting the current findings in this report, it is important to recognize that the observational, cross-sectional design can only infer, but not prove, a cause and effect relationship between certificate of need status and CABG surgery outcomes. In addition, several other potential methodological limitations should be considered.

First, the analysis was limited to Medicare beneficiaries and, thus, only includes roughly half of all patients undergoing CABG surgery. However, it is likely that if patterns of care were different for Medicare patients relative to other patients, these differences would be similar across states and would not necessarily bias study findings.

Second, any associations between certificate of need regulations and post-CABG surgery mortality, hospital procedure volumes, and surgery use may represent confounding due to other factors that may differ according to certificate of need status. These factors may include managed care penetration; regional physician practice variation; efforts to report and disseminate post-CABG surgery outcomes data to hospitals, clinicians, third-party payers, and the public; and differences in population and physician density and specialty mix, although the degree to which certificate of need status is related to these factors has not been established. Furthermore, alternative study designs to more definitively determine causality (ie, randomization to certificate of need) are not feasible.

Third, the analysis may also be confounded by regional differences in the use of PTCA as an alternative treatment for coronary insufficiency. Differences in PTCA use may directly affect CABG surgery use and lead to selection bias in analyses comparing post-CABG surgery mortality rates. The direction of such bias is difficult to estimate, given that PTCA may be preferentially used in patients with less severe forms of coronary artery disease or in patients with severe disease, but at high operative risk.

Fourth, there is likely to be heterogeneity in the character of certificate of need regulations for open heart surgery across individual states, which may lead to differences in the scope and stringency of regulation. In addition, specific regulations within a given state can vary from year to year, and certain aspects of certificate of need regulation may be phased out over time. Furthermore, states without certificate of need regulations may have other types of health care regulatory mechanisms, such as licensure or limits on capital diffusion.

Last, the risk-adjustment models based on administrative data are subject to limitations. The reliability of individual diagnoses coded in administrative data may vary across hospitals, and important prognostic variables (eg, left ventricular ejection fraction, vital signs, functional status) cannot be ascertained from administrative data. However, in the absence of a national clinical database of patients undergoing CABG surgery, which exists for patients undergoing CABG in Veterans Affairs hospitals[23,24] or in New York State,[25,26] administrative databases represent the only vehicle for examining the potential impact of state-level differences in certificate of need regulation.

Despite these limitations, the current study has several important implications for health services research and policymakers. First, this analysis provides evidence that post-CABG surgery mortality may be higher in states without certificate of need regulation than in states with such regulations. The analysis found no systematic differences in the prevalence of individual risk factors or in the overall predicted risk of death that would account for mortality differences. In addition, the analysis found that average hospital volumes in states without certificate of need regulation were substantially lower and that patients in such states were substantially more likely to undergo CABG surgery in low-volume hospitals. Furthermore, states that recently repealed certificate of need regulations experienced large decreases in hospital volume in the years following the repeal. The higher proportion of patients undergoing CABG surgery in low-volume hospitals may underlie the higher risk-adjusted mortality in states without certificate of need regulations. While there are limitations to the study, this analysis suggests that policymakers should carefully consider the potential adverse effects of repeal of certificate of need regulations. In a time when patient safety, medical errors, and patient outcomes are coming under greater scrutiny, certificate of need regulations may be an important and effective regulatory mechanism for ensuring higher quality care and better patient outcomes.

Author Contributions: *Study concept and design:* Vaughan-Sarrazin, Hannan, Gormley, Rosenthal.
Acquisition of data: Vaughan-Sarrazin.
Analysis and interpretation of data: Vaughan-Sarrazin, Hannan, Rosenthal.
Drafting of the manuscript: Vaughan-Sarrazin, Rosenthal.
Critical revision of the manuscript for important intellectual content: Vaughan-Sarrazin, Hannan, Gormley, Rosenthal.
Statistical expertise: Vaughan-Sarrazin, Hannan.
Obtained funding: Gormley, Rosenthal.
Administrative, technical, or material support: Gormley, Rosenthal.
Study supervision: Rosenthal.

Funding/Support: This research was supported by a contract with the Florida Hospital Association and by grant ACC 97-004 from the Health Services Research and Development Service, Veterans Health Administration, Department of Veterans Affairs.

Disclaimer: The views expressed in this article are those of the authors and do not necessarily represent the views of the Department of Veterans Affairs or the Florida Hospital Association.

REFERENCES

1. Altman SH, Ostby EK. Paying for hospital care: the impact on federal policy. In: Ginzberg E, ed. *Health Services Research: Key to Health Policy.* Cambridge, Mass: Harvard University Press; 1991:46-68.
2. Sloan F, Steinwald B. Effects of regulation on hospital costs and input use. *J Law Econ.* 1980;23:81-109.
3. Conover CJ, Sloan FA. Does removing certificate of need regulations lead to a surge in health care spending? *J Health Polit Policy Law.* 1998;23:455-481.
4. Harrington C, Swan JH, Nyman JA, Carrillo H. The effect of certificate of need and moratoria policy on change in nursing home beds in the United States. *Med Care.* 1997;35:574-588.
5. Howell JR. Evaluating the impact of certificate of need regulation using measures of ultimate outcome: some cautions from experience in Massachusetts. *Health Serv Res.* 1997;19:587-613.
6. Shortell SM, Hughes EF. The effects of regulation, competition, and ownership on mortality rates among hospital inpatients. *N Engl J Med.* 1988;318:1100-1107.
7. Robinson JL, Nash DB, Moxey E, O'Connor JP. Certificate of need and the quality of cardiac surgery. *Am J Med Qual.* 2001;16:155-160.
8. Mitchell JB, Bubolz T, Paul JE, et al. Using Medicare claims for outcomes research. *Med Care.* 1994;32(suppl):38-51.
9. *National Directory of Health Planning, Policy, and Regulatory Agencies, 1993-2000.* Falls Church, Va: American Health Planning Association; 2000.
10. Hannan EL, Racz MJ, Jollis JG, Peterson ED. Using Medicare claims data to assess provider quality for CABG surgery: does it work well enough? *Health Serv Res.* 1997;31:659-678.
11. Hannan EL, Kilburn H Jr, Lindsey M, Lewis R. Clinical versus administrative databases for CABG surgery: does it matter? *Med Care.* 1992;30:892-907.
12. Ash AS, Schwartz M. Evaluating the performance of risk-adjustment methods: dichotomous measures. In: Iezzoni LI, ed. *Risk Adjustment for Measuring Health Care Outcomes.* 2nd ed. Chicago, Ill: Health Administration Press; 1997:427-470.
13. Lemeshow S, Hosmer DW Jr. A review of goodness of fit statistics for use in the development of logistic regression models. *Am J Epidemiol.* 1982;115:92-106.
14. Huber PJ. The behavior of maximum likelihood estimates under non-standard conditions. In: *Proceedings of the Fifth Berkeley Symposium on Mathematical Statistics and Probability.* Berkeley: University of California Press; 1967:221-233.
15. White H. A heteroskedasticity-consistent covariance matrix estimator and a direct test for heteroskedasticity. *Econometrica.* 1980;48:817-830.
16. Feinstein AR. *Clinical Epidemiology: The Architecture of Clinical Research.* Philadelphia, Pa: WB Saunders Co; 1985:441-445.
17. Hannan EL, O'Donnell JF, Kilburn H Jr, Bernard HR, Yazici A. Investigation of the relationship between volume and mortality for surgical procedures performed in New York State hospitals. *JAMA.* 1989;262:503-510.
18. Luft HS, Bunker JP, Enthoven AC. Should operations be regionalized: the empirical relation between surgical volume and mortality. *N Engl J Med.* 1979;301:1364-1369.
19. Luft HS, Junt SS, Maerki SC. The volume-outcome relationship: practice makes perfect or selective referral patterns? *Health Serv Res.* 1987;22:157-182.
20. Showstack JA, Rosenfeld KE, Garnick DW, Luft HS, Schaffarzick RE, Fowles J. Association of volume with outcome of coronary artery bypass graft surgery. *JAMA.* 1987;257:785-789.
21. Escarce JJ, Van Horn RL, Pauly MV, Williams SV, Shea JA, Chen W. Health maintenance organizations and hospital quality for coronary artery bypass surgery. *Med Care Res Rev.* 1999;56:340-362.
22. Milstein A, Galvin RS, Delbanco SF, Salber P, Buck CR. Improving the safety of health care: the Leapfrog initiative. *Effective Clin Pract.* 2000;3:313-316.
23. Grover FL, Hammermeister KE, Burchfiel C. Initial report of the Veterans Administration preoperative risk assessment study for cardiac surgery. *Ann Thorac Surg.* 1990;50:12-28.
24. Grover FL, Johnson RR, Marshall G, Hammermeister KE. Factors predictive of operative mortality among coronary artery bypass subsets. *Ann Thorac Surg.* 1993;56:1296-1306.
25. Hannan EL, Kilburn H Jr, O'Donnell JF, Lukacik G, Shields EP. Adult open heart surgery in New York State. *JAMA.* 1990;264:2768-2774.
26. Hannan EL, Kilburn H Jr, Racz M, Shields E, Chassin MR. Improving the outcomes of coronary artery bypass surgery in New York State. *JAMA.* 1994;271:761-766.

Circulation. 2006 Nov 14;114(20):2122-9. doi: 10.1161/CIRCULATIONAHA.105.591214.
Epub 2006 Oct 30.

Contemporary impact of state certificate-of-need regulations for cardiac surgery: an analysis using the Society of Thoracic Surgeons' National Cardiac Surgery Database

Verdi J DiSesa [1], Sean M O'Brien, Karl F Welke, Sarah M Beland, Constance K Haan, Mary S Vaughan-Sarrazin, Eric D Peterson

Affiliations
PMID: 17075012 DOI: 10.1161/CIRCULATIONAHA.105.591214

Abstract

Background: Prior research using administrative data associated certificate-of-need (CON) regulation for open heart surgery with higher hospital coronary artery bypass grafting (CABG) volume and lower CABG operative mortality rates in elderly patients. It is unclear whether these findings apply in a general population and after controlling for detailed clinical characteristics and region.

Methods and results: Using the Society of Thoracic Surgeons' (STS) National Cardiac Surgery Database, we examined isolated CABG surgery volume, operative mortality, and the composite end point of operative mortality or major morbidity for the years 2000 to 2003. The presence of CON regulations for open heart surgery was ascertained from the National Directory of the American Health Policy Association and by contacting CON administrators. Results were analyzed nationally, by state, and by region (West, Northeast, Midwest, South) and were adjusted for clinical factors and both population density and region with mixed-effects hierarchical logistic regression models. During 2000 to 2003, there were 314,710 isolated CABG surgeries performed at 294 STS hospitals in CON states (n=27, including Washington, DC) and 280 512 procedures at 343 STS hospitals in non-CON states (n=24). Patient clinical characteristics were similar among CON and non-CON hospitals. States with CON regulations tended to have higher population densities and had significantly higher median hospital annual CABG volumes in each of the years 2000 to 2003 ($P<0.005$). This difference remained significant after adjustment for region and population density. Operative mortality was 2.52% for CON versus 2.62% for non-CON states ($P=0.32$). There was a significant association between CON law and operative mortality in the South. After adjustment for patient risk factors and region, there was a marginally significant reduction of mortality risk in states with CON regulation (adjusted OR 0.92, 95% CI 0.86 to 1.00). However, this difference was not statistically significant when a revised model accounted for random state effects. Similar volume and outcomes results were seen when the analysis was repeated with data from the national Medicare database.

Conclusions: CON states have significantly higher hospital CABG surgery volumes but similar mortality compared with non-CON states. CON regulation alone is not a sufficient mechanism to ensure quality of care for CABG surgery.

Comment in

Does government regulation enhance quality of cardiovascular procedures?
Jones RH.
Circulation. 2006 Nov 14;114(20):2090-1. doi: 10.1161/CIRCULATIONAHA.106.657734.
PMID: 17101866 No abstract available.

Related information

Cited in Books

LinkOut - more resources

Full Text Sources

Atypon

Ovid Technologies, Inc.

Medical

MedlinePlus Health Information

JAMA. 2006 May 10;295(18):2141-7. doi: 10.1001/jama.295.18.2141.

Certificate of need regulations and use of coronary revascularization after acute myocardial infarction

Ioana Popescu [1], Mary S Vaughan-Sarrazin, Gary E Rosenthal

Affiliations
PMID: 16684984 DOI: 10.1001/jama.295.18.2141

Abstract

Context: Certificate of need regulations were enacted to control health care costs by limiting unnecessary expansion of services. While many states have repealed certificate of need regulations in recent years, few analyses have examined relationships between certificate of need regulations and outcomes of care.

Objective: To compare rates of coronary revascularization and mortality after acute myocardial infarction in states with and without certificate of need regulations.

Design, setting, and participants: Retrospective cohort study of 1,139,792 Medicare beneficiaries aged 68 years or older with AMI who were admitted to 4587 US hospitals during 2000-2003.

Main outcome measures: Thirty-day risk-adjusted rates of coronary revascularization with either coronary artery bypass graft surgery or percutaneous coronary intervention and 30-day all-cause mortality.

Results: The 624,421 patients in states with certificate of need regulations were less likely to be admitted to hospitals with coronary revascularization services (321,573 [51.5%] vs 323,695 [62.8%]; P<.001) or to undergo revascularization at the admitting hospital (163,120 [26.1%] vs 163,877 [31.8%]; P<.001) than patients in states without certificates of need but were more likely to undergo revascularization at a transfer hospital (73,379 [11.7%] vs 45,907 [8.9%]; P<.001). Adjusting for demographic and clinical risk factors, patients in states with highly and moderately stringent certificate of need regulations, respectively, were less likely to undergo revascularization within the first 2 days (adjusted hazard ratios, 0.68; 95% confidence interval [CI], 0.54-0.87; P = .002 and 0.80; 95% CI, 0.71-0.90; P<.001) relative to patients in states without certificates of need, although no differences in the likelihood of revascularization were observed during days 3 through 30. Unadjusted 30-day mortality was similar in states with and without certificates of need (109,304 [17.5%] vs 90,104 [17.5%]; P = .76), as was adjusted mortality (odds ratio, 1.00; 95% CI, 0.97-1.03; P = .90).

Conclusions: Patients with acute myocardial infarction were less likely to be admitted to hospitals offering coronary revascularization and to undergo early revascularization in states with certificate of need regulations. However, differences in the availability and use of revascularization therapies were not associated with mortality.

Comment in

Evaluating and improving the quality of care for acute myocardial infarction: can regionalization help?
Hannan EL.
JAMA. 2006 May 10;295(18):2177-9. doi: 10.1001/jama.295.18.2177.
PMID: 16684989 No abstract available.

LinkOut - more resources

Full Text Sources

Ovid Technologies, Inc.

Silverchair Information Systems

Medical

MedlinePlus Health Information

FULL TEXT LINKS

ELSEVIER FULL-TEXT ARTICLE

Comparative Study > Am Heart J. 2004 Mar;147(3):442-8. doi: 10.1016/j.ahj.2003.05.002.

Certificate of need, volume, and percutaneous transluminal coronary angioplasty outcomes

Vivian Ho [1]

Affiliations
PMID: 14999192 DOI: 10.1016/j.ahj.2003.05.002

Abstract

Background: Florida seeks high hospital volumes for percutaneous transluminal coronary angioplasty (PTCA) by enforcing certificate of need (CON) laws, whereas California has no such laws. This study compares the volume-outcome relation for PTCA in Florida and California.

Methods: The relation between the number of PTCA procedures performed at hospitals and the rate of inhospital bypass graft surgery and death for 292,457 patients in Florida and 390,880 patients in California between 1988 and 1998 was examined with descriptive statistics and logistic regressions.

Results: In 1988, the mean hospital PTCA volumes in Florida (237) and California (218) were not significantly different (P =.44). By 1998, Florida hospital volumes were significantly larger (724 vs 389, P <.001). Logistic regressions indicate that higher log (volume) was associated with lower mortality and urgent bypass grafting rates in both Florida and California during the sample period. Regression estimates indicate that a California hospital with the mean 1998 PTCA volume of 389 procedures had a predicted inpatient mortality rate of 1.4% and urgent bypass grafting rate of 2.2%. If the PTCA volume was raised to the 1998 Florida mean of 724 procedures, the inpatient mortality rate would not fall, although urgent bypass grafting rates were predicted to fall to 2.0%.

Conclusions: Florida CON laws were associated with higher average PTCA volumes relative to California hospitals, where no such laws exist. Because a higher PTCA volume was associated with moderately better outcomes, CON may be marginally effective in improving outcomes for PTCA. Future studies should revisit this hypothesis with data from several states.

Comment in

Hospital volume and outcome after coronary angioplasty: is there a role for certificate of need regulation?
Vaughan Sarrazin MS, Rosenthal GE.
Am Heart J. 2004 Mar;147(3):383-5. doi: 10.1016/j.ahj.2003.10.013.
PMID: 14999182 No abstract available.

LinkOut - more resources

Full Text Sources

Elsevier Science
Ovid Technologies, Inc.

Medical

MedlinePlus Health Information

Certificate of Need Regulation and Cardiac Catheterization Appropriateness After Acute Myocardial Infarction

Joseph S. Ross, MD, MHS; Vivian Ho, PhD; Yongfei Wang, MS; Stephen S. Cha, MD, MHS; Andrew J. Epstein, PhD, MPP; Frederick A. Masoudi, MD, MSPH; Brahmajee K. Nallamothu, MD, MPH; Harlan M. Krumholz, MD, SM

***Background*—**Certificate of need (CON) regulation was introduced to control healthcare costs and improve quality of care in part by limiting the number of facilities providing complex medical care. Our objective was to examine whether rates of appropriate cardiac catheterization after admission for acute myocardial infarction varied between states with and without CON regulation of cardiac catheterization.

***Methods and Results*—**We performed a retrospective analysis of chart-abstracted data for 137 279 Medicare patients admitted for acute myocardial infarction between 1994 and 1996 at 4179 US acute-care hospitals. Using 3-level hierarchical generalized linear modeling adjusted for patient sociodemographic and clinical characteristics and physician and hospital characteristics, we compared catheterization rates within 60 days of admission for states (and the District of Columbia) with (n=32) and without (n=19) CON regulation in the full cohort and stratified by catheterization appropriateness. Appropriateness was categorized as strongly, equivocally, or weakly indicated. We found CON regulation was associated with a borderline-significant lower rate of catheterization overall (45.8% versus 46.5%; adjusted risk ratio [RR] 0.91, 95% confidence interval 0.82 to 1.00, $P=0.06$). After stratification by appropriateness, CON regulation was not associated with a significantly lower rate of catheterization among 63 823 patients with strong indications (49.9% versus 50.3%; adjusted RR 0.94, 95% confidence interval 0.86 to 1.02, $P=0.17$). However, CON regulation was associated with significantly lower rates of catheterization among 65 077 patients with equivocal indication (45.0% versus 46.0%; adjusted RR 0.88, 95% confidence interval 0.78 to 1.00, $P=0.05$) and among 8379 patients with weak indications (19.8% versus 21.8%; adjusted RR 0.84, 95% confidence interval 0.71 to 0.98, $P=0.04$). Associations were weakened substantially after adjustment for hospital coronary artery bypass graft surgery or cardiac catheterization capability.

***Conclusions*—**CON regulation was associated with modestly lower rates of equivocally and weakly indicated cardiac catheterization after admission for acute myocardial infarction, but no significant differences existed in rates of strongly indicated catheterization. **(*Circulation*. 2007;115:1012-1019.)**

Key Words: angioplasty ■ myocardial infarction ■ certificate of need ■ quality of health care ■ government regulation

Certificate of need (CON) regulation, federally mandated as part of the 1974 National Health Planning and Resources Development Act, was introduced to restrain healthcare costs and improve healthcare quality, in part by limiting the number of facilities providing complex, high-cost medical care, such as cardiac, surgical, and imaging services. In 1984, the federal mandate ended, which allowed each state to determine whether to maintain CON regulation,[1] and more than one third eliminated

Received August 14, 2006; accepted December 19, 2006.

From the Department of Geriatrics and Adult Development, Mount Sinai School of Medicine, New York, NY, and the Geriatrics Research, Education, and Clinical Center, James J. Peters VA Medical Center, Bronx, NY (J.S.R.); Baker Institute for Public Policy (V.H.), Rice University, Houston, Tex; Section of Cardiovascular Medicine, Department of Medicine (Y.W., H.M.K.), Department of Medicine (adjunct; S.S.C.), and Section of Health Policy and Administration, Department of Epidemiology and Public Health (A.J.E., H.M.K.), Yale University School of Medicine, New Haven, Conn; Section of Cardiovascular Medicine, Department of Medicine, Denver Health Medical Center, and the Colorado Health Outcomes Program, Department of Medicine, University of Colorado at Denver Health Sciences Center, Denver, Colo (F.A.M.); Division of Cardiovascular Medicine, Department of Medicine, University of Michigan, and the Health Services Research and Development Center of Excellence, Ann Arbor VA Medical Center, Ann Arbor, Mich (B.K.N.); and Robert Wood Johnson Clinical Scholars Program, Yale University School of Medicine and the Yale-New Haven Hospital Center for Outcomes Research and Evaluation, New Haven, Conn (H.M.K.)

Neither the Robert Wood Johnson Foundation nor the Department of Veterans Affairs had any role in the design or conduct of the study; collection, management, analysis, or interpretation of the data; or preparation, review, or approval of the manuscript. The content of this publication does not necessarily reflect the views or policies of the US Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the US Government. The Centers for Medicare & Medicaid Services reviewed and approved the manuscript (tracking No. MASOUDICON-001-OK-0506).

This work was presented at the 2006 Society of General Internal Medicine Annual Meeting on April 27, 2006, in Los Angeles, Calif.

Correspondence to Joseph S. Ross, MD, MHS, Department of Geriatrics and Adult Development, Mount Sinai School of Medicine, One Gustave L. Levy Pl, Box 1070, New York, NY, 10029. E-mail joseph.ross@mssm.edu

Circulation **is available at http://www.circulationaha.org** **DOI: 10.1161/CIRCULATIONAHA.106.658377**

it soon thereafter. During the 1990s, CON regulation was eliminated in 7 other states. Missouri eliminated CON regulation in 2003 and Florida in 2004, and the merits of CON regulation are being actively debated in several states, including Virginia and Vermont, as well as the District of Columbia.[2] Currently, 37 states have CON regulations.[3] The Federal Trade Commission and the Department of Justice recently called for the complete elimination of CON regulation, citing its failure to contain healthcare costs and its anticompetitive risks.[4] Because CON regulation is not associated with substantially restrained healthcare costs,[5,6] the reluctance to maintain CON regulation may be partly because research examining its effect on healthcare quality has found inconsistent results.

Clinical Perspective p 1019

The earliest study demonstrated an association between CON regulation and increased mortality for several medical and surgical conditions.[7] Subsequent research has focused primarily on cardiac procedures, and these studies show that states with CON regulation are more likely to have patients treated at higher-volume centers,[8–11] which may indicate higher-quality care.[12] However, CON regulation of either CABG surgery or cardiac catheterization has only been associated with lower mortality in 1 study[11] and not in 4 others.[8–10,13] Moreover, CON regulation has been associated with lower early revascularization rates after acute myocardial infarction (AMI),[10] which may indicate lower-quality care given the beneficial effects of acute revascularization,[14] and similar nonacute revascularization rates.

Given these described differences in revascularization rates between states with and without CON regulation,[10] along with the wide variations in cardiac procedure use across different areas within the United States,[15] examining procedure appropriateness is critical to understanding the impact of a policy that limits the number of facilities that provide a procedure, because it may affect the rates of both more and less appropriate care delivered. For instance, as has been suggested,[10,16] without CON regulation to limit facilities, market forces may increase the use of revascularizations among less appropriate patients who derive little benefit. Conversely, limiting facilities and thereby concentrating patients at higher-volume centers may reduce the pressure to maintain facility volumes, which would reduce the likelihood that less appropriate patients would be referred for revascularization.

Our objective was to examine whether rates of appropriate catheterization after admission for AMI varied between states with and without CON regulation of cardiac catheterization. Our hypothesis was that CON regulation would be associated with lower rates of catheterization among patients with equivocal and weak indications but equal or higher rates among those with strong indications. We used the Cooperative Cardiovascular Project (CCP), medical record data abstracted for Medicare beneficiaries hospitalized with AMI between 1994 and 1996, which provided a unique opportunity to use a large, nationally representative database that permits comparison of state policies while also providing detailed clinical information that allows determination of procedure appropriateness.[17–19] Moreover, CCP data were collected shortly before the discontinuation of CON regulation in several states, which enabled the examination of a more diverse group of state programs than would be possible today.

Methods

CCP and the Study Cohort

CCP has been described elsewhere in detail.[20] Briefly, the medical records of all Medicare patients hospitalized with a primary discharge diagnosis of AMI (International Classification of Diseases, 9th Revision, Clinical Modification [ICD-9-CM] code 410.X, with the exception of readmission code 410.X2)[21] were abstracted, by state, for an 8-month period between January 1994 and February 1996. Among the 234 769 hospitalizations in CCP, we excluded patients younger than 65 years of age (n=17 593) or without a chart-confirmed AMI (n=31 186). Patients were sorted by admission date and readmissions were excluded (n=23 773). In addition, we excluded patients who were transferred during their hospitalization for whom index hospitalization information was not available (n=14 943); patients who were transferred and for whom index hospitalization information was available were assigned to the hospital in which they were initially hospitalized, a method suggested for hospital performance research.[22] We also excluded patients for whom American Hospital Association (n=2363), American Medical Association (n=6796), 1990 US Census (n=10 810), or Medicare Part A (n=34 187) data were not available. Finally, we excluded 1765 patients hospitalized outside of the United States, 77 patients discharged after the study period, and 325 patients with unknown mortality status. A total of 97 490 patients met 1 or more of these criteria; the remaining 137 279 patients constitute the study cohort.

CON Regulation

Information about states' CON regulation was obtained from a survey of state regulators contracted through the American Health Planning Association. Individual states and the District of Columbia were categorized according to whether state laws required CON regulation of cardiac catheterization from 1994 through 1996. Regulation was present for 32 states and absent in 19. Nevada, North Dakota, and Oregon all discontinued CON regulation in 1995, after CCP data collection in each state, and so were included among states with regulation present.

Cardiac Catheterization Use

The principal outcome was use of cardiac catheterization within 60 days of hospital admission, as determined by evaluating the hospital medical record and Medicare Part A billing records for ICD-9-CM procedure codes associated with cardiac catheterization (37.22, 37.33, and 88.53 to 88.57).

Cardiac Catheterization Appropriateness

Indications for having cardiac catheterization were evaluated after the acute phase of infarction (>12 hours after symptom onset). Using the 1996 American College of Cardiology/American Heart Association (ACC/AHA) guidelines[17] and appropriateness criteria previously reported by Guadagnoli and colleagues,[18] we classified patients into 3 groups (Table 1), as we have done previously.[19] The strong indication group consisted of patients in whom cardiac catheterization was generally recognized as "beneficial, useful, and effective" (ACC/AHA class I).[17] The equivocal group included patients for whom data on the effectiveness of the procedure were unclear (ACC/AHA class IIa [evidence may favor catheterization]; ACC/AHA class IIb [evidence may not favor catheterization]) or patients with uncomplicated AMIs (neither ACC/AHA class I, II, or III). The weak indication group consisted of patients who had conditions for which cardiac catheterization was considered unlikely to be effective (ACC/AHA class III). For patients who met >1 classification criterion (for example, a patient who had ischemia observed on an exercise stress test and concomitant metastatic cancer), classifications were prioritized by the following order: weak indications, strong indications, and equivocal indications; this was

TABLE 1. Cardiac Catheterization Appropriateness Criteria*

Strong indications (ACC/AHA class I)
Angina >24 h after admission
Ischemia observed on an exercise stress test
Reinfarction during hospitalization
Hypotension during hospitalization
Shock on admission or during hospitalization
Equivocal indications (ACC/AHA class II)
Left ventricular ejection fraction <0.40
Previous bypass surgery or angioplasty
Congestive heart failure or pulmonary edema on admission or during hospitalization
Non–Q-wave myocardial infarction
Weak indications (ACC/AHA class III)
Hepatic failure
Metastatic cancer
Terminal illness (life expectancy <6 mo)
Flexion withdrawal, decorticate, decerebrate, or no motor response to cues

*Derived from ACC/AHA guidelines[17] and Guadagnoli et al.[18]

done to maximize specificity among patients classified with strong indications.

Statistical Analysis

We compared states with and without CON regulation of cardiac catheterization for differences in patient sociodemographic characteristics, clinical presentation, past medical history, and comorbid conditions, and physician and hospital characteristics using χ^2 and t test analyses. In addition, we compared patients in states with and without CON regulation by the appropriateness indications, and we compared states with and without CON regulation by the crude cardiac catheterization rates, both overall and stratified by procedure appropriateness.

We developed 3-level (patient, hospital, and state) hierarchical generalized linear models to compare rates of cardiac catheterization between states with and without CON regulation in the full study cohort and stratified by procedure appropriateness. The baseline model examined the unadjusted association between CON regulation and cardiac catheterization rate.

In the adjusted analyses, the first-level model specification included patient sociodemographic characteristics, clinical presentation, past medical history, and comorbid conditions and physician characteristics. Patient sociodemographic characteristics included age, gender, race, and residential ZIP code measures of income and education, as reported in the 1990 US Census.[23] We accounted for the many clinical presentation characteristics ascertained at admission (Table 2). In addition, we based medical history measures on clinical experience and previously identified predictors of procedure use, and we also accounted for other comorbid conditions (Table 2). Physician characteristics (Table 2) were derived from the American Medical Association Masterfile.[24]

The second-level model specification included hospital characteristics (Table 3), which we obtained from the 1994 American Hospital Association Survey of Hospitals.[25] Of note, we created 2 different models, 1 including and 1 excluding the variable that defined hospital cardiac procedure availability: none, cardiac catheterization, or cardiac catheterization and CABG surgery. Because CON regulations limit the number of facilities that are authorized to provide cardiac catheterization and CABG surgery, and because a hospital's availability of these cardiac services is associated with their use,[26,27] adjustment for this variable may mediate the effect of CON regulation.

The third-level model specification included the state-level presence of CON regulation. Hospital-level and state-level random effects, which account for the clustering (nonindependence) of patients within the same hospital and the clustering (nonindependence) of hospitals within the same state, were included in all analyses, unadjusted and adjusted. In addition, for adjusted analyses, missing data were imputed as the population median for continuous variables, assigned as nonpresence for dichotomous variables and considered as a category for categorical variables. Only 2 variables were missing data for >5% of patients. For left ventricular ejection fraction (35.5% missing), a missing category was created for analyses, whereas for serum albumin (26.6% missing), we categorized those missing data as having >3 g/dL and also used a dummy variable for the missing data for analyses. To facilitate interpretation of our results, ORs from adjusted analyses were converted to risk ratios (RR) by standard techniques.[28] Statistical analyses were conducted with SAS software, version 9.1 (SAS Institute, Inc, Cary, NC). All statistical tests were 2-tailed.

The authors had full access to the data and take full responsibility for their integrity. All authors have read and agree to the manuscript as written.

Results

Among the 137 279 patients hospitalized for AMI included in the present cohort, 68.5% were in states with CON regulation, the mean age was 77 years, 90.9% were white, and 50.8% were male. Compared with patients in states without CON regulation, patients in states with CON regulation were more likely to be white and female and more likely to have hypertension, diabetes mellitus, heart failure, or previous AMI; however, they were less likely to be admitted by a cardiologist, to be admitted to a public or nonteaching hospital, or to be admitted to a hospital where either catheterization or CABG surgery was available (Table 2). Indications for catheterization among patients in states with CON regulation were not significantly different than among patients in states without CON regulation; 46.5% had strong indications, 47.5% had equivocal indications, and 6.0% had weak indications, compared with 46.5%, 47.2%, and 6.3%, respectively (P=0.09).

There were 4179 hospitals in the present cohort, 60.2% of which were in states with CON regulation. Hospitals in states with CON regulation had significantly greater AMI volumes, were less likely to have public or for-profit ownership, and were more likely to be teaching hospitals and to have either CABG surgery or catheterization available than hospitals in states without regulation (Table 3). Crude rates of cardiac catheterization in states with CON regulation were 45.8% overall, 49.9% among patients with strong indications, 45.0% among patients with equivocal indications, and 19.8% among patients with weak indications, whereas in states without CON regulation, rates were 46.5%, 50.3%, 46.0%, and 21.8%, respectively (Table 4).

In unadjusted analyses, CON regulation was not associated with a significantly lower overall rate of catheterization (RR=0.95, 95% CI 0.87 to 1.03, P=0.22; Table 5). CON regulation was not associated with significantly lower rates of catheterization among patients with strong indications (RR=0.97, 95% CI 0.90 to 1.04, P=0.39), among patients with equivocal indications (RR=0.92, 95% CI 0.82 to 1.01, P=0.10), or among patients with weak indications (RR=0.90, 95% CI 0.77 to 1.03, P=0.14). However, there was a nonsignificant

TABLE 2. Patient, Physician, and Hospital Baseline Characteristics (Patient-Level)*

	All Patients (n=137 279)	States With CON Regulation (n=93 986)	States Without CON Regulation (n=43 293)	*P*†
Patient characteristics				
Mean age±SD, y	76.6±7.4	76.6±7.4	76.6±7.4	0.93
Female, %	49.2	49.5	48.4	<0.001
White race, %	90.9	91.8	88.8	<0.001
Mean annual household income±SD, US dollars	30 495±11 480	30 393±11 269	30 716±11 921	<0.001
High school degree or higher, %	45.3	45.5	45.1	<0.001
Clinical presentation				
Mean heart rate±SD	88.0±24.9	88.3±24.9	87.4±24.9	<0.001
Mean SBP±SD, mm Hg	144.9±33.1	144.9±33.0	144.9±33.4	0.89
Killip class: I/II/III/IV, %	50.4/12.1/35.2/2.4	50.1/12.3/35.4/2.3	51.0/11.6/34.8/2.6	<0.001
LVEF: unknown/<0.20/0.20–0.39/0.40–0.54/≥0.55, %	36.6/3.1/21.0/29.0/10.3	35.4/3.2/21.9/29.6/9.8	39.2/2.8/19.2/27.6/11.3	<0.001
Anterior infarction, %	46.7	46.5	47.1	0.03
Q-wave infarction, %	59.7	59.1	61.1	<0.001
ST-segment elevation infarction, %	29.2	28.9	29.8	<0.001
Medical history, %				
Hypertension	61.6	62.0	60.8	<0.001
Diabetes mellitus	30.6	31.4	29.0	<0.001
Previous AMI	29.2	29.7	28.2	<0.001
Congestive heart failure	21.5	21.9	20.7	<0.001
Current tobacco use	14.6	14.5	14.8	0.09
Cerebrovascular disease	14.0	14.0	13.7	0.41
Peripheral vascular disease	10.7	10.8	10.5	0.039
Comorbid conditions, %				
Nursing facility admission	5.5	5.5	5.4	0.29
Functional status: independently mobile/mobile with assistance/unable to walk	80.8/16.1/3.2	80.5/16.4/3.1	81.3/15.4/3.2	<0.001
Immunocompromised	1.6	1.6	1.5	0.12
Urinary incontinence	7.3	7.5	7.0	0.002
Dementia	6.1	6.2	5.8	0.007
Anemia (hematocrit <30%)	4.7	4.8	4.4	0.01
Hypoalbuminemia (serum albumin <3 g/dL)	4.6	4.7	4.4	0.02
Liver disease	0.4	0.4	0.4	0.97
Chronic obstructive pulmonary disease	20.4	20.4	20.3	0.76
Physician characteristics				
Mean age±SD, y	47.4±9.0	47.4±9.1	47.6±8.8	<0.001
Female, %	12.8	12.6	13.3	<0.001
White race, %	55.4	55.7	54.7	<0.001
Specialty: cardiology/internal medicine subspecialty/internal medicine/family medicine/other, %	26.3/9.7/21.8/13.9/28.3	24.6/10.0/22.0/14.6/28.9	30.1/9.1/21.4/12.4/27.0	<0.001
Practice type: solo/joint/group/medical school–affiliated/other, %	28.5/8.3/35.3/1.6/26.2	28.6/8.8/34.8/1.6/26.2	28.3/7.3/36.5/1.6/26.3	<0.001
Mean period in practice±SD, y	20.8±9.2	20.7±9.3	20.9±9.2	<0.001
Hospital characteristics				
Mean AMI volume±SD	113.5±97.5	122.6±105.6	93.7±73.1	<0.001
Cardiac procedure availability: none/cardiac catheterization/CABG surgery, %	40.0/23.9/36.2	40.4/26.0/33.6	38.9/19.2/41.8	<0.001
Urban location, %	78.6	77.8	80.2	<0.001
Ownership: public/not-for-profit/for-profit, %	12.4/77.2/10.4	10.4/80.0/9.6	16.7/71.2/12.1	<0.001
Teaching status: nonteaching/residency or fellowship program–affiliated/COTH, %	67.1/21.7/11.2	65.5/21.7/12.8	70.5/21.9/7.6	<0.001

COTH indicates Council of Teaching Hospitals; LVEF, left ventricular ejection fraction; CABG, coronary artery bypass graft; and SBP, systolic blood pressure.
*Percentages may not sum to 100 because of rounding.
†For comparison between patients in states with and without CON regulation.

TABLE 3. Hospital Baseline Characteristics (Hospital-Level)*

Hospital Characteristics†	All Hospitals (n=4179)	States With CON Regulation (n=2515)	States Without CON Regulation (n=1664)	P†
Mean AMI volume±SD	53.3±65.0	60.7±71.6	41.9±51.5	<0.001
Cardiac procedure availability: none/cardiac catheterization/CABG surgery, %	65.4/15.6/19.0	64.9/17.5/17.5	66.2/12.7/21.1	<0.001
Urban location, %	57.7	57.9	57.5	0.78
Ownership: public/not-for-profit/for-profit, %	24.7/61.8/13.5	19.9/68.7/11.3	32.0/51.2/16.8	<0.001
Teaching status: nonteaching/residency or fellowship program–affiliated/COTH, %	81.3/12.4/6.3	79.3/13.2/7.6	84.3/11.4/4.3	<0.001

COTH indicates Council of Teaching Hospitals; CABG, coronary artery bypass graft.
*Percentages may not sum to 100 because of rounding.
†For comparison between hospitals in states with and without CON regulation.

trend toward CON regulation being associated with a lower rate of less appropriate cardiac catheterizations.

After adjustment for patient-level and hospital-level characteristics, excluding hospital cardiac procedure availability, there was a significant trend toward CON regulation being associated with a lower rate of less appropriate cardiac catheterizations. CON regulation was associated with a borderline-significant lower overall rate of catheterization (RR=0.91, 95% CI 0.82 to 1.00, P=0.06; Table 5). Among patients with strong indications, CON regulation was not associated with a significantly lower rate of catheterization (RR=0.94, 95% CI 0.86 to 1.02, P=0.17). However, CON regulation was associated with significantly lower rates of catheterization among patients with equivocal (RR=0.88, 95% CI 0.78 to 1.00, P=0.05) and weak (RR=0.84, 95% CI 0.71 to 0.98, P=0.04) indications.

When we included hospital cardiac procedure availability in the hierarchical models, the associations observed were substantially weakened. CON regulation was no longer associated with a significantly lower overall rate of catheterization (RR=0.96, 95% CI 0.88 to 1.03, P=0.27; Table 5), nor was CON associated with significantly lower rates of catheterization among patients with strong indications (RR=1.00, 95% CI 0.93 to 1.06, P=0.88), among patients with equivocal indications (RR=0.92, 95% CI 0.83 to 1.02, P=0.14), or among patients with weak indications (RR=0.91, 95% CI 0.79 to 1.05, P=0.21). Finally, we included an interaction term between CON status and cardiac catheterization appropriateness in our fully adjusted analyses, excluding cardiac procedure availability, and found that the relationship between CON regulation and catheterization appropriateness was not significantly different depending on catheterization indication (P=0.14).

Discussion

CON regulation is associated with significantly lower rates of cardiac catheterization 60 days after admission for AMI among Medicare patients with equivocal and weak indications for the procedure and no significant rate difference among patients with strong indications, although the estimate is modestly lower. The lower rate of cardiac catheterization for patients with equivocal or weak indications was eliminated after adjustment for the variable defining hospital availability of cardiac catheterization or CABG surgery, which suggests that CON regulation is associated with a lower rate of cardiac catheterization among patients with equivocal and weak indications because it limits the number of healthcare facilities authorized to provide catheterization services.

On the basis of prior work on the relationship between supply and utilization of cardiac procedures,[26,27] in addition to a recent study that examined the effect of CON regulation on revascularization rates and mortality,[10] we thought that not only was it likely that limiting facilities via CON regulation would affect where patients receive care, it would also affect which patients received care. The present study supports our hypothesis that CON regulation would be associated with lower rates of catheterization among patients with equivocal and weak indications, which suggests either that physicians do discriminate on the basis of procedure appropriateness when faced with reduced capacity to provide care or that facilities refer fewer less-appropriate patients for catheterization when greater facility volume is ensured.

The present study offers support for the rationale behind the introduction of CON regulation: We found regulation of

TABLE 4. Number of Patients Hospitalized for AMI and Posthospitalization Crude Rates of Cardiac Catheterization in States With and Without CON Regulation Among All Patients and Stratified by Procedure Appropriateness

	All Patients		States With CON Regulation		States Without CON Regulation		
	No. Hospitalized	Cardiac Catheterization Rate, %	No. Hospitalized	Cardiac Catheterization Rate, %	No. Hospitalized	Cardiac Catheterization Rate, %	P*
All indications	137 279	46.0	93 986	45.8	43 293	46.5	0.02
Cardiac catheterization appropriateness							
Strong	63 823	50.0	43 711	49.9	20 112	50.3	0.32
Equivocal	65 077	45.3	44 627	45.0	20 450	46.0	0.02
Weak	8379	20.4	5648	19.8	2731	21.8	0.03

*For comparison between crude rates of cardiac catheterization among patients hospitalized for AMI in states with and without CON regulation.

TABLE 5. Unadjusted and Adjusted Association Between CON Regulation of Cardiac Catheterization Services and Use of Cardiac Catheterization After Hospitalization for AMI, Stratified by Procedure Appropriateness

	RR (95% CI)	*P*
Unadjusted models*		
Overall	0.95 (0.87–1.03)	0.22
Appropriateness		
Strong (ACC/AHA class I)	0.97 (0.90–1.04)	0.39
Equivocal (ACC/AHA class IIa or IIb or not classified)	0.92 (0.82–1.01)	0.10
Weak (ACC/AHA class III)	0.90 (0.77–1.03)	0.14
Full adjusted models†		
Overall	0.91 (0.82–1.00)	0.06
Appropriateness		
Strong (ACC/AHA class I)	0.94 (0.86–1.02)	0.17
Equivocal (ACC/AHA class IIa or IIb or not classified)	0.88 (0.78–1.00)	0.05
Weak (ACC/AHA class III)	0.84 (0.71–0.98)	0.04
Full adjusted models,† also including cardiac procedure availability		
Overall	0.96 (0.88–1.03)	0.27
Appropriateness		
Strong (ACC/AHA class I)	1.00 (0.93–1.06)	0.88
Equivocal (ACC/AHA class IIa or IIb or not classified)	0.92 (0.83–1.02)	0.14
Weak (ACC/AHA class III)	0.91 (0.79–1.05)	0.21

*Unadjusted models account for clustering (nonindependence) of patients within the same hospital and clustering (nonindependence) of hospitals within the same state.

†Full adjusted models also account for patient sociodemographic characteristics, clinical presentation, past medical history, and comorbid conditions and physician and hospital characteristics.

cardiac catheterization was associated with the continued delivery of more appropriate care after admission for AMI and reduced delivery of less appropriate care. From a policy perspective, increasing more appropriate care and decreasing less appropriate care are considered quality improvements.[29,30] However, we found substantial underuse of appropriate care, because only 50% of patients with strong indications in states with and without CON regulation received cardiac catheterization after admission for AMI, a rate described in prior work.[31] Therefore, although the present study was consistent with part of our hypothesis, that CON regulation would be associated with lower rates of catheterization among patients with equivocal and weak indications, CON regulation was not associated with higher rates of catheterization among patients with strong indications and may have exacerbated the known underuse of appropriate care.[32]

Unexpectedly, we found that a greater proportion of hospitals in states without CON regulation had neither catheterization nor CABG surgery available compared with hospitals in states with regulation; however, a greater proportion of patients in states with CON regulation were admitted to hospitals that had neither catheterization nor CABG surgery available compared with patients in states without regulation, which is consistent with expectations and prior work.[10] This hospital-level finding may be a consequence of state geography, because states without CON regulation are less densely populated than are states with CON regulation (62.4 versus 84.9 persons per square mile),[23] although the proportion of urban hospitals in both groups of states was similar. In addition, a greater number of hospitals exist in states without CON regulation, where the mean number of general hospitals in 1994 was 2.11 per 100 000 residents compared with 1.88 per 100 000 residents in states with CON regulation.[33] This may be because states that have a CON program regulating 1 healthcare service may be more likely to regulate another, such as acute-care hospital beds.

Study Limitations

Although the present study used data from 1994 through 1996 and was limited to a population insured solely by Medicare, our results remain important and relevant to the current health policy debate for multiple reasons. First, it is unlikely that patterns of care were different for Medicare beneficiaries relative to insured adults, because both Medicare and other commercial plans provide substantial reimbursement for cardiac catheterization. However, cardiac catheterization rates among the uninsured may be lower than among the insured, because lack of health insurance is recognized as a major barrier to receiving medical care, even for serious and morbid symptoms.[34] Second, although US healthcare delivery has experienced substantial change since the mid-1990s, we would expect the patterns of care by appropriateness that we found to persist today, even with greater managed-care penetration[18] and regionalization of care.[31] Third, although there was a 31% increase in US cardiac catheterization capacity from 1993 to 1998,[35] the indications for catheterization have only expanded.[36,37] Moreover, the increased capacity was less than the increase in cardiac catheterization rates among this population, as 1 study demonstrated a 45% increase in rates of cardiac catheterization for Medicare enrollees during this same period, without a corresponding increase in underlying disease rates.[38] Perhaps physicians have been forced to become more discriminating in patient referral for catheterization since the mid-1990s, because they may now be faced with greater absolute but lower relative capacity for care, which may strengthen the effect of CON regulation.

Other issues should be considered when interpreting the present study. Unlike the most recent study of CON regulation that examined overall revascularization after AMI (CABG surgery and catheterization),[10] we only examined cardiac catheterization; however, clear guidelines that can be translated into appropriateness criteria with administrative data exist for cardiac catheterization[17,18] but not for CABG surgery. In addition, catheterization is a gateway to CABG surgery, so understanding the effect of CON regulation on its use has wider implications. Second, CON regulation of cardiac catheterization is likely to be heterogeneous in character, which may lead to differences in the scope and stringency of the regulation. However, we found different patterns of care in states with and without CON regulation despite this heterogeneity. Third, the observational, cross-sectional design can only suggest but not prove a cause-and-effect relationship between CON regulation and use of cardiac catheterization. Finally, any association between CON regulation and use of cardiac catheterization may represent confounding due to other factors that differ systematically according to CON status. Hospital cardiac catheterization capacity,[26,27] shorter distances between patients' residences and catheterization facilities,[39] and increased diagnostic testing[40] are all determinants of cardiac catheterization after AMI. However, adjustment for these variables may overcontrol for the effect of CON regulation, because these are the processes by which its effects may be mediated. Further research is needed to determine whether these practice patterns vary at least in part because of CON regulation. The present analysis is unique in that it accounted for patient clinical presentation and medical history, along with physician and hospital characteristics, taking advantage of a clinically rich data source and allowing for analytic complexity prohibited by traditional administrative data.

Conclusions

As healthcare leaders promote systems-based solutions to improve healthcare quality,[41] the present study informs policy makers with evidence from a current state regulation that is associated with reduced delivery of less appropriate care and continued delivery of more appropriate care, although not with increased delivery of more appropriate care. The present study suggests that CON regulation is associated with higher quality of care with respect to the use of cardiac catheterization for patients admitted for AMI, which supports part of the rationale behind the program. These benefits should be considered when decisions are made about the future of state CON regulations.

Sources of Funding

Dr Ross was a scholar in the Robert Wood Johnson Clinical Scholars Program at Yale University sponsored by the Robert Wood Johnson Foundation and Dr Cha was a scholar in the Robert Wood Johnson Clinical Scholars Program at Yale University sponsored by the Department of Veterans Affairs during part of their project involvement. The survey of state regulators about state CON status was contracted through the American Health Planning Association with support from a grant awarded to Dr Ho by the National Heart, Lung, and Blood Institute (R01 HL073825). The analyses on which this publication is based were performed under contract No. OK0412SC, funded by the Centers for Medicare & Medicaid Services, an agency of the US Department of Health and Human Services.

Disclosures

Dr Krumholz has research contracts with the Colorado Foundation for Medical Care and the American College of Cardiology, serves on an advisory board of Amgen and of UnitedHealthcare, is a subject matter expert for VHA, Inc, and is Editor-in-Chief of *Journal Watch Cardiology* of the Massachusetts Medical Society. No other authors have financial conflicts of interest to disclose.

References

1. Altman SH, Ostby EK. Paying for hospital care: the impact of federal policy. In: Ginzburg E, ed. *Health Services Research: Key to Health Policy.* Cambridge, Mass: Harvard University Press; 1991:46–68.
2. Romano M. Pros and cons of certificates: American Health Planning Association directory suggests that certificate-of-need process is regulatory in theory, not in practice. *Mod Healthc*. 2003;33:1,4–5.
3. American Health Planning Association. Certificate of Need information page. 2006. Available at: http://www.ahpanet.org/copn.html. Accessed November 22, 2006.
4. Federal Trade Commission and the Department of Justice. *Improving Health Care: A Dose of Competition.* July 2004. Available at: http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf. Accessed November 22, 2006.
5. Conover CJ, Sloan FA. Does removing certificate-of-need regulations lead to a surge in health care spending? *J Health Polit Policy Law*. 1998;23:455–481.
6. Sloan FA, Steinwald B. Effects of regulation on hospital costs and input use. *J Law Econ*. 1980;23:81–109.
7. Shortell SM, Hughes EF. The effects of regulation, competition, and ownership on mortality rates among hospital inpatients. *N Engl J Med*. 1988;318:1100–1107.
8. DiSesa VJ, O'Brien SM, Welke KF, Beland SM, Haan CK, Vaughan-Sarrazin MS, Peterson ED. Contemporary impact of state certificate-of-need regulations for cardiac surgery: an analysis using the Society of Thoracic Surgeons' National Cardiac Surgery Database. *Circulation*. 2006;114:2122–2129.
9. Ho V. Certificate of need, volume, and percutaneous transluminal coronary angioplasty outcomes. *Am Heart J*. 2004;147:442–448.
10. Popescu I, Vaughan-Sarrazin MS, Rosenthal GE. Certificate of need regulations and use of coronary revascularization after acute myocardial infarction. *JAMA*. 2006;295:2141–2147.
11. Vaughan-Sarrazin MS, Hannan EL, Gormley CJ, Rosenthal GE. Mortality in Medicare beneficiaries following coronary artery bypass graft surgery in states with and without certificate of need regulation. *JAMA*. 2002;288:1859–1866.
12. Epstein AM. Volume and outcome: it is time to move ahead. *N Engl J Med*. 2002;346:1161–1164.
13. Robinson JL, Nash DB, Moxey E, O'Connor JP. Certificate of need and the quality of cardiac surgery. *Am J Med Qual*. 2001;16:155–160.
14. Ryan TJ, Antman EM, Brooks NH, Califf RM, Hillis LD, Hiratzka LF, Rapaport E, Riegel B, Russell RO, Smith EE III, Weaver WD, Gibbons RJ, Alpert JS, Eagle KA, Gardner TJ, Garson A Jr, Gregoratos G, Ryan TJ, Smith SC Jr. 1999 update: ACC/AHA guidelines for the management of patients with acute myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Management of Acute Myocardial Infarction). *J Am Coll Cardiol*. 1999;34:890–911.
15. Wennberg DE. *The Dartmouth Atlas of Cardiovascular Health Care*. Chicago, Ill: American Hospital Publishing; 2000.
16. Hannan EL. Evaluating and improving the quality of care for acute myocardial infarction: can regionalization help? *JAMA*. 2006;295:2177–2179.

17. Ryan TJ, Anderson JL, Antman EM, Braniff BA, Brooks NH, Califf RM, Hillis LD, Hiratzka LF, Rapaport E, Riegel BJ, Russell RO, Smith EE Jr, Weaver WD. ACC/AHA guidelines for the management of patients with acute myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Management of Acute Myocardial Infarction). *J Am Coll Cardiol*. 1996;28:1328–1428.
18. Guadagnoli E, Landrum MB, Peterson EA, Gahart MT, Ryan TJ, McNeil BJ. Appropriateness of coronary angiography after myocardial infarction among Medicare beneficiaries: managed care versus fee for service. *N Engl J Med*. 2000;343:1460–1466.
19. Rathore SS, Wang Y, Radford MJ, Ordin DL, Krumholz HM. Sex differences in cardiac catheterization after acute myocardial infarction: the role of procedure appropriateness. *Ann Intern Med*. 2002;137:487–493.
20. Marciniak TA, Ellerbeck EF, Radford MJ, Kresowik TF, Gold JA, Krumholz HM, Kiefe CI, Allman RM, Vogel RA, Jencks SF. Improving the quality of care for Medicare patients with acute myocardial infarction: results from the Cooperative Cardiovascular Project. *JAMA*. 1998;279:1351–1357.
21. Health Care Financing Administration. *International Classification of Diseases, 9th Revision, Clinical Modification: ICD-9-CM*. 6th ed. Washington, DC: US Government Printing Office; 1997.
22. Kosseim M, Mayo NE, Scott S, Hanley JA, Brophy J, Gagnon B, Pilote L. Ranking hospitals according to acute myocardial infarction mortality: should transfers be included? *Med Care*. 2006;44:664–670.
23. Bureau of the Census. *State and Metropolitan Area Date Book, 1991*. Washington, DC: US Government Printing Office; 1991.
24. Cherkin D, Lawrence D. An evaluation of the American Medical Association's Physician Masterfile as a data source: one state's experience. *Med Care*. 1977;15:767–769.
25. American Hospital Association. *The Annual Survey of Hospitals Database: Documentation for 1994 Data*. Chicago, Ill: American Hospital Publishing; 1994.
26. Every NR, Larson EB, Litwin PE, Maynard C, Fihn SD, Eisenberg MS, Hallstrom AP, Martin JS, Weaver WD; Myocardial Infarction Triage and Intervention Project Investigators. The association between on-site cardiac catheterization facilities and the use of coronary angiography after acute myocardial infarction. *N Engl J Med*. 1993;329:546–551.
27. Dendukuri N, Normand SL, McNeil BJ. Impact of cardiac service availability on case-selection for angiography and survival associated with angiography. *Health Serv Res*. 2003;38:21–40.
28. Zhang J, Yu KF. What's the relative risk? A method of correcting the odds ratio in cohort studies of common outcomes. *JAMA*. 1998;280:1690–1691.
29. Blumenthal D. Part 1: quality of care: what is it? *N Engl J Med*. 1996;335:891–894.
30. Brook RH, McGlynn EA, Cleary PD. Quality of health care: part 2: measuring quality of care. *N Engl J Med*. 1996;335:966–970.
31. Petersen LA, Normand SL, Leape LL, McNeil BJ. Regionalization and the underuse of angiography in the Veterans Affairs Health Care System as compared with a fee-for-service system. *N Engl J Med*. 2003;348:2209–2217.
32. McGlynn EA, Asch SM, Adams J, Keesey J, Hicks J, DeCristofaro A, Kerr EA. The quality of health care delivered to adults in the United States. *N Engl J Med*. 2003;348:2635–2645.
33. *Area Resource File (ARF)*. Rockville, Md: US Department of Health and Human Services, Health Resources and Services Administration, Bureau of Health Professions; 1995.
34. Baker DW, Shapiro MF, Schur CL. Health insurance and access to care for symptomatic conditions. *Arch Intern Med*. 2000;160:1269–1274.
35. Sheldon WC. Trends in cardiac catheterization laboratories in the United States. *Catheter Cardiovasc Interv*. 2001;53:40–45.
36. Antman EM, Anbe DT, Armstrong PW, Bates ER, Green LA, Hand M, Hochman JS, Krumholz HM, Kushner FG, Lamas GA, Mullany CJ, Ornato JP, Pearle DL, Sloan MA, Smith SC Jr, Alpert JS, Anderson JL, Faxon DP, Fuster V, Gibbons RJ, Gregoratos G, Halperin JL, Hiratzka LF, Hunt SA, Jacobs AK. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1999 Guidelines for the Management of Patients With Acute Myocardial Infarction). *Circulation*. 2004;110:e82–e292.
37. Braunwald E, Antman EM, Beasley JW, Califf RM, Cheitlin MD, Hochman JS, Jones RH, Kereiakes D, Kupersmith J, Levin TN, Pepine CJ, Schaeffer JW, Smith EE III, Steward DE, Theroux P, Gibbons RJ, Alpert JS, Faxon DP, Fuster V, Gregoratos G, Hiratzka LF, Jacobs AK, Smith SC Jr. ACC/AHA guideline update for the management of patients with unstable angina and non-ST-segment elevation myocardial infarction–2002: summary article: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on the Management of Patients With Unstable Angina). *Circulation*. 2002;106:1893–1900.
38. Lucas FL, DeLorenzo MA, Siewers AE, Wennberg DE. Temporal trends in the utilization of diagnostic testing and treatments for cardiovascular disease in the United States, 1993–2001. *Circulation*. 2006;113:374–379.
39. McClellan M, McNeil BJ, Newhouse JP. Does more intensive treatment of acute myocardial infarction in the elderly reduce mortality? Analysis using instrumental variables. *JAMA*. 1994;272:859–866.
40. Wennberg DE, Kellett MA, Dickens JD, Malenka DJ, Keilson LM, Keller RB. The association between local diagnostic testing intensity and invasive cardiac procedures. *JAMA*. 1996;275:1161–1164.
41. Berwick DM, Calkins DR, McCannon CJ, Hackbarth AD. The 100,000 lives campaign: setting a goal and a deadline for improving health care quality. *JAMA*. 2006;295:324–327.

CLINICAL PERSPECTIVE

Certificate of need (CON) regulation was introduced originally by the federal government to control healthcare costs and improve quality of care, in part by limiting the number of facilities providing complex medical care. CON regulation is now under the auspices of state governments, and 37 states currently maintain CON regulation. Our objective was to examine whether rates of appropriate cardiac catheterization after admission for acute myocardial infarction varied between states with and without CON regulation of cardiac catheterization. We used the Cooperative Cardiovascular Project, medical record data abstracted for Medicare beneficiaries hospitalized with acute myocardial infarction between 1994 and 1996, which provided a unique opportunity to use a large, nationally representative database that permits comparison of state policies while also providing detailed clinical information that allows determination of procedure appropriateness. Although the absolute difference in procedure rates was small, we found that CON regulation was associated with a slightly lower overall rate of catheterization in our adjusted analyses. However, after stratification by appropriateness, CON regulation was associated with modestly lower rates of equivocally and weakly indicated cardiac catheterization after admission for acute myocardial infarction but no significant difference in rates of strongly indicated catheterization. Importantly, this association was no longer significant when we included hospital capacity to perform coronary artery bypass surgery or cardiac catheterization in our adjusted analyses, which suggests that CON regulation is associated with a lower rate of cardiac catheterization among patients with equivocal and weak indications because it limits the number of healthcare facilities authorized to provide catheterization services.

HSS Journal® SAGE

HSS J. 2020 Dec; 16(Suppl 2): 264–271.
Published online 2019 Jul 29. doi: 10.1007/s11420-019-09693-z

PMCID: PMC7749925
PMID: 33380956

Certificate-of-Need Programs Are Associated with a Reduced Incidence, Expenditure, and Rate of Complications with Respect to Knee Arthroscopy in the Medicare Population

Jourdan M. Cancienne, MD,[1] Robert Browning, MD,[1] Emmanuel Haug, MD,[2] James A. Browne, MD,[2] and Brian C. Werner, MD[2]

Abstract

Background

To curb costs at the state level, improve care quality, and promote access to care, certificate-of-need (CON) laws were established in many states in 1974. It is not known how CON regulations have affected the provision of knee arthroscopy, one of the most common orthopedic procedures performed in the USA.

Questions/Purposes

We sought to characterize the effects of CON regulations on knee arthroscopy in the national Medicare population by examining trends in procedure volumes, comparing trends in procedure charges, evaluating distribution of procedure volumes between high-, mid-, and low-volume facilities, and comparing adverse event and complication rates after knee arthroscopy between states with and without CON regulations.

Methods

events between the two groups.

Results

The rate of decrease in the incidence of knee arthroscopy was significantly greater in CON states than that in non-CON states. CON states also had significantly lower charges at all time points, and overall, compared with non-CON states. There were significantly more high- and mid-volume facilities in CON states than in non-CON states, and there were significantly more low-volume facilities in non-CON states than in CON states. Finally, there were significantly higher rates of emergency room visits within 30 days and infection within 6 months in non-CON states than in CON states.

Conclusions

CON regulations appear to have achieved several of their intended goals for knee arthroscopy. Further research is needed to determine if CON regulations affect the quality and sustainability of care provided to patients undergoing knee arthroscopy.

Keywords: certificate-of-need regulations, knee arthroscopy

Introduction

Health care expenditures continue to rise in the USA, and as a result, the health share of the gross domestic product is expected to rise from 17.8% in 2015 to nearly 20% by 2025 [23]. Furthermore, despite spending more money on health care than any other country in the world, the USA has been ranked 37th among countries in health efficiency globally [18]. Health policy experts have hypothesized that at least a part of the reason for the poor yield per dollar spent on health care in the USA is due to the duplication of medical services [13]. For instance, instead of limiting medical care that meets the demands and needs of a certain population, the supply of services is duplicated to maximize profit and convenience, possibly at the expense of quality. Furthermore, when facilities such as ambulatory surgical centers are duplicated, they rely on procedural and patient volume to meet fixed costs. With a fixed patient population, each hospital or physician then serves fewer total patients, possibly resulting in worse outcomes and lower quality of care.

In an effort to curb the rapid expansion of services and health care costs at a state level, improve quality of care, and promote equal access to care, certificate-of-need (CON) laws were established in 1974. CON regulations require health care providers to obtain approval of a state board before opening new health facilities or expanding existing facilities [1]. Despite an end to the federal mandate in 1987, 36 states continue to rely on these regulations to contain health care spending [1].

lion, accounting for 5% of the gross domestic product and nearly 30% of all health care expenditures in the USA by 2023 [22]. Knee arthroscopy represents three of the six most common orthopedic procedures performed in the USA, and more than 700,000 are performed annually [4, 5, 15]. However, despite its popularity—knee arthroscopy for patients with degenerative knee disease is often encountered in the Medicare population—research has shown it is no more effective or therapeutic than conservative management strategies [2]. Although there has been increasing evidence against the use of arthroscopy to treat degenerative knee conditions found more frequently in Medicare-age populations, little epidemiological data exists on how common orthopedic procedures are affected by government policy and health care regulations.

Therefore, the goals of our study were to characterize the effects of CON regulations on knee arthroscopy in the Medicare population by (1) examining and comparing trends in procedure volumes in states with CONs and those without, (2) comparing trends in procedure charges between states with CONs and states without, (3) evaluating distribution of procedure volumes between high-, mid-, and low-volume facilities between CON and non-CON states, and (4) comparing adverse event and complication rates after knee arthroscopy between states with and without CON regulations.

Materials and Methods

The PearlDiver Patient Records Database (www.pearldiverinc.com, Fort Wayne, IN, USA), a for-fee insurance-based patient record database, was used for the present study. The database consists of several separate private insurers and a Medicare database with procedural volumes and patient demographics for patients with International Classification of Diseases, 9th Revision (ICD-9), diagnoses and procedures, or Current Procedural Terminology (CPT) codes. The data obtained is anonymous, and thus, this study was deemed exempt by the authors' Institutional Review Board. The data for the present study was derived from the Medicare database within PearlDiver that contains approximately 55 million individual patient records from 2005 to 2014. The Medicare data contained within the database is the complete 100% Medicare Standard Analytical File, indexed and reorganized to allow for patient tracking over time among other benefits. The Medicare dataset was chosen for this study because a nationwide repository of data was needed to accurately represent all states. Private-payer databases do not equally represent the USA, and thus, a large amount of bias would be unavoidable should this dataset have been used.

The goal study population was Medicare-only patients who underwent isolated simple knee arthroscopy, including partial meniscectomy and/or chondroplasty. The database was first queried for all patients who fit these criteria using CPT codes 29880 (arthroscopic partial medial and lateral meniscectomies), 29881 (arthroscopic partial medial or lateral meniscectomy), and/or 29877 (arthroscopic chondroplasty of knee). Patients with any concomitant open or arthroscopic knee procedure were then subsequently excluded from this cohort using CPT codes, including pa-arthroscopy for a diagnosis of infection were also excluded.

Patients who underwent subsequent contralateral isolated knee arthroscopy were counted only once for whichever surgery occurred first. Patients who underwent subsequent ipsilateral knee arthroscopy were also counted only once, for only the index procedure. The state in which each patient had their surgical procedure performed is provided within the Medicare data; each patient was then grouped according to which state their procedure was performed.

The presence or absence of CON laws governing inpatient or outpatient surgical procedures during the study period for each of the 50 states and the District of Columbia was determined using data provided by the National Conference of State Legislatures (NCSL) website (http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx). Patients in states with CON regulations during the study period covering both inpatient and outpatient operating rooms formed the study group (n = 25 states, including AK, CT, DE, FL, GA, HI, IL, IA, KY, ME, MD, MA, MI, MS, NV, NH, NY, NC, RI, SC, TN, VT, VA, WV, and DC). Patients in states without CON laws, or with CON laws which did not cover operating rooms during the study period, formed the control group (n = 20 states, including AZ, AR, CA, CO, ID, IN, KS, LA, MN, NE, NM, ND, OH, OK, PA, SD, TX, UT, WI, WY). Three states had CON laws covering only outpatient or ambulatory ORs but not inpatient ORs, and three states had CON laws which covered only inpatient ORs. Patients with procedures performed in these six states were excluded from the analysis.

The following outcomes were assessed. The number of knee arthroscopy procedures for CON states and non-CON states was determined from the standard database output. The incidence of knee arthroscopy procedures was also determined by normalizing the number of procedures performed to the number of insured patients each year for the CON states and non-CON states. These data were compared between groups both as overall incidences and as a change in normalized incidence from the index year (2005).

The overall and yearly average costs for knee arthroscopy procedures were compared between CON and non-CON states by examining both per-patient procedural charges and per-patient procedural reimbursements.

The volume of procedures performed in facilities was also assessed. The facilities in which the arthroscopy procedures were performed are reported in the SAF data. For each study year, the number of procedures performed at all facilities that performed a knee arthroscopy procedure was determined and categorized into low-volume (10 or fewer procedures per year), mid-volume (11 to 49 procedures per year), and high-volume (50 or more procedures per year) facilities. As there is no data to guide what should be considered "low," "mid," or "high" volume, these cutoffs were determined by examining the facility breakdowns from the present dataset.

hospital discharge code; thus, patients who die at home without admission to an ER or hospital are not captured in this analysis. ER visits, hospital admissions, and infections were determined using ICD-9 and CPT codes.

Statistical Analysis

Comparisons of overall procedure volumes and incidences were performed using Student's *t* χ^2 analyses. Trends in procedure volumes and incidences were compared using linear regression analyses. Comparisons of charges and reimbursements were performed using Student's *t* tests. Yearly comparisons of high-, mid-, and low-volume facilities between CON and non-CON states were performed using χ^2 tests. Comparisons of post-operative complication rates were performed using a logistic regression analysis to control for confounding variables, including patient demographics (age, sex, body mass index) and numerous medical comorbidities (tobacco use, alcohol abuse, inflammatory arthritis, depression, diabetes mellitus, hyperlipidemia, hypertension, peripheral vascular disease, congestive heart failure, coronary artery disease, chronic kidney disease, chronic lung disease, chronic liver disease, thyroid disease, hypercoagulable state, and current hemodialysis use). Statistical analyses were performed in both SPSS version 24 (Armonk, NY, USA) and Microsoft Excel (Microsoft, Redmond, WA, USA).

Results

We identified 28,748,281 patients in CON states and 25,196,027 patients in non-CON states who underwent knee arthroscopy over the period studied. Both the changes in normalized knee arthroscopy rate and overall incidence of knee arthroscopy per year were observed to steadily decrease over the period studied. However, the incidence of knee arthroscopy was significantly lower in CON states compared with non-CON states ($p < 0.0001$). In addition, the rate of decrease in the incidence of knee arthroscopy over the period studied was significantly greater in CON states compared with non-CON states ($p < 0.006$) (Fig. 1).

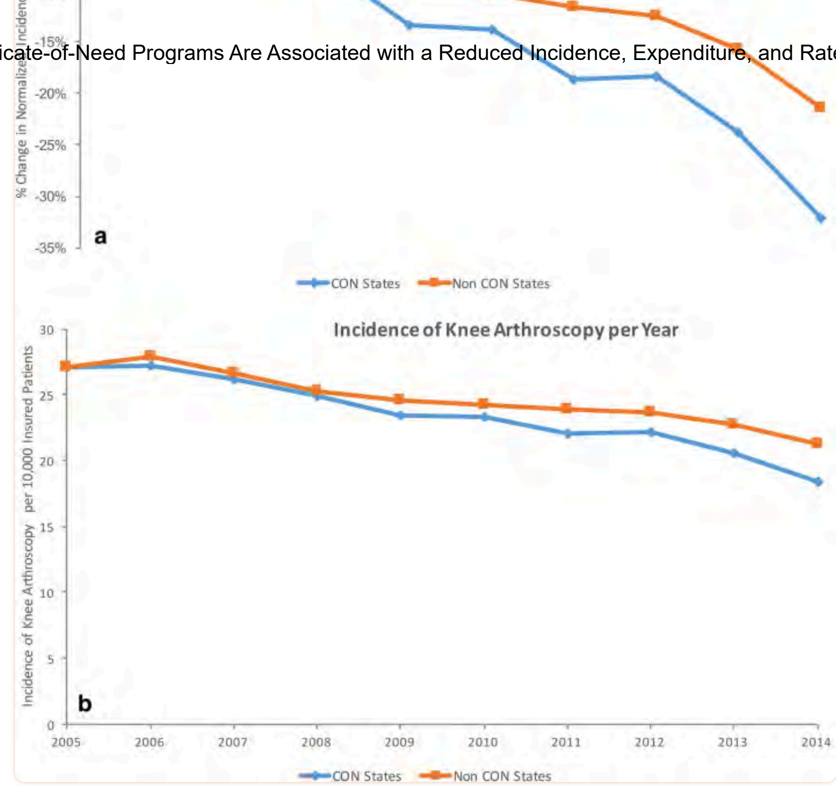


Fig. 1

a Percentage change in the normalized knee arthroscopy rate, and **b** in the incidence of knee arthroscopy, 2005–2014, in states with and without certificate-of-need (CON) regulations.

CON states had significantly lower average per-patient charges for knee arthroscopy at all time points and overall compared with non-CON states ($3719 and $4769, respectively; $p < 0.001$ for all comparisons) (Fig. 2a). Average per-patient charges for knee arthroscopy steadily increased over the period studied for both CON and non-CON states. However, per-patient procedural reimbursements between CON and non-CON states were not statistically different ($1790.36 and $1813.09, respectively; $p = 0.429$) (Fig. 2b).

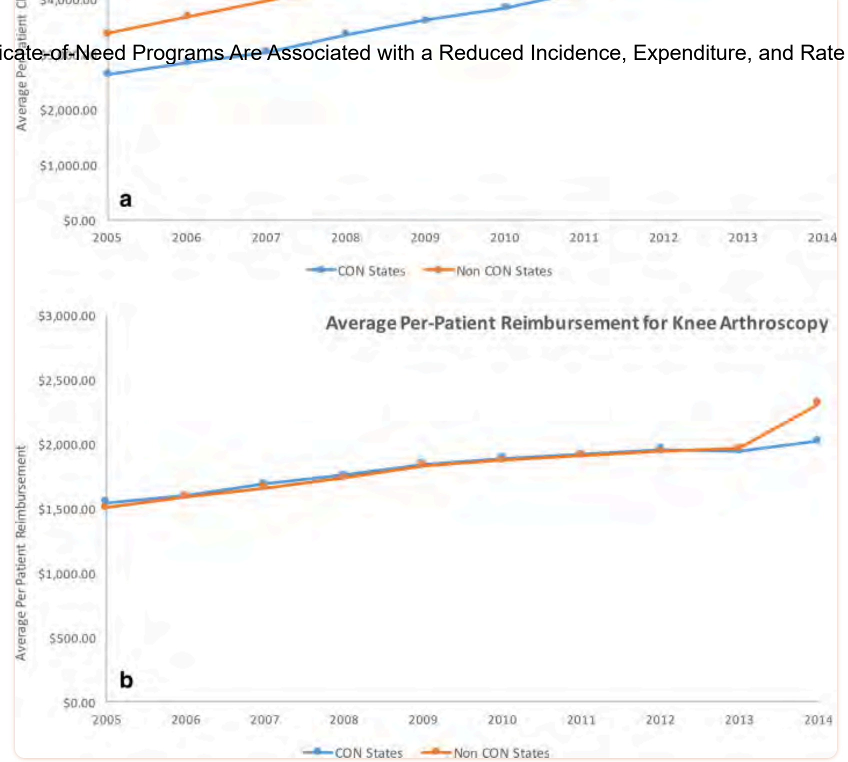


Fig. 2

a Average per-patient charges (USD$) for knee arthroscopy, 2005–2014, in states with and without certificate-of-need (CON) regulations. **b** Average per-patient reimbursements (USD$) for knee arthroscopy, 2005–2014, in states with and without CON regulations.

There were significantly more high- and mid-volume facilities in CON states than in non-CON states ($p < 0.0001$) (Fig. 3a, b). In addition, there were significantly more low-volume facilities in non-CON states than in CON states ($p < 0.0001$) (Fig. 3c).

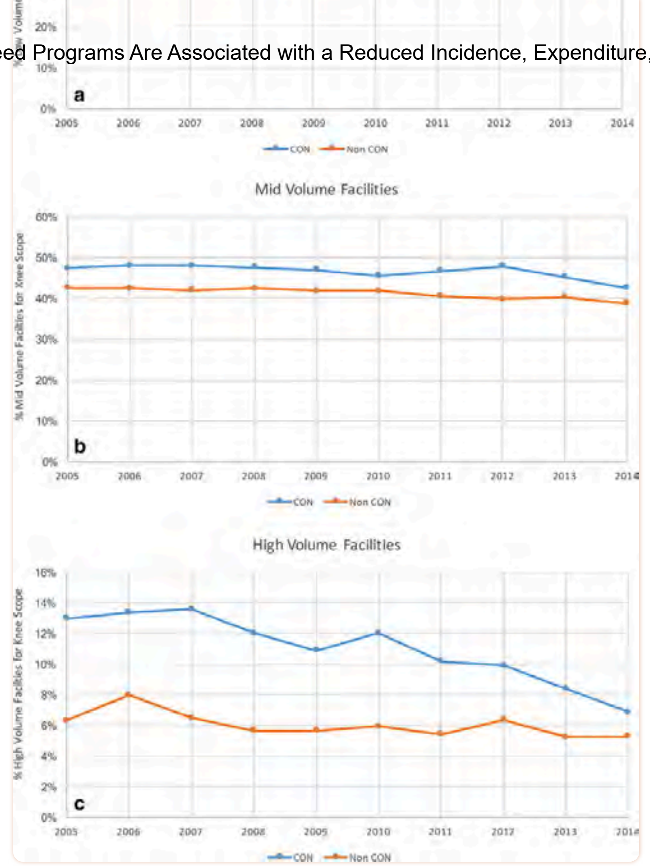


Fig. 3

a Percentage of low-volume knee arthroscopy facilities (≤ 10 procedures/year), 2005–2014, in states with and without certificate-of-need (CON) regulations. **b** Percentage of mid-volume knee arthroscopy facilities (11–49 procedures/year), 2005–2014, in states with and without CON regulations. **c** Percentage of high-volume knee arthroscopy facilities (≥ 50 procedures/year), 2005–2014, in states with and without CON regulations.

Finally, the incidence of ER visits within 30 days and infection within 6 months of surgery was significantly higher in non-CON states than that in CON states ($p < 0.001$ and $p = 0.005$, respectively) (Table 1). There was no significant difference in the incidence of in-hospital deaths and readmissions within 30 days of surgery between CON and non-CON states.

Complication	CON States		Non-CON states		Statistical analysis		
	n	%	*n*	%	OR	95% CI	*p*
In-hospital death (1 year)	835	0.25	698	0.25	1.03	[0.93–1.14]	0.535
Emergency room visit (30 days)	8319	2.54	7268	2.59	0.94	[0.91–0.97]	< 0.001
Hospital admission (30 days)	1531	0.47	1318	0.47	0.96	[0.89–1.03]	0.282
Infection (6 months)	3107	0.95	2744	0.98	0.93	[0.88–0.98]	0.005

Discussion

The US health care system continues to struggle with the challenge of providing expanded access to high-quality health care while controlling costs. CON regulations were established to aid in constraining costs while maintaining a high quality of care by moving more procedures into high-volume centers and restricting unnecessary duplication of services. By using a population-based approach, our study evaluated the effect of CON regulations on one of the most common orthopedic procedures, knee arthroscopy. We found that although there has been an overall decrease in the incidence of knee arthroscopy, compared with states without CON regulations, those with CON regulations had significantly lower normalized incidences and were decreasing at a faster rate. In states with CON regulations, there were also significantly lower charges and significantly more high- and mid-volume hospitals performing knee arthroscopy with lower adverse event and complication rates. This study represents the first analysis of the impact of CON regulations on orthopedic surgery and suggests that CON regulations appear to have achieved several of their intended goals for knee arthroscopy.

Our findings must be interpreted within the limitations of the study design. First, the power of our analysis and results relies on the quality of data sampled and the accuracy of procedural coding within the database. Miscoding and noncoding are therefore potential sources of error. Second, we focused on Medicare patients only, and these findings may not apply to a private-payer populations or datasets. This is particularly important because indications for knee arthroscopy in an elderly, Medicare population are far different from those for a younger, active population. Thus, these results may not translate to a younger population. Furthermore, CON regulations are not uniform, and variations based on a state-by-state level that are unidentifiable are possible sources of confounding. However, we were careful to review the specific CON regulations for each state and assure that only states with specific regulations covering both inpatient and outpatient or ambulatory operating rooms were included. Similarly, states without CON regulations have regulatory mechanisms and bylaws in place to control costs and the distribution of health services that are also unable to be identified. Future studies should seek more uniformity in such regulations be-market, thus reducing the unnecessary expansion of duplicative health care services [1, 6]. While these regulations have not been successful in decreasing the utilization of certain treatments such as intensity-modulated radiation therapy to treat prostate cancer or urologic robotic surgery in the broader literature, no studies have investigated similar effects on orthopedic surgical procedures [9, 10]. We found a significantly lower utilization of knee arthroscopy in the Medicare population within CON states compared with non-CON states. In addition, the rate of this decrease was significantly greater in CON states compared with non-CON states. Given increasing evidence that patients with degenerative knee disease incur very little benefit with knee arthroscopy, it is expected that the overall incidence of knee arthroscopy would decrease over time during the study period, particularly in the Medicare population studied [2]. However, as seen in CON states, this decrease was much more rapid, suggesting that these regulations might aid in more quickly limiting unnecessary procedures and decreasing the overall use of such a procedure.

Another central tenet of CON regulations is to control unnecessary health care expenditures. In the present study, we observed that CON states had significantly lower charges for the same procedures at all time points, and overall, compared with non-CON states. In addition, there were significantly more high- and mid-volume facilities within CON states performing these procedures compared with non-CON states, where there were significantly more low-volume facilities. This data demonstrates the intended goals of CON regulations, to move more procedures into higher-volume facilities that meet the needs of the populations they are serving. The mechanism of the trends reported might be because CON regulations have been shown to serve as an effective barrier to entry for ambulatory surgical centers, where most knee arthroscopic procedures take place [1]. Prior studies have similarly demonstrated that CON regulations control the supply, and thus overall cost, of certain health services. Hellinger demonstrated an association between CON regulations and reductions in the number of hospital beds and health expenditures [6]. As with our study, studies in cardiothoracic research have demonstrated a decrease in the expansion of coronary intervention services leading to higher per-provider volumes in states with CON regulations [7, 8, 19]. While the true socioeconomic reason for the association is much more complex and beyond the scope of our study, there appears to be a real relationship between higher-volume and lower-cost arthroscopic knee surgery in CON states than in those without such regulations that is similar to the prior studies mentioned.

Finally, perhaps the most important goal of CON regulations is improving care quality. Prior orthopedic research has well established the relationships among higher-volume centers, improved outcomes, and lower complications [11, 21]. Thus, one would expect that the concentration of procedures being performed at high-volume centers in CON states would yield lower complications compared with non-CON states. Despite the exceedingly low incidence of complications following knee arthroscopy, we did observe significantly higher rates of ER visits within 30 days and infeccerns about the regulations. For instance, some have argued that CON programs decrease competition, limit care access in certain rural areas, and are too variable from state to state. It is difficult to obtain objective, accurate data on the true efficacy of CON programs, and more epidemiologic research is needed to better evaluate in which states and under what circumstances these regulations aid in care delivery.

In conclusion, our findings demonstrate that, in at least the ways evaluated, CON regulations appear to have achieved their goals for knee arthroscopy. Further research is needed to determine whether CON regulations impact the quality and sustainability of care provided to patients undergoing knee arthroscopy.

Compliance with Ethical Standards

Conflict of Interest

Jourdan M. Cancienne, MD, Robert Browning, MD, and Emmanuel Haug, MD, declare that they have no conflicts of interest. James A. Browne, MD, reports board or committee membership from the American Association of Hip and Knee Surgeons, the American Joint Replacement Registry, Southern Orthopaedic Association, Virginia Orthopaedic Society, and the Journal of Arthroplasty; royalties and fees as a consultant from DJ Orthopaedics; publishing royalties from Journal of Bone and Joint Surgery and Saunders/Mosby-Elsevier; fees as a consultant from Norvartis and OsteoRemedies; and stock or stock options from Radlink, outside the submitted work. Brian C. Werner, MD, reports grants and personal fees from Arthrex, Inc., Zimmer Biomet, and Integra LifeScience, as well as board or committee membership with the American Orthopaedic Society for Sports Medicine and American Shoulder and Elbow Surgeons, outside the submitted work.

Human/Animal Rights

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2013.

Informed Consent

Informed consent was waived from all patients for being included in this study.

Required Author Forms

Disclosure forms provided by the authors are available with the online version of this article.

1. Bailey J. The effect of certificate of need laws on all-cause mortality. *Health Serv Res.* 2018;53(1):49–62. doi: 10.1111/1475-6773.12619. [PMC free article] [PubMed] [CrossRef] [Google Scholar]

2. Brignardello-Petersen R, Guyatt GH, Buchbinder R, et al. Knee arthroscopy versus conservative management in patients with degenerative knee disease: a systematic review. *BMJ Open.* 2017;7:e016114. doi: 10.1136/bmjopen-2017-016114. [PMC free article] [PubMed] [CrossRef] [Google Scholar]

3. Cancienne JM, Mahon HS, Dempsey IJ, Miller MD, Werner BC. Patient-related risk factors for infection following knee arthroscopy: an analysis of over 700,000 patients from two large databases. *Knee.* 2017;24(3):594–600. doi: 10.1016/j.knee.2017.02.002. [PubMed] [CrossRef] [Google Scholar]

4. Cullen KA, Hall MJ, Golosinskiy A. Ambulatory surgery in the United States, 2006. *Natl Health Stat Report.* 2009;11:1–25. [PubMed] [Google Scholar]

5. Garrett WE, Swiontkowski MF, Weinstein JN, et al. American Board of Orthopaedic Surgery Practice of the Orthopaedic Surgeon: Part-II, certification examination case mix. *J Bone Joint Surg Am.* 2006;88(3):660–667. doi: 10.2106/00004623-200603000-00027. [PubMed] [CrossRef] [Google Scholar]

6. Hellinger FJ. The effect of certificate-of-need laws on hospital beds and healthcare expenditures: an empirical analysis. *Am J Manag Care.* 2009;15:737–744. [PubMed] [Google Scholar]

7. Ho V. Certificate of need, volume, and percutaneous transluminal coronary angioplasty outcomes. *Am Heart J.* 2004;147:442–448. doi: 10.1016/j.ahj.2003.05.002. [PubMed] [CrossRef] [Google Scholar]

8. Ho V, Ku-Goto M-H, Jollis JG. Certificate of Need (CON) for cardiac care: controversy over the contributions of CON. *Health Serv Res.* 2009;44:483–500. doi: 10.1111/j.1475-6773.2008.00933.x. [PMC free article] [PubMed] [CrossRef] [Google Scholar]

9. Jacobs BL, Zhang Y, Skolarus TA, et al. Certificate of need legislation and the dissemination of robotic surgery for prostate cancer. *J Urol.* 2013;189:80–85. doi: 10.1016/j.juro.2012.08.185. [PubMed] [CrossRef] [Google Scholar]

10. Khanna A, Hu JC, Gu X, Nguyen PL, Lipsitz S, Palapattu GS. Certificate of need programs, intensity modulated radiation therapy use and the cost of prostate cancer care. *J Urol*. 2013;189:75–79. [PubMed]

11. Laucis NC, Chowdhury M, Dasgupta A, Bhattacharyya T. Trend toward high-volume hospitals and the influence on complications in knee and hip arthroplasty. *J Bone Joint Surg Am.* 2016;98:707–712. doi: 10.2106/JBJS.15.00399. [PMC free article] [PubMed] [CrossRef] [Google Scholar]

12. Lorch SA, Maheshwari P, Even-Shoshan O. The impact of certificate of need programs on neonatal intensive care units. *J Perinatol.* 2012;32:39–44. doi: 10.1038/jp.2011.47. [PubMed] [CrossRef] [Google Scholar]

13. Otsubo T, Imanaka Y, Lee J, Hayashida K. Evaluation of resource allocation and supply-demand balance in clinical practice with high-cost technologies. *J Eval Clin Pract.* 2011;17:1114–1121. doi: 10.1111/j.1365-2753.2010.01484.x. [PubMed] [CrossRef] [Google Scholar]

Scholar]

16. Ross JS, Ho V, Wang Y, et al. Certificate of need regulation and cardiac catheterization appropriateness after acute myocardial infarction. *Circulation.* 2007;115:1012–1019. doi: 10.1161/CIRCULATIONAHA.106.658377. [PubMed] [CrossRef] [Google Scholar]

17. Short MN, Aloia TA, Ho V. Certificate of need regulations and the availability and use of cancer resections. *Ann Surg Oncol.* 2008;15:1837–1845. doi: 10.1245/s10434-008-9914-1. [PubMed] [CrossRef] [Google Scholar]

18. Tandon A, Jl C, Jeremy M, Lauer A, Evans DB. *Measuring Overall Health System Performance for 191 Countries.* Geneva: World Health Organization; 2000. [Google Scholar]

19. Vaughan-Sarrazin MS, Hannan EL, Gormley CJ, Rosenthal GE. Mortality in Medicare beneficiaries following coronary artery bypass graft surgery in states with and without certificate of need regulation. *JAMA.* 2002;288:1859–1866. doi: 10.1001/jama.288.15.1859. [PubMed] [CrossRef] [Google Scholar]

20. Vaughan Sarrazin MS, Bayman L, Cram P. Trends during 1993-2004 in the availability and use of revascularization after acute myocardial infarction in markets affected by certificate of need regulations. *Med Care Res Rev.* 2010;67:213–231. doi: 10.1177/1077558709346565. [PubMed] [CrossRef] [Google Scholar]

21. Weinheimer KT, Smuin DM, Dhawan A. Patient outcomes as a function of shoulder surgeon volume: a systematic review. *Arthroscopy.* 2017;33(7):1273–1281. doi: 10.1016/j.arthro.2017.03.005. [PubMed] [CrossRef] [Google Scholar]

22. Yu S, Zuckerman JD. Orthopedics in US health care. *Am J Orthop (Belle Mead NJ)* 2015;44:538–541. [PubMed] [Google Scholar]

23. US Centers for Medicare and Medicaid Services. National Health Expenditure Fact Sheet. Available from https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html. Accessed 25 April 2019.

Medical Care Research and Review

http://mcr.sagepub.com/

The Association of Hospital Cost-Inefficiency With Certificate-of-Need Regulation

Michael D. Rosko and Ryan L. Mutter

Med Care Res Rev 2014 71: 280 originally published online 22 January 2014
DOI: 10.1177/1077558713519167

The online version of this article can be found at:
http://mcr.sagepub.com/content/71/3/280

Published by:

SAGE

http://www.sagepublications.com

Medical Care Research and Review
2014, Vol. 71(3) 280–298

DOI: 10.1177/1077558713519167
mcr.sagepub.com

The Association of Hospital Cost-Inefficiency With Certificate-of-Need Regulation

Michael D. Rosko[1] and Ryan L. Mutter[2]

Abstract

Certificate-of-need (CON) regulations can promote hospital efficiency by reducing duplication of services; however, there are practical and theoretical reasons why they might be ineffective, and the empirical evidence generated has been mixed. This study compares the cost-inefficiency of urban, acute care hospitals in states with CON regulations against those in states without CON requirements. Stochastic frontier analysis was performed on pooled time-series, cross-sectional data from 1,552 hospitals in 37 states for the period 2005 to 2009 with controls for variations in hospital product mix, quality, and patient burden of illness. Average estimated cost-inefficiency was less in CON states (8.10%) than in non-CON states (12.46%). Results suggest that CON regulation may be an effective policy instrument in an era of a new medical arms race. However, broader analysis of the effects of CON regulation on efficiency, quality, access, prices, and innovation is needed before a policy recommendation can be made.

Keywords

certificate-of-need, efficiency, hospitals, stochastic frontier analysis

This article, submitted to *Medical Care Research and Review* on April 30, 2013, was revised and accepted for publication on December 5, 2013.

[1]Widener University, Chester, PA, USA
[2]Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, Rockville, MD, USA

Corresponding Author:
Michael D. Rosko, School of Business Administration, Widener University, One University Place, Chester, PA 19013, USA.
Email: mdrosko@widener.edu

Introduction

Containment of hospital costs has been a significant public policy concern for more than 50 years. Various approaches have been implemented to restrain hospital expenditures, including the following: (a) revenue regulation, (b) utilization controls, (c) fostering competition and creating market-like incentives, and (d) limiting capital expansion through certificate of need (CON) regulations. This article focuses on the later.

CON regulation was widely embraced in the 1970s as a cost-containment policy instrument. By 1980, every state except for Louisiana had passed CON legislation (Hellinger, 2009). However, support for CON waned in the 1980s as the introduction of market-like incentives in prospective payment programs introduced by Medicare and several states and the growth of risk-contracting caused the competitive paradigm to shift from service-based competition toward price-leadership (Devers, Brewster, & Casalino, 2003). Eleven states repealed their CON laws in the 1980s, and 12 additional states later repealed sections of their CON laws that covered acute care hospitals. Currently, 27 states have CON requirements for acute care hospitals (American Health Planning Association, 2013).

It was hoped that CON laws could slow the medical arms race in which hospitals compete on the basis of providing the latest medical technology and services that could result in expensive duplication of services and inefficient use of capital (Luft, Robinson, Garnick, Maerki, & McPhee, 1986). CON regulation could slow increases in hospital expenditures in two ways: (a) it could limit the building of new hospitals or (b) it could restrict the growth of new services. Either would concentrate capital in fewer providers, thereby enhancing capital utilization. However, empirical research has provided mixed support for the efficacy of CON regulations as a cost containment tool. For example, a review of early studies concluded CON regulation exerted little or no influence on hospital expenditures (Rosko & Broyles, 1988). Noether (1988) concluded that CON regulation was associated with higher costs because of inefficient resource allocation and that CON laws may also serve as entry barriers that deter competitive pressures to reduce costs. Ho and Ku-Goto (2013) and Rivers, Fottler, and Younis (2007) also associated CON with increased hospital costs. Similarly, a report by the Federal Trade Commission and Department of Justice (2004) concluded: "The Agencies believe that, on balance, CON programs are not successful in containing health care costs, and that they pose serious anticompetitive risks that usually outweigh their purported economic benefits" (p. 22). It is possible that even if CON laws were associated with increased efficiency, the benefit to consumers might be limited if providers exercise market power and keep prices up in order to reap higher margins.

Although some in policy circles believe that CON regulation is a poor fit for today's U.S. health care system, there is evidence that a new medical arms race is emerging. In the contemporary landscape providers are practicing a "retail strategy" in which services in the most profitable product-lines are expanded (Berenson, Bodenheimer, & Pham, 2006). This can be done by expanding services in general acute care hospitals or expanding services in other related entities such as ambulatory surgical centers and small specialty hospitals. At acute care hospitals, the medical arms race is associated with specialization and accreditation (e.g., acquiring trauma center status). This expansion of medical technology was part of what CON laws were intended to guard against.

Another change in the health care environment is the passage of the Affordable Care Act (ACA). The implementation of the ACA will eventually give millions of Americans greater access to health care. However, without commensurate increases in supply or improvements in efficiency, health care price inflation might accelerate. Following health care reform in Massachusetts, expenditures for health care services have increased (Mechanic, Altman, & McDonough, 2012). While a precise determination of the source of these expenditure increases has not been made, some research suggests they could have occurred because of a surge in hospital demand by those who were uninsured previously (Thompson, Huerta, & Ford, 2012). Total hospital expenditures increased at an estimated annual rate of 4.1% in 2013 and are projected to increase by 5.8% in 2014. The implementation of the ACA was cited as an important factor driving the acceleration of spending for hospital care in 2014 and beyond (Cuckler et al., 2013). While much of this demand may be for primary care, there certainly can be effects on acute care hospital services. For example, the Rand Study provided some evidence that inpatient hospital care and outpatient care are complements (Phelps, 2010). Expansion in the supply of hospital-based acute care services might be necessary to meet increased demand stemming from the expansion of health insurance coverage; however, supply increases will need to occur in ways that do not contribute to cost and price increases themselves. CON laws may be a useful strategy toward that end.

Only a few studies have examined the empirical association between CON regulation and hospital efficiency. Whereas cost decreases alone could occur through the reduction of services (with adverse consequences for access), efficiency is an important metric to analyze because efficiency increases potentially allow expenditures to be decreased and access to be increased simultaneously. Two of the three studies that examined the association of CON laws with efficiency employed nonparametric frontier techniques (Bates, Mukherjee, & Santerre, 2006; Ferrier, Leleu, & Valdmanis, 2010). The other used regression analysis (Eakin, 1991). Mixed results were reported. For example, Bates et al. (2006) used a two-stage approach and estimated three Tobit models and the coefficient of CON was significant ($p < .05$) and positive in only one model, suggesting that CON either had no association or a slight positive association with technical efficiency. Ferrier et al. (2010), who estimated directional distance functions (Debreu, 1951), reported that CON states had higher technical efficiency but lower scale efficiency compared with non-CON states. Therefore, further evidence on this topic is warranted.

New Contribution

This study examines the association between state use of CON laws and hospital efficiency using stochastic frontier analysis (SFA) with a recent panel data set that has a rich set of controls. Most studies examining the association of CON regulation with costs or efficiency have used data well over a decade old, and the most current study used a data series that ended in 2002. Thus, most CON studies do not pertain to the current era in which a new medical arms race featuring service-line competition may be prevalent (Bates et al., 2006; Bazzoli, Gerland, & May, 2006; Devers et al., 2003). Our use of SFA to study the association of cost inefficiency with CON regulation offers an important advance in the CON literature. Unlike basic DEA studies like that conducted by Bates et al. (2006), SFA considers inefficiency from all sources (i.e., including allocative, scale, and scope inefficiencies), not just technical inefficiency. There is debate about the relative merits of DEA and SFA (Coelli, Rao, O'Donnell, & Battese, 2005). A strength of SFA is that it allows for measurement error and random shocks that might affect the estimation of efficiency. In contrast, DEA assumes that all departures from the best practice production frontier (i.e., where a completely efficient hospital would operate given its inputs and outputs) are due to inefficiency. Also, unlike previous studies that measured the association of CON programs with hospital efficiency, this study uses a rich set of product descriptor and quality variables. This helps avoid potential misclassification of product heterogeneity as inefficiency (Greene, 2004).

Stochastic Frontier Analysis

Stochastic frontier analysis (SFA) was developed independently by Aigner, Lovell, and Schmidt (1977) and Meeusen and van den Broeck (1977). Rosko and Mutter (2010) summarized the results from 27 U.S. hospital SFA studies. Although frontier analysis can have a production or cost orientation, this article employs the latter, which is consistent with most hospital applications (Rosko & Mutter, 2008).[1] SFA decomposes variations from the best practice cost frontier into a random or classical error and a deterministic error, which is assumed to represent cost-inefficiency. SFA studies of hospitals typically use a model that includes cost function variables and inefficiency-effects variables. The cost function variables are used to estimate a best practice cost frontier (i.e., where a completely efficient hospital would operate given its input prices and outputs). The inefficiency-effects variables locate a hospital with respect to the cost frontier on the basis of correlates of cost-inefficiency.

The estimation of the best practice cost frontier begins with the neo-classical cost function that assumes that total expenses depend on input prices and volume(s) of output(s). Inputs are not used as they belong in a production function (Kumbhakar & Lovell, 2000). However, recognizing that outputs, like admissions, are heterogeneous, it is important to control variations in input requirements for different types of admissions by including product descriptor variables that reflect differences in care needs and quality. Following theory (Kumbhakar & Lovell, 2000) and the hospital literature (Grannemann, Brown, & Pauly, 1986; Rosko & Mutter, 2008), we use the following hybrid cost function:

$$TC_{it} = f\left(Y_{it},\ W_{it,} PD_{it}\right) + e_{it}, \tag{1}$$

where *TC* represents total costs; *Y* is a vector of outputs; *W* is a vector of input prices; *PD* is a vector of product descriptors; *i* and *t* are the respective indexes for the hospital being observed and the year when the observation was made; and *e* is the error term, which can be decomposed as follows:

$$e_{it} = v_{it} + u_{it}, \tag{2}$$

where *v* is statistical noise (i.e., assumed to be distributed as $N(0, \sigma^2)$) and *u* consists of positive departures from the cost-frontier and represents cost-inefficiency (i.e., the percentage by which observed costs exceed minimum costs predicted for the best practice cost frontier; Lovell, 1993). Although *u* is frequently assumed to follow a half-normal distribution, there is no theoretical reason for the selection of this or other distributional forms for *u*. Coelli et al. (2005) indicate that the specification of a more general distribution, such as the truncated normal (Stevenson, 1980), has partially alleviated this problem. Concerns about this issue may be overstated as reviews of both the general literature (Coelli et al., 2005) and the health care literature (Rosko & Mutter, 2008) have consistently reported that varying assumptions about the distribution of the deterministic error has little impact on estimated inefficiencies.

Cost-inefficiency aggregates technical, allocative, scale, and scope inefficiency into a single measure. Technical inefficiency arises when the firm does not maximize output given a set of inputs employed. For example, if a hospital that employed a combination of inputs that was capable of producing 1,000 units of output produced only 700 units of output, it would be considered 30% inefficient or 70% efficient. Allocative inefficiency results when firms do not use the least costly combination of inputs in producing output. This occurs when the ratio of the marginal product of capital to the price of capital is not equal to the ratio of the marginal product of labor to the price of labor. Scale inefficiencies occur when the firm departs from the minimum point of its long-run average cost curve. When this occurs, firms are said to be operating at a point on their long-run average cost curve where either increasing returns (i.e., the firm is too small) or decreasing returns (i.e., the firm is too large) exist. Thus, scale inefficiencies are reflective of the size of the firm. Scope inefficiencies are due to the firm's inability to reap the advantages that sometimes occur in the joint production of outputs that require similar inputs (e.g., providing medical and surgical care in the same general hospital). They reflect the scope of the firm's operations (e.g., whether it is too specialized or too diversified).

Controlling heterogeneity is an important concern in conducting hospital SFA studies because variations in the amount or type of care required by patients could otherwise be confused with inefficiency (Greene, 2004; Rosko & Mutter, 2008). For example, without adjustment for case-mix intensity, the cost-inefficiency of academic medical centers and other hospitals that serve a disproportionate number of severely ill patients would be systematically overstated. Mutter, Rosko, and Wong (2008) demonstrate the importance of controlling for quality and patient burden of illness in studies of hospitals using SFA. In their review of hospital SFA studies, Rosko and Mutter (2008) found that output heterogeneity is usually controlled by including product descriptor variables for quality and case-mix. The former include structural measures such as teaching activities and risk-adjusted outcomes while the latter include a variety of inpatient and outpatient case-mix measures.

Research Design and Method

Data Sources

This study is based on panel data of 1,552 U.S. short-term, urban acute care hospitals for the period 2005 to 2009 ($T = 5$). Since it was critical to control for heterogeneity by including patient burden of illness variables and in-hospital outcome measures of quality in the model, the study was restricted to the 37 states[2] for which the State Inpatient Databases (SIDs)[3] were available through the Healthcare Cost and Utilization Project (HCUP)[4] for the entire study period. A balanced panel was used. We compared hospital cost-inefficiency in states having CON programs that regulated acute care beds during the study period with hospitals in states that did not.[5] We restricted the study to urban areas because rural areas might face different market conditions and because previous work (Folland & Hofler, 2001; Zuckerman, Hadley, & Iezzoni, 1994) found that it would be inappropriate to pool urban and rural hospitals because their cost structures differ.

The primary source for hospital-level data was the American Hospital Association (AHA) Annual Survey of Hospitals. Medicare Hospital Cost Reports were used to calculate the price of capital and the percentage of acute care beds. The case-mix index came from the Centers for Medicare & Medicaid Services. Health maintenance organization (HMO) penetration at the county level came from Thomson Reuters. AHA data were used to calculate a Herfindahl–Hirschman Index (HHI) to reflect hospital competition at the county level.

Model Specification

Following the methods of Mutter et al. (2008), a hybrid translog cost function was employed in the SFA. The general form of the translog cost model was used to estimate the stochastic frontier for U.S. hospitals. It can be expressed as follows:

$$\ln TC_{it} = \alpha_0 + \sum_{j=1}^{J}\alpha_j \ln Y_{jit} + \sum_{k=1}^{K}\beta_k \ln W_{kit} + .5\sum_{j=1}^{J}\sum_{l=1}^{J}\delta_{jl}\ln Y_{jit}\ln Y_{lit} + \\ .5\sum_{k=1}^{K}\sum_{m=1}^{K}\gamma_{km}\ln W_{kit}\ln W_{mit} + \sum_{j=1}^{J}\sum_{k=1}^{K}\rho_{jk}\ln Y_{jit}\ln W_{kit} + \sum_{r=1}^{R}\eta_r PD_{rit} + v_{it} + u_{it} \tag{3}$$

where *TC, Y, W, PD, v*, and *u* are the variables described above; *J* is the number of output variables; *K* is the number of price variables; *R* is the number of product descriptor variables; and α, β, δ, γ, η, and ρ are parameters to be estimated.

To estimate hospital-specific inefficiency, we used a time-varying model proposed by Battese and Coelli (1995). In this model the inefficiency effects are defined by

$$u_{it} = \sum_{n=1}^{N} \kappa_n Z_{it} + w_{it}, u_{it} \geq 0 \tag{4}$$

where Z_{it} is a vector of N explanatory variables associated with the inefficiency-effects; κ is a vector of unknown parameters to be estimated; and w_{it} are unobservable random variables, assumed to be independently distributed with mean zero and unknown variance, σ^2. This model allows an estimation of the impact of firm-specific and environmental factors on inefficiency (Hjalmarsson, Kumbhakar, & Heshmati, 1996). By including time in the Z vector with other firm-specific variables, inefficiency can differ by firm and over time.

The parameters of the cost frontier and the inefficiency effects variables were simultaneously estimated by a maximum likelihood method using the FRONTIER 4.1 program, which uses a random-effects regression technique (Coelli, 1996). The cost efficiency of the *i*th hospital in the *t*th year is defined as the ratio of the estimated stochastic frontier total costs to observed total costs. The stochastic total cost frontier is defined by the value total costs would be if u_{it} (i.e., the cost efficiency effect) were equal to zero (i.e., full efficiency). Battese, Heshmati, and Hjalmarsson (2000) show that

$$CE_{it} = \exp(-u_{it}), \tag{5}$$

where CE_{it} is the cost efficiency and u_{it} as defined previously. This indicates that cost efficiency is no greater than 1 and the reciprocal of this quantity, $\exp(u_{it})$, is no less than 1. The amount by which $\exp(u_{it})$ exceeds 1 is a measure of cost-inefficiency.

Cost Function Variables

The standard assumption of linear homogeneity in input prices is imposed by normalizing the equation by the wage rate. Thus, the dependent variable is the logarithm of total expenses divided by the wage rate. The continuous output and input price variables are log-transformed. Inpatient admissions, postadmission days (equals total inpatient days minus total admissions), and outpatient visits are included as outputs in the cost function. Hospital outputs were treated as exogenous, an assumption common to hospital cost studies (Grannemann et al., 1986).

Two inputs, capital and labor, are recognized by the cost-function. The price of labor was approximated by the area average annual salary per full-time-equivalent employee and the price of capital was approximated by depreciation and interest expenses per bed. For both inputs, the average price was computed for all short-term general hospitals in the Core Based Statistical Area in which the study hospital was located. A more complete specification of input prices would be desirable. However, given the relatively poor quality of input price information, we followed past practices (Grannemann et al., 1986; Rosko & Mutter, 2008; Zuckerman et al., 1994) and used this limited set of price variables.

To control variations in output, a variety of product descriptor variables were employed. Since we are estimating a cost function, we limit these to variables that reflect output quality and intensity of care required to produce output. These variables include the following: the Medicare Case-Mix Index, ratio of emergency department visits to total outpatient visits, ratio of outpatient surgeries to total outpatient visits, proportion of total hospital beds classified as acute care, and ratio of births to total admissions. These variables are consistent with the model employed by Rosko and Mutter (2008). All of these reflect severity case-mix and the first four are expected to have positive coefficients. The absence of publicly available case-mix indices for outpatient care necessitated the use of proxies for this measure. While the Medicare Case-Mix Index has been shown to be highly correlated with the overall case-mix index of hospitals, we included the ratio of births to total admissions to reflect one dimension of case-mix among the non-Medicare population. Since some hospitals serve a mixture of acute care and nonacute care patients, we included the proportion of total hospital beds classified as acute care to reflect patients who would not be included in the DRG-based Medicare Case-Mix Index. Teaching status was incorporated by the use of binary variables for major (i.e., member of the Council of Teaching Hospitals) and other teaching hospitals. Nonteaching hospitals are the omitted reference category. In addition to these variables, a vector of 29 log-transformed comorbidity variables measuring the rates of those comorbidities per discharge at the hospital level were also included (Elixhauser, Steiner, Harris, & Coffey, 1998). The comorbidity variables were identified by the application of the Comorbidity Software to HCUP data and control for patient burden of illness.[6] Mutter et al. (2008) found that without these controls, differences in patient burden of illness can masquerade as hospital inefficiency.

To control for patient safety and inpatient quality, we included four risk-adjusted, hospital-level measures of patient safety from the application of Version 3.2a of the Agency for Healthcare Research and Quality (AHRQ) Patient Safety Indicator (PSI) software to the SID: rates of failure to rescue, iatrogenic pneumothorax, infection due to medical care, and accidental puncture/laceration. We included five risk-adjusted, hospital-level measures of inpatient quality from Version 3.2a of the AHRQ Inpatient Quality Indicator (IQI) software applied to the SID: rates of in-hospital mortality for acute myocardial infarction (AMI), congestive heart failure (CHF), stroke, gastrointestinal hemorrhage, and pneumonia. To maintain an adequate sample size, we selected IQIs and PSIs that had nonzero denominators for at least 1,500 hospitals per year and which were not among the PSIs found to have a high percentage of events that were present on admission (Houchens, Elixhauser, & Romano, 2008). The IQIs and PSIs were transformed by taking their square root since some hospitals had a value of zero for those variables (Mutter, Wong, & Goldfarb, 2008).

We included a measure of reservation quality in the cost function. The use of reservation quality is consistent with the notion that all empty beds are not waste (Folland & Hofler, 2001). Rather, they provide for the contingency of surges in demand to prevent situations in which there are no available beds for newly admitted patients. Folland and Hofler (2001) point out that the use of this variable may reduce a potential bias against small hospitals that typically experience greater variability in inpatient utilization. Our method of calculating reservation quality by dividing the difference between total beds and average daily census by the square root of average daily census follows the approach of Joskow (1980). We also included a time trend in the cost function.

Inefficiency Effects Variables

To correctly draw inferences about the impact of CON regulation on hospital cost-inefficiency, it is important to control for major factors that may affect hospital inefficiency. While a binary variable for the presence of CON regulation is of primary interest, we also controlled for other correlates of cost inefficiency. We developed this set of control variables from X-inefficiency Theory (Leibenstein, 1987) and a review of hospital SFA studies (Rosko & Mutter, 2010).

To control for the effect of ownership form on inefficiency, binary variables (1/0) for investor-owned hospitals and public hospitals were used. Not-for-profit hospitals served as the omitted reference category. Variables for Medicare share of admissions and Medicaid share of admissions were used to reflect pressures associated with public payers. Since November 1983, a prospective payment system (PPS) has been used to regulate payment rates made by Medicare. Hospitals are allowed to keep the surplus between the payment rate and actual costs of providing service. Conversely, hospitals can lose money if their costs exceed the PPS rate. Medicaid payment policies vary across states. Many states have implemented some form of PPS; however, even in states where PPS is not used, the payment rates generally are set well below cost (Santerre & Neun, 2007).

Since a number of SFA studies have shown that hospitals belonging to multihospital systems are more efficient than free-standing hospitals (Rosko & Mutter, 2010), system membership was entered as a (1/0) binary variable. HHI was used to reflect competitive pressures. It was calculated by summing the squares of the market shares of admissions for all of the general acute care hospitals in the county. In this calculation, hospitals in the same health care system in the same county were treated as the same producer. This index takes on a value of 1 in monopolistic markets and approaches 0 as output is dispersed among more firms. Thus, higher values reflect less competitive pressure. If service-based competition is being practiced, then cost-inefficiency should be greater in more competitive markets.

HMO penetration, defined as the percentage of the population in the county that is enrolled in HMOs, reflects the financial pressures exerted by managed care organizations. Rosko and Mutter's (2010) review of SFA studies found that HMO penetration rate is usually positively associated with hospital cost-efficiency. However, other results were found in a few studies.

The final control variable is time trend (equal to 1 in 2005, equal to 2 in 2006, etc.). This variable allows time-varying efficiency. In contrast, the trend variable in the cost function permits a neutral shift in the cost frontier. Descriptive statistics are provided in Table 1.

Table 1. Variable Names and Descriptive Statistics.

Variable name	CON states Mean	CON states *SD*	Non-CON states Mean	Non-CON states *SD*
Cost function variables				
Total expenses (000s)	257,668	259,190	235,675	245,989
Inpatient admissions	15,714	11,640	13,997	9,214
Outpatient visits	241,525	264,184	209,486	232,599
Postadmission days	67,654	58,620	54,836	42,650
Price of capital	523.053	122.366	531.399	130.431
Acute care beds as a percentage of total beds in hospital	88.8347	12.0099	88.8276	12.5751
Births as a percentage of total admissions in hospital	10.2605	6.5904	14.1339	8.6341
Emergency department visits as a percentage of total outpatient visits in hospital	29.2163	16.8242	29.2701	17.0693
Medicare Case-Mix Index	1.4658	0.2188	1.4828	0.2261
Member of the Council of Teaching Hospitals (COTH) (binary variable 1, 0)	0.1626	0.3690	0.1217	0.3270
Other teaching hospital (binary variable equals 1 if hospital has medical residents but is not a member of COTH)	0.3564	0.4790	0.3183	0.4659
Outpatient surgical operations as a percentage of total outpatient visits in hospital	4.1988	3.3115	4.4090	4.2202
Reservation quality	6.6312	3.4808	6.8620	3.4027
Inefficiency-effects variables				
State has Certificate of Need requirement (binary variable 1, 0)	1.0000	0.0000	0.0000	0.0000
Government, nonfederal hospital (binary variable 1, 0)	0.1103	0.3133	0.1166	0.3210
Herfindahl–Hirschman Index	0.4479	0.2817	0.3585	0.2471
HMO penetration rate in county	22.3536	8.1933	29.1125	14.7297
Investor-owned hospital (binary variable 1, 0)	0.1512	0.3583	0.1865	0.3895
Medicaid admissions as a percentage of total admissions in hospital	17.7861	9.8449	18.3206	10.8281
Medicare admissions as a percentage of total admissions in hospital	44.0752	9.7226	41.5380	10.3710
Member of multihospital health care system (binary variable 1, 0)	0.6488	0.4774	0.7351	0.4413

Note. CON = certificate-of-need; HMO = health maintenance organization. The regression model also included control variables for comorbidities, risk-adjusted mortality rates, and risk-adjusted patient safety event rates. Descriptive statistics for these are available on request to the authors.

Results

Our preferred model was based on the results of a number of likelihood ratio tests (Greene, 2011). See Table 2. As result of the tests, we used SFA (instead of OLS), a translog cost function, and assumed the composed error followed a truncated-normal distribution (*Note*: When a normal-half-normal distribution was used, the mean cost-inefficiency estimate fell slightly from 10.50% to 10.45%; the hospital-level cost-inefficiency estimates from the two models were highly correlated [r = .999]). The results also suggest that the inefficiency-effects variables as a group have significant ($p < .01$) explanatory power.

Table 2. Generalized Likelihood-Ratio Tests of Null Hypotheses for Parameters of the Translog Stochastic Cost Frontier Model.

Model	Log likelihood	Lambda[a]	Implication
OLS, translog	1778.6039	NA	NA
SFA, translog, truncated-normal	2092.1339	627.0601	Use SFA rather than OLS
SFA, Cobb-Douglas, truncated normal	1889.6815	404.9048	Use translog rather than Cobb-Douglas
SFA, translog, truncated-normal, no efficiency-effects variables	1812.6299	559.0080	Use inefficiency effects variables
SFA, translog, half-normal	2087.4160	9.4358	Use normal-truncated normal error rather than normal-half-normal distribution for residuals

Note. NA = not available; OLS = ordinary lease square; SFA = stochastic frontier analysis.
a. All Lambda values are significant at $p < .01$.

Table 3 provides parameter estimates for the cost function components of the preferred model. Some of the estimated coefficients of the input price and output variables were counterintuitive or not significantly different from zero ($p < .05$). This occurred because the translog cost function requires the use of squared and interaction terms for these variables, which are highly correlated. As is well known, multicollinearity reduces the reliability of parameter estimates but does not introduce a bias. When the Cobb-Douglas model (which restricts the parameters of the squared and interaction terms to equal zero) was used, the estimates of the input price and output variables were highly significant ($p < .001$) and positive as expected.

Most of the product descriptor variables reflecting case mix were positive and statistically significant. The Medicare Case Mix Index was positive and significant. The coefficient for the major teaching hospital variable was larger than that estimated for the other teaching hospital variable. Having a higher percentage of acute care beds, more emergency department visits as a percentage of total outpatient visits, and more outpatient surgical operations as a percentage of outpatient visits to the hospital were also associated with higher costs. Higher reservation quality was also associated with higher costs.

Parameter estimates for the inefficiency-effects variables are shown in Table 4. Eight of the nine inefficiency-effects variables had significant parameter estimates. HHI was the exception.

The coefficient on CON regulation was negative and significant, which suggests that hospitals located in states that have CON regulation are more cost-efficient than hospitals located in other states. Univariate analysis (see Table 5) found that hospitals operating under a regime of CON regulation had a mean cost-inefficiency score of 8.10%, while hospitals in the comparison group had a mean cost-inefficiency score of 12.46%.

Table 3. Parameter Estimates for the SFA Cost Frontier Model (Translog With Truncated-Normal Residual, n = 7,760; 2005-2009 Panel).

Variable	Coefficient	*t* Ratio
Cost-function variables		
Constant	13.4022	13.5068*
Ln(Inpatient admissions)	−0.0030	−0.0100
Ln(Outpatient visits)	0.0475	0.4493
Ln(Postadmission days)	0.0471	0.1811
Ln(Price of capital)	−1.8139	−6.4435*
Ln(Price of capital-squared)	0.3363	6.8360*
Ln(Inpatient admissions-squared)	−0.2778	−6.8618*
Ln(Outpatient visits-squared)	−0.0191	−2.4267**
Ln(Postadmission days-squared)	−0.1880	−6.1324*
Ln(Inpatient admissions * Outpatient visits)	0.0247	0.8040
Ln(Inpatient admissions * Postadmission days)	0.5556	8.8636*
Ln(Outpatient visits * Postadmission days)	−0.0051	−0.2049
Ln(Price of capital * Inpatient admissions)	−0.0123	−0.2795
Ln(Price of capital * Outpatient visits)	0.0496	3.3100*
Ln(Price of capital * Postadmission days)	−0.0521	−1.4061
Medicare Case-Mix Index	0.4718	30.1367*
Member of the Council of Teaching Hospitals	0.1134	12.1166*
Other teaching hospital	0.0206	3.8585*
Acute care beds as a percentage of total beds in hospital	0.0008	3.2702*
Births as a percentage of total admissions in hospital	0.0001	0.1697
Emergency department visits as a percentage of total outpatient visits in hospital	0.0008	3.7643*
Outpatient surgical operations as a percentage of total outpatient visits in hospital	0.0116	13.9808*
Reservation quality	0.0068	10.1703*
Trend	−0.0083	−2.6043*

Note. The regression model also included control variables for comorbidities, risk-adjusted mortality rates, and risk-adjusted patient safety event rates.
*p < .01. **p < .05.

This difference between the two groups was highly significant (p < .001). Compared with the unregulated hospitals, hospitals in CON states had a higher occupancy rate (67.73% vs. 65.49%) and a lower average adjusted (for case-mix and outpatient activity) cost per admission ($9,037 vs. $9,849) and lower operating margin (−0.0159 vs. −0.0064). There was not a significant difference in labor productivity (t = 0.887).

The inefficiency-effects results also indicate that for-profit hospitals are the most cost-efficient ownership category while public hospitals are the least. Hospitals with a greater proportion of admissions covered by Medicare or by Medicaid tend to be more cost-efficient. Hospitals that were members of multihospital systems tended to be

Table 4. Parameter Estimates for the SFA Inefficiency-Effects Variables.

Inefficiency-effects variables	Coefficient	*t* Ratio
MU	–0.6465	–8.9848*
State has Certificate of Need requirement	–0.6456	–9.8262*
Investor-owned hospital	–0.8141	–12.3268*
Government, nonfederal hospital	0.3265	11.6366*
Medicare admissions as a percentage of total admissions in hospital	–0.0135	–9.9898*
Medicaid admissions as a percentage of total admissions in hospital	–0.0098	–8.1961*
Member of multihospital health care system	–0.3337	–10.7889*
Herfindahl–Hirschman Index	–0.0717	–1.8311**
HMO penetration rate in county	0.0064	7.4267*
Trend	0.1198	9.8333*
Sigma-squared	0.1824	23.2196*
Gamma	0.8603	120.2799*

*$p < .01$. **$p < .10$.

more cost-efficient than their free-standing counterparts. Hospitals located in areas with more HMO penetration tended to be less cost-efficient.[7] Finally, the coefficient of the HHI was negative but only weakly significant ($p < .10$). The negative sign is consistent with service-based competition.

Discussion

This study has a number of potential limitations. First, it relies on SFA, an approach that has drawbacks. Some concerns about SFA that have been raised in the past include that it relies on strong assumptions about the nature of the cost function and the assumed distribution of the composed error term and that the heterogeneity of hospital output could skew results (Newhouse, 1994). As noted above, subsequent empirical work and greater access to hospital data and advances in measurement have alleviated some of these concerns. Second, the analysis was restricted to hospitals in 37 states that participated in HCUP during the entire study period. The results, while from a diverse group of states, are not necessarily generalizable to non-HCUP states. However, the mean values of variables reflecting size, ownership and system membership of hospitals in the study states are very similar to those of all 50 states.

Contrary to the conventional wisdom that CON regulations have either been ineffective or counterproductive, we found that hospitals in states with CON regulations for acute care beds were more cost-efficient than hospitals located in other states. Our analyses suggest the differences could be driven by variations in capital efficiency. Mean total capital expenses per bed were significantly ($p < .01$) less in the hospitals in the CON states ($55,058) than in other states ($57,972). Also, the mean occupancy rate (see Table 5) was 2.24% higher in hospitals that operated under a CON regime

Table 5. Variable Names and Descriptive Statistics for Performance Variables.

	CON states		Non-CON states	
Performance variables[a]	Mean	*SD*	Mean	*SD*
Cost-inefficiency	0.0810	0.0371	0.1246	0.1050
Capital expenditures per bed	$55,057.97	26,522.89	$57,971.52	29,190.74
Cost per CMI-adjusted admission	$9,036.78	3,089.27	$9,848.51	4,020.18
Labor productivity	0.6733	0.1990	0.6690	0.2251
Occupancy rate	0.6773	0.1384	0.6549	0.1331
Operating margin	−0.0159	0.1207	−0.0064	0.1590

a. All performance variables (except labor productivity) have mean differences between CON and non-CON states that are significantly different at $p < .01$.

than in those located in other states. Combined with results from other studies that have found that physician-owned specialty hospitals have grown less in states that have CON laws than in states that do not restrict capital formation, our findings suggest that CON could potentially temper the new medical arms race and promote efficiency in hospitals (Carey, Burgess, & Young, 2008).

We also found that labor productivity was similar in the states with or without CON regulations and that hospitals located in CON states had lower profitability as measured by the operating margin. Both results inform the debate on the efficacy of CON regulation. The labor productivity result suggests that, contrary to some concerns about unintended consequences of CON regulation, labor is not being substituted for the more highly regulated capital inputs. Also, concerns about CON being used to dampen competition are mitigated by both the profitability result and the cost-efficiency result.

The efficacy of CON programs has been under considerable debate for a lengthy period of time. Some have argued that it was conceptually better fitted for the environments of the 1960s and 1970s when a medical arms race was fueled by cost-based reimbursement. However, the emergence of a new medical arms race during the new millennium (and the possibility that the ACA will add more fuel to the inflationary fire) may call for rethinking the future of CON programs (Berenson et al., 2006; Devers et al., 2003). While many new hospitals (i.e., a net gain [new hospitals minus closed hospitals] of 59 hospitals) have been built in the last 5 years (Medicare Payment Advisory Commission, 2013), it is not completely clear that CON is needed to dampen service-line competition. For example, the provisions of the ACA of 2010 prohibited expansion of existing physician-owned hospitals and banned any new physician-owned hospitals not built and Medicare-certified by December 31, 2010. Another option to deal with the new medical arms race is to adjust prices so that the incentive to expand formerly high-profit service lines is reduced. Baker (2008) points out that private health plans have taken advantage of excess capacity in certain services lines to reduce prices in their markets. However, government administered-pricing schemes such as those used by Medicare[8] have lacked the flexibility to do this.

In conclusion, our results have found a plausible association between CON regulation and greater hospital cost-efficiency. We believe that our research informs the often contentious debate over the efficacy of CON laws. After a period of aggregate contraction the pace of hospital construction has seen recent increases (Baker, 2008; Bazzoli et al., 2006). And increased capacity may be associated with increased expenditures and reduced quality (via the volume–outcomes relationship). However, findings to the obverse are also available. CON regulation has a complex impact on costs, prices, access, and quality in a variety of settings that extend beyond acute hospital care, which is the focus of this study. We recommend that a meta-analysis on the impact of CON regulation on cost, pricing behavior, access, innovation, and quality be conducted to determine the efficacy of CON laws in a new environment that features service-based competition, accountable care organizations and high-deductible health plans. It is possible that while CON regulation might facilitate the efficient production of hospital care, other policy mechanisms are superior when a broader context is considered.

Authors' Note

This research was done while Ryan L. Mutter was at Agency for Healthcare Research and Quality, Center for Delivery, Organization and Markets. This article does not represent the policy of either the Agency for Healthcare Research and Quality (AHRQ) or the U.S. Department of Health and Human Services (DHHS). The views expressed herein are those of the authors and no official endorsement by AHRQ or DHHS is intended or should be inferred.

Acknowledgments

We gratefully acknowledge the data organizations in participating states that contributed data to HCUP and that we used in this study: Arizona Department of Health Services, Arkansas Department of Health, California Office of Statewide Health Planning & Development, Colorado Hospital Association, Connecticut Hospital Association, Florida Agency for Health Care Administration, Georgia Hospital Association, Hawaii Health Information Corporation, Illinois Department of Public Health, Indiana Hospital Association, Iowa Hospital Association, Kansas Hospital Association, Kentucky Cabinet for Health and Family Services, Maryland Health Services Cost Review Commission, Massachusetts Center for Health Information and Analysis, Michigan Health & Hospital Association, Minnesota Hospital Association, Missouri Hospital Industry Data Institute, Nebraska Hospital Association, New Hampshire Department of Health & Human Services, New Jersey Department of Health, New York State Department of Health, Nevada Department of Health and Human Services, North Carolina Department of Health and Human Services, Ohio Hospital Association, Oklahoma State Department of Health, Oregon Association of Hospitals and Health Systems, Rhode Island Department of Health, South Carolina Budget & Control Board, South Dakota Association of Healthcare Organizations, Tennessee Hospital Association, Texas Department of State Health Services, Utah Department of Health, Vermont Association of Hospitals and Health Systems, Washington State Department of Health, West Virginia Health Care Authority, and Wisconsin Department of Health Services.

We thank Andrew Karasick, research assistant in the Graduate Program of Health Care Management at Widener University, for his assistance in the preparation of the article.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

Notes

1. A production orientation, which would measure technical inefficiency, is difficult to use for multiproduct organizations like hospitals. It would require a composite output measure that would be difficult if not impossible to validly construct. On the other hand, cost-inefficiency SFA models can include multiple outputs and/or multiple product descriptors as independent variables.
2. The 37 states are Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, New Hampshire, New Jersey, New York, Nevada, North Carolina, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Washington, West Virginia, and Wisconsin.
3. The SID contains the universe of the inpatient discharge abstracts in participating states, translated into a uniform format to facilitate multistate comparisons and analyses. See https://www.hcup-us.ahrq.gov/sidoverview.jsp for more information.
4. HCUP is a family of health care databases and related software tools and products developed through a federal–state–industry partnership and sponsored by the Agency for Healthcare Research and Quality. See http://www.hcup-us.ahrq.gov/ for more information.
5. According to the American Health Planning Association (2013), during the study period 27 states enforced CON regulations for acute care hospital beds. The states that require a CON for acute care hospitals are the following: Alabama, Alaska, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Iowa, Kentucky, Maine, Maryland, Michigan, Mississippi, Missouri, Nevada, New Hampshire, New Jersey, New York, North Carolina, Rhode Island, South Carolina, Tennessee, Vermont, Virginia, Washington, and West Virginia.
6. The Comorbidity Software assigns variables that identify comorbidities in hospital discharge records using the diagnosis coding of International Classification of Diseases, Ninth Edition, Clinical Modifications (ICD-9-CM). The comorbidities are described in Elixhauser et al. (1998). The software is available for free download at http://www.hcup-us.ahrq.gov/toolssoftware/comorbidity/comorbidity.jsp.
7. This result was counterintuitive. We considered the possibility that the demand for HMOs might be greater areas where hospitals are more cost-inefficient. This would constitute an endogenous relationship. Methods for detecting and dealing with endogeneity are not as well developed in SFA as they are in linear regression methods (Mutter, Greene, Spector, Rosko, & Mukamel, 2013). However, as a crude test (Note: the Hausman test is not appropriate for SFA) we substituted an instrumental variable for HMO penetration based on Rosko (2001). The results did not change when this variable was included in the model.
8. Medicare has refined its DRG system to address cream-skimming by specialty hospitals (Medicare Payment Advisory Commission, 2005). However, its impact has not been definitively determined.

References

Aigner, D., Lovell, K., & Schmidt, P. (1977). Formulation and estimation of stochastic frontier: production models. *Journal of Econometrics*, *6*, 21-37.

American Health Planning Association. (2013). *Certificate of need coverage summary by state, 2010*. Retrieved from http://www.ahpanet.org/matrix_copn.html

Baker, L. (2008). *The challenges of health system capacity growth* (NIHCM Research Brief). Washington, DC: National Institute for Health Care Management.

Bates, L., Mukherjee, K., & Santerre, R. (2006). Market structure and technical efficiency in the hospital services industry: A DEA approach. *Medical Care Research and Review*, *63*, 499-524.

Battese, G., & Coelli, T. (1995). A model for technical inefficiency effects in a stochastic frontier production function for panel data. *Empirical Economics*, *20*, 325-332.

Battese, G., Heshmati, A., & Hjalmarsson, L. (2000). Efficiency of labour use in the Swedish banking industry: A stochastic frontier approach. *Empirical Economics*, *25*, 623-640.

Bazzoli, G., Gerland, A., & May, J. (2006). Construction activity in U.S. hospitals. *Health Affairs*, *25*, 783-791.

Berenson, R., Bodenheimer, T., & Pham, H. (2006). Specialty-service lines: Salvos in the new medical arms race. *Health Affairs*, *25*, 337-343.

Carey, K., Burgess, J., & Young, G. (2008). Specialty and full-service hospitals: A comparative cost analysis. *Health Services Research*, *43*, 1869-1887.

Coelli, T. (1996). *A guide to FRONTIER Version 4.1: a computer program for production and cost function estimation* (CEPA Working Paper No. 96/07). Armidale, New South Wales, Australia: University of New England.

Coelli, T., Rao, D., O'Donnell, C., & Battese, G. (2005). *An introduction to efficiency and productivity analysis* (2nd ed.). New York, NY: Springer.

Cuckler, G., Sisko, A., Keehan, S., Smith, S., Madison, A., Poisal, J., Wolfe, C., Lizonitz, J., & Stone, D. (2013). National Health Expenditure Projections, 2012-22: Slow growth until coverage expands and economy improves. *Health Affairs*, *32*, 1820-1831.

Debreu, G. (1951). The coefficient of resource utilization. *Econometrica*, *19*, 273-292.

Devers, K. J., Brewster, L. R., & Casalino, L. P. (2003). Changes in hospital competitive strategy: A new medical arms race? *Health Services Research*, *38*, 447-469.

Eakin, K. (1991). Allocative inefficiency in the production of hospital services. *Southern Economic Journal*, *58*, 240-248.

Elixhauser, A., Steiner, C., Harris, R., & Coffey, R. (1998). Comorbidity measures for use with administrative data. *Medical Care*, *36*, 8-27.

Federal Trade Commission and Department of Justice. (2004). *Improving health care: A dose of competition*. Retrieved from http://www.justice.gov/atr/public/health_care/204694.pdf

Ferrier, G., Leleu, H., & Valdmanis, V. (2010). The impact of CON regulation on hospital efficiency. *Health Care Management Science*, *13*, 84-100.

Folland, S., & Hofler, R. (2001). How reliable are hospital efficiency estimates? Exploiting the dual to homothetic production. *Health Economics*, *10*, 683-698.

Grannemann, T., Brown, R., & Pauly, M. (1986). Estimating hospital costs: A multiple-output analysis. *Journal of Health Economics*, *5*, 107-127.

Greene, W. (2004). Distinguishing between heterogeneity and inefficiency: Stochastic frontier analysis of the world health organization's panel data on national health care systems. *Health Economics*, *13*, 959-980.

Greene, W. (2011). *Econometric analysis* (7th ed.). Upper Saddle River, NJ: Prentice Hall.

Hellinger, F. (2009). The effect of certificate-of-need laws on hospital beds and healthcare expenditures: An empirical analysis. *American Journal of Managed Care*, *15*, 737-744.

Hjalmarsson, L., Kumbhakar, S., & Heshmati, A. (1996). DEA, DFA, and SFA: A comparison. *Journal of Productivity Analysis*, *7*, 303-328.

Ho, V., & Ku-Goto, M. (2013). State deregulation and Medicare costs for acute cardiac care. *Medical Care Research and Review*, *70*, 185-205.

Houchens, R., Elixhauser, A., & Romano, P. (2008). How often are potential "patient safety events" present on admission? *Joint Commission Journal on Quality*, *34*, 154-163.

Joskow, P. (1980). The effects of competition and regulation on hospital bed supply and the reservation quality of the hospital. *Bell Journal of Economics*, *11*, 421-447.

Kumbhakar, S., & Lovell, C. A. K. (2000). *Stochastic frontier analysis*. Cambridge, England: Cambridge University Press.

Leibenstein, H. (1987). *Inside the firm: The inefficiencies of hierarchy*. Cambridge, MA: Harvard University Press.

Lovell, C. K. (1993). Production frontiers and productive efficiency. In H. Fried, C. K. Lovell, & S. S. Schmidt (Eds.), *The measurement of productive efficiency* (pp. 3-67). New York, NY: Oxford University Press.

Luft, H., Robinson, J., Garnick, D., Maerki, S., & McPhee, S. (1986). The role of specialized clinical services in competition among hospitals. *Inquiry*, *23*, 83-94.

Medicare Payment Advisory Commission. (2005, March). *Physician-owned specialty hospitals: Report to the Congress*. Washington, DC: Author.

Medicare Payment Advisory Commission. (2013). *A data book: Health Care Spending and the Medicare Program*. Retrieved from http://www.medpac.gov/documents/Jun12DataBookEntireReport.pdf

Mechanic, R., Altman, S., & McDonough, J. (2012). The new era of payment reform, spending targets, and cost containment in Massachusetts: Early lessons for the nation. *Health Affairs*, *31*, 2334-2342.

Meeusen, W., & van den Broeck, J. (1977). Efficiency estimation from Cobb-Douglas production functions with composed error. *International Economic Review*, *18*, 435-444.

Mutter, R., Greene, W., Spector, W., Rosko, M., & Mukamel, D. (2013). Investigating the impact of endogeneity on inefficiency estimates in the application of stochastic frontier analysis to nursing homes. *Journal of Productivity Analysis*, *39*, 101-110.

Mutter, R., Rosko, M., & Wong, H. (2008). Measuring hospital inefficiency: The effects of controlling for quality and patient burden of illness. *Health Services Research*, *43*, 1992-2013.

Mutter, R., Wong, H., & Goldfarb, M. (2008). The effects of hospital competition on inpatient quality of care. *Inquiry*, *45*, 263-279.

Newhouse, J. (1994). Frontier estimation: How useful a tool for health economics? *Journal of Health Economics*, *13*, 317-322.

Noether, M. (1988). Competition among hospital. *Journal of Health Economics*, *7*, 259-284.

Phelps, C. (2010). *Health economics* (4th ed.). New York, NY: Addison-Wesley.

Rivers, P., Fottler, M., & Younis, M. (2007). Does certificate of need really contain hospital costs in the United States? *Health Education Journal*, *66*, 229-244.

Rosko, M. (2001). Cost efficiency of U.S. hospitals: A stochastic frontier approach. *Health Economics*, *10*, 539-551.

Rosko, M., & Broyles, R. (1988). *The economics of health care: A reference handbook*. Westport, CT: Greenwood Press.

Rosko, M., & Mutter, R. (2008). Stochastic frontier analysis of hospital inefficiency: A review of empirical issues and an assessment of robustness. *Medical Care Research and Review*, *65*, 131-166.

Rosko, M., & Mutter, R. (2010). What have we learned from the application of stochastic frontier analysis to U.S. hospitals? *Medical Care Research and Review*, *68*, 75S-100S.

Santerre, R., & Neun, S. (2007). *Health economics: Theories, insights and industry studies* (4th ed.). Mason OH: Thomson-South-Western.

Stevenson, R. (1980). Likelihood functions for generalized stochastic frontier estimation. *Journal of Economics*, *13*, 57-66.

Thompson, M., Huerta, T., & Ford, E. (2012). Mandatory insurance coverage and hospital productivity in Massachusetts: Bending the curve? *Health Care Management Review*, *37*, 294-300.

Zuckerman, S., Hadley, J., & Iezzoni, L. (1994). Measuring hospital efficiency with frontier cost functions. *Journal of Health Economics*, *13*, 255-280.

The Effect of Certificate-of-Need Laws on Hospital Beds and Healthcare Expenditures: An Empirical Analysis

Fred J. Hellinger, PhD

Objective: To estimate the effect of certificate-of-need legislation on hospital bed supply and healthcare expenditures.

Study Design: This study uses state data on several variables, including healthcare expenditures, hospital bed supply, and the existence of a certificate-of-need program, from 4 periods (1985, 1990, 1995, and 2000).

Methods: We estimate 2 multivariate regression equations. In the first equation, hospital bed supply is the dependent variable, and certificate of need is included as an independent variable. In the second equation, healthcare expenditures is the dependent variable, and hospital bed supply and certificate of need are included as independent variables.

Results: Certificate-of-need laws have reduced the number of hospital beds by about 10% and have reduced healthcare expenditures by almost 2%. Certificate-of-need programs did not have a direct effect on healthcare expenditures.

Conclusion: Certificate-of-need programs have limited the growth in the supply of hospital beds, and this has led to a slight reduction in the growth of healthcare expenditures.

(Am J Manag Care. 2009;15(10):737-744)

For author information and disclosures, see end of text.

Certificate-of-need programs attempt to curtail the construction of unnecessary healthcare facilities and to limit the acquisition of costly equipment that provides little benefit by compelling hospitals and other healthcare entities to acquire prior approval from a governmental entity.[1-3] Indeed, efforts to control the growth of healthcare facilities and acquisition of expensive equipment have been ongoing for more than 60 years.[4]

The 1946 federal Hill-Burton program provided funds for new hospital construction contingent on the adoption of a state health plan that detailed the process by which proposed projects would be evaluated.[5,6] The Hill-Burton program encouraged local planning to facilitate the recognition and classification of local needs.

State and local Comprehensive Health Planning agencies (so-called A and B agencies) were created by the 1966 amendments to the Public Health Service Act. These agencies were obligated to produce a state plan for healthcare facilities growth, but they were given no statutory power to implement their judgments and were incapable of mandating the submittal of capital budgets. Consequently, their effectiveness was limited. Nevertheless, many Blue Cross plans refused to reimburse for the interest and depreciation expenses associated with unapproved capital projects.

The Medicare program was enacted in 1966 and adopted a cost-based reimbursement method for short-term hospital services. Following the enactment of Medicare, large increases in hospital and healthcare costs created an intense interest among third-party payers, lawmakers, and the public in the size and expense of short-term hospitals.[7]

In 1967, New York became the first state to enact a certificate-of-need program. Shortly thereafter, Rhode Island, Maryland, and California passed certificate-of-need legislation.[8]

Section 1122 of the 1972 amendments to the Public Health Service Act incorporated controls on capital expansion by healthcare facilities through the withholding of Medicare and Medicaid funds for the interest and depreciation expenses associated with unapproved projects. States were allowed to designate either their state health planning agency or Hill-Burton agency to determine the need for new capital expenditures.

In this article
Take-Away Points / p738
www.ajmc.com
Full text and PDF

The National Health Planning and Resources Development Act of 1974 required states to enact certificate-of-

Take-Away Points

This study uses statewide data from 4 periods (1985, 1990, 1995, and 2000) to estimate the effect of state certificate-of-need laws on the supply of short-term hospital beds and on healthcare expenditures. The study found the following:

- State certificate-of-need laws reduce the supply of hospital beds.
- Certificate-of-need laws reduce aggregate healthcare spending in the state.
- "Strict" certificate-of-need laws have a much greater effect on hospital bed supply and costs.

need laws to receive funds through the Public Health Service Act.[9] Only Louisiana failed to implement a certificate-of-need law, but Louisiana operated a section 1122 program during this period and in 1991 passed a certificate-of-need law. In 1986, Congress repealed the federal mandate to implement certificate of need to receive funds under the Public Health Service Act.

The sanctions included in the National Health Planning and Resources Development Act of 1974 were never imposed, although 3 states (Utah, Idaho, and New Mexico) repealed their certificate-of-need law in the early 1980s before the federal mandate was rescinded (Table 1).[8,10] Eight more states (Arizona, Minnesota, Kansas, Texas, California, South Dakota, Wyoming, and Colorado) dismantled their certificate-of-need program during the late 1980s, and 2 states (North Dakota and Pennsylvania) dismantled their program in the mid-1990s.

Several studies[11-14] of the effect of certificate-of-need laws found that they had little effect on the supply of hospital beds or on the cost of care. However, Salkever and Bice[3,15] found that certificate-of-need laws reduced the number of hospital beds but did not decrease a hospital's investment in other plant assets, and Cromwell[16] found that certificate-of-need laws reduced the number of hospital beds but did not affect other measures of hospital investment. These studies are based on data from before 1986, when the federal mandate to operate certificate-of-need programs was overturned.

In contrast, the present study uses data from 1985, 1990, 1995, and 2000 to examine the effect of certificate-of-need legislation. It will be relevant to ascertain whether these findings change when more recent data become available. Indeed, there is concern that many state certificate-of-need programs have become too lenient, suggesting that the effect of state certificate-of-need laws on hospital bed supply has lessened in recent years.[17,18]

METHODS

Data

Because all but 1 state (Louisiana) operated some form of certificate-of-need process until the early 1980s, it is difficult to isolate and estimate the effect of this legislation using data from before 1986 unless data from before 1974 are used, as this is when certificate-of-need legislation was mandated for all states. It is possible to estimate the effect of certificate-of-need laws using data after 1983 because 11 states repealed their certificate-of-need laws after 1983 and before 1990 (Table 1). In addition, 2 states (Indiana and Wisconsin) repealed and reinstated their certificate-of-need laws in the early 1990s, and 2 states (Pennsylvania and North Dakota) repealed their programs after 1990. Meanwhile, Louisiana implemented its first certificate-of-need program in 1991.

Another 9 states repealed the sections of their certificate-of-need laws covering short-term hospitals, while maintaining controls on other types of facilities, and 7 of these states did so in the 1980s. Consequently, statewide data from the 1980s and 1990s provide a contrast between states that operated certificate-of-need programs and those that did not operate a certificate-of-need program, as well as between states with a certificate-of-need program that covered hospitals and states without such a program. Moreover, because most states that repealed their certificate-of-need laws did so in the 1980s, data from the 1990s provide a contrast between states that had no certificate-of-need law for several years and states with a certificate-of-need program that had been in place for more than a decade.

An array of independent variables are included in our model to explain the supply of short-term hospital beds per 100,000 civilian residents and the level of healthcare expenditures per capita. Three of these relate to certificate-of-need legislation: (1) a dichotomous variable indicating whether a state had a certificate-of-need law in a given year, (2) a dichotomous variable indicating whether a state had a certificate-of-need law that covered short-term acute care hospitals in a given year, and (3) a dichotomous variable indicating whether a state had a stringent certificate-of-need process as designated by the American Health Planning Association.[10]

The supply of physicians is included in our model as an independent variable. It is assumed that states with more physicians will have more short-term hospital beds and higher healthcare expenditures, and physician availability is measured by the number of active nonfederal physicians practicing in each state per 100,000 civilian residents. The mean personal per capita income also is included as an independent variable in our model. States with higher personal incomes are assumed to have a greater demand for healthcare services and higher healthcare expenditures, and for this reason we

Table 1. State Certificate-of-Need Status (1967 to Present)[a]

State	Certificate-of-Need Law That Covered Short-Term Acute Care Hospitals	Any Certificate- of-Need Law	Stringent Certificate-of-Need Process
Alabama	1977-present	1977-present	—
Arizona	1971-1985	1971-1985	—
Arkansas	1975-1989	1975-present	—
California	1969-1987	1969-1987	—
Colorado	1983-1987	1973-1987	—
Connecticut	1973-present	1973-present	1973-present
Delaware	1978-present	1978-present	—
Florida	1973-present	1973-present	—
Georgia	1979-present	1979-present	1979-present
Idaho	1980-1983	1980-1983	—
Illinois	1974-present	1974-present	—
Indiana	1980-1985	1980-1995, 1997-1999	—
Iowa	1977-1996	1977-present	—
Kansas	1972-1985	1972-1985	—
Kentucky	1972-present	1972-present	—
Louisiana	—	1991-present	—
Maine	1978-present	1978-present	1978-present
Maryland	1968-present	1968-present	—
Massachusetts	1972-1988	1972-present	—
Michigan	1972-present	1972-present	—
Minnesota	1971-1985	1971-1985	—
Mississippi	1979-present	1979-present	—
Missouri	1979-present	1979-present	1979-present
Montana	1975-1989	1975-present	—
Nebraska	1996-present	1979-present	—
Nevada	1971-present	1971-present	—
New Hampshire	1979-present	1979-present	—
New Jersey	1971-present	1971-present	1971-present
New Mexico	1978-1983	1978-1983	—
New York	1967-present	1967-present	1967-present
North Carolina	1978-present	1978-present	—
North Dakota	1971-1995	1971-1995	—
Ohio	1975-1988	1975-present	—
Oklahoma	1971-1989	1971-present	—
Oregon	1971-1985	1971-present	—
Pennsylvania	1979-1995	1979-1995	—
Rhode Island	1968-present	1968-present	—
South Carolina	1971-present	1971-present	1971-present
South Dakota	1972-1988	1972-1988	—
Tennessee	1973-present	1973-present	—
Texas	1975-1985	1975-1985	—
Utah	1979-1984	1979-1984	—
Vermont	1979-present	1979-present	1979-present
Virginia	1973-present	1973-present	—
Washington	1971-present	1971-present	—
West Virginia	1977-present	1977-present	1977-present
Wisconsin	1977-1987	1977-1987, 1993-present	—
Wyoming	1977-1989	1977-1989	—

[a]From the 2005 and 1999 *National Directory of Health Planning, Policy, and Regulatory Agencies*[5,6], and from Thomas R. Piper, American Health Planning Association information coordinator and Missouri certificate-of-need director, and Jane Fussell, Oregon Health Division certificate-of-need coordinator.

include personal income as an independent variable in our model.

Similarly, it is assumed that states with higher unemployment rates are likely to have decreased demand for health services, fewer hospital beds, and lower healthcare expenditures. For this reason, we include a state's unemployment rate in our model.

Because it is likely that population density is a proxy for omitted measures of price, we expect to find an inverse relationship between population density and hospital bed supply. It is also possible that there are fewer hospital beds in sparsely populated areas because of the longer distances involved for patients seeking physician care or hospital care, and it is likely that citizens in less densely populated states are more likely to receive healthcare in states that are more densely populated. For these reasons, we include a variable that measures the number of citizens (measured in thousands) per square mile for each state.

A recent publication states: "In general, individuals with lower income, less education, and lower-status occupations and employment have poorer health. Therefore, it would seem that raising educational levels would reduce health-related expenditures for the public sector, as well as for individuals."[19(p1)] We include the proportion of the state's population who graduated from high school, the proportion of residents without health insurance, and the proportion of residents enrolled in a health maintenance organization. We anticipate that each of these variables is inversely related to healthcare expenditures per capita.

We also include a variable measuring the political climate in a state because the political climate may affect the likelihood that a state repeals certificate-of-need legislation and the amount spent on healthcare. We chose the proportion of voters in the state who voted for the Democratic candidate for president in the most recent election to measure the political climate in a state. In addition, we include a variable measuring the number of deaths per 1000 residents to adjust for the health and age of the state's population.

A greater proportion of a state's population working on farms is assumed to be negatively related to the demand for health services, and a variable measuring the proportion of a state's domestic product that is attributable to farm income is included in the hospital bed supply and healthcare expenditures equations. Indeed, studies[20,21] provide evidence supporting the hypothesis that farm residents have less access to healthcare services and are less likely to receive healthcare services even after adjusting for insurance coverage and income.

Older citizens have a greater demand for healthcare services than younger citizens because of the increased frequency of illness, and citizens older than 64 years are almost always covered by Medicare. Therefore, it is hypothesized herein that the proportion of the population who are older than 64 years is positively related to the number of hospital beds per capita and to the level of healthcare expenditures per capita.

Data on the population of each state and the number of square miles in each state were obtained from the US Census Bureau (US Department of Commerce).[22] Data on state unemployment rates were obtained from the US Department of Labor's Current Population Survey.[23] Data on the mean state per capita income were obtained from the US Bureau of Economic Analysis (US Department of Commerce) as published in various issues of the *Survey of Current Business*.[24] Data on the proportion of the state's domestic product that is attributable to farm income were obtained from reports issued by the National Agricultural Statistics Service and the Economic Research Service of the US Department of Agriculture.[25] The number of hospital beds in each state was obtained from the American Hospital Association (AHA) in various issues of *AHA Hospital Statistics*.[26] The number of active nonfederal physicians practicing in each state was obtained from various issues of the American Medical Association's *Physician Characteristics and Distribution in the US*.

Analytic Approach

In this study, we hypothesized that the effect of certificate-of-need laws on healthcare expenditures is realized through its effect on the supply of hospital beds. Hence, we included the supply of hospital beds as an independent variable in an equation explaining healthcare expenditures and measured the effect of certificate-of-need laws on healthcare expenditures by multiplying the coefficient of certificate of need in the hospital bed supply equation by the coefficient of hospital bed supply in the healthcare expenditures equation. We also estimated the direct effect of certificate-of-need laws on healthcare expenditures by including certificate of need in the healthcare expenditures equation.

We estimated our equations using several different certificate-of-need variables. The first variable is set equal to 1 if the state had a certificate-of-need law in a given year, the second variable is set equal to 1 if the state had a certificate-of-need law that covers short-term acute care hospitals, and the third variable is set equal to 1 if the state had a stringent certificate-of-need process as determined by the American Health Planning Association. We used data from 4 periods (1985, 1990, 1995, and 2000) to estimate the number of hospital beds per 100,000 civilian residents in a state. After explaining the hospital bed supply, we used data from the same 4 periods to estimate the logarithm of the cost of per capita healthcare expenditures in a state. Because of normality issues, we estimated the cost equations using logarithms.

In this study, we used generalized estimating equations[27] to estimate a model that includes dummy variables for time effects and error terms that are correlated for the same cross-sectional units observed through time. One of the central suppositions of the generalized linear model is the serial independence of the error terms. However, if data from different periods are used, the assumption of serially independent error terms is not credible, and although ordinary least squares estimates in the generalized linear model will produce unbiased estimates, it is likely to result in serious underestimates of the SEs of the estimated coefficients.[28]

One technique of estimating models based on data from repeated observations of the same cross-sectional unit is to use a fixed-effects model.[29] Such a model has a constant slope, with intercepts that vary according to the cross-sectional unit (ie, by state in our study). We did not use a fixed-effects model because we have too many cross-sectional units of observations and too few periods, necessitating too many dummy variables for their specification (ie, including 49 dummy variables would deplete the number of *df* available to perform the necessary statistical tests).

An article by Betrand and colleagues[30] found that serial correlation was a serious problem in studies that used multivariate regression analytic techniques to study causal relationships. They found that serial correlation led to overestimates of the statistical significance of the estimated coefficients and to serious underestimates of the SEs of the estimated coefficients in investigations using ordinary least squares estimates.

Betrand and colleagues[30] found that using empirically estimated variance-covariance matrices to produce estimates of the coefficients and SEs generally eliminated this problem if the data did not possess any cross-sectional heteroscedasticity. We tested our model for cross-sectional heteroscedasticity (White[31] test and Breusch-Pagan[32] test were used) and found no evidence of heteroscedasticity. To account for serial correlation resulting from correlated data observations from the same state, we used generalized estimating equations. As expected, we found that the SEs derived using generalized estimating equations were considerably larger than those derived using ordinary least squares. We also tested our model for autocorrelation and found no evidence of autocorrelation using the Durbin-Watson test.[33]

RESULTS

The means of the variables in our model analyses are given in Table 2. The mean annual healthcare expenditures per capita in a state in our data set totaled $2672 in nominal US dollars, and a mean of 13% of the population in each state were older than 64 years. In the average state, almost 4 of 5 residents older than 25 years had at least a high school education, and slightly more than 15% of the population were enrolled in a health maintenance organization. The mean number of hospital beds (short-term nonfederal) per 100,000 civilian residents in a state in our data set was 384.

The estimated coefficients and their associated SEs are given in Table 3 and Table 4. We did not report the equation for the certificate-of-need variable with the 5-year lag because its coefficient was similar to the coefficient without the lag component. The coefficients of the certificate-of-need variables are statistically significant in each of the equations given in Table 3.

The coefficient of the first certificate-of-need variable (equation 1 in Table 3) indicates that states with any type of certificate-of-need programs average 34 fewer hospital short-term hospital beds per 100,000 civilian residents than states without a certificate-of-need program. Because the mean number of hospital beds per 100,000 civilian residents is 384, this implies that certificate-of-need programs reduce the number of hospital beds per 100,000 civilian residents by almost 10%. Similarly, states with certificate-of-need programs that covered short-term acute care hospitals average 41 fewer beds, or slightly more than 10%, and states with stringent certificate-of-need programs average 76 fewer beds, which represents a 20% reduction.

The dependent variable for the 3 equations in Table 4 is the natural logarithm of state healthcare expenditures per capita. The coefficient in Table 4 for the variable measuring the number of hospital beds per 100,000 civilian residents is 0.00045. The results from equation 4 imply that, if a state reduced the number of hospital beds per 100,000 civilian residents by 1, then the mean per capita healthcare expenditures levels would fall by 0.045% ($e^{0.00045} - 1 = 1.00045 - 1 = 0.00045 = 0.045\%$, where *e* indicates expenditures). This implies that states with certificate-of-need programs that cover short-term hospitals experience healthcare expenditures per capita that are 1.8% (41 × 0.045%) lower than those in states without such a certificate-of-need program. Similarly, this implies that states with stringent certificate-of-need programs experience healthcare expenditures per capita that are 3.4% (76 × 0.045%) lower than those in states without stringent certificate-of-need programs.

The coefficients in equations 5 and 6 in Table 4 indicate that certificate of need does not have a direct effect on healthcare expenditures per capita. Indeed, neither the coefficient for the certificate-of-need variable in equation 5 nor the coefficient for the certificate-of-need variable in equation 6 approaches statistical significance.

Because policy interventions in an empirical statistical analysis are not experimental variables, the omission of

Table 2. State Data From 1985, 1990, 1995, and 2000

Explanatory Variable	Mean (N = 196)
Annual healthcare expenditures per capita, $	2672
No. of physicians per 100,000 civilian residents	208
Population >64 y, %	13.08
Deaths per 1000 residents	8.64
Hospital beds per 100,000 civilian residents	384
Population unemployed, %	5.71
Population per square mile of land area	695
Personal income per capita, $	14,766
Farm income as % of state domestic product	2.73
Population without health insurance coverage, %	16.04
Population enrolled in a health maintenance organization, %	15.62
Population that graduated from high school, %	79.45

variables that are related to both the adoption of the policy intervention and the dependent variable is potentially a serious problem.[29] Consequently, we estimated the equations using a 2-stage least squares method, and the coefficients of the relevant variables did not change appreciably.

DISCUSSION

In 1974, Congress mandated that states adopt certificate-of-need laws and required states to establish comprehensive health plans. This mandate was repealed effective January 1, 1987. Today, 36 states operate certificate-of-need programs, and there is still considerable debate about the effect of this legislation on the availability, access, and cost of healthcare. Moreover, bills are introduced each year in a dozen or more state legislatures to expand, modify, and eliminate state certificate-of-need laws.[7]

Proponents of certificate-of-need laws emphasize that a primary cause of rising healthcare costs is the proliferation of healthcare facilities and the diffusion of expensive medical equipment. They maintain that certificate-of-need

Table 3. State Data From 1985, 1990, 1995, and 2000 on the Effect of Certificate-of-Need Laws on Hospital Bed Supply[a]

	Generalized Estimating Equation Coefficient (SE) (N = 196)		
Explanatory Variable	Equation 1 Any Certificate-of-Need Law	Equation 2 Certificate-of-Need Law That Covered Short-Term Acute Care Hospitals	Equation 3 Stringent Certificate-of-Need Process
Population >64 y, %	5.63 (4.49)	6.01 (4.26)	6.37 (4.18)
Deaths per 1000 residents	16.03 (6.27)[b]	14.40 (5.91)[b]	15.12 (5.81)[b]
Democratic votes, %	0.45 (1.19)	0.42 (1.22)	–0.17 (1.09)
Unemployment rate, % of civilian noninstitutionalized population	0.74 (4.15)	0.39 (3.92)	1.64 (3.86)
Population density in 1000s of residents per square mile	–0.001 (0.005)	–0.001 (0.004)	–0.003 (0.004)
Personal income per capita, $1000s	0.0009 (0.0020)	0.0003 (0.0020)	–0.002 (0.001)
Farm income as % of state domestic product	13.54 (2.09)[b]	11.19 (1.97)[b]	12.88 (1.93)[b]
Population without health insurance coverage, %	–5.35 (1.47)[b]	–6.78 (1.41)[b]	–5.65 (1.37)[b]
No. of physicians per 100,000 civilian residents	0.15 (0.16)	0.13 (0.15)	0.28 (0.14)[b]
Population enrolled in a health maintenance organization, %	–3.63 (0.73)[b]	–3.66 (0.68)[b]	–4.15 (0.69)[b]
Population that graduated from high school, %	–4.78 (1.35)[b]	–5.22 (1.32)[b]	–4.24 (1.28)[b]
Any certificate-of-need law, 1 = yes, 0 = no	**–34.26 (12.19)**[b]	—	—
Certificate-of-need law that covered short-term acute care hospitals, 1 = yes, 0 = no	—	**–40.88 (11.82)**[b]	—
Stringent certificate-of-need law, 1 = yes, 0 = no	—	—	**–76.34 (17.25)**[b]
Total R^2 from ordinary least squares model	0.77	0.74	0.78

[a]Data for intercept and time variables are excluded.
[b]Statistically different from 0 at 95% level of significance.
Bolding represents coefficients for certificate-of-need variables.

Table 4. State Data From 1985, 1990, 1995, and 2000 on the Effect of Hospital Bed Supply on the Logarithm of Healthcare Expenditures[a]

	Generalized Estimating Equation Coefficient (SE) (N = 196)		
Explanatory Variable	**Equation 4**	**Equation 5**	**Equation 6**
Population >64 y, %	0.017 (0.005)[b]	0.017 (0.006)[b]	0.020 (0.007)[b]
Deaths per 1000 residents	–0.003 (0.007)	–0.004 (0.016)	–0.003 (0.015)
Democratic votes, %	0.003 (0.001)[b]	0.002 (0.002)	0.002 (0.002)
Unemployment rate, % of civilian noninstitutionalized population	–0.002 (0.004)	–0.003 (0.005)	–0.003 (0.006)
Population density in 1000s of residents per square mile	0.000006 (0.000006)	0.000005 (0.000006)	0.000004 (0.000007)
Personal income per capita, $1000s	0.000009 (0.000002)[b]	0.000008 (0.000002)[b]	0.000007 (0.000002)[b]
Farm income as % of state domestic product	–0.003 (0.004)	–0.002 (0.003)	–0.002 (0.004)
Population without health insurance coverage, %	0.00010 (0.00003)[b]	0.00020 (0.00002)[b]	0.00010 (0.00002)[b]
No. of physicians per 100,000 civilian residents	0.00100 (0.00017)[b]	0.00110 (0.00020)[b]	0.00120 (0.00032)[b]
Population enrolled in a health maintenance organization, %	–0.0022 (0.0008)[b]	–0.0023 (0.0009)[b]	–0.0018 (0.0008)[b]
Population that graduated from high school, %	–0.0022 (0.0016)	–0.0023 (0.0024)	–0.0041 (0.0024)
Hospital beds per 100,000 civilian residents	0.00045 (0.00008)[b]	0.00044 (0.00006)[b]	—
Any certificate-of-need law, 1 = yes, 0 = no	—	0.007 (0.015)	–0.006 (0.016)
Total R^2 from ordinary least squares model	0.94	0.95	0.92

[a]Data for intercept and time variables are excluded
[b]Statistically different from 0 at 95% level of significance

programs impose much-needed economic discipline on the healthcare industry and, because the fixed cost of an empty hospital bed is estimated to be about two-thirds the cost of an occupied bed, that hospitals have an incentive to admit more patients when new hospital beds are brought online.

Opponents of certificate-of-need laws often argue that these laws stifle competition and, because of the political power of large healthcare providers, that certificate-of-need agencies are often coerced into approving unworthy projects. They also contend that certificate-of-need agencies have few incentives to limit their approval of questionable applications because they do not benefit directly from limiting costs and they are not at risk for cost increases. Indeed, much of the cost of providing new services in an area will be borne by taxpayers in other states because Medicare and Medicaid are major payers. Therefore, supporters of new projects may argue that the citizens of the region will reap all of the benefits of a new facility or service, while bearing little of the cost.

CONCLUSIONS

Between 1985 and 2000, there were numerous changes in our healthcare system that affected the number of hospital beds in a state, and we included variables in our model of hospital bed supply (eg, age, unemployment rate, income per capita, health insurance, physician availability, percentage graduated from high school, health maintenance organization penetration) that may be expected to influence hospital bed supply. Nevertheless, it is impossible to rule out factors such as the growth of highly integrated health systems in specific states that may have led to a reduction in hospital bed supply relative to states without such developments. Yet, our inclusion of the proportion of persons enrolled in a health maintenance organization to some extent reflects changes in the growth of managed care across states and its effect on hospital bed supply.

Certificate-of-need programs vary across states in their coverage, application procedures, and stringency of review. Measurement error in a predictor variable in a regression model does not affect the regression coefficient. Nonetheless, it augments the SE of the coefficient, diminishing accuracy in tests of statistical significance.[29]

This study uses data from 1985, 1990, 1995, and 2000 to ascertain the effect of certificate-of-need laws on hospital bed supply and on healthcare expenditures. We were unable to use more recent data because data on state healthcare expenditures are unavailable for any years after 2000. State healthcare expenditures estimates for years after 2000 will be available in the near future, and it would be relevant to compare the findings in this study with findings using more recent data. It also would be useful if future studies compared the costs and benefits of certificate-of-need programs, as there are no studies to date on the effect of these programs that include estimates of the cost of operating the program, although there have been numerous complaints about the burden imposed by these laws on providers who apply for a certificate of need.

Acknowledgments

I thank Thomas R. Piper, BA, American Health Planning Association information coordinator and Missouri certificate-of-need director, and Jana Fussell, BA, Oregon Health Division certificate-of-need coordinator, for their assistance in creating Table 1.

Author Affiliations: Center for Delivery, Organization, and Markets, Agency for Healthcare Research and Quality, Rockville, MD.

Funding Source: This study was not funded.

Author Disclosures: Dr Hellinger reports no relationship or financial interest with any entity that would pose a conflict of interest with the subject matter of this article.

Authorship Information: Concept and design; acquisition of data; analysis and interpretation of data; drafting of the manuscript; critical revision of the manuscript for important intellectual content; statistical analysis; provision of study materials or patients; administrative, technical, or logistic support; and supervision.

Address correspondence to: Fred J. Hellinger, PhD, Center for Delivery, Organization, and Markets, Agency for Healthcare Research and Quality, 540 Gaither Rd, Room 5319, Rockville, MD 20850. E-mail: fred.hellinger@ahrq.hhs.gov.

REFERENCES

1. Hellinger FJ. The effect of certificate-of-need legislation on hospital investment. *Inquiry.* 1976;13(2):187-193.

2. Conover CJ, Sloan FA. *Evaluation of Certificate of Need in Michigan.* Vol 2. Durham, NC: Center for Health Policy, Law and Management, Terry Sanford Institute of Public Policy, Duke University; May 2003.

3. Salkever DS, Bice TW. The impact of certificate-of-need controls on hospital investment. *Milbank Mem Fund Q Health Soc.* Spring 1976;54(2):185-214.

4. Arnold J, Mendelson DN. *Certificate of Need: A Policy Synthesis.* Falls Church, VA: Lewin-VHI Inc; March 1, 1993.

5. Havighurst C. Regulation of health facilities and services by certificate of need. *Va Law Rev.* 1973;59(7):1143-1232.

6. Lave J, Lave L. *The Hospital Construction Act: Evaluation of the Hill-Burton Program 1948-1973.* Washington, DC: American Enterprise Institute; 1974.

7. Romano M. Pros and cons of certificates: American Health Planning Association directory suggests that certificate-of-need process is regulatory in theory, not in practice. *Mod Healthc.* 2003;33(16):4-5, 1.

8. *National Directory of Health Planning, Policy, and Regulatory Agencies.* 16th ed. Falls Church, VA: American Health Planning Association; 2005.

9. *Improving Health Care: A Dose of Competition.* Washington, DC: Federal Trade Commission and Department of Justice; July 2004.

10. *National Directory of Health Planning, Policy, and Regulatory Agencies.* 11th ed. Falls Church, VA: American Health Planning Association; 1999.

11. Sloan FA, Steinwald B. Effects of regulation on hospital costs and input use. *J Law Econ.* April 1980;23(1):81-109.

12. Ashby JL Jr. The impact of hospital regulatory programs on per capita costs, utilization, and capital investment. *Inquiry.* 1984;21(1):45-59.

13. Mendelson DN, Arnold J. Certificate of need revisited. *Spectrum.* Winter 1993;66(1):36-44.

14. Hellinger FJ. The effect of certificate-of-need legislation on hospital investment. *Inquiry.* 1976;13(2):187-193.

15. Salkever DS, Bice TW. Hospital certificate-of-need legislation and hospital costs. In: Zubkoff M, Raskin IE, Hanft RS, eds. *Hospital Cost Containment: Selected Notes for Future Policy.* New York, NY: Prodist for Milbank Memorial Fund; 1979:429-460.

16. Cromwell J. Impact of state hospital rate setting on capital formation. *Health Care Financ Rev.* 1987;8(3):69-82.

17. Manard BB, Kaplan SJ, Keiller A, Cameron R. *The Georgia Certificate of Need Program.* Falls Church, VA: Lewin-VHI, Inc; December 1995.

18. Remis RE. Health care and the federal antitrust laws: the likelihood of a harmonious coexistence. *J Contemp Health Law Policy.* 1996;13(1):113-135.

19. *Healthier and Wealthier: Decreasing Health Care Costs by Increasing Educational Attainment.* New York, NY: Alliance for Excellent Education; November 2006. Issue brief.

20. Loba LM. *Locality and Inequality: Farm and Industry Structure and Socioeconomic Conditions.* Albany: State University of New York Press; October 1990.

21. Dodge JL, Mills PK, Riordan DG. Cancer survival in California Hispanic farmworkers, 1988-2001. *J Rural Health.* 2007;23(1):33-41.

22. US Department of Commerce, Bureau of the Census. *Census of Population and Housing Population and Housing Unit Counts.* Washington DC: US Department of Commerce, 1990 and 2000 Census publications.

23. US. Department of Labor, Bureau of Labor Statistics. *Geographic Profile of Employment and Unemployment,* Various years.

24. US Department of Commerce, Bureau of Economic Analysis. Interactive access to annual state personal income accounts tables. http://www.bea.gov/regional/spi/default.cfm?seltable=sa05n. Accessed April 2009.

25. Health Forum. *American Hospital Association Hospital Statistics.* Chicago, IL: American Hospital Association, Various issues.

26. American Medical Association. *Physician Characteristics and Distribution in the US.* Chicago, IL: American Medical Association, Various issues.

27. Liang KY, Zeger SL. Longitudinal data analysis using generalized linear models. *Biometrika.* 1986;73(1):13-22.

28. SAS Institute Inc. *SAS/ETS User's Guide: Version 6.* 2nd ed. Cary, NC: SAS Institute Inc; 1993.

29. Greene WH. *Econometric Analysis.* 2nd ed. New York, NY: Macmillan Publishing Co; 1993.

30. Betrand M, Duflo E, Mullainathan S. How much should we trust differences-in-differences estimates? *Q J Econ.* 2004;119(1):249-275.

31. White H. A heteroskedasticity-consistent covariance matrix estimator and a direct test for heteroskedasticity. *Econometrica.* 1980;48(4):817-838.

32. Breusch T, Pagan A. A simple test for heteroscedasticity and random coefficient variation. *Econometrica.* 1979;47:1287-1294.

33. Durbin J, Watson GS. Testing for serial correlation in least squares regression. *Biometrika.* 1951;37:409-428.

J Perinatol. 2012 Jan;32(1):39-44. doi: 10.1038/jp.2011.47. Epub 2011 Apr 28.

The impact of certificate of need programs on neonatal intensive care units

S A Lorch [1], P Maheshwari, O Even-Shoshan

Affiliations
PMID: 21527902 DOI: 10.1038/jp.2011.47

Abstract

Objective: To determine the impact of state certificate of need programs (CON) on the number of hospitals with neonatal intensive care units (NICU) and the number of NICU beds.

Study design: The presence of a CON program was verified from each state's department of health. Multivariable regression models determined the association between the absence of a CON program and each outcome after controlling for socioeconomic and demographic differences between states.

Result: A total of 30 states had CON programs that oversaw NICUs in 2008. Absence of such programs was associated with more hospitals with a NICU (Rate Ratio (RR) 2.06, 95% CI 1.74 to 2.45) and NICU beds (RR 1.96, 95% CI 1.89 to 2.03) compared with states with CON legislation, and increased all-infant mortality rates in states with a large metropolitan area.

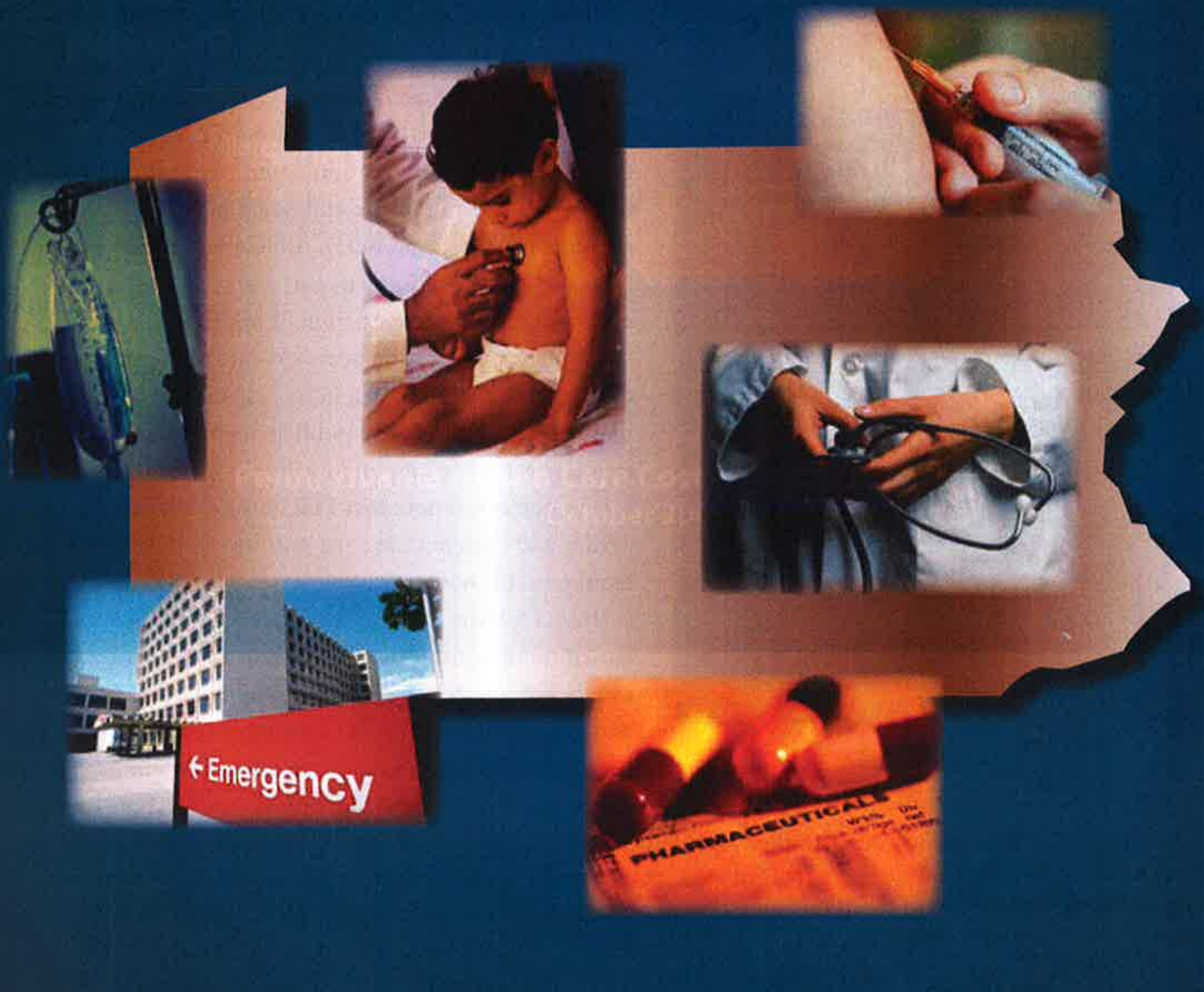
Conclusion: There has been an erosion of CON programs that oversee NICUs. CON programs are associated with more efficient delivery of neonatal care.

LinkOut - more resources

Full Text Sources
Nature Publishing Group
Ovid Technologies, Inc.

CRITICAL CONDITION

The State of Health Care in Pennsylvania



Pennsylvania Health Care Cost Containment Council
October 2007

Critical Condition: The State of Health Care in Pennsylvania

Over 20 years ago, in the Pennsylvania Health Care Cost Containment Council's (PHC4's) enabling legislation of 1986, the Pennsylvania General Assembly cited "a major crisis because of the continuing escalation of costs for health care services." This crisis, which continues at unsustainable levels, still looms large both in Pennsylvania and across the rest of the nation. In fact, by 2016, health care is expected to account for $1 of every $5 spent in the United States.[1]

Critical Condition: The State of Health Care in Pennsylvania is an attempt to address the nature of this crisis by discussing various concerns about the health care system that are embodied in Act 89 (as amended by Act 14 of 2003). PHC4 has undertaken this effort as part of its charge to report to the General Assembly on the escalation of health care costs in the state, as well as on access-to-care and quality-of-care issues. PHC4 is an independent state agency that collects, analyzes and publicly reports information relative to the cost and quality of health care. It is important to note that PHC4 is a data-driven agency and does not have the statutory authority to require health system change.

In Act 89, the General Assembly found that the escalation of health care costs was "attributable to a number of interrelated causes, including…the absence of a concentrated and continuous effort in all segments of the health care industry to contain health care costs." The analysis and comparisons contained in this report lead to the inescapable conclusion that while there have been numerous, well-intentioned efforts to control health care costs over the past ten years, those efforts have been largely unsuccessful. Thus, the health care crisis has persisted and has resulted in increasingly damaging consequences to the state's economy and health status of its citizens.

The purpose of this report is not to point blame at any particular segment of the health care industry but to show the interrelated causes at play. This report is a departure from most PHC4 publications,

Table of Contents

PHC4 wishes to thank David B. Acker, former Chair of PHC4's Education Committee, for his contributions to this publication. His thoughtful guidance, leadership and input were essential in spearheading this new report.

which typically present detailed information about specific health care issues. Instead, it provides a global understanding of key health care trends and focuses on the "big picture" with respect to what has happened: How much did we in Pennsylvania spend on health care, what did we spend it on, where did the money go and what did we get in return?

While the report does not touch upon every related subject, it gives policymakers, providers, consumers and other stakeholders an overview of major trends. Topics addressed include health care spending, health insurance coverage, provider and insurer finances, supply and utilization trends and health status. Whenever possible, the report offers then-and-now comparisons – for instance, what the state of health care was in 2005 versus 1995.

Unfortunately, the report shows that many of the state's emergent trends have not been positive. For example, as health care costs have consistently increased over the past ten years, the number of people covered by traditional employment-based health insurance has declined. The number of uninsured has increased, as has the number enrolled in Medicaid and other government programs – all of which increase financial pressure on provider bottom lines and state tax dollars. Additionally, as the state's population becomes increasingly older, Medicare under-reimbursements to hospitals, combined with a shrinking commercial insurance base, have weakened hospitals' financial pictures, placing small to medium-size community hospitals, especially those in rural areas, at risk of becoming an endangered species. These are a few of the trends discussed in this report.

In short, the health care crisis that the General Assembly identified two decades ago has worsened and shows no sign of abating. And like a house of cards approaching collapse, the problems are deeply interconnected, exacerbated by stressors that continue to mount.

Absent a comprehensive national health care strategy, health care stakeholders will be forced to seek new solutions on a state-by-state basis. And unless Pennsylvania acts now, in a coordinated and aggressive fashion, the economy and quality of life of its residents will deteriorate. Health care is the single largest employer in the Commonwealth, and the dependency of the state's economy on a system which is not economically sustainable without substantial modifications should be of enormous concern to all Pennsylvanians.

State Demographics

Several key demographic characteristics must be considered as a backdrop when examining the state of health care in Pennsylvania. The relatively flat growth in the state's total population, its proportion of older adults, the number of poor and the rural/urban divide all impact our state's health care delivery system and will be described throughout the report.

Population Growth: Pennsylvania's population only grew by 1.7% from 1995 (12,198,403) to 2005 (12,405,348).[2]

65 and Older: In 2005, Pennsylvania was the third "oldest" state with 14.6% of its residents 65 and older.[3] Only Florida and West Virginia had higher percentages in this age group. Whereas Pennsylvania's 65 and over population grew by 4.9% from 1990 to 2000, its 85 and over population grew by 38.3% during this ten-year span.[4]

Poverty: In 2005, 11.2% of all Pennsylvanians (1,372,000) were living below the poverty level, and 27.4% (3,353,000) were living below 200% of the poverty level.[5]

Urban and Rural: Despite its large urban population, Pennsylvania had the third largest number of rural residents among all states in 2000.[6]

Key Findings

- **Growth in health care spending.** The growth in health care expenditures in Pennsylvania is outpacing the growth in our economy, our population and the general rate of inflation. This growth, however, is a double-edged sword. Health care is Pennsylvania's largest employer and is especially vital to rural economies. The expenditures by state government on health care exceed $18.8 billion. Additionally, personal health spending accounted for 16.1% ($74.5 billion) of the gross state product in 2004. Yet, rising health care costs are an increasing burden for our employers competing in a global economy and our citizens who see medical expenses rising faster than their income.

- **Employment-based health insurance.** The number of Pennsylvanians receiving health insurance through employment decreased by an estimated 450,000 people from 2000 (8,569,000) to 2005 (8,119,000). Employer-based health insurance premiums for family coverage increased from $6,721 per employee in 2000 to $11,801 in 2006. This decline in employer-sponsored coverage, combined with the demands of Pennsylvania's aging population, has put a larger financial burden on our state and federal government.

- **The uninsured.** Despite the increase in the number of Pennsylvanians participating in government-funded health care programs, the percentage of Pennsylvanians without health insurance is increasing. The number of uninsured Pennsylvanians rose by an estimated 291,000 people from 2000 (905,000) to 2005 (1,196,000). Still, the rate of uninsured in Pennsylvania continues to remain below the national average.

- **Uncompensated care.** Despite the growth in the uninsured population, uncompensated care – the portion of total hospital care that must be written off as bad debt or charity care – has remained relatively constant. However, hospitals annually absorb over a half-billion dollars in foregone revenue. The cost of this care is partially passed on to private payors.

- **Cost shifting.** While the number of Pennsylvanians receiving health insurance from governmental programs has increased and those receiving insurance from commercial insurance has decreased, commercial insurers pay an increasing percent of health care costs. The failure of governmental insurers to pay for the increasing cost of care has shifted costs to the commercial payors, and is partly responsible for the decline in employees accessing health insurance through employment.

- **Economic viability of hospitals.** Statewide general acute care (GAC) hospital profits nearly doubled in the last 10 years, rising from $761 million in FY95 to $1.3 billion in FY05. The largest proportion of these profits has centered around large, urban tertiary care medical centers. According to generally-accepted industry standards, an economically viable hospital should produce an operating profit of at least 2% and a total margin of at least 4%. However, 67% of the state's hospitals operated with total margins below 4% for the three-year period from FY03 to FY05. During the same three-year period, 34% of all hospitals had a bottom line loss, compared to 22% in the three-year period from FY95 to FY97. In short, more than one-third of all hospitals are presently in significant financial distress, and two-thirds are performing at levels considered below long-term economic viability.

- **Aging plant.** In order to maintain economic viability, GAC hospitals must have a certain level of profit to reinvest in property, plant and equipment as it ages and to invest in new technology necessary for modern care. While financially healthy hospitals have been able to make investments in their facilities and equipment, many hospitals find improvements in new technology, access to capital, and the upgrading of old equipment very challenging. In general, the average age of Pennsylvania's hospital facilities and equipment is increasing and aging beyond the national average.

- **Outpatient care.** The migration of outpatient diagnostic and surgical (D&S) procedures to the burgeoning number of ambulatory surgical centers (ASCs) is contributing to increases in capacity and utilization. While these predominately physician-owned ASCs may be improving the efficiency of the delivery of outpatient D&S care, they are siphoning income away from GAC hospitals – income that has traditionally supported many essential hospital services.

- **Health care workforce.** While there is no consensus on the adequacy of physician supply in Pennsylvania, there is a shortage of nurses and other health care workers. For example, the projected growth in the shortage of nurses – the largest segment of health care workers – may have a significant effect on future access and quality of care.

- **Chronic disease.** Three-quarters (75%) of the health care costs in Pennsylvania can be traced to the 25% of patients with chronic illness. Continuing to expand disease management and preventive care will improve the quality of life for a portion of the population and could help to reduce hospitalizations and restrain associated costs. Lifestyle changes that reduce obesity, cigarette use, and other health risks may help to restrain rising health care utilization and costs related to chronic disease.

- **Health status.** Some measures of the population's health status have worsened. From 1995 to 2005, the percent of adult Pennsylvanians considered overweight or obese rose from 54% to 62%. The percent of adults considered obese rose from 16% to 25%. The number of adults who were told that they have diabetes rose from approximately 6% (57 per 1,000) to 8% (81 per 1000). This level of decline in key health status indicators is alarming since Pennsylvania's personal health care spending rose from $45 billion in 1995 to $74.5 billion in 2004.

- **The case for public reporting.** Pennsylvania is one of the pioneering states in developing public reporting of hospital performance. During Pennsylvania's years of public reporting, hospitals and physicians have achieved large reductions in patient mortality for a broad range of procedures and diseases. In fact, since PHC4 began publicly reporting patient mortality rates for Pennsylvania hospitals, in-hospital mortality rates for all conditions dropped from significantly above to significantly below the national average.

The health care industry is the state's leading employer.

Pennsylvania's personal health care spending was more than 16% of the gross state product in 2004.

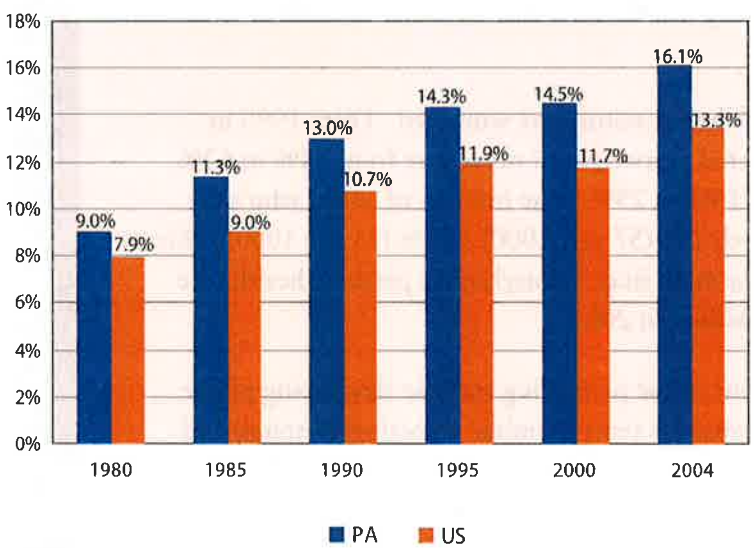
Health care as an industry is integral to Pennsylvania's economy. The health care and social assistance sector was the state's leading employer in 2005.[7] Health care and social assistance jobs (912,867 jobs) comprised 12.8% of Pennsylvania's total jobs, ahead of retail (11.6%), government and government enterprise (11.4%) and manufacturing (10.0%). Ten years earlier, health care and social assistance only comprised 11.4% of the state's total jobs.[8] Nationally, health care and social assistance ranked as the third largest employer in 2005, behind government and the retail sector.[9] Health care and social assistance are included in the same sector due to difficulties in distinguishing between the boundaries of the two activities; the services provided in this sector are delivered by health practitioners or social workers.

In 2005, hospital employees alone topped 275,000.[10] While the role of hospitals as employers is significant statewide, hospitals are vitally important to rural economies. Over 90% of rural hospitals are among their communities' three largest employers.[11]

In FY03, the Commonwealth of Pennsylvania's expenditures on health care, including federal and state funding, exceeded $18.8 billion.[12] Most of the spending supports Medicaid, the state's health insurance program for low-income people. The state's Children's Health Insurance Program (CHIP), state employees' health benefits, corrections health care, medical education, medical liability, and public health are among the other expenditures.

Additionally, total personal health care expenditures account for a significant and growing portion of Pennsylvania's Gross State Product (GSP). In 2004, total personal health care expenditures accounted for 16.1% of the GSP, up from 11.3% in 1985.[13] While health care is also a major contributor to the U.S. economy, total personal health care expenditures accounted for only 13.3% of the Gross State Product for the United States in 2004.

Total Personal Health Care Expenditures as a Percent of Gross State Product



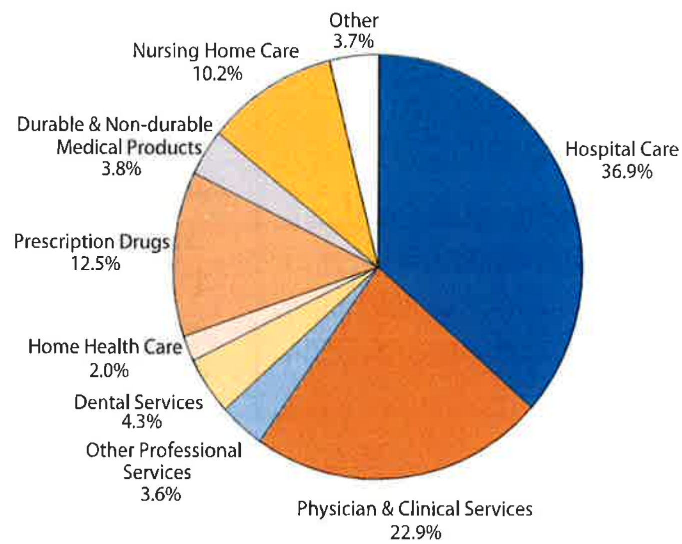
Source: Centers for Medicare & Medicaid Services
Note: Gross State Product for the U.S. equals the sum of Gross State Product in all states.

Health Care Spending

From 1995 to 2004, Pennsylvania personal health care expenditures increased by 65% from $45.0 billion to $74.5 billion.[14] During this same period, personal health care expenditures in the nation rose 80%. Still, it is important to point out that the U.S. population grew by 10% during this time while Pennsylvania's grew less than 2%.[15]

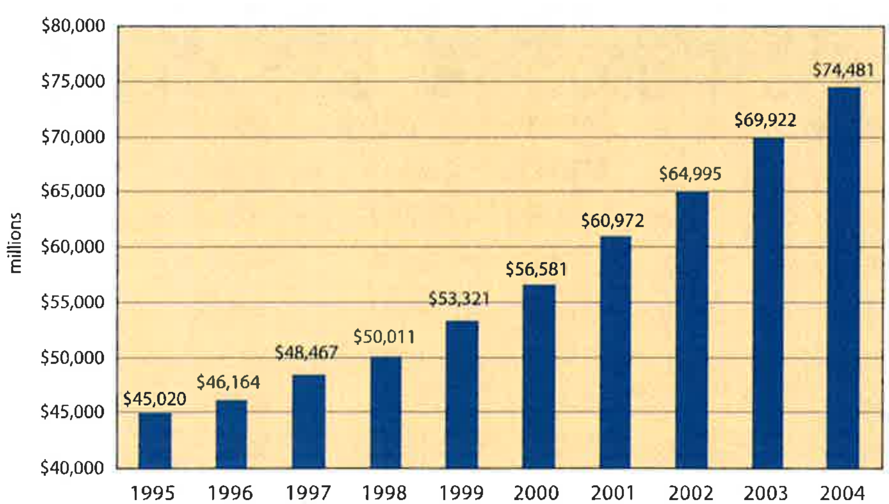
In 2004, the largest components of personal health care expenditures in Pennsylvania were hospital care (36.9%), physician and clinical services (22.9%), prescription drugs (12.5%) and nursing home care (10.2%).[16] As a percentage of Pennsylvania's total personal health care expenditures, hospital care dropped by 14% and prescription drugs increased by 64% from 1995 to 2004.

Distribution of Personal Health Care Expenditures Pennsylvania, 2004



Source: Centers for Medicare & Medicaid Services
Note: Numbers may not add up due to rounding.

Pennsylvania Personal Health Care Expenditures 1995-2004



Source: Centers for Medicare & Medicaid Services

Personal health care spending in Pennsylvania rose 65.4% from 1995 to 2004 – from $45 billion to $74.5 billion.

Health Care Spending

The prescription drugs category has seen the steepest increase among all categories of personal health care spending.

The largest increases from 1995 to 2004 were seen in hospital care (+42%), physician and clinical services (+70%), prescription drugs (+172%), and nursing home care (+67%).[17] Since hospital care, physician services and nursing home care also include prescription drugs administered, part of the increases in these sectors can be attributed to prescription drugs.

The tremendous growth in health care spending is also evident on a per capita basis. Nationally, per capita personal health care expenditures were $5,598 in 2005, an increase of almost 54% from $3,647 in 1998.[18] Adding in non-personal health care expenditures (which include such things as government administration, the net cost of private health insurance, public health activities and investments in research, structures and equipment), per capita health care spending reached $6,697 in 2005.

In 2004, Medicare paid for 21.8% of Pennsylvania personal health care expenditures, and Medicaid paid for 17.2%.[19] Private insurance, out-of-pocket payments and other public and private programs accounted for the remainder. Compared to the United States as a whole, Pennsylvania had a slightly larger portion of Medicare personal health care expenditures in 2004.

Pennsylvania Personal Health Care Expenditures* (in millions)

	Pennsylvania			U.S.
	1995	2004	% Increase	% Increase
Total Personal Health Care	$45,020	$74,481	65%	80%
Hospital Care	$19,331	$27,504	42%	66%
Physician & Clinical Services	$10,041	$17,072	70%	79%
Other Professional Services	$1,647	$2,658	61%	84%
Dental Services	$1,916	$3,232	69%	83%
Home Health Care	$1,168	$1,518	30%	40%
Prescription Drugs	$3,415	$9,278	172%	212%
Other Non-Durable Medical Products	$1,202	$1,809	50%	28%
Durable Medical Products	$685	$1,036	51%	51%
Nursing Home Care	$4,555	$7,594	67%	55%
Other Personal Health Care	$1,061	$2,781	162%	132%

*Does not include other health expenditures such as government administration, the net cost of private health insurance, government public health activities, or investment in research, structures and equipment.

Source: Centers for Medicare & Medicaid Services
Note: Numbers may not add up to totals due to rounding. A portion of the increase in health care expenditures can be attributed to general inflation. The increase in the Consumer Price Index for All Urban Consumers (CPI-U) between 1995 and 2005 was 28.8% in the U.S., 28.7% in the Philadelphia area and 27.2% in the Pittsburgh area. (U.S. Dept. of Labor, Bureau of Labor Statistics)

Health Insurance Coverage

Another disturbing trend is that an estimated 450,000 fewer Pennsylvanians had job-based health insurance in 2005 than 2000.[20] In 2005, 66.1% of all Pennsylvanians were covered by job-based plans, down from 71.6% five years earlier. Nationally, an even smaller percentage (60.2%) of persons had job-based coverage in 2005.

As expected, with job-based coverage on the decline, persons covered by government programs increased. The number of Pennsylvanians covered by Medicare, Medicaid and military health care grew by 18.9% from 2000 to 2005.[21]

While Pennsylvania's uninsured rate is lower than the nation's, it did increase from 7.6% in 2000 to 9.7% in 2005.[22] In addition to the 1,196,000 Pennsylvanians without health insurance, an undetermined number are underinsured. Underinsured people have some coverage, but are not adequately protected against catastrophic health care bills. Nationally, an estimated 16 million adults were underinsured in 2005.[23]

Pennsylvania's uninsured rate among low-income children is also lower than the nation's. Of Pennsylvania children below 200% of poverty, 14.5% (156,000) were not covered by health insurance in 2005.[24] Nationally, 18.3% were not covered. Unfortunately, most of these children are eligible for public health coverage, but remain unenrolled because of a lack of awareness about eligibility, administrative barriers and other factors.

Persons Without Health Insurance

Year	Pennsylvanians without Health Insurance		U.S. Percent without Health Insurance
	Number	Percent	
1995	1,195,000	9.9	15.4
2000	905,000	7.6	14.0
2005	1,196,000	9.7	15.3

Source: U.S. Census Bureau
Note: All figures are estimates. In March 2007, the Census Bureau released revised coverage estimates for 2005 based on an enhancement to the process that assigns coverage to dependents. The 2005 data in this table reflects this enhancement. Revised figures for 1995 and 2000 have not been released yet.

Health Insurance Coverage in Pennsylvania - by Type of Insurance

		2000		2005	
		Number	% of Total Persons	Number	% of Total Persons
Private Insurance	Any private plan	9,780,000	81.7%	9,469,000	77.1%
	Employment-based	8,569,000	71.6%	8,119,000	66.1%
	Direct-purchase	NA		1,408,000	11.5%
Government Insurance	Any government plan	2,781,000	23.2%	3,306,000	26.9%
	Medicare	1,693,000	14.1%	1,930,000	15.7%
	Medicaid	1,100,000	9.2%	1,452,000	11.8%
	Military health care	210,000	1.8%	229,000	1.9%
No Insurance	Not covered at any time during the year	905,000	7.6%	1,196,000	9.7%

Source: U. S. Census Bureau
Note: Some persons are covered by more than one source. In 2005, 10.4% of persons were covered by both Medicare and private insurance, 3.0% were covered by Medicaid and private insurance, and 1.6% were covered by Medicare and Medicaid. All figures are estimates. In March 2007, the Census Bureau released revised coverage estimates for 2005 based on an enhancement to the process that assigns coverage to dependents. The 2005 data in this table reflects this enhancement. Revised figures for 2000 have not been released yet.
NA - Not available

Health Insurance Costs

On average, health insurance premiums for Pennsylvania families increased by 75.6% from 2000 to 2006.

Premiums for family coverage rose 5.7 times faster than median earnings from 2000 to 2006.

For employers and workers alike, the cost of health insurance continues to be a growing concern. Increases in the nation's employer health plan premiums consistently outpace overall inflation and workers' earnings. Premiums for family coverage increased by 9.2% in 2005.[25] Despite the fact that this was the first year of single-digit increases in five years, it still exceeded both the overall inflation rate and the increase in workers' earnings by about 6%.

In Pennsylvania, families and businesses are feeling the burden of increases in employer-based health insurance premiums. One study found that the average annual premium for family health coverage in Pennsylvania increased from $6,721 in 2000 to $11,801 in 2006 – a 75.6% increase.[26] For family coverage, the employer share in premium spending went up 73.2%, and the employee share went up 85.6%. Since median earnings for Pennsylvania families only increased by 13.3% during this same time period, that means premiums grew 5.7 times faster.

Premiums for individual coverage saw similar increases. From 2000 to 2006, the average annual premium for individual health coverage in Pennsylvania increased 71.7% from $2,467 to $4,236.[27] For individual coverage, the employer share in premium spending went up 65.8%, and the employee share went up 104.7%.

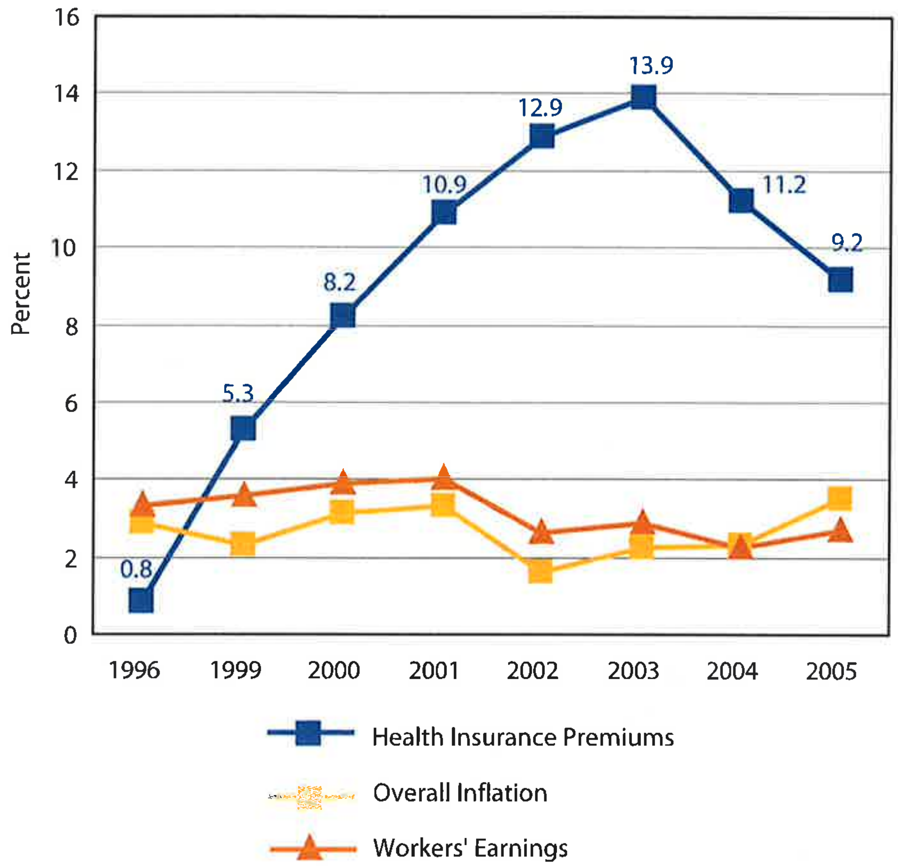
Employer-based Health Insurance Premiums for Family Coverage Pennsylvania, 2000-2006

Premiums by Source of Payment	2000	2006	Dollar Change	Percent Change
Total Premium Spending per Worker (Employer and Worker Share)	$6,721	$11,801	$5,080	75.6%
Share of Premium Paid by Employer	$5,424	$9,394	$3,970	73.2%
Share of Premium Paid by Worker	$1,297	$2,407	$1,110	85.6%

Source: Families USA, *Premiums versus Paychecks: A Growing Burden for Pennsylvania's Workers*

Health Insurance Costs

Increases in the Nation's Employer Health Plan Premiums Compared to Other Indicators, 1996-2005



Nationally, the 9.2% increase in employer health plan premiums in 2005 exceeded both the overall inflation rate and the increase in workers' earnings by about 6%.

Increases in:	1996	1999	2000	2001	2002	2003	2004	2005
Health Insurance Premiums	0.8	5.3*	8.2*	10.9*	12.9*	13.9	11.2*	9.2*
Overall Inflation	2.9	2.3	3.1	3.3	1.6	2.2	2.3	3.5
Workers' Earnings	3.3	3.6	3.9	4.0	2.6	3.0	2.1	2.7

Source: Kaiser Family Foundation

* Estimate is statistically different from estimate for the previous year shown (p<.05). No statistical tests are conducted for years prior to 1999.

Note: Data on premium increases reflect the cost of health insurance premiums for a family of four. The average premium increase is weighted by covered workers.

Health Insurer Finances

From 2001 to 2005, the total after-tax net income realized by Pennsylvania health insurers collectively grew from almost $462 million to $810 million.[28] During this same period, their collective income margins increased from 2.51% to 3.30%. Their medical loss ratio – the percentage of dollars these companies spend on health care – decreased from 87.08% to 85.00%.

The reserve and surplus levels of Pennsylvania's health insurers have been the subject of public debate in recent years. The words "reserve" and "surplus" are sometimes used interchangeably when, in fact, they have very different meanings.

Reserves are funds that are maintained to pay for claims that have been incurred but not yet paid. Having adequate funds to pay forthcoming claims expense is recognized as a liability on insurance company balance sheets. *Surpluses* represent an insurer's "net worth" or "net capital" after all of its liabilities have been recognized. Surpluses can be used to support investment needs and to help insurers through adverse business conditions and catastophic events.

The surplus level maintained by Pennsylvania's health insurers grew from nearly $5.6 billion in 2001 to $8.5 billion in 2005.[29] Following an investigation, the Pennsylvania Insurance Department issued a decision in February 2005 determining that the Pennsylvania Blue plans were not operating with excess surplus.[30]

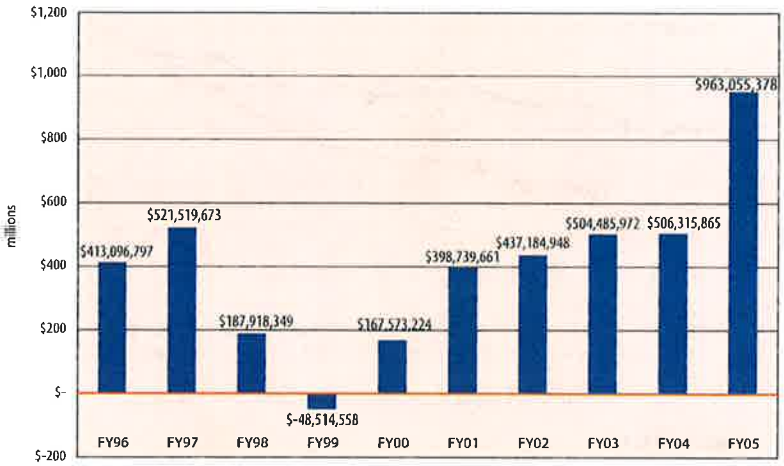
Pennsylvania Health Insurer Finances

	2001	2005
Total Revenue	$18,422,440,355	$24,522,346,392
Net Income (after taxes)	$461,866,607	$809,929,560
Net Income Margin	2.51%	3.30%
Premium Revenue	$18,406,288,194	$24,509,866,491
Total Medical & Hospital Expenses	$16,027,669,873	$20,832,539,702
Medical Loss Ratio	87.08%	85.00%
Surplus	$5,582,545,176	$8,469,743,226

Source: Health Annual Statements filed with the Pennsylvania Insurance Department and the National Association of Insurance Commissioners. The data reflects Pennsylvania-based lines of business for 26 health insurance companies for calendar year 2001 and 28 companies for 2005. This includes commercial plans, as well as not-for-profit Blue Cross/Blue Shield plans. Dental and behavioral health plans were not included.

Provider Profits and Margins

Operating Income
Pennsylvania General Acute Care Hospitals
FY96 - FY05



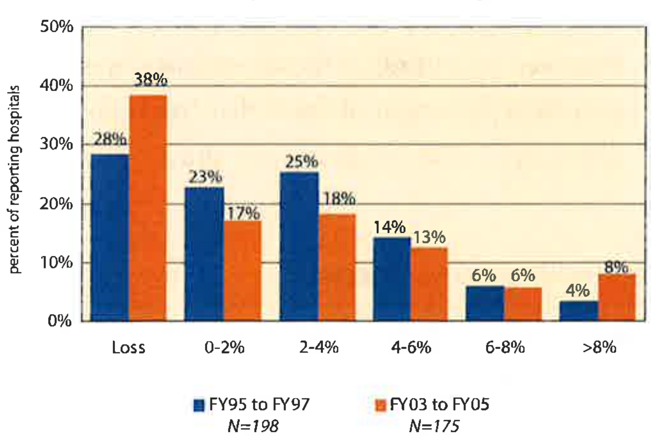
Source: PHC4

In FY05, there was some good news for the state's hospital industry: hospital financial margins in general acute care (GAC) hospitals had risen for the third straight year and were, in fact, at their highest levels in recent history. These higher margins were due in large part to higher statewide operating income, which rose to $963 million in FY05, a 90% increase from $506 million in FY04. Most of this growth was derived from the payments made to hospitals by private health insurers.

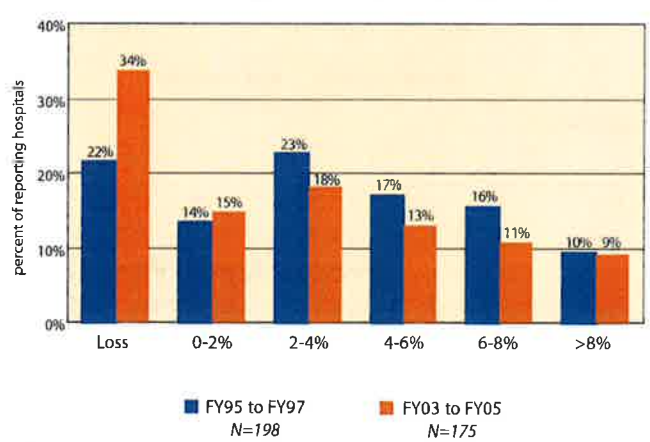
However, a closer look reveals the financial disparities among Pennsylvania's "have" and "have-not" GAC hospitals. In FY05, 44% ($428 million) of this unprecedented increase in statewide operating income was earned by the top five money-making GAC hospitals. That's five hospitals out of a total of 177.

Over the three-year period FY03 to FY05, 59 Pennsylvania hospitals lost money. Fifty-six of those are small to medium-size community hospitals, many of which are in rural areas. In general, these hospitals cannot rely on a larger health system or for-profit corporation for financial support, and will find improvements in new

Statewide Distribution of Three-Year Average Operating Margin Pennsylvania GAC Hospitals

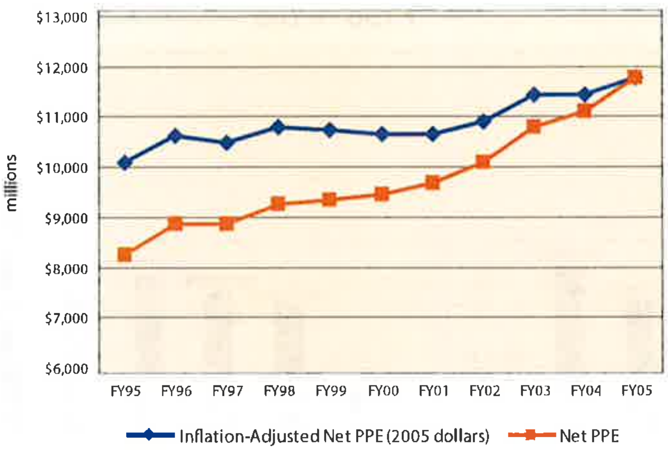


Statewide Distribution of Three-Year Average Total Margin Pennsylvania GAC Hospitals



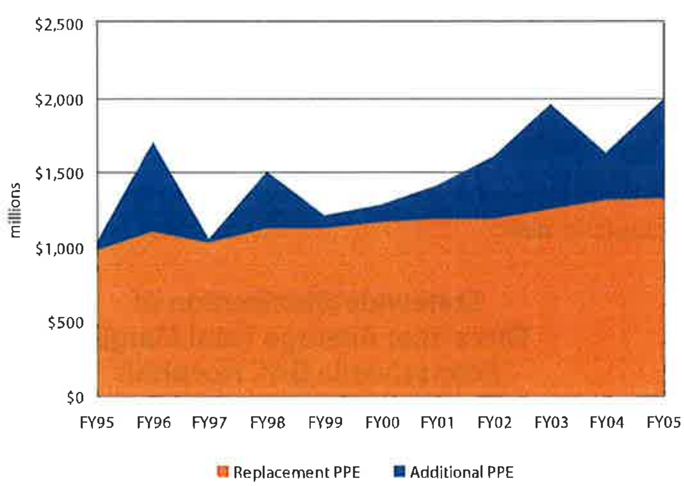
Source: PHC4

Property, Plant & Equipment (PPE) Pennsylvania GAC Hospitals



Source: PHC4
Note: The inflation-adjusted Property, Plant & Equipment (PPE) helps correct for the effect of inflation on the book value of PPE. Each of the ten years prior to FY05 were converted to 2005 dollars.

PPE Replacement and Growth Pennsylvania GAC Hospitals



Source: PHC4

technology, access to capital, recruitment of new staff (especially nurses and physician specialists), and the upgrading of old or obsolete equipment very challenging. These hospitals also tend to care for disproportionately more Medicare and uninsured patients, which makes it harder to break even.

Since hospitals finance capital acquisitions with their net income, the ability of hospitals to expand or replace their equipment and facilities is dependent on income levels. With the disparities in hospital total margins across the Commonwealth, there are also disparities in the ability of hospitals to make investments in their facilities.

Financially unhealthy hospitals that are posting negative operating margins must spend their depreciation on operating expenses to keep the doors open, instead of saving for necessary equipment replacement or upgrades. Conversely, many of those with historically strong margins are undergoing a building boom.

After adjusting for inflation, Pennsylvania hospitals collectively increased the value of their facilities and equipment by 16.5% from FY95 to FY05. In FY05, they procured about $2 billion in new property, plant and equipment (PPE). However, two-thirds of those new assets were actually replacement of assets that had been depreciated. The remaining one-third – $655

Average Age of Plant (Years) - Pennsylvania GAC Hospitals

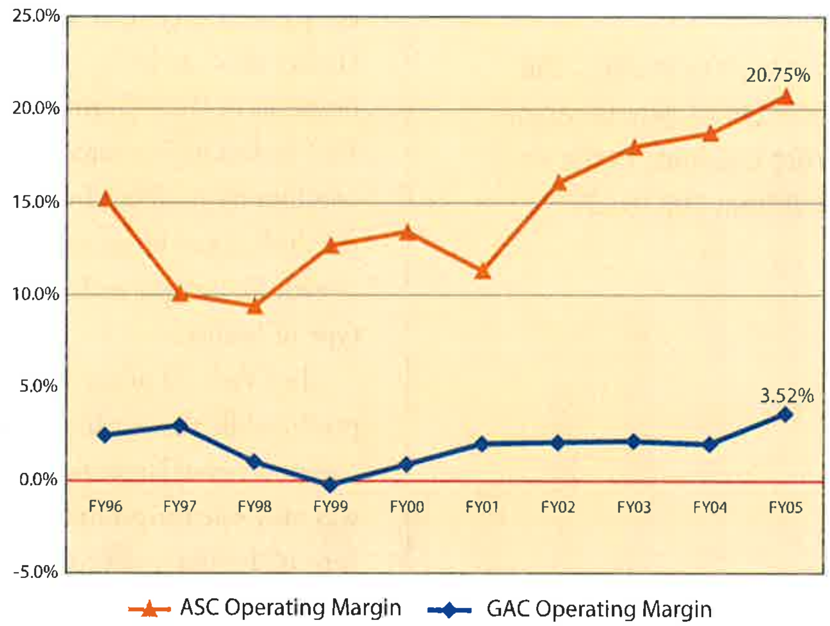
	FY95	FY96	FY97	FY98	FY99	FY00	FY01	FY02	FY03	FY04	FY05
PA	9.2	8.2	9.6	9.3	9.7	10.0	10.6	11.0	11.3	11.5	12.0
U.S.	8.8	8.9	9.2	9.3	9.2	9.4	9.7	9.8	9.8	9.8	9.8

Sources: PHC4, American Hospital Association million – was additional facilities and equipment.

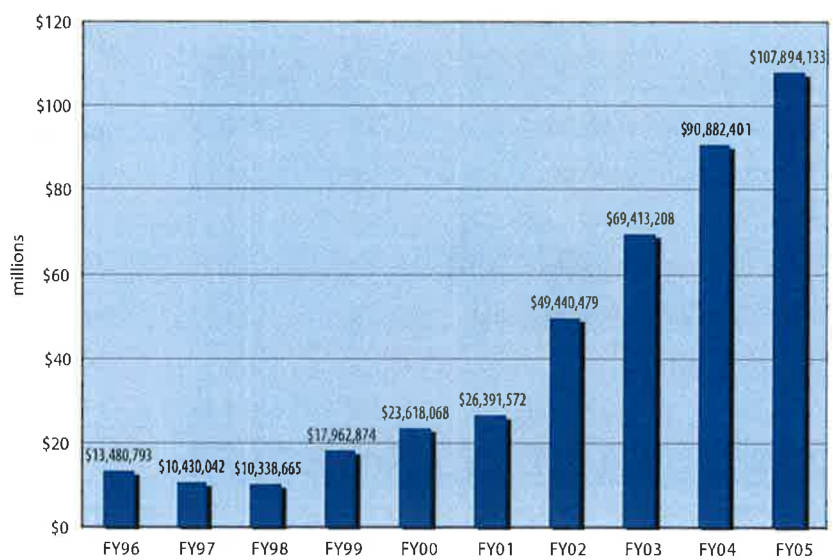
Also relevant to this "have/have-not" discussion is the fact that Pennsylvania's PPE is getting older and is aging more rapidly than the rest of the nation. In FY05, the most recent year that national data is available, the average age of hospital facilities and equipment in Pennsylvania was 2.2 years older than the national average.[31] The average age of plant at Pennsylvania hospitals has increased by nearly three years from 9.2 years in FY95 to 12.0 years in FY05. This suggests that hospitals as a group have slowed their acquisitions and upgrades of facilities and equipment. Therefore, despite the media attention given to hospital expansions in parts of the state, not all are able to do so.

Just as there are financial disparities between Pennsylvania's hospitals, there are marked financial differences between its GAC hospitals and ambulatory surgery centers (ASCs). In FY05, the statewide pre-tax operating margin for ASCs (20.75%) was almost six times greater than the statewide operating margin for GACs (3.52%). ASCs are no longer the relatively minor presence they were a decade ago. In fact, operating revenues for ASCs increased by more than 700% from FY96 ($13.5 million) to FY05 ($107.9 million).

Average Operating Margins - Ambulatory Surgery Centers and General Acute Care Hospitals Pennsylvania, FY96-FY05



Operating Income - Ambulatory Surgery Centers Pennsylvania, FY96 - FY05



Source: PHC4

Note: The operating income shown in this graph is for reporting facilities only. In FY96, 21 of the 44 ASCs did not report, and in FY05, 43 of the 177 ASCs were too new to report, and one was non-compliant.

From 1995 to 2005, the number of general acute care hospitals in the state fell from 206 to 177.

General Acute Care Hospitals

Hospitals are vitally important community institutions, for the patients they treat, the people they employ and the economic vitality they can bring. Yet, the number of general acute care (GAC) hospitals in Pennsylvania fell from 206 in 1995 to 177 in 2005. This 14.1% decline is greater than the nation's 5.0% decline in number of community hospitals from 1995 to 2005.[32] In Pennsylvania, not all of the decline can be attributed to hospital closures. Eight GAC hospitals closed, 22 merged with another GAC, and four converted into another type of facility.

In FY05, 20 of the 177 GAC hospitals in Pennsylvania were for-profit, while the rest functioned solely as non-profit organizations or as components of larger non-profit organizations. Ten years earlier, there was only one for-profit hospital in the state. Whereas all income or "profit" from a non-profit hospital's operations is retained within the organization and used as reinvestments or reserves, for-profit hospitals may distribute a portion of their income to shareholders as dividends.

From FY95 to FY05, the number of staffed beds in Pennsylvania GAC hospitals fell from 48,114 to 37,351 – a 22.4% reduction. In 2005, there were 3.19 beds per 1,000 persons – higher than the national rate of 2.71 beds per 1,000 persons.[33] In Pennsylvania, the average occupancy rate rose from 65.5% in FY95 to 71.4% in FY05, while the number of total inpatient days declined from 11.42 million to 9.67 million during the same time period. Overall, hospital stays have been getting shorter – the average length of an inpatient stay (ALOS) has declined every year since FY95.

Number of Facilities in Pennsylvania by Facility Type

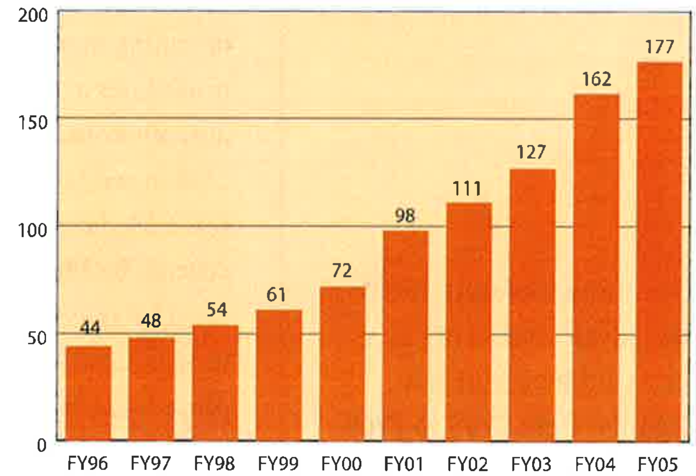
Facility Type	1995	2005
General Acute Care Hospitals	206	177
Rehabilitation Hospitals	20	21
Psychiatric Hospitals	23	17
State Psychiatric Hospitals	11	9
Long-Term Acute Care Hospitals	4	24
Specialty Hospitals	8	6
Ambulatory Surgery Centers	44	177
Total	312	431

Source: PHC4
The number of ambulatory surgery centers does not include capitalized Class A facilities, which are only registered with and not licensed by the State. As of Dec. 2006, there were only six Class A facilities.

Ambulatory Surgery Centers

While the number of GAC hospitals has declined, there has been dramatic growth in the number of licensed ambulatory surgery centers (ASCs) in Pennsylvania during the last decade. The number of ASCs has quadrupled since FY96, growing from 44 in FY96 to 177 in FY05. Pennsylvania's ASC growth trend is especially pronounced, since the number of freestanding ASCs in the nation more than doubled from 1996 to 2005.[34]

Number of Ambulatory Surgery Centers in Pennsylvania



Source: PHC4
Note: Pennsylvania's certificate of need (CON) act sunsetted in December 1996.

The addition of more facilities to the health care system raises questions about the impact on utilization, costs, quality of care and access to care. Certain regions of the state may have excess capacity, i.e., more health care facilities and services than the population needs. Studies have shown that increased capacity can increase utilization.[35] Pennsylvania's certificate of need (CON) legislation, which regulated the construction of various health care facilities, including ASCs and hospitals, sunsetted in December 1996, and the state has been without such provisions since then.

The number of ambulatory surgery centers statewide has quadrupled, from 44 in FY96 to 177 in FY05.

Outpatient Diagnostic and Surgical Procedures

In the past decade, there has been pronounced growth in the number of outpatient diagnostic and surgical (D&S) cases in Pennsylvania at both ASCs and GACs. There was a 93.7% growth in the total number of D&S cases statewide from FY96 to FY05. While the growth in outpatient D&S cases at ASCs (842.3%) outpaced the growth at GACs (52.1%) during this period, the total growth was split almost evenly between ASCs (47.3%) and GACs (52.7%) [See chart on page 18.] In 2005 alone, ASCs performed one of every four outpatient D&S procedures in the state. The most common procedures performed at Pennsylvania ASCs include colonoscopies and eye surgeries.

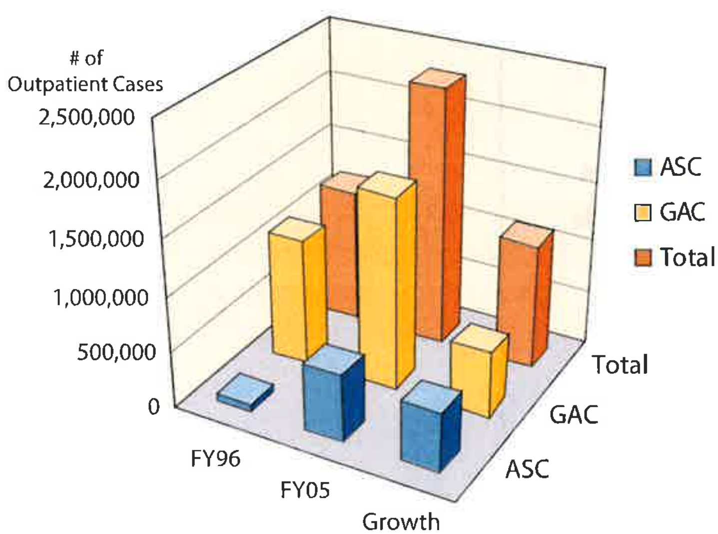
The number of outpatient diagnostic and surgical cases statewide nearly doubled from FY96 to FY05.

As previously mentioned, in terms of profitability, ASCs have become very successful models. In FY05, the statewide pre-tax operating margin for ASCs was six times greater than the statewide operating margin for GACs. Looking at the payor mix between D&S procedures at ASCs and GAC hospitals for FY05, one noticeable difference was in the portion of patients participating in Medicaid. One in ten (10.3%) of GAC outpatients undergoing a D&S procedure was a Medicaid participant, while only 3.1% of ASC patients were covered by Medicaid.

The growth and profitability of ASCs has caused tensions. Even though GAC hospitals still perform the majority of outpatient procedures, hospitals contend that ASCs are draining off important, profitable procedures. This is hard for hospitals to take when they have to underwrite money-losing services and operate on such slim margins.

Another concern generated by ASCs is physician ownership and the role that plays in physician self-referrals. In Pennsylvania, physicians were the majority owners of 65% or 112 of the state's 172 ASCs providing ownership information for FY05. Nationally, 83% of ASCs were owned at least in part by physicians in 2004.[36]

Growth in Outpatient Diagnostic and Surgical Cases* in Pennsylvania



	Number of Outpatient D&S Cases				
	FY96	FY05	Growth	% Growth by Facility Type	% of Total Growth
ASC	63,120	594,755	531,635	842.3	47.3
GAC	1,136,612	1,728,773	592,161	52.1	52.7
Total	1,199,732	2,323,528	1,123,796	93.7	100.0

Source: PHC4
* Excludes outpatient cases at long-term GAC facilities and specialty hospitals which typically represent about 0.1% of all outpatient cases.

Registered Nurse Supply

The estimated shortage of registered nurses in Pennsylvania is slightly less than the national shortage. In 2005, it was estimated that the supply of full-time equivalent (FTE) registered nurses statewide was 105,900 while demand was 115,000 – an 8% shortage.[37] Nationally, the projected shortage in 2005 was 10%.

Given current trends, the Pennsylvania shortage is expected to grow worse. By 2010, the shortage of FTE nurses is projected to be 21,100 or 18%; in 2020, the shortage is projected to be 54,800 or 41%.[38]

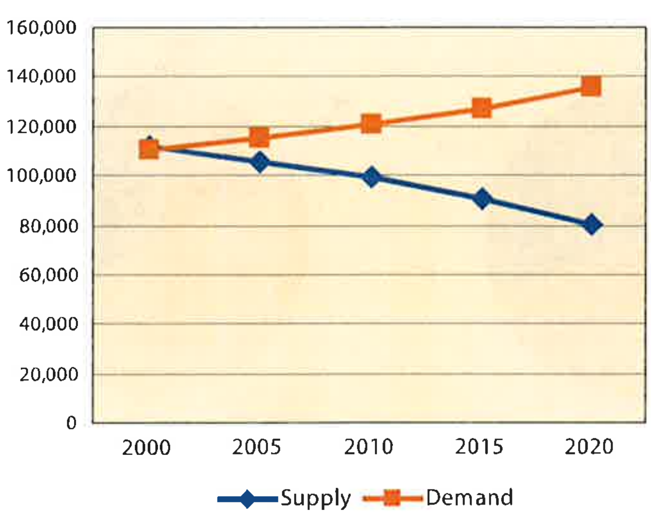
Demand is increasing faster than supply for a number of reasons. Overall population growth and aging population demands are increasing the need for services. Many nurses are at or nearing retirement age. And recruitment and retention in this industry remains challenging.

Since nurses represent the largest group of hospital health care workers, a shortage could potentially affect access to care and quality of care. Recent studies have found low nurse staffing levels are linked to medical errors and poorer patient outcomes.[39]

Statistics about the number of physicians practicing in Pennsylvania and related manpower issues are not included in this report. This information was left out intentionally as there is strong disagreement about which data sources Pennsylvanians should use to draw conclusions about how many physicians are practicing statewide, how many are trained in Pennsylvania, how many are leaving the state, and what impact supply has on access to care. To develop sound public policy, reliable trend data on these issues should be collected and multi-stakeholder groups should begin working together to address this crucial issue.

Registered Nurses in Pennsylvania
Projected Supply and Demand, 2000-2020

	2000	2005	2010	2015	2020	Change from 2000 to 2020
Supply	111,800	105,900	99,200	90,600	80,400	-28%
Demand	110,200	115,000	120,300	127,200	135,200	+23%
Difference	1,600	-9,100	-21,100	-36,600	-54,800	



Source: U.S. Dept. of Health and Human Services, Health Resources and Services Administration (HRSA)

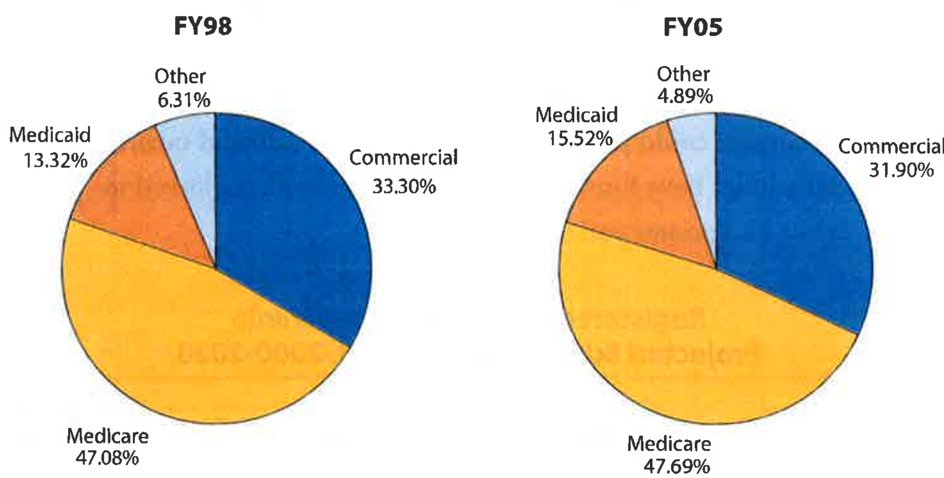
Hospital Revenues & Cost Shifting

Even though Medicare beneficiaries continue to make up the largest share of inpatient discharges, the percent of statewide inpatient revenue from Medicare has dropped from 54.01% in FY98 to 47.25% in FY05.

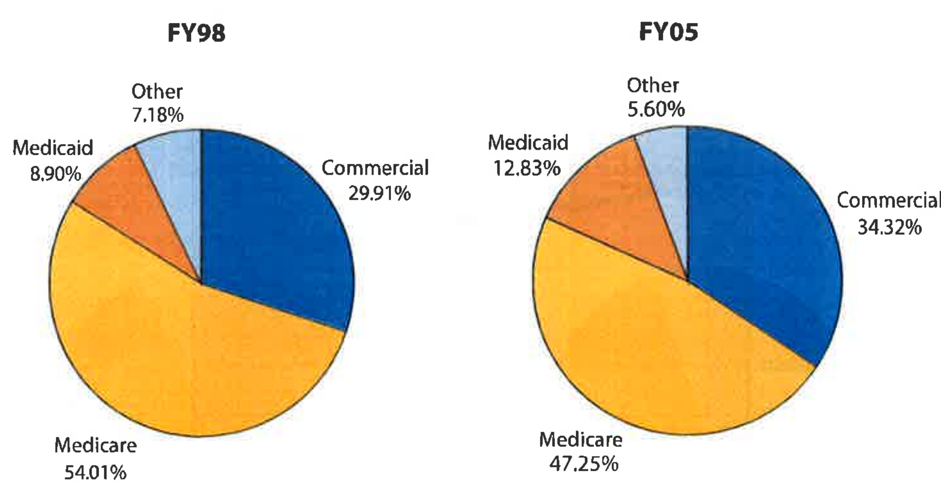
Medicare underpayments for inpatient hospital care present major problems for Pennsylvania and the rest of the nation. Payments from Medicare continue to shrink and the costs of treating Medicare patients (which tend to be the sickest and most expensive) are being shifted to commercial insurers – even though the portion of inpatient discharges covered by Medicare has increased and the portion covered by commercial insurers has decreased.

Despite the fact that commercially insured patients are making up a smaller fraction of total inpatient discharges, the percentage of statewide

Inpatient Discharges by Payor



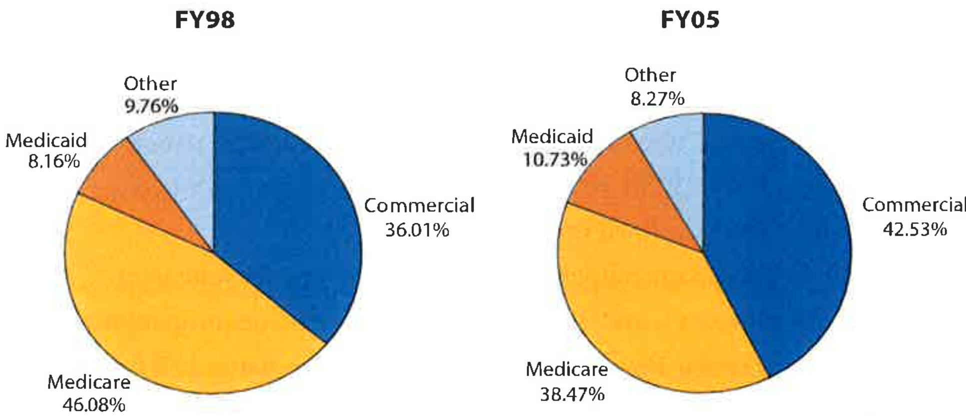
Statewide Inpatient Revenue by Payor - GAC Hospitals



Source: PHC4

Hospital Revenues & Cost Shifting

Statewide Net Patient Revenue by Payor - GAC Hospitals



Source: PHC4

inpatient revenue derived from commercial insurers is going up. From FY98 to FY05, the percentage increased from about 30% to 34%. Conversely, during the same period, the percentage of statewide inpatient revenue derived from Medicare fell from 54% to 47%.

Between FY98 and FY05, commercial insurers surpassed Medicare as the largest payor for general acute care hospital services. FY05 was the sixth straight year that the growth in Medicare revenue lagged behind both the commercial and Medicaid payor categories.

PHC4's financial data suggests that, in FY05, Medicare may have been under-reimbursing by about 16% compared to the average of all payors, and since Medicaid does not account for a large volume of patients, the bulk of the increases in payments is clearly coming from the commercial market. In the end, those increases are not actually paid by health insurance companies; they are passed along to the actual bill payors – Pennsylvania's businesses and labor unions (purchasers) that provide health benefits to their employees and members, and to individuals who pay for their own insurance.

The unintended consequences of this cycle are that purchasers of health benefits are dropping health care coverage as they continue to face skyrocketing insurance premiums. This is forcing more patients into Medicaid or into the ranks of the uninsured, further increasing the financial pressures on providers, government and purchasers.

Commercial health insurance payments have replaced Medicare as the single largest source of hospital net patient revenue in recent years.

PHC4 data suggests Medicare was under-reimbursing by about 16% in FY05, compared to the average for all payors.

On a statewide basis, hospitals provided a total of $544 million in uncompensated care in FY05, up from $461 million in FY01.

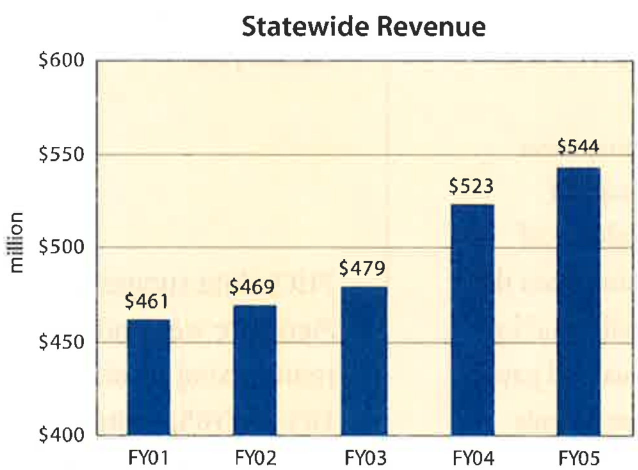
Uncompensated care as a percent of net patient revenue has dropped from 2.46% in FY01 to 2.10% in FY05.

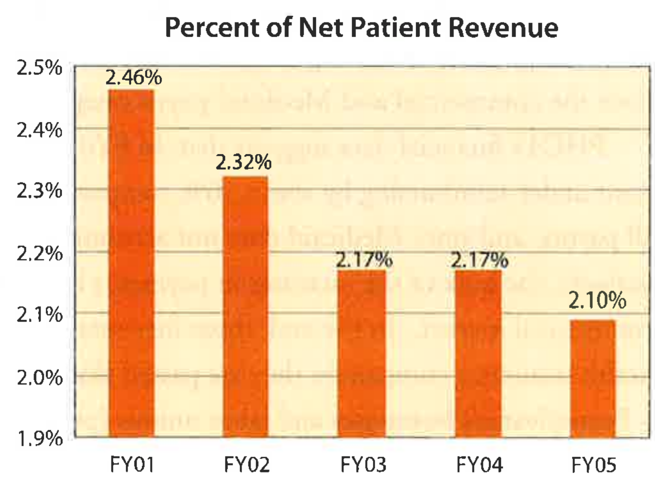
Uncompensated Care

In FY05, Pennsylvania hospitals provided $544 million in uncompensated care, up from $461 million in FY01. Uncompensated care is a combination of bad debt and charity care. While the dollar value has grown, uncompensated care as a portion of all patient care has fallen. From FY01 to FY05, uncompensated care as a percent of patient revenue declined from 2.46% to 2.10%.

In FY05, the uncompensated care rates across the state were relatively uniform with 91% of hospitals reporting uncompensated care rates between 1% and 4%. Only seven of the state's 177 hospitals had an uncompensated care rate below 1%, and 12 hospitals had rates above 4%. Of these 12 hospitals with the highest rates, all were small facilities, and seven were rural.

Uncompensated Care* - Pennsylvania GAC Hospitals





Source: PHC4
*Uncompensated Care Revenue is an estimate of the revenue hospitals would have received for uncompensated care based on actual reimbursements in the respective reporting years.

Health Status

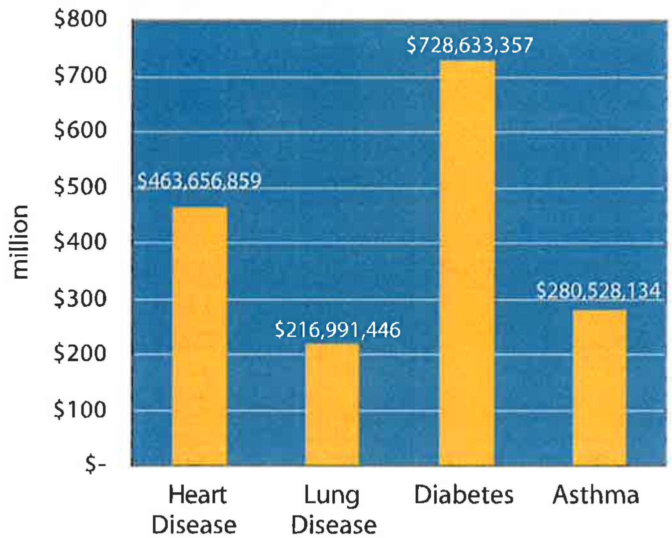
While there are countless ways to measure the health of a population, this report focuses on several of the most costly chronic conditions and modifiable personal health behaviors. This approach was taken for two reasons. The first is that 75% of health care costs in Pennsylvania can be traced to the 25% of patients with chronic diseases.[40] The second is that most of these chronic illnesses are made worse due to modifiable behaviors, such as physical inactivity, poor diets and smoking.

Seventy-five percent of health care costs in Pennsylvania can be traced to the 25% of patients with chronic conditions.

The human cost of chronic disease in Pennsylvania is staggering. In 2004, over 54,000 deaths in the state could be attributed to six chronic diseases: heart disease, hypertension, stroke, chronic lower respiratory disease, diabetes and asthma.[41] In 2005, there were some 63,000 hospitalizations for heart disease, lung disease, diabetes and asthma, which incurred $1.7 billion in statewide hospital charges.[42] As these 2005 hospitalizations just take into account people under age 65, the actual numbers are undoubtably greater.

By 2020, it is estimated that half of all Pennsylvanians will have at least one chronic condition.[43] It is hoped that a redoubling of disease management and preventive care efforts will impact hospitalization rates for chronic illnesses.

Pennsylvania Hospital Charges for Potentially Avoidable Hospitalizations* for Chronic Diseases in 2005



Source: Governor's Office of Healthcare Reform/PHC4
Note: Hospitalizations for persons 65 and over not included.
* Based on the Agency for Healthcare Research and Quality (AHRQ) Prevention Quality Indicators (PQIs).

Hospitalizations for Chronic Conditions

	Number of Hospitalizations		Total Charges	
	1995	2005	1995	2005
Diabetes				
Short-Term Complications	4,312	5,186	$53,335,933	$134,911,417
Long-Term Complications	9,521	13,677	$143,525,035	$490,048,318
Uncontrolled Diabetes	3,681	1,975	$22,549,328	$28,016,909
Chronic Obstructive Pulmonary Disease	27,222	26,710	$342,680,665	$662,748,538
Congestive Heart Failure	58,941	61,294	$741,074,334	$1,704,567,339
Adult Asthma	14,231	17,231	$122,666,845	$330,844,325

Source: PHC4
Note: Includes hospitalizations for all age groups including 65 and over.

The number of diabetes hospitalizations increased by 19% from 1995 to 2005.

Diabetes

Diabetes is a widespread, chronic disease caused by the inability of the body to produce or properly use insulin. It is characterized by high blood sugar levels. Diabetes predisposes people to costly complications, including heart disease, hypertension and stroke. It is the leading cause of new cases of blindness, end-stage renal failure, and non-traumatic lower extremity amputation. Despite advances in education, detection and disease management efforts, diabetes continues to be an enormous public health concern across the Commonwealth.

Estimated Diagnosed Diabetes Prevalence Per 1,000 Pennsylvania Adults, 1995-2005

Source: PA Department of Health, Pennsylvania Behavioral Risk Factor Surveillance System Survey

Approximately 81 out of every 1,000 Pennsylvania adults reported that they had been diagnosed with diabetes in 2005, compared to 57 out of 1,000 in 1995.[44] In 2005, there were 20,838 hospitalizations for uncontrolled diabetes and its short- and long-term complications in Pennsylvania; these hospitalizations accounted for 113,000 hospital days and more than $652 million in hospital charges. In 1995, there were 17,514 diabetes hospitalizations – 19% fewer. One positive diabetes trend is that the in-hospital mortality rates for its short-term and long-term complications, as well as for uncontrolled diabetes, have all decreased from 1995 to 2005.

Adult asthma hospitalizations increased by 21% from 1995 to 2005.

Asthma

Asthma is a chronic inflammatory disease of the lungs' airways which makes breathing difficult. It is the most common chronic childhood disease. Studies have shown that when patients are taught how to control their disease by following established asthma management guidelines, hospitalizations, repeat hospitalizations and emergency room visits can be decreased and quality of life improved.

In 2005, 8.1% of Pennsylvania adults reported they had been told by a health professional they have asthma and that they still have asthma.[45] In 2005, 10.1% of children (under age 18) currently had asthma based upon reporting by an adult in the household that a health professional told them the child has asthma. There were 17,231 adult asthma hospitalizations statewide in 2005, accounting for 71,000 hospital days and more than $330 million in hospital charges. In 1995, there were 14,231 adult asthma hospitalizations – 21% fewer.

Chronic Obstructive Pulmonary Disease

Chronic obstructive pulmonary disease (COPD) is an incurable disease of the lungs. It includes chronic lung disorders that obstruct the airways or damage the air sacs deep in the lungs. The disease results from damage to the lungs over a period of years from such factors as smoking, occupational exposure (breathing chemical fumes, cotton, wood or mining dust), or from bacterial or viral infections.

From 1995 to 2005, the number of COPD hospitalizations in Pennsylvania decreased from 27,222 to 26,710. Despite this decline, total hospital charges for COPD increased from $343 million to $663 million during the same period.

Congestive Heart Failure

Congestive heart failure (CHF) occurs when the heart loses its ability to pump enough blood through the body. Heart failure usually worsens over time as the heart gradually loses its pumping ability and works less efficiently, resulting in high blood pressure and fluid collection in the lungs.

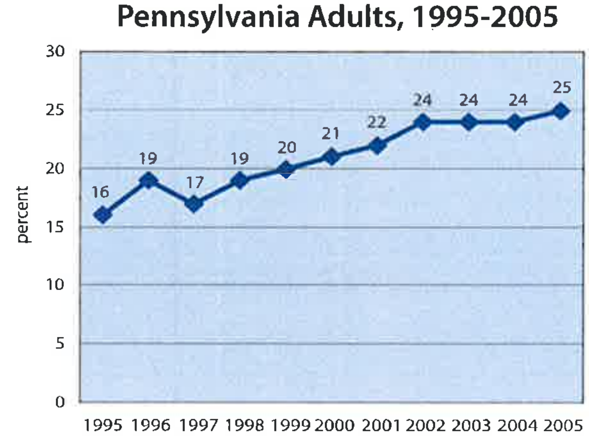
From 1995 to 2005, the number of CHF hospitalizations in Pennsylvania increased from 58,941 to 61,294. In terms of total hospital charges, CHF is one of the most expensive chronic conditions. In 2005 alone, CHF hospitalizations for all age groups incurred $1.7 billion in charges. While the price tag for this condition has increased over the past decade, the good news is that the in-hospital mortality rate for CHF decreased by 36% from 1995 to 2005.

Overweight/Obesity & Exercise

Research has shown that health care utilization and costs increase as body mass increases.[46] Compared to a decade ago, more Pennsylvanians are obese.[47] Adults with a

In 2005, congestive heart failure, which is one of the most expensive chronic conditions, accounted for $1.7 billion in hospital charges.

Estimated Percent Obese Pennsylvania Adults, 1995-2005



Source: PA Department of Health, Pennsylvania Behavioral Risk Factor Surveillance System Survey

In 2005, one of every four Pennsylvania adults were cigarette smokers.

Body Mass Index (BMI) of 25 to 29.9 are considered overweight, and those with a BMI greater than or equal to 30 are considered obese. In 2004, $4.1 billion of the state's medical expenditures were attributable to adult obesity.[48]

In 2005, 61.9% of the state's adults were overweight or obese, and 25.3% were obese.[49] In 1995, 53.6% of adults were overweight or obese, and 16.4% were obese. One in three children in the state are overweight or at risk of becoming overweight, and the percentage of overweight Pennsylvania youth (18%) exceeds the national average (15.4%).[50]

Regular physical activity can help prevent or manage a variety of chronic diseases. Yet, in both 1995 and 2005, approximately one in four Pennsylvania adults engaged in no leisure time physical activity.[51]

Tobacco Use

In addition to the increased health risks among individuals, smoking bears an incredible economic burden to the Commonwealth. In 2004, the health costs related to tobacco use (cigarettes, pipes, cigars, smokeless tobacco, etc.) in Pennsylvania topped $5 billion.[52] The prevalence estimates for current smokers did, however, fall slightly from 1995 to 2005. In 1995, approximately 24.2% of Pennsylvania adults were current smokers, compared to 23.6% in 2005.[53] Among the state's youth, 29.4% of high school students and 13.8% of middle school students used tobacco products in 2002.[54]

Mortality Rates

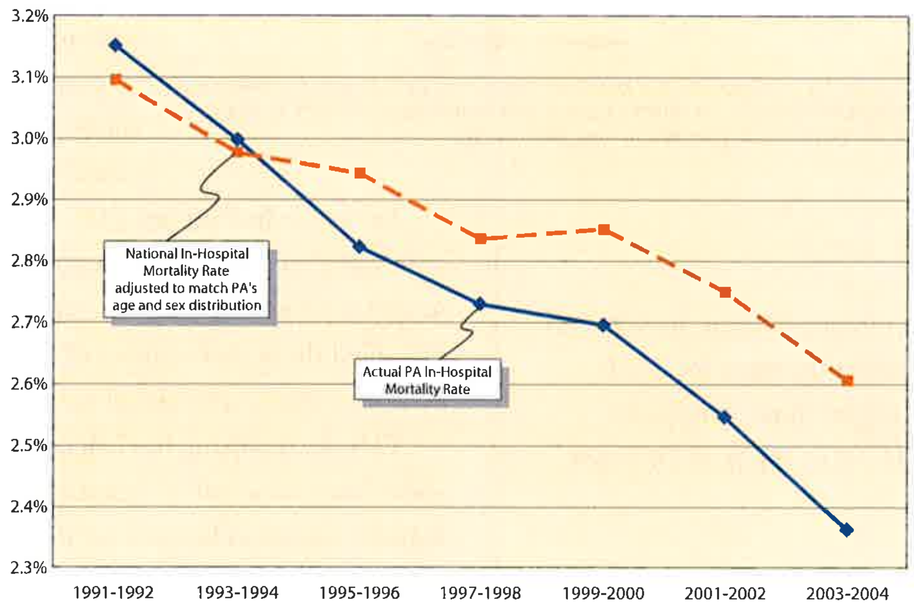
Mortality rates are key indicators of health care quality. Since PHC4 began publicly reporting patient mortality rates for Pennsylvania hospitals in its annual *Hospital Performance Report*, in-hospital mortality rates for all conditions dropped from significantly above to significantly below the national average.[55]

Also mirroring Pennsylvania's years of public reporting is the decline in in-hospital mortality for coronary artery bypass graft (CABG) surgery. In Pennsylvania, mortality rates for CABG have dropped 51.7% in the past 15 years. According to the most recent PHC4 cardiac surgery report, in-hospital patient mortality following CABG surgery in Pennsylvania fell from 1.98% to 1.90% between 2004 and 2005. That is the lowest mortality rate for the cardiac procedure in the 15 years since PHC4 began publicly reporting on this form of open-heart surgery.

The benefits of publicly reporting hospital performance and CABG surgery outcomes have been documented in the recent literature. In 2003, Dr. Judith Hibbard and colleagues from the University of Oregon found that Wisconsin hospitals that publicly reported hospital performance were significantly more likely to improve quality than two comparison groups where private reporting or no reporting was done.[56] Additionally, another 2003 study found that while CABG mortality rates have dropped nationally, they have dropped more significantly in states with public reporting, like Pennsylvania and New York, or where there are aggressive hospital-based quality improvement activities,

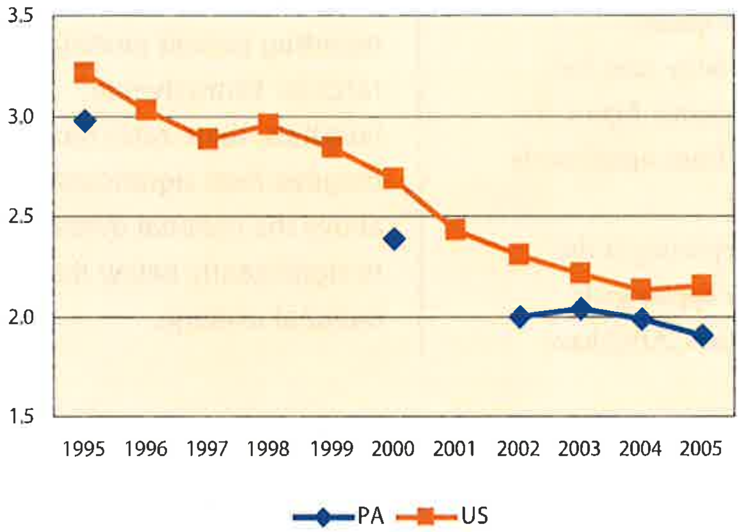
Since PHC4 began publicly reporting patient mortality rates for Pennsylvania hospitals, these rates have dropped from significantly above the national average to significantly below the national average.

In-hospital Mortality for All Conditions



Sources: (1) CDC NCHS National Hospital Discharge Survey 1991-2004; (2) PHC4

In-hospital Mortality for CABG Surgery



Sources: (1) U.S. Department of Health and Human Services' Agency for Healthcare Research and Quality. Healthcare Costs and Utilization Project (HCUP); (2) PHC4
Note: The two study populations may differ slightly.

such as the Northern New England Heart Consortium.[57]

Hospital-acquired Infections

In addition to the quality improvements that hospital performance and heart surgery report cards have achieved, PHC4 is striving to achieve similar results in terms of publicly reporting hospital-acquired infections. In 2005, Pennsylvania – through PHC4 – became the first state to publicly report such infections. PHC4's initial research brief reported the results of 11,668 hospital-acquired infection cases confirmed and submitted by Pennsylvania hospitals for the year 2004.

In Pennsylvania, in-hospital mortality rates for CABG surgery have dropped 51.7% in the past 15 years.

While CABG mortality rates have dropped nationally, they have dropped more significantly in states with public reporting, like Pennsylvania and New York.

Since this first report, PHC4 has released two additional briefs on hospital-acquired infections. Most recently, in 2006, PHC4 broke new ground by releasing the nation's first hospital-specific report that identified the actual number of hospital-acquired infections reported by Pennsylvania's individual hospitals.

PHC4's reporting has helped to change the national conversation about hospital-acquired infections. The reports received significant national attention because for the first time, actual numbers, rather than estimates or extrapolations, were made public. They have also highlighted the quality-of-care and financial consequences of hospital-acquired infections.

But perhaps the most important result of PHC4's work has been its contribution to the discussion among patients, policymakers, purchasers and medical professionals that hospital-acquired infections are not inevitable, unavoidable by-products of health care, and that many can be prevented. This has helped to lend force to the tidal wave of positive action already occurring in many health care institutions. These actions include cultural and behavioral changes that are saving numerous patient lives, improving the quality of life for countless others and saving ample health care dollars today.

References

Note: Only external sources are included in the following list. Information that is not cited is PHC4-derived.

[1]Poisal, J.A., et al."Health Spending Projections Through 2016: Modest Changes Obscure Part D's Impact." *Health Affairs*. 26(2), February 21, 2007.

[2]U.S. Census Bureau, Annual Population Estimates, http://www.census.gov/popest/archives/2000s/vintage_2001/CO-EST2001-12/CO-EST2001-12-42.html and http://www.census.gov/popest/national/files/NST_EST2006_ALLDATA.csv

[3]U.S. Census Bureau, Percent of the Total Population who are 65 Years and Over: 2005, http://factfinder.census.gov/servlet/GRTTable?_bm=y&-_box_head_nbr=R0103&-ds_name=ACS_2005_EST_G00_&-_lang=en&-format=US-30

[4]U.S. Census Bureau, *65+ in the United States: 2005*, at pages 124 and 126, http://www.census.gov/prod/2006pubs/p23-209.pdf

[5]U.S. Census Bureau, Poverty Status by State: 2005, http://pubdb3.census.gov/macro/032006/pov/new46_100125_01.htm and http://pubdb3.census.gov/macro/032006/pov/new46_185200_01.htm

[6]U.S. Census Bureau, American FactFinder, Census 2000 Summary File 3, Detailed Table P5. Urban and Rural [7].

[7]U.S. Department of Commerce's Bureau of Economic Analysis. Total Full-time and Part-time Employment by Industry – Pennsylvania: 2005.

[8]U.S. Department of Commerce's Bureau of Economic Analysis. Total Full-time and Part-time Employment by Industry – Pennsylvania: 1995.

[9]U.S. Department of Commerce's Bureau of Economic Analysis. *Survey of Current Business,* August 2006, at page 141, http://www.bea.gov/scb/pdf/2006/08August/0806_NIPA-Tables-Account-06.pdf

[10]The Hospital & Healthsystem Association of Pennsylvania. *Pennsylvania Hospitals: Partners for Economic Prosperity*. Spring 2006, at page 1.

[11]The Hospital & Healthsystem Association of Pennsylvania. *Pennsylvania Hospitals: Partners for Economic Prosperity*. Spring 2006, at page 2.

[12]Milbank Memorial Fund, National Association of State Budget Officers, and The Reforming States Group. 2002-2003 State Health Care Expenditure Report, Table 14, Milbank Memorial Fund.

[13]Centers for Medicare & Medicaid Services, Health Expenditures by State of Provider: State-specific Tables, 1980-2004, February 2007, http://www.cms.hhs.gov/NationalHealthExpendData/downloads/nhestatespecific2004.pdf

[14]Centers for Medicare & Medicaid Services, Health Expenditures by State of Provider: State-specific Tables, 1980-2004, February 2007, http://www.cms.hhs.gov/NationalHealthExpendData/downloads/nhestatespecific2004.pdf

[15]U.S. Census Bureau, Annual Population Estimates, http://www.census.gov/popest/archives/2000s/vintage_2001/CO-EST2001-12/CO-EST2001-12-42.html, http://www.census.gov/popest/archives/EST90INTERCENSAL/US-EST90INT-07/US-EST90INT-07-1995.csv, and http://www.census.gov/popest/states/tables/NST-EST2006-01.xls

[16]Centers for Medicare & Medicaid Services, Health Expenditures by State of Provider: State-specific Tables, 1980-2004, February 2007, http://www.cms.hhs.gov/NationalHealthExpendData/downloads/nhestatespecific2004.pdf

[17]Centers for Medicare & Medicaid Services, Health Expenditures by State of Provider: State-specific Tables, 1980-2004, February 2007, http://www.cms.hhs.gov/NationalHealthExpendData/downloads/nhestatespecific2004.pdf

[18]Centers for Medicare & Medicaid Services, National Health Expenditures Web Tables, http://www.cms.hhs.gov/NationalHealthExpendData/downloads/tables.pdf

[19]Centers for Medicare & Medicaid Services, Health Expenditures by State of Provider: State-specific Tables, 1980-2004, February 2007, http://www.cms.hhs.gov/NationalHealthExpendData/downloads/nhestatespecific2004.pdf

[20]U.S. Census Bureau, Health Insurance Coverage Status and Type of Coverage by State for All People: 2000 and 2005. http://pubdb3.census.gov/macro/032001/health/h05_000.htm and http://pubdb3.census.gov/macro/032006/health/h05_000.htm

[21]U.S. Census Bureau, Health Insurance Coverage Status and Type of Coverage by State for All People: 2000 and 2005. http://pubdb3.census.gov/macro/032001/health/h05_000.htm and http://pubdb3.census.gov/macro/032006/health/h05_000.htm

[22]U.S. Census Bureau, Health Insurance Coverage Status and Type of Coverage by State for All People: 2000 and 2005. http://pubdb3.census.gov/macro/032001/health/h05_000.htm and http://pubdb3.census.gov/macro/032006/health/h05_000.htm

[23]The Commonwealth Fund. *The Best Health System in the World*, President's Message 2006 Annual Report, http://www.cmwf.org/usr_doc/Pres_Message_2006_FINAL_small_file.pdf

[24]U.S. Census Bureau, Number and Percent of Children Under 19 At or Below 200% of Poverty by Health Insurance Coverage and State: 2005, http://pubdb3.census.gov/macro/032006/health/h10_000.htm

[25]Kaiser Family Foundation, *Employer Health Benefits 2007 Summary of Findings*, http://www.kff.org/insurance/7672/upload/Summary-of-Findings-EHBS-2007.pdf

[26]Families USA. *Premiums Versus Paychecks: A Growing Burden for Pennsylvania's Workers*. October 2006, http://www.familiesusa.org/assets/pdfs/premiums-vs-paychecks/pennsylvania.pdf

[27]Families USA. *Premiums Versus Paychecks: A Growing Burden for Pennsylvania's Workers*. October 2006, http://www.familiesusa.org/assets/pdfs/premiums-vs-paychecks/pennsylvania.pdf

[28]Health Annual Statements filed with the Pennsylvania Insurance Department and the National Association of Insurance Commissioners, 2001 and 2005.

[29]Health Annual Statements filed with the Pennsylvania Insurance Department and the National Association of Insurance Commissioners, 2001 and 2005.

[30]Pennsylvania Insurance Department, Determination & Order on Reserve and Surplus Levels of State Blue Plans, February 9, 2005, http://www.ins.state.pa.us/ins/lib/ins/whats_new/2004bc/BCBS_DETERMINATION.PDF

[31]American Hospital Association, TrendWatch Chartbook 2007, http://www.aha.org/aha/trendwatch/2007/cb2007chapter4.ppt#268,13,Chart 4.10: Median Average Age of Plant, 1990 – 2005

[32]American Hospital Association, TrendWatch Chartbook 2007, http://www.aha.org/aha/trendwatch/2007/cb2007appendix2.ppt#257,2,Table 2.1: Number of Community Hospitals,(1) 1981 – 2005

[33]American Hospital Association, TrendWatch Chartbook 2007, http://www.aha.org/aha/trendwatch/2007/cb2007appendix2.ppt#258,3,Table 2.2: Number of Beds and Number of Beds per 1,000 Persons, 1981 – 2005 and http://www.aha.org/aha/trendwatch/2007/cb2007appendix2.ppt#259,4,Table 2.3: Beds per 1,000 Persons by State, 2004 and 2005

[34]American Hospital Association, TrendWatch Chartbook 2007, http://www.aha.org/aha/trendwatch/2007/cb2007chapter2.ppt#266,9,Chart 2.6: Number of Freestanding Ambulatory Care Surgery Centers, 1996, 1998, and 2000 – 2006

[35]The Dartmouth Atlas Project, http://www.dartmouthatlas.org/faq.shtm

[36]American Hospital Association, *The Migration of Care to Non-hospital Settings: Have Regulatory Structures Kept Pace with Changes in Care Delivery?*, at page 5, http://www.aha.org/aha/trendwatch/2006/twjuly2006migration.pdf

[37]U.S. Department of Health and Human Services' Health Resources and Services Administration. *What is Behind HRSA's Projected Supply, Demand and Shortage of Registered Nurses?* September 2004, ftp://ftp.hrsa.gov/bhpr/workforce/behindshortage.pdf

[38]U.S. Department of Health and Human Services' Health Resources and Services Administration. *What is Behind HRSA's Projected Supply, Demand and Shortage of Registered Nurses?* September 2004, ftp://ftp.hrsa.gov/bhpr/workforce/behindshortage.pdf

References

[39]American Association of Colleges of Nursing, Nursing Shortage Fact Sheet, http://www.aacn.nche.edu/Media/FactSheets/NursingShortage.htm

[40]Pennsylvania Governor's Office of Health Care Reform, *Rx for Quality*, January 2007, http://www.ohcr.state.pa.us/prescription-for-pennsylvania/Rx-for-Quality.pdf

[41]Pennsylvania Governor's Office of Health Care Reform, *Prescription for Pennsylvania,* January 2007, at page 33, http://www.ohcr.state.pa.us/prescription-for-pennsylvania/Prescription-for-Pennsylvania.pdf

[42]Pennsylvania Governor's Office of Health Care Reform, Governor Rendell's Prescription for Pennsylvania Presentation, January 2007, http://www.ohcr.state.pa.us/prescription-for-pennsylvania/Rx-for-Pennsylvania-Presentation.pdf

[43]Pennsylvania Governor's Office of Health Care Reform, *Prescription for Pennsylvania,* January 2007, at page 33, http://www.ohcr.state.pa.us/prescription-for-pennsylvania/Prescription-for-Pennsylvania.pdf

[44]Pennsylvania Department of Health, Behavioral Risk Factor Surveillance System Surveys: 1995 and 2005.

[45]Pennsylvania Department of Health, Behavioral Risk Factor Surveillance System Surveys: 1995 and 2005.

[46]Sturm, R. "The Effects of Obesity, Smoking, and Drinking on Medical Problems and Costs." *Health Affairs*. 21(2), March/April 2002.

[47]Pennsylvania Department of Health, Behavioral Risk Factor Surveillance System Surveys: 1995 and 2005.

[48]Pennsylvania Governor's Office of Health Care Reform, *Prescription for Pennsylvania,* January 2007, at page 41, http://www.ohcr.state.pa.us/prescription-for-pennsylvania/Prescription-for-Pennsylvania.pdf

[49]Pennsylvania Department of Health, Behavioral Risk Factor Surveillance System Surveys: 1995 and 2005.

[50]Pennsylvania Governor's Office of Health Care Reform, *Prescription for Pennsylvania,* January 2007, at page 39, http://www.ohcr.state.pa.us/prescription-for-pennsylvania/Prescription-for-Pennsylvania.pdf

[51]Pennsylvania Department of Health, Behavioral Risk Factor Surveillance System Surveys: 1995 and 2005.

[52]Pennsylvania Governor's Office of Health Care Reform, *Prescription for Pennsylvania,* January 2007, at page 41, http://www.ohcr.state.pa.us/prescription-for-pennsylvania/Prescription-for-Pennsylvania.pdf

[53]Pennsylvania Department of Health, Behavioral Risk Factor Surveillance System Surveys: 1995 and 2005.

[54]Pennsylvania Governor's Office of Health Care Reform, *Prescription for Pennsylvania,* January 2007, at page 39, http://www.ohcr.state.pa.us/prescription-for-pennsylvania/Prescription-for-Pennsylvania.pdf

[55]Centers for Disease Control and Prevention's National Center for Health Statistics, National Hospital Discharge Survey Data, 1991-2004, http://www.cdc.gov/nchs/about/major/hdasd/listpubs.htm

[56]Hibbard, J.H., et al. "Does Publicizing Hospital Performance Stimulate Quality Improvement Efforts." *Health Affairs*, 22(2), 2003.

[57]Hannan, E.L., et al. "Provider Profiling and Quality Improvement Efforts in CABG Surgery: The Effect on Short-term Mortality among Medicare Beneficiaries." *Medical Care*, 41(10), 2003.

Council Members

- David R. Kreider, Chair (Pennsylvania Chamber of Business & Industry - Business)
- David H. Wilderman, Vice-Chair (Pennsylvania AFL-CIO - Labor)
- Randall N. DiPalo, Treasurer (Plumbers & Pipefitters Union - Labor)
- Joel Ario (Acting Commissioner, Pennsylvania Department of Insurance - State Government)
- David B. Campbell, MD (Milton S. Hershey Medical Center - Physicians)
- Paul N. Casale, MD (The Heart Group - Physicians)
- Thomas F. Duzak (Steelworkers Health and Welfare Fund - Labor)
- Stuart H. Fine (Grand View Hospital - Hospitals)
- Catherine A. Gallagher (Lehigh Valley Business Conference on Health Care - Business)
- Joseph Huxta (AB Volvo-Mack Trucks, Inc. - Business)
- Calvin B. Johnson, MD, MPH (Secretary, Pennsylvania Department of Health - State Government)
- Brian W. Kelly (Pennsylvania Chamber of Business & Industry - Business)
- Joseph M. Kleman (AFSCME Council 13 - Labor)
- Donald Liss, MD (Aetna - Commercial Insurance Plans)
- Cynthia J. Mazer (Rohm & Haas - Business)
- Mary Ellen McMillen (Independence Blue Cross - Blue Cross/Blue Shield Plans)
- Bernard K. Murray (Pennsylvania Federation of Teachers - Labor)
- Ana L. Pujols-McKee, MD (Penn Presbyterian Medical Center)
- Estelle B. Richman (Secretary, Pennsylvania Department of Public Welfare - State Government)
- Julie A. Sochalski, PhD, RN (University of Pennsylvania School of Nursing - Nurses)
- Francis S. Soistman, Jr. (Coventry Health Care, Inc. - Health Maintenance Organizations)
- Jack Steinberg (Philadelphia Federation of Teachers - Labor)
- Stephen A. Wolfe (Indiana Regional Medical Center - Hospitals)

PHC4

Pennsylvania Health Care Cost Containment Council

Marc P. Volavka, Executive Director

225 Market Street, Suite 400, Harrisburg, PA 17101

Phone: 717-232-6787 • Fax: 717-232-3821

www.phc4.org

Legislative Budget and Finance Committee

A JOINT COMMITTEE OF THE PENNSYLVANIA GENERAL ASSEMBLY
Offices: Room 400 • Finance Building • Harrisburg • Tel: (717) 783-1600
Mailing Address: P.O. Box 8737 • Harrisburg, PA 17105-8737
Facsimile (717) 787-5487

Quality Assurance for Specialized Clinical Services

Conducted Pursuant to HR 356 of 2003

April 2005

Table of Contents

Table of Contents (Continued)

Page

Table of Contents (Continued)

Page

Summary and Recommendations

House Resolution 356 of 2003 directed the Legislative Budget and Finance Committee, in consultation with health care experts and specialists, to study health care services requiring extraordinary expertise and resources, such as cardiac catheterization, open heart surgery, and organ transplants. The resolution also requires identification of standards for the safe and effective provision of such services, including volume proficiency standards, and information on how their quality has been assured since the sunset of Pennsylvania's Certificate of Need Program (CON) in December 1996. Pennsylvania was one of 14 states[1] without CON programs in 2004.

Quality of Care and Patient Safety for Highly Specialized Clinical Services

Certain medical procedures are associated with risks of known serious complications, including death, and have success and failure rates that are associated with operator skill and expertise. Highly specialized clinical services, such as those identified in HR 356, are among the medical procedures with higher risk of serious complications and success and failure rates associated with operator skill and expertise.

As higher risk procedures have been introduced, professionals and health care experts—those closest to the delivery system who see themselves as most responsible for health care quality and safety—have developed practice guidelines for the provision of such services. The American College of Cardiology and the American Heart Association (ACC/AHA), for example, have task forces that regularly gather information based on research findings and make recommendations for the safe and effective provision of therapeutic catheterizations and open heart surgery—the two most common interventional and invasive procedures used to treat heart disease. The ACC/AHA guidelines typically include a variety of standards, including operator and facility proficiency volume standards in view of research showing the relationship between procedural volumes and increased likelihood of patient survival.

Using New York state's mandatory, audited cardiac databases, which were developed and are overseen by a group of cardiologists and national health research experts, Hannon and colleagues found:[2]

- Patients undergoing therapeutic catheterizations (PCI) had higher risk adjusted rates of inpatient deaths and emergency open heart surgery compared to the statewide average when the procedure was performed by cardiologists with annual procedure volumes less than 75 procedures per year, at hospitals performing fewer than 400 procedures per year.
- Patients undergoing open heart surgery (Coronary Artery Bypass Graft, or CABG) performed by higher volume surgeons in higher volume hospitals have the lowest mortality rates. The lowest risk-adjusted CABG mortality occurred for patients undergoing surgery in hospitals with 600 or more CABGs per year and surgeons performing at least 125 procedures per year.

Also using New York's database, Babak and colleagues found:

- Patients receiving therapeutic catheterizations to treat "heart attacks" when procedures were performed by high-volume physicians at high volume hospitals had a 49 percent lower in-hospital mortality rate than those treated at low-volume hospitals. The benefit of procedures performed by high-volume physicians, moreover, was muted when the procedure was performed at a low-volume hospital.

The Department of Health and Human Services' Agency for Healthcare Research and Quality (AHRQ)—the lead federal agency charged with supporting research designed to improve the quality of patient care and safety—has developed a series of inpatient quality of care indicators. Procedure volumes and mortality are among AHRQ's quality of care indicators. The following Exhibit displays the AHRQ procedure volume and mortality quality indicators for therapeutic catheterization and cardiac surgery along with relevant medical specialty society practice guidelines and reported mortality rates from national cardiology registries. Major health benefit managers involved in promoting health care quality have also developed proficiency volumes for certain highly specialized clinical services. These are also shown. The AHRQ recommends that facilities performing below its minimum procedure benchmarks or having mortality rates above its benchmarks should have their performance reviewed to assure the quality of their care.

[1]Other states without CON programs include: Arizona, California, Colorado, Idaho, Indiana, Kansas, Minnesota, New Mexico, North Dakota, South Dakota, Texas, Utah, and Wyoming.
[2]Citations for the peer reviewed journals in which the research was reported are found in the full report.

Quality of Care Indicators for Highly Specialized Cardiac Services

Therapeutic Catheterization (PCI)

	Procedural Volume	Mortality
AHRQ Quality Benchmark	*Recommended: Facility:* 400 procedures annually. *Minimum: Facility:* 200 procedures annually.	1.46%
ACC/AHA Guidelines	*Recommended:* *Facility*—400 procedures annually. *Operator*—75 procedures annually. *Minimums:* *Facility:* 200 procedures annually. Facilities performing fewer than 200 procedures should carefully consider whether to continue to offer service, unless in a geographically underserved area. *Operators* performing fewer than 75 procedures should develop a defined mentoring relationship with a highly experienced operator who performs greater than 150 procedures annually.	1.4[a]
Other	*Major Employer Group:* Employees should be directed to facilities performing 400 procedures annually.	

Open Heart Surgery (CABG)

	Procedural Volume	Mortality
AHRQ Quality Benchmark	100-200 procedures annually.	3.54%
ACC/AHA Guidelines	Ongoing outcome tracking with close monitoring of individuals and institutions performing fewer than 100 procedures annually.	3.5[b]
Other	*American College of Surgeons:* 100 to 125 cases annually to maintain quality programs, and 200 cases annually for the facility to function efficiently. *Major Employer Group:* 450 procedures annually.	

[a]American College of Cardiology National Cardiovascular Data Registry—Observed Mortality Rate.
[b]Society of Thoracic Surgeons National Cardiac Surgical Database—1994 risk adjusted rate.
Source: Developed by LB&FC staff.

AHRQ does not have quality indicators for organ transplant services. The federal Department of Health and Human Services' Center for Medicare and Medicaid Services (CMS), however, has established proficiency volumes and survival rates for such services, and the federal organ transplant network publishes national survival rates by center volume. The exhibit below provides CMS's proficiency volumes and survival rates.

Center for Medicare and Medicaid's Organ Transplant Quality Indicators

	Heart	Liver	Lung	Kidney[a]
Proficiency Volumes[b]	12 transplants/year	12 transplants/year	10 transplants/year	15 transplants/year
Survival Rates	73% survival after 1 year and 65% after 2 years.	77% survival after 1 year and 60% after 2 years	69% survival after 1 year and 62% after 2 years.	Expected rates vary by age and type of transplant

[a]Medicare's minimum utilization rate for unconditional designation as a renal transplant center. Conditional designation may be granted centers performing 7 to 14 transplants annually.
[b]On February 4, 2005, Medicare proposed revised volumes and survival rates for programs providing transplants to Medicare enrollees.
Source: Developed by LB&FC staff.

State Use of Practice Guidelines and Proficiency Volumes for Highly Specialized Clinical Services

Typically, states that regulate (either through certificate of need and/or licensure) highly specialized clinical services rely on national practice guidelines such as those of the ACC/AHA to assure quality of care. Several neighboring and large states that regulate cardiac services, for example, reference such guidelines and have established provider proficiency volumes as part of their efforts to assure quality of care. Maryland, Massachusetts, New Jersey, and Ohio require that therapeutic catheterization providers perform a minimum of 200 such procedures annually. Florida, Michigan, New York, and West Virginia require 300 or 400 procedures annually.[3] Massachusetts removes the license of diagnostic catheterization providers that do not perform 150 procedures annually.[4]

The Pennsylvania Department of Health previously incorporated nationally recognized practice guidelines, including proficiency volumes, in its State Health Services Plan. As part of the CON program, health care providers seeking to offer highly specialized clinical services in the Commonwealth had to meet the standards

[3]Massachusetts, Michigan, and New Jersey also have established minimum proficiency volumes for physicians performing such highly specialized clinical procedures.
[4]Florida, Maryland, Massachusetts, Michigan, Ohio, and West Virginia require 200 to 300 open heart procedures annually for facilities. New Jersey requires 350 procedures and New York 500. Massachusetts, Michigan, and West Virginia also have minimum physician proficiency volumes.

incorporated into the plan. With the sunset of the CON program in December 1996, Pennsylvania health care facilities were no longer required to comply with the plan's quality assurance standards.

In January 1997, therefore, the Department established work groups to review relevant plan parts to determine if it included quality assurance and patient safety criteria that should be added to existing licensure regulations. The work groups reported to the Secretary of Health that the state's licensure regulations did not include standards in national practice guidelines[5] and recommended revision of hospital licensure regulations to address cardiac catheterization, open heart surgery, and vital organ transplantation.

In 1998, the Department of Health issued regulations which incorporated many of the work groups' recommendations and some parts of national practice guideline standards. The final regulations issued by the Department, however, did not include specific proficiency volume or other quality performance benchmarks. They also did not provide for the cardiac oversight committee recommended by work groups to assist the Department with review of clinical performance data for certain services, which cardiac service providers routinely submitted to the Department.

The Department's 1998 regulations required hospitals performing highly specialized cardiac procedures to maintain and provide the Department on a quarterly basis data on:

- Patient mortality and morbidity.
- Infection and complications (such as rates of stroke, myocardial infarction, vascular complications, and emergency bypass surgery associated with therapeutic catheterizations).
- Patient risk factors.
- Volume of procedures performed.

The regulations also required hospitals to integrate such data into their quality assurance programs. In the preamble to its regulations, the Department indicated it would review the required data, and if its review raised quality of care concerns, the Department would undertake a review to determine if the concerns were valid.

In its proposed regulations for cardiac catheterization services, the Department indicated it would publish proposed values for the quality performance

[5]In 2003, when the Governor issued a comprehensive Medical Malpractice Liability Reform Plan to address state medical malpractice issues and improve patient safety, it provided for a series of reforms, including the drafting of new hospital regulations to replace current regulations that are basically 20 years old. The Governor's Office of Health Care Reform has been working with the Department to revise the state's hospital licensure regulations. The Department had not published such proposed regulations as of January 2005.

measure that might trigger further review by the Department. When issuing final regulations, the Department indicated it would not identify values that might trigger a performance review, noting that it did not think low procedure volume "proved" a quality of care problem. The preamble was silent on whether other quality performance indicators, such as patient death rates or higher than expected procedural complication rates, might trigger a quality assurance review by the Department.

In an effort to avoid duplicate data collection, the Department later advised hospitals they were no longer required to submit cardiac data they had been submitting to the Department, noting that the data hospitals submitted to the Pennsylvania Health Care Cost Containment Council (PHC4) would meet hospital licensure requirements. The data collected by the PHC4,[6] however, does not currently address all of the items previously reported to the Department and needed to address relevant patient risk factors and complications identified in DOH hospital regulations.

The Department also entered into an agreement with the Council for annual cardiac service reports that include proficiency volumes and other performance data. Since 1998, the PHC4 has provided such reports to the Department of Health for its use in identifying potential quality of care problems for highly specialized clinical services. The LB&FC staff reviewed the reports PHC4 prepares for the Department and other relevant data. We found:

- *Since 1996, the number of hospitals offering specialized cardiac services has substantially increased.* As of mid-2002, 38 of Pennsylvania's 67 counties had cardiac catheterization laboratories—seven more counties than in 1996, with an additional 15 counties having more laboratories than they did in 1996. Twenty-seven counties had open heart surgery programs—six more than in 1996, with nine counties having more programs than in 1996.

  In some areas, proliferation of cardiac services has occurred. Luzerne County, for example, went from having one open heart surgery program in 1996 to three in 2002, and Chester County went from having no program to three. The report lists the 107 facilities providing diagnostic catheterization (including the 21 post-CON programs), 68 providing therapeutic catheterizations (including 31 post-CON programs), and the 65 open heart surgery programs (including 23 post-CON programs) through December 2003.

[6]The Council's rich data set, does not include many of the items previously collected by the Department to take into account patient and procedure risk, such as the patient's New York Heart Association classification, or relevant patient outcomes such as rates of emergency bypass surgery and stroke associated with cardiac catheterizations. The Council's data for cardiovascular services, moreover, does not include 70 percent of the data reported to the American College of Cardiology National Cardiovascular Data Registry, and important elements required to adequately adjust for patient and procedural risk.

- *In 2002, one-third (7 of 21) of the cardiac catheterization programs with open heart surgery that started after the sunset of CON were not meeting the ACC/AHA's minimum proficiency volumes, though all adult cardiac catheterization facilities with open heart surgery programs approved under CON were meeting them.* The AHRQ recommends that when facilities do not meet its minimum procedural volume for therapeutic catheterizations, further review occur to assess the program's quality of care. The ACC/AHA suggests that programs not meeting its minimum proficiency volumes consider whether to continue their programs, unless they operate in an underserved geographic region.

- *The average number of catheterizations performed by programs without open heart surgery programs declined between 1996 and 2002, resulting in more of these diagnostic catheterization programs not meeting the volume proficiency standards that had been in place in the Department of Health's last State Health Service Plan (300 procedures annually).* Fourteen of the catheterization programs without open heart surgery performed fewer than 300 procedures annually in 1996, including two that performed fewer than 100 procedures. By 2002, the number of programs performing fewer than 300 procedures increased to 27, with 7 performing fewer than 100 procedures. Eleven of these programs would be "delicensed" if operating in Massachusetts, and the remainder be subjected to quality assurance review by the state licensure agency and its cardiac advisory committee.

- *Pennsylvania facilities are performing more therapeutic catheterizations than expected based on the federal AHRQ quality utilization indicator.* Utilization rates are also relevant quality of care indicators since rates for certain procedures vary widely with differences not accounted for by age or clinical factors. AHRQ reports the expected rate of therapeutic catheterizations is 528.16 procedures per 100,000 population at risk (i.e., those 40 years and older). Based on AHRQ's quality utilization indicator and state population data, Pennsylvania would expect to have had approximately 30,000 therapeutic catheterizations performed in 2000. Significantly more (over 40,000 annually), however were reported in the FY 1999-00 and FY 2000-01 Department of Health Annual Hospital Questionnaire Data.

- *Therapeutic catheterization mortality rates are higher at facilities that do not meet the ACC/AHA and AHRQ recommended proficiency procedural volumes.* Pennsylvania facilities' performance was consistent with the literature. Facilities performing more than 400 therapeutic catheterizations annually had average observed mortality rates of 1.35 percent, while those performing fewer than 100 procedures had a 1.78 percent average mortality rate. Eighty-seven percent of the approximately 155,000 catheterizations in our analysis were performed by high volume facilities. Nonetheless, 6 of the 18 facilities in our analysis performing fewer than 200 therapeutic catheterizations annually had mortality rates greater than the AHRQ mortality benchmark (1.46 percent) that should trigger a quality assurance review.

- *New York's observed mortality rate for therapeutic catheterizations is roughly half that of Pennsylvania's.* In 2002, Pennsylvania's therapeutic catheterization providers had a 1.28 percent observed mortality rate compared with New York's rate of 0.70 percent for the same period. When multi-year data (2000 through 2002) are considered, Pennsylvania providers had a 1.45 percent mortality compared with New York's rate of 0.72 percent. New York providers performed an average number of procedures roughly twice that of Pennsylvania providers.

- *PHC4 reports prepared for the Department of Health identify deaths of patients receiving outpatient diagnostic and therapeutic catheterizations each year since 1998.* In 2003, nine facilities reported deaths of nine patients that received outpatient diagnostic catheterizations, and five reported deaths of five patients that received outpatient therapeutic catheterizations. The Department of Health's 1998 licensure regulations indicate outpatient catheterizations are only to be performed for low-risk patients. The Department, however, did not adopt the last State Health Services Plan definition of low risk patients, did not define "low risk" patients in its 1998 regulations, and did not form a cardiac advisory committee to assist with the development of "low risk" patient criteria, as recommended in 1998 by the Pennsylvania Chapter of the American College of Cardiology.

- *PHC4 reports prepared for the Department of Health show deaths of children receiving open heart surgery at adult open heart surgery program.* In 2003, two open heart surgery deaths for children were reported by adult open heart surgery programs. This is of concern because heart surgery programs for children have different requirements than programs for adults.

- *In late 2002, the Department of Health with limited public input started to issue exceptions to current hospital licensure regulations authorizing selected health care facilities to perform emergency and elective therapeutic catheterizations (PCI) without onsite open heart surgery backup, despite the ACC/AHA practice guidelines recommending most (i.e., elective) therapeutic catheterizations be performed at programs with onsite open heart surgery backup.* The committee of career professional (medical, nursing, legal) staff within the Department responsible for reviewing licensure exception requests denied selected hospitals' requests to perform therapeutic catheterizations without onsite open heart surgery, according to the documentation provided to the LB&FC. ACC/AHA guidelines (and the Pennsylvania Department of Health) recommend that all elective PCI be performed at hospitals with onsite open heart surgery. Subsequently, and without prior notice of the decision being published in the Pennsylvania Bulletin, the then Secretary of Health approved an exception to hospital licensure regulations to allow certain hospitals without onsite cardiac surgery units to perform emergent and elective PCI as part of a state demonstration. All of the demonstration sites have programs providing therapeutic catheterizations with onsite open heart surgery within the county and/or in neighboring counties. Most (5 of 8) are in areas where not all existing programs are meeting ACC/AHA's minimum proficiency volume standards.

The licensure exceptions issued by the Department are controversial since medical researchers are not in agreement that the benefits to patients outweigh the increased risks associated with provision of PCI without onsite cardiac surgery backup. States that regulate cardiac services, moreover, typically do not permit such procedures.[7]

West Virginia is the only state regulating cardiac services that also has a state PCI demonstration project underway. Pennsylvania's demonstration sites, however, would not meet the criteria West Virginia established for its demonstration. Pennsylvania demonstration sites, for example, are not required to comply with ACC/AHA minimum proficiency guidelines for facilities and operators. Two of three Pennsylvania sites operating in 2003, performed an average of four therapeutic catheterizations monthly—far fewer than the monthly number required to perform a minimum of 200 procedures annually.

Pennsylvania sites do not have standard requirements, such as standardized informed patient consent forms. One site, for example, advises patients there is less than 0.1 percent risk of death associated with therapeutic catheterizations, even though the American College of Cardiology National Cardiovascular Data Registry's observed in-hospital mortality rates for emergent PCI on stable patients is 5.4 percent. In 2004, the Department of Health began requiring new demonstration projects to advise patients of nearby programs able to provide PCI with cardiac surgery backup and require the hospitals to notify their malpractice insurance carriers they are providing therapeutic PCI without onsite cardiac surgery; these steps, however, are not required of the existing demonstration projects.[8]

[7]LB&FC staff reviewed lists of hospitals that report providing elective PCI in states that regulate cardiac services. When we contacted relevant state officials in states such as Iowa, New Hampshire, North Carolina, Tennessee, and Washington, we were advised the state does not permit elective PCI at facilities without onsite open heart surgery programs. We were further advised the hospital "should not be doing it." In the case of a facility in New Hampshire, state officials indicated the hospital started its program prior to state regulation and, therefore, was exempt from the state regulation. Other states on the list are in western states that do not regulate cardiac services. Wharton reported in late 2000 that 68 sites in the United States performed PCI without onsite open heart surgery (out of a total of approximately 800 sites), but only 22 of the 68 performed elective PCI, and many of these sites had low volumes.

[8]Medical malpractice lawsuits are generally based on tort law, which includes both statutes and court decisions. A tort is a wrongful act or omission that causes harm. Typically, a malpractice tort would be based on the claim that the health care provider was negligent, had failed to meet the acceptable standard of care owed to the patient, and thus caused injury to the patient.

In June 2004, the Department for the first time received information for three demonstration sites to review their performance. The reports the Department received were designed by the selected hospitals. They do not identify the number of emergent and elective PCIs performed. They also do not demonstrate that relevant patient selection criteria are being followed, or that procedures were subject to peer review, including instances in which patient death or other adverse patient consequences occurred. They do show, however, that most emergent PCIs are not performed within 120 minutes of arrival at the hospital, as recommended by ACC/AHA guidelines (because of the importance of rapid restoration of blood flow to the heart) and required by the Department of Health as criteria for receipt of a hospital licensure exception.

- One of the three hospitals with licensure exceptions (operating in 2003) did not meet the criteria for any of its relevant patients.

- Two of the three hospitals did not meet the criteria for 60 percent or more of their relevant patients.

LB&FC staff also found discrepancies in the number of procedures and deaths reported by one of the facilities to a voluntary registry for submission to the Department and the data reported to the PHC4 as required by state law. The hospital had reported one death in the catheterization laboratory in the voluntary dataset, though two deaths were captured in the PHC4 dataset. The hospital subsequently advised us it had not reported all therapeutic catheterizations to the PHC4, and confirmed two patient deaths had occurred, as shown in the PHC4 data. Other differences in the reporting occurred because of differences in the way the hospital reported attempted and unsuccessful PCI.[9] Complete reporting to the PHC4 is mandatory in state law.

When the Department of Health initiated the PCI demonstration a national clinical trial was not available for interested hospitals. A national clinical trial is currently being developed. States that regulate cardiac services, including Maryland, New York, New Jersey, and Ohio may allow selected hospitals to participate in the national trial. Researchers from Johns Hopkins are interested in qualified Pennsylvania hospitals participating in the national trial.

- *Despite a 15 percent drop in the number of CABG surgeries from 1995 to 2002, 18 new cardiac surgery programs opened.* The two factors combined have resulted in the average volume of procedures performed in Pennsylvania going from 450 annually—the facility volume required in Pennsylvania's last State Health Services Plan—to 270 procedures. In 2000, New York and New Jersey cardiac service providers were performing over 50 percent more procedures on average than Pennsylvania providers.

[9]LB&FC staff have been advised that attempted and unsuccessful PCI should be rare occurrences.

- *Over one-half of Pennsylvania's transplant programs have lower than expected one year patient survival rates for adult patients receiving kidney, liver, heart, and lung transplants. For most programs, however, the differences between their actual and expected survival rates did not reach thresholds requiring further evaluation by the Organ Procurement and Transplant Network (OPTN)—the federally established organization responsible for the national list of patients waiting for organ transplants and matching organ donors and recipients.* Each transplant program in Pennsylvania has expected patient (and graft) survival rates established by the Scientific Registry of Transplant Recipients (SRTR) based on the characteristics of those served in their programs and the experience of programs nationwide serving similar types of patients during the same time-frame. The SRTR is federally required to post center specific survival and other data at its website twice each year. The SRTR website provides data for groups of transplant recipients at different periods of time, and as a result, a specific center's expected survival and actual survival rates continually change. The SRTR website notes that survival rates cannot be compared across programs. The Medicare program has reported that based on the Scientific Registry data posted in July 2004, 10 percent of the adult kidney, liver, heart and lung programs nationwide had lower than expected one-year patient and graft survival rates and met all of the criteria used by the OPTN to 'flag' possible poor performances. LB&FC staff reviewed similar scientific registry data from January 2005 and found that only 8.62 percent of Pennsylvania's programs had lower than expected one-year patient and graft survival that met all OPTN thresholds that would trigger a performance review. This suggests that Pennsylvania organ transplant programs as a group perform as well as programs nationwide. In addition to the OPTN provisions, the Department of Health regulations state that the Department is to review programs when actual survival rates are lower than their OPTN (i.e., SRTR) expected rates. In June 2004, the Department advised the LB&FC staff that information on all of its investigations and reviews of licensed facilities could be found at its website. We reviewed the information available at the website for all facilities with actual organ transplant patient survival rates lower than their expected rates, but were unable, however, to identify any reviews the Department had conducted of any of these programs.

Recommendations

1. **The Department of Health should routinely review the cardiac data hospitals submit as part of state licensure requirements.** The purpose of this review would be to identify programs that are not meeting Agency for Healthcare Research and Quality and other recognized performance benchmarks and to identify programs that may not be in compliance with existing licensure provisions related to performance of outpatient catheterizations and open heart surgery for children. To facilitate its review, the Department should work with the Pennsylvania Health Care Cost Containment Council to revise the current reports to incorporate the AHRQ quality benchmarks. Hospitals not meeting the relevant benchmarks, or hospital licensure requirements, should be requested to document steps they have taken or are taking to address quality concerns, and where necessary, submit a corrective action plan.

   The federal Medicare program and voluntary accreditation agencies are moving to incorporate evidenced-based performance measures in their processes for assuring quality care and patient safety. Recently, Congress required hospitals to start reporting on an initial set of quality performance indicators or have their Medicare payment levels reduced. The Department of Health currently serves as the designated state survey agency for the Medicare and Medicaid programs. Implementation of the quality performance reviews provided for in existing state licensure requirements for highly specialized clinical services, such as cardiac services, is consistent with Medicare and Medicaid programs efforts to assure quality of care.

2. **The Department of Health, working with the Pennsylvania Chapter of the American College of Cardiology, should take steps to form a cardiac oversight committee to assist the Department.** The cardiac clinical oversight committee (of state and national experts) should be used by the Department to:

   - develop clinical guidelines to inform hospital regulations, including guidelines for identification of low risk cardiac patients for whom outpatient catheterization procedures are appropriate and instances where cardiac surgery may be performed for children in adult programs;
   - develop performance criteria including rates of complications and mortality and proficiency volumes, for highly specialized cardiac services;
   - assist with the refinement of reporting requirements for such services since data currently reported to the PHC4 is not consistent with Department of Health regulations and does not lend itself to adjusting for relevant differences in patients and procedures;
   - review and interpret current and future data available to the Department and the Council;

- review plans of correction that are submitted to the Department; and
- develop guidelines and standards for peer review.

In 1996, the Legislative Budget and Finance Committee recommended the Department utilize a cardiac oversight committee for highly specialized cardiac services, and in 1998, the Pennsylvania Chapter of the American College of Cardiology recommended that such a committee be formed. More recently, legislation introduced in the House of Representatives directs the Department to establish clinical oversight committees to assist with quality assurance for highly specialized clinical services, including cardiac services.

3. **The Department of Health should institute a moratorium on approval of additional hospital licensure exceptions for provision of PCI without cardiac surgery onsite.** The ACC/AHA guidelines, and the Department of Health, recommend that patients undergo PCI at programs with cardiac surgery onsite. Medical researchers are not in agreement that PCI can routinely be provided without onsite cardiac surgery without further exposing patients to adverse consequences. PCI and cardiac surgery programs, moreover, are available throughout the state, PCI with onsite cardiac surgery would appear to be the current community standard of care in Pennsylvania, and existing PCI programs with cardiac surgery appear to have the ability to perform additional procedures based on their current procedure volumes.

4. **The Department of Health should require all current PCI demonstration sites to join a national clinical trial and comply with all requirements and protocols of the national clinical trial.** The Department of Health in late 2002 granted exceptions to hospital regulations to allow selected hospitals to perform primary and elective therapeutic catheterizations without onsite open heart surgery allowing them to conduct a two year demonstration. Such highly specialized clinical services present considerable risk to patients. At the time the Department provided two year approval for such projects to operate, a national trial was not available for interested hospitals. We recommend Pennsylvania hospitals that have received hospital licensure exceptions to perform PCI without onsite open heart surgery should be permitted to continue to do so only as part of a national clinical trial with well developed protocols and supervision provided by the trial principals.

Hospitals whose licensure exception will expire in 2005 should be allowed until January 2006 to gain admission to the national trial. During this period, when oversight and responsibility for the quality of care and patient safety rests with the Department of Health, the Department should require demonstration sites to use a standard patient consent form reviewed and approved by a committee of interventional cardiologists and follow the requirements recently established by

the Department for new demonstration projects (regarding notification of nearby hospitals with cardiac surgery units and notification to malpractice insurers).

The Department should also utilize the cardiac advisory committee to develop reporting requirements and standards for programs that have received exceptions to hospital licensure regulations, and a system for peer review of procedures performed at such sites, including 100 percent review of all cases with adverse patient occurrences, and all attempted and unsuccessful procedures. Failure to accurately and fully report all procedures, including unsuccessful PCI, to the PHC4 and the Department of Health should have consequences, possibly even immediate revocation of the licensure exception.

5. **The Department of Health should routinely review survival data for individual transplant programs and follow-up with programs with lower than expected survival rates.** Such data are readily available to the Department of Health and the public. The Department should assure that a system of follow-up is in place as set forth in Pennsylvania hospital licensure regulations.

I. Introduction

House Resolution 356 of 2003 directed the Legislative Budget and Finance Committee, in consultation with health care experts and specialists, to study health care services requiring extraordinary expertise and resources and how their quality has been assured since the sunset of Pennsylvania's Certificate of Need (CON) in December 1996. The resolution specifically identified cardiac catheterization and open heart surgery and organ transplant as services requiring extraordinary expertise and resources. (Appendix A provides a copy of the resolution.)

Study Objectives

Specifically, the study sought to:

- Identify highly specialized clinical services requiring extraordinary expertise and proficiency for their safe and effective delivery.
- Identify Pennsylvania health care facilities providing such services.
- Identify recognized standards for provision of such service, including volume standards related to clinical proficiency, staff training and expertise, and resources required to effectively respond to clinical emergencies with provision of such specialized services.
- Assess the extent to which such standards are included in voluntary quality assurance programs and state health care facility regulations in Pennsylvania and other states.
- Identify ways to ensure that health care facilities are performing services requiring extraordinary clinical expertise and resources according to recognized standards.

Scope and Methodology

To identify highly specialized clinical services requiring extraordinary expertise and proficiency, we consulted with the Department of Health, the Pennsylvania Medical Society, and the Hospital & Healthsystem Association of Pennsylvania. We also examined peer reviewed and published health care research focusing on quality performance measures.

Our consultation and review confirmed the specific services identified in House Resolution 356 require specialized expertise and resources for their safe and effective provision. While experts have identified other services that also require specialized clinical expertise for their safe and effective provision, and we have

noted examples of such services within the report, our study's analysis focused specifically on the services identified within the resolution.

To identify health care facilities providing certain highly specialized clinical services in Pennsylvania, we analyzed Department of Health data from the Annual Hospital Questionnaire. We also relied on Pennsylvania Health Care Cost Containment Council data. While there are differences in the two data sets, together they provide the most complete overtime and current lists of specialized clinical service providers in Pennsylvania.

To identify standards for provision of highly specialized services, we consulted with health care experts, reviewed published guidelines of professional groups such as the American College of Cardiology and the American Heart Association, and reviewed health care research. We also reviewed the 2000, Institute of Medicine's report *Interpreting the Volume-Outcome Relationship in the Context of Health Care Quality*, the July 2004, *Guide to Inpatient Quality Indicators: Quality of Care in Hospitals—Volume, Mortality, and Utilization* prepared by the Department of Health and Human Services, Agency for Healthcare Research and Quality, and relevant federal regulations for transplant centers.

To assess the extent to which such standards are included in voluntary quality assurance programs and state health care facility regulations in Pennsylvania and other states, we reviewed voluntary quality assurance program standards. We also reviewed Pennsylvania's regulatory requirements to assure quality of care for highly specialized services and those of selected states.

To identify ways to ensure that health care facilities are performing services requiring extraordinary clinical expertise and resources according to recognized standards, we reviewed the approaches taken in Pennsylvania and in other states. We also spoke with health care experts and specialists in Pennsylvania. As quality assurance standards for certain highly specialized services rely on review of performance data, we examined the available quality performance data for highly specialized clinical services provided in the Commonwealth.

Within the report when reporting cardiac services performance measures, we have typically reported observed hospital mortality rates for the state and groups of health care providers. The LB&FC would have preferred to utilize performance data that has been risk adjusted to take into account differences in patient and procedural risk factors. Such data, however, are not available for comparison to national and other state data.

In October 1998, the Department of Health published notice in the Pennsylvania Bulletin that hospitals were no longer required to submit data on cardiac services to the Department of Health for the Department to assess their compliance with its cardiac service regulatory requirements and for quality assurance. The Department further advised hospitals they could fulfill their licensure regulatory requirement by providing information specified in the regulations to the Pennsylvania Health Care Cost Containment Council. The published notice indicates that the Council apprised the Department it would provide the information to the Department in quarterly reports for its use.

LB&FC staff has used the reports prepared by the Council for the Department using hospital discharge data from mid-1998 through calendar year 2003. We combined the quarterly data for individual facilities into single- and multi-calendar years for purposes of analysis and comparison with the Agency for Healthcare Research and Quality benchmarks and states such as New York, which have nationally recognized cardiac databases. The Council's reports are currently the only mandated source of information on volume of cardiac procedures and hospital patient mortality associated with such procedures.

Hospitals report significant data to the Pennsylvania Health Care Cost Containment Council, and the Council has a rich data set. Nonetheless, the data the Council gathers for cardiovascular services such as therapeutic catheterizations does not include 70 percent of the data reported to the American College of Cardiology National Cardiovascular Data Registry, including data elements required to adequately adjust for procedural risk. The Council's data (and the reports it provides to the Department of Health) do not include significant information on patient risk factors, such as the patient's New York Heart Association classification. The dataset, moreover, does not include information on adverse patient outcomes, such as rates of emergency bypass surgery, strokes, or heart attacks associated with the procedure, which are specifically referenced in the Department of Health regulations. In part for these reasons, we reviewed, but did not rely upon, the quarterly adjusted data provided by the Council to the Department of Health in our analysis.

Acknowledgments

We appreciate the cooperation we received from the Secretary and staff of the Pennsylvania Department of Health and the Pennsylvania Health Care Cost Containment Council. We also appreciate the assistance and support provided by the Hospital & Healthsystem Association of Pennsylvania, the Pennsylvania Medical Society, the American College of Cardiology staff, and physicians from the Pennsylvania Chapter of the American College of Cardiology who assisted our work.

Important Note

This report was developed by Legislative Budget and Finance Committee staff. The release of this report should not be construed as an indication that the Committee or its individual members necessarily concur with the report's findings and recommendations.

Any questions or comments regarding the contents of this report should be directed to Philip R. Durgin, Executive Director, Legislative Budget and Finance Committee, P.O. Box 8737, Harrisburg, Pennsylvania 17105-8737.

II. Findings and Conclusions

Quality of Care and Procedure Proficiency Volumes

A. Procedure proficiency volumes are recognized indicators of health care quality.

Certain medical procedures are associated with risks of known serious complications, including death, and have success and failure rates that are associated with operator skill and expertise. Highly specialized clinical services, such as cardiac catheterization,[1] open heart surgery, and organ transplant services identified in HR 356, are among the medical procedures with higher risk of serious complications and success and failure rates associated with operator skill and expertise.

Professional care providers, those closest to the delivery of health care, typically see themselves as most responsible for the quality of health care. Historically, such professionalism has resulted in self examination and the development of professional standards and guidelines for provision of care to which professional care providers voluntarily adhere.

In 1996, the American Board of Medical Specialties, for example, approved a New Certificate of Added Qualification (CAQ) in Interventional Cardiology to address the minimum training, experience, and cognitive and technical skills judged by the profession to be necessary for the competent performance of therapeutic catheterization. Such additional requirements are considered necessary because admission to one of the medical specialty boards is not intended to bestow a special license or particular credential, and ". . . it has never been a guarantee that an individual possesses specific technical or procedural skill."[2]

As increased numbers of patients are exposed to higher risk procedures, medical professionals and health care experts have also developed practice guidelines associated with their provision. The American College of Cardiology and the American Heart Association (ACC/AHA), for example, have task forces to gather information based on research findings and make recommendations about appropriate diagnosis and treatment of patients with cardiovascular disease. Such practice

[1]Cardiac catheterization is a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in a patient; subsequently the free end of the catheter is manipulated by a physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays and an electronic image intensifier are used as aides in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures.
[2]Topal, E., *Textbook of Interventional Cardiology*, Philadelphia: W.B.Saunders Company, p. 922.

guidelines are in place for interventional and invasive procedures such as PCI[3, 4] and Coronary Artery Bypass Graft Surgery.[5] The ACC/AHA's most recent guidelines for PCI, for example, address patient selection criteria, procedural complications, outcomes for various interventions, patient management including appropriate settings for provision of service, quality assurance, and operator and institutional competency, including proficiency volume standards.

Use of National Practice Guidelines and Efforts to Improve Quality of Care and Assure Patient Safety

The medical profession is not the only group concerned with healthcare quality and patient safety. State governments, voluntary accreditation organizations and health care providers, federal agencies, and major health care purchasers also focus on quality and ways to improve quality of care, including the quality of highly specialized clinical services.

State Governments: States often rely on the national practice guidelines to establish state standards for provision of specialized clinical services. As discussed below in Findings D and E, states often incorporate ACC/AHA practice guideline standards in their certificate of need requirements and/or licensure requirements.

Voluntary Accreditation Organizations: National voluntary accreditation organizations, such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), do not require that accredited healthcare organizations comply with national practice guidelines as a condition for accreditation. They do, however, suggest that national practice guidelines are excellent benchmarks for use by medical staff when granting clinical privileges to provide specific services.

JCAHO also encourages the use of performance data in quality assurance. The purpose of introducing such measures into the accreditation process is to accurately understand the basis for current performance so that better results can be achieved through focused improvement actions.

[3]Smith, SC, Jr, Dove JT, Jacobs AK, Kennedy JW, Kereiakes D, Kern MJ, Kuntz RE, Popma JJ, Schaff HV, Williams DO. *ACC/AHA guidelines for percutaneous coronary intervention: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines* (Committee to Revise the 1993 Guidelines for Percutaneous Transluminal Coronary Angioplasty). J Am Coll Cardiol 2001; 37:2239 i-lxvi.
[4]PCI (percutaneous coronary interventions) refers to the broad group of percutaneous techniques capable of relieving coronary narrowing. Such techniques include rotational atherectomy, directional atherectomy, extraction atherectomy, laser angioplasty, implantation of intracoronary stents and other devises for treating coronary atherosclerosis, including percutaneous transluminal coronary angioplasty (PTCA).
[5]Eagle KA, Guyton RA, Davidoff R, Ewy GA, Fonger J, Gardner TJ, Gott JP, Herrmann HC, Marlow RA, Nugent WC, O'Connor GT, Orszulak TA, Rieselbach RE, Winters WL, Yusuf S. *ACC/AHA guidelines for coronary artery bypass graft surgery: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines* (Committee to Revise the 1991 Guidelines for Coronary Artery Bypass Graft Surgery). J Am Coll Cardiol 1999; 34:1262-346.

JCAHO has introduced core performance measures into the accreditation process for acute myocardial infarction, heart failure, pneumonia and related conditions, and surgical infection prevention. Starting in 2004, JCAHO accredited hospitals with an average daily census greater than 10 must select core measure sets that meet JCAHO's requirements, and as part of the accreditation process, Commission surveyors will assess how health care organizations have integrated performance measures into their quality improvement activities.

Federal agencies: The federal Center for Medicare and Medicaid Services (CMS)[6] in the Department of Health and Human Services has been working with various organizations to identify clinical quality measures and promote public reporting of performance on such measures as part of its voluntary Hospital Quality Initiative. In 2003, Congress provided strong incentives for voluntary reporting on a "starter set" of 10 quality measures[7] when it enacted legislation stipulating that hospitals not voluntarily reporting data for 10 quality measures would have lower Medicare payment updates (0.4 percent lower) than hospitals reporting such data. In July 2004, the Department of Public Welfare reported to the Medical Assistance Advisory Committee it had initiated discussions with the hospital industry about including quality and performance standards as part of the state's Medicaid payment system.

CMS has also initiated a quality incentive demonstration as part of its Hospital Quality Initiative. This initiative involves voluntary reporting on an expanded set of quality measures.[8] Several Pennsylvania hospitals are participating in this CMS initiative.[9]

As part of its efforts to promote quality of care and public information on hospital care performance, the Department of Health and Human Services requested the National Quality Forum (NQF)[10] to begin work to develop national consensus standards for hospital care performance measures. NQF's initial set of quality measures include several involving specialized clinical services, including:

[6]Formerly referred to as the Health Care Financing Administration (HCFA).
[7]The starter set of 10 hospital quality measures for acute myocardial infarction/heart attack include aspirin at arrival, aspirin at discharge, beta-blocker at arrival, beta-blocker at discharge, ACE inhibitor for left ventricular systolic dysfunction; for heart failure include left ventricular functional assessment, ACE inhibitor for left ventricular systolic dysfunction; and for pneumonia include initial antibiotic timing, pneumococcal vaccination, and oxygenation assessment.
[8]Such measures include PCI received within 120 minutes of hospital arrival for AMI, AMI inpatient mortality rates, and CABG inpatient mortality rates.
[9]Pennsylvania hospitals participating in the Premier Hospital Quality Incentive demonstration include Albert Einstein Medical Center, Bon Secours Holy Family Regional Health System Altoona, Bryn Mawr Hospital, Frankford Hospital, Lankenau Hospital, Meadville Medical Center, Methodist Hospital Philadelphia, Paoli Memorial Hospital, South Hills Health System—Jefferson Hospital, St. Luke's Allentown, St. Luke's Hospital Bethlehem, St. Vincent Health Center Erie, and Thomas Jefferson University Hospital. Such hospitals may qualify for financial payments if they demonstrate provision of superior quality care.
[10]The National Quality Forum was established in 1999 to facilitate widespread healthcare quality improvements in part by endorsing national healthcare quality performance measurement and reporting systems.

- PCI volume
- PCI mortality
- PCI within 120 minutes of arrival for AMI/heart attack
- CABG volume
- CABG mortality

Within the federal Department of Health and Human Services, the Agency for Healthcare Research and Quality (AHRQ) is the lead agency charged with supporting research designed to improve the quality of health care and patient safety. AHRQ has developed a series of inpatient quality of care indicators that take advantage of available hospital discharge data. They include:

- *Volume*: These indicators are proxy, or indirect, measures of quality based on evidence suggesting that hospitals performing more of certain intensive, high-technology, or highly complex procedures may have better outcomes for such procedures.
- *Mortality*: These indicators include procedures and conditions where mortality has been shown to vary across institutions and for which there is evidence that higher mortality may be associated with deficiencies in the quality of care.
- *Utilization*: High or low rates for these indicators are likely to represent inappropriate or inefficient delivery of care.[11]

The AHRQ's most recent set of inpatient quality indicators include specific volume and mortality indicators for seven conditions and procedures, including two common procedures used to treat coronary artery disease: [12]

- Therapeutic cardiac catheterizations, i.e., Percutaneous Transluminal Coronary Angioplasty (PTCA/ PCI) and
- Coronary Artery Bypass Graft Volume (CABG), the major type of open heart surgery.

The AHRQ acknowledges its quality indicators rely on administrative data, and not direct clinical measures, but stresses that such administrative data can serve as a starting point for further investigation to assess potential quality-of-care problems and identify approaches to address such problems. Health care providers with poor outcomes on a particular indicator, for example, can initiate reviews of

[11]Department of Health and Human Services, Agency for Healthcare Research and Quality, *Guide to Inpatient Quality Indicators: Quality of Care in Hospitals—Volume, Mortality, and Utilization*, June 2002 AHRQ Pub. No. 02-RO204, Revision 3 (July 21, 2004).
[12]The other conditions include: Pediatric Heart Surgery, Esophageal Resection, Pancreatic Resection, Abdominal Aortic Aneurysm Repair, and Carotid Endarterectomy.

patient records to verify the reported outcomes and investigate potential quality of care problems.

Major Employers: Major employers are also involved in efforts to improve the quality of care and patient safety. The Leapfrog Group for Patient Safety, for example, is a group of Fortune 500 companies and other large private and public health benefit managers whose mission is to trigger giant leaps in safety, quality, and affordability of healthcare. The group as part of its evidence-based safety standards has developed proficiency volumes for highly specialized cardiac (and other) services that it encourages employers to use in referring employees for care.

B. Research shows procedure volumes are associated with quality of care for highly specialized clinical services.

Research has shown procedure volumes are associated with health care quality, including quality of care for highly specialized clinical services. In 2000, the Institute of Medicine (IOM)—a unit of the National Academy of Sciences—held a workshop to bring together health care experts to consider the evidence of the relationship between volume and quality. During the workshop, medical researchers summarized their systematic review of published research to assess the caliber of the research and what is known about how volume and quality of care are associated. Based on their review for eight medical conditions and procedures, including cardiac services such as PCI and CABG surgery,[13] they concluded:

> There can be little doubt that for a wide variety of surgical procedures and medical conditions higher volumes (whether assessed by hospital or by physician) is associated with better health outcomes. . . . the uniformity with which the published research documents or confirms the existence of the association is compelling. Fully 77 percent of the studies we reviewed found statistically significant associations between higher volume and better outcomes. The remaining 23 percent did not find statistically significant relationships. No study demonstrated a statistically significant association in the opposite direction. Finally, all 16 of the studies with the highest [methodology] quality scores found statistically significant associations.[14]

The medical researchers further noted, while the hypothesis that "practice makes perfect" is appealing, existing research has not been able to demonstrate what skills or practices improve as hospitals or physicians gain experience with

[13]The other procedures and conditions include acute myocardial infarction, pediatric cardiac surgery, carotid endarterectomy, abdominal aortic aneurysm repair, cancer surgery, and acquired immunodeficiency syndrome (AIDS).
[14]Halm, E., et al. "How is Volume Related to Quality in Health Care? A Systematic Review of the Research Literature," Appendix C, The Institute of Medicine's *Interpreting the Volume-Outcome Relationship in the Context of Health Care Quality: Workshop Summary*, Washington, D.C. 2000.

particular kinds of patients and how these relate to volume. The researchers suggest that the relationship is complex and includes factors such as:

- patient selection,
- severity and comorbidity (i.e., other diseases such as diabetes),
- specific processes of care,
- physician skill,
- skill of other clinicians, and
- hospital skill.

Research on Volume and Quality of Specialized Cardiac Services

When discussing the impact of surgeon and hospital volumes on CABG mortality, the researchers gave high marks to the published work of Hannan and his colleagues. Unlike other published research that relies on administrative data or voluntarily reported clinical data, Hannan's research uses the state of New York's cardiac database.

New York's cardiac database includes all providers of cardiac services in the state, is independently audited to assure its accuracy and completeness, and contains not only administrative data, but also clinical data elements. Such data allowed Hannan and his colleagues to develop a risk adjustment model for use in their work, which over the years has shown statistically significant relationships between volume and quality of care for both physicians and hospitals.

In 2003, Hannan and colleagues[15] studied 57,150 CABG procedures from 1997 to 1999 to examine the individual and combined impact of annual hospital and surgeon volume on in-hospital mortality. The study found:

- Higher volume surgeons and hospitals continue to have lower risk-adjusted mortality rates.
- Patients undergoing surgery performed by higher volume surgeons in higher volume hospitals have the lowest mortality rates.
- The lowest risk-adjusted CABG mortality (1.89 percent) occurred for patients undergoing surgery in hospitals with 600 or more CABGs per year and surgeons performing at least 125 procedures per year. For patients undergoing surgery in hospitals with fewer than 600 CABG procedures

[15]Hannan, E., et al. *Circulation*. 2003; 108:795-801.

and surgeons performing fewer than 125 procedures, the risk adjusted mortality was 2.67 percent.

The study's findings remained the same when all types of open heart surgeries, not just CABG surgeries, were included.

Hannan and colleagues also examined over 62,000 procedures performed in New York in 1991 to 1994 using the New York State Department of Health Coronary Angioplasty Reporting System database, which contains clinical variables specifically identified by the New York State Cardiac Advisory Committee as necessary to account for risk factors associated with outcomes for such procedures. They reported that patients undergoing angioplasty had higher risk adjusted rates of inpatient deaths and emergency CABG surgery compared to the statewide average when the procedure was performed:

- By cardiologists with annual volumes less than 75 procedures per year.
- At hospitals that performed fewer than 400 angioplasties a year.

They further reported that both cardiologists' and hospitals' volumes independently contributed to clinical outcomes.[16]

Research on Volume and Quality of Organ Transplant Services

Medical research has shown relationships between volume and improved patient outcomes for other procedures. Such procedures include vital organ transplantation.

The Department of Health and Human Services reported a 1995 study found that the probability of death for patients receiving a heart transplant between 1986 and 1991 at Medicare-approved transplant centers, which must treat a high volume of transplant patients, was 7 percent within 30 days and 16.2 percent within one year compared with 9.2 percent within 30 days and 19.2 percent within one year at facilities not approved by Medicare. Such differences were not attributable to patient demographics or medical risk factors encountered in heart transplantation. Similarly, a study on liver transplant services found that liver transplant programs that perform 20 or fewer transplants per year have mortality rates significantly higher than those that perform more than 20 per year.[17]

[16]Hannan, E. et al. JAMA, March 19, 1997—Vol. 277, No. 11, pp. 892-898.
[17]Edwards, E et al., New England Journal of Medicine, Vol. 341, Number 27: 2049-2053.

Possible Options in View of the Volume Quality Relationship

During the Institute of Medicine's 2000 workshop, medical researchers suggested in view of the evidence demonstrating a relationship between procedure volumes and mortality and other adverse patient outcomes several actions reasonably might be taken. These include the following:

- The public be provided data on health care provider procedural volumes.
- State governments take action to limit the number of hospitals permitted to perform certain procedures.
- Private purchasers require or provide incentives for managed care plans or employers to steer patients to high volume providers.
- Government (or other state or regional entities) use the data on volume and outcomes to promote improved performance.

C. Proficiency volumes have been identified for highly specialized clinical services, including cardiac and organ transplant services.

In view of the relationship between procedural volume and improved patient outcomes, medical specialty societies, federal agencies, and major employer groups have identified specific proficiency volumes for specialized cardiac and organ transplant services.

Proficiency Volumes for Specialize Cardiac Services

PCI Proficiency Volume: Current ACC/AHA practice guidelines for therapeutic cardiac catheterizations recommend that they be performed by:

- Operators that perform 75 or more procedures annually at facilities that perform more than 400 procedures annually.

They further recommend:

- Institutions with a PCI volume less than 200 procedures per year should carefully consider whether to continue to offer service, unless it operates in an underserved geographic region.

The federal AHRQ has incorporated such volume proficiency thresholds into its quality benchmarks. AHRQ's quality indicators for health care facilities provide for a minimum volume of 200 procedures per year and a suggested benchmark of 400 procedures per year. The Leapfrog Group for Patient Safety also recommends health care purchasers refer patients in need of therapeutic catheterizations to facilities that perform more than 400 procedures annually.

Proficiency Volumes for Specialized Organ Transplant Services

The Medicare program has recognized the relationship between volume and performance outcomes (such as one and two year patient survival rates) for major organ transplants.[18] It has established proficiency volumes in its requirements for facilities seeking to participate as organ transplantation centers and provide transplantation services to Medicare enrollees. Medicare requires that programs demonstrate proficiency for purposes of Medicare participation by annually performing:

- 15 kidney transplants.
- 12 heart transplants.
- 12 liver transplants.
- 10 lung transplants.

As discussed in Finding P, Medicare in February 2005 proposed modifications to its current requirements.

[18]See 52 *Federal Register* 10935, dated April 6, 1987, 56 *Federal Register* 15008, dated April 12, 1991, and 60 *Federal Register*, dated February 2, 1995, and 42 CFR 405.2130. The preamble to the federal regulations provides information on the basis for the federal standards.

Pennsylvania's Past and Current Standards

D. Prior to 1997, Pennsylvania assured quality of care for highly specialized clinical services through incorporation of national practice guidelines, including proficiency volumes and performance outcome monitoring, in its certificate of need (CON) standards.

Pennsylvania's certificate of need (CON) program was allowed to sunset in December 1996.[19] As part of the CON program, the Department of Health required health care providers seeking to offer clinically related health services, including cardiac catheterization, open heart surgery, and organ transplant services,[20] to meet standards specified in the Department of Health's State Health Services Plan. Pennsylvania's State Health Services Plan incorporated national practice guidelines for provision of clinically related health services, and included minimum proficiency volume standards and performance outcome measures for highly specialized clinical services with known risks of serious complications and where success and failure rates are known to be associated with operator skill and proficiency.[21]

Cardiac Catheterization Services – 1994 State Health Services Plan Requirements

Pennsylvania's last State Health Services Plan[22] required facilities that were awarded a certificate of need to provide cardiac catheterization services to:

- Perform a minimum of 300 adult angiography cases per year, with each angiographer performing 150 per year in not more than two institutions.[23]

Mirroring recognized practice guidelines, the State Health Services Plan also required.

[19]Pennsylvania is one of 14 states that do not currently have certificate of need (CON) programs. Other states without CON programs include: Arizona, California, Colorado, Idaho, Indiana, Kansas, Minnesota, New Mexico, North Dakota, South Dakota, Texas, Utah, and Wyoming, according to an early 2004 survey conducted on behalf of the Maryland Health Care Commission.
[20]Other clinically related services that required a CON included ambulatory surgery, neonatal intensive care, alcohol or other drug rehabilitation provided in hospital or non-hospital inpatient treatment programs lasting less than 60 days, inpatient comprehensive medical rehabilitation resonance imaging, inpatient medical surgical, positron emission tomography, inpatient psychiatric care, and inpatient surgery.
[21]Pennsylvania's Health Care Facilities Act specifically requires that in developing rules and regulations for licensure the Department shall take into consideration (i) federal certification standards, (ii) the standards of other third party payors for health care services, and (iii) such nationally recognized accrediting agencies as the department may find appropriate. 35 P.S. §§448.101-448.906, at §448.806.
[22]The Pennsylvania State Health Services Plan, approved June 17, 1994.
[23]The 1994 changes to the State Health Services Plan did not specify a minimum volume standard for quality assurance for pediatric facilities. Prior to 1994, the Plan called for pediatric facilities to perform 150 procedures within three years of opening.

- Cardiac catheterization services be provided in a licensed acute care hospital with inpatient medical/surgical services, a coronary care unit with 24-hour a day monitoring capability, a peripheral vascular surgery program, and the capacity to provide non-invasive cardiac diagnostic modalities.
- Therapeutic catheterizations services be performed in hospitals with open heart surgery programs and not in any other facilities.
- Cardiac catheterization services in hospitals without open heart surgery on site only perform diagnostic procedures on low risk patients.[24]
- Hospitals collect prospective data and monitor clinical outcomes related to service.

To assure hospitals were only performing appropriate cardiac catheterization procedures and help it assure quality of care, the Department of Health required submission of data on each diagnostic catheterization performed by hospitals. Exhibit 1 provides a list of the data hospitals reported to the Department of Health. The Department also formed a Cardiac Catheterization Oversight Committee to advise the Department concerning the data submitted since it had eliminated certain quality outcome performance standards[25] that had been in place since 1983 and replaced them with plans for a "peer monitoring" process.

The Department of Health's Cardiac Oversight Committee: When the Department first convened the Cardiac Catheterization Oversight Committee in July 1990, it directed the Committee to:

- Determine the expected occurrence of normal findings and set a threshold value for monitoring the possible "overuse" of cardiac catheterization procedures.
- Define "serious complications" and determine the expected incidence beyond which additional steps might be necessary for quality assurance.
- Evaluate the outcome data submitted by cardiac catheterization facilities and make recommendations for appropriate corrective action.

[24] The 1994 State Health Services Plan defined low risk patients to include adults with stable symptoms who have no active congestive heart failure, no significant arrhythmias, and no significant comorbid conditions (including no hypertension, diabetes, or renal insufficiency), and whose cardiac disease does not result in inability to carry on any physical activity without discomfort and whose symptoms of cardiac insufficiency or of angina may be present even at rest (New York Heart Association Class IV Patient). High risk patients included those with any one of the following pre-catheterization conditions: angina with unstable symptoms, clinical evidence suggestive of left main coronary artery disease, history of left main coronary artery disease, uncompensated congestive heart failure, hemodynamically significant stenotic valve disease, active, infective endocarditis or cyanotic congestive heart disease.

[25] The 1990 State Health Services Plan eliminated the requirement that mortality rates not exceed 0.3 percent and procedure repetition rates not exceed 2.0 percent

The Department convened the Cardiac Oversight Committee three times in 1991. After the Department postponed a scheduled June 1991 meeting, it did not reconvene the Committee until four years later, when laboratories approved after the 1990-91 Plan revisions were having problems meeting the minimum procedural volume standards to assure quality of care. Data reports from 46 facilities that had started to perform catheterizations after the 1990 State Health Services Plan changes showed that 26 hospitals performed fewer than 300 catheterization procedures in 1994, with five performing fewer than 100. By comparison, only four hospitals performed fewer than 300 procedures in 1987.

When the Department reconvened the Committee in 1995, the Committee recommended that any laboratory performing fewer than 100 cases per year after two or more years of operations be required to undergo another CON review. Laboratories doing between 100 and 300 cases should be given an additional year to meet the minimum volume standard. Subsequently, the Department reported to the Committee that of the three hospitals that had completed fewer than 50 catheterizations, one had resubmitted a new CON application, another had relocated the lab to a different facility within the same health system, and the third had closed the laboratory.

In 1995, the Department also requested the Committee review the clinical outcome data catheterization labs submitted to the Department of Health. The data showed that nearly one-half of the catheterization laboratories performing fewer than 300 catheterizations annually were reporting more than 25 percent of their cases with normal findings, in other words, there was no finding of coronary blockage. The ACC/AHA guidelines at the time indicated that the current proportion of normal cases should not exceed 10 to 20 percent, and that 15 percent was an acceptable rate.

In December 1995, the Department indicated that it had not identified the additional steps it would take to ensure quality at cardiac catheterization laboratories doing fewer than 300 cases per year. In 1996, the Department did not reconvene the Cardiac Oversight Committee.

Open Heart Surgery – 1994 State Health Services Plan Requirements

The Department's last State Health Services Plan included a variety of standards for provision of open heart surgery based on national practice guidelines, and also included volume proficiency standards. The plan required that within three years of initiation, the open heart surgery program perform:

- 450 cases annually and each cardiac surgeon caring for patients with ischemic heart disease perform an annual minimum of 150 open heart operations.

Organ Transplant Services – 1994 State Health Services Plan Requirements

Organ transplant services typically have been available on a regional basis, in part because of the limited availability of vital organs and the national system in place for procuring and distributing organs for transplant.[26] The Department's last State Health Services Plan required facilities approved to provide transplant services to meet annual proficiency volumes after a three year start up period. Such volumes included:

- 30 kidney transplants per year.
- 15 heart transplants per year.
- 20 liver transplants per year.
- 15 lung or heart/lung transplants per year.
- 8 pancreas transplants per year.

E. In 1998, the Department of Health revised its hospital licensure regulations to include standards for certain specialized clinical services, but it did not include volume proficiency standards or specify other quality outcome standards as benchmarks to trigger quality assurance reviews.

Historically, the Department of Health relied on CON approval standards as set forth in the State Health Services Plan to assure quality of care for highly specialized clinical services since it did not routinely revise health care facility licensure standards to reflect changes in the practice of health care. In 2003, when the Governor issued a comprehensive Medical Malpractice Liability Reform Plan to address state medical malpractice liability issues and improve patient safety, it provided for a series of reforms, including the drafting of new hospital regulations, many of which are 20 years old. The Governor's Office of Health Care Reform has been working with the Department to revise the state's hospital licensure regulations. As of January 2005, the Department had not proposed revised regulations.

With the sunset of Pennsylvania's CON program in December 1996, health care facilities were no longer required to comply with the quality assurance standards in the State Health Services Plan. In January 1997, therefore, the Department of Health established work groups to review relevant parts of the plan sections to determine if it included quality assurance and patient safety criteria that

[26]In 1984, Congress passed the National Organ Transplant Act. Under the Act, the federal Department of Health and Human Services contracts for the operation of the Organ Procurement and Transplant Network (OPTN) that is responsible for the national list of patients waiting for organ transplants and the organ placement centers that matches donors and recipients, and for the Scientific Registry of Transplant Recipients (SRTR) that collects and analyzes data on all recipients of kidney, liver, heart, lung, and other organ transplants. The United Network for Organ Sharing (UNOS) operates the Organ Procurement and Transplant Network (OPTN). The University Renal Research and Education Association (URREA) operates the Scientific Registry of Transplant Recipients (SRTR).

should be added to existing health care facility licensure regulations. The work groups presented recommendations to the Secretary of Health concerning the need for facility licensure standards for six services, including cardiac catheterization, open heart surgery, and vital organ transplantation.[27]

Cardiac Catheterization – Pennsylvania's 1998 Hospital Licensure Standards and Standards in Other States

The Work Group on Cardiac Catheterization Services, after reviewing the Department's facility licensure regulations, stated that it:

> . . . found them insufficient to ensure the quality of cardiac catheterization services. In fact, the current licensure regulations do not address cardiac catheterization or contain any specific requirements for the provision of this service.

The Work Group went on to note:

> There are national guidelines for cardiac catheterization developed by the American College of Cardiology/American Heart Association (ACC/AHA), and the workgroup suggests that these be considered by all catheterization providers. Currently, there are no requirements [in Pennsylvania's health care facility licensure regulations] that these guidelines be followed.[28]

The Cardiac Catheterization Work Group recommended:

- Cardiac catheterization service be authorized under the overall license of the hospital, rather than separately.
- Diagnostic and therapeutic catheterizations be recognized as separate services.
- Adult and pediatric catheterizations be recognized as separate services.
- Freestanding and/or mobile catheterization laboratories not be permitted.
- High risk diagnostic and therapeutic catheterizations be limited to hospitals with onsite open heart surgery programs.
- The Cardiac Catheterization Oversight Committee be continued to advise and assist the Department in ensuring quality of care by reviewing outcome data gathered on cardiac catheterization procedures.

When in May 1997 the Department of Health published proposed regulations amending the standards a hospital needed to satisfy to secure authorization to perform cardiac catheterization services, the Department included most of the Work

[27]The other services included ambulatory surgical care, long-term care, and neonatal care.
[28]PA Department of Health, Quality Assurance '97, Draft Recommendations of the Work Group on Cardiac Catheterization Services, February 5, 1997.

Group's recommendations in its proposed regulations. While the proposed regulation provided for a quality assurance oversight mechanism, it did not provide for a Cardiac Catheterization Oversight Committee to advise and assist the Department.

The proposed regulations in part addressed quality assurance by requiring that hospitals providing cardiac catheterization services must maintain data on:

- patient mortality and morbidity,
- infections and complications (rates of stroke, myocardial infarction, vascular complications, emergency bypass surgery associated with PCI, etc.),
- patient risk factors, and
- volume of procedures performed (including separate volumes for diagnostic visualizations, PCI, and electrophysiology procedures).

They required hospitals to provide such information to the Department on a quarterly basis and integrate the data into the hospital's quality assurance program. The Department indicated in the proposed regulations it would review the data submitted by hospitals and other relevant information and publish values or standards, or both, for each of the factors reported to the Department. If the Department's review of such information raised concerns with the quality of care in a cardiac service program, the Department indicated it would undertake a review to determine if the concerns were valid.

In June 1998, when the Department published final regulations for cardiac catheterization service, the section on quality management retained many provisions in the proposed regulations, including the requirement that hospitals retain patient data on mortality/morbidity, infections and complications, and patient risk factors and that such information be provided to the Department. Subsequently, in an effort to avoid duplicate data collection, the Department modified its data submission requirements by allowing hospitals to submit only the data required by the PHC4, which does not include all data required by DOH regulation. (See Chapter I for additional information on currently reported data.)

The final regulations also deleted references to the Department publishing standards and values for catheterization procedures. The preamble to the Department's final regulation indicates that the Department decided not to issue proficiency volume standards for cardiac services as there is no definitive volume number that can "prove" that a program is providing substandard care. The preamble is silent on other performance outcomes such as patient death rates and higher than expected procedural complications or normal findings, which conceivably, alone or in combination with low procedure volume, might trigger a quality assurance review by the Department.

In the preamble to its final regulation, the Department of Health noted the representative of the state chapter of the American College of Cardiology recommended the Department:

> Seek ongoing professional input as the [cardiac catheterization service] regulations are implemented. Important issues which will have a direct effect on the practice of cardiac services in this state have yet to be defined, e.g., definition of 'high risk' cardiac catheterization and determination of acceptable complication rates for cardiac catheterization. During the deliberations of the work group on catheterization services, we discussed the possibility that DOH restructure and/or reconstitute the previous advisory committee. The State Chapter of the American College of Cardiology would welcome the opportunity to continue to be involved in this process.

In addition to Pennsylvania's Chapter of the American College of Cardiology, the Legislative Budget and Finance Committee's 1996 review of Pennsylvania's Certificate of Need Program [29] recommended the Department of Health:

- Convene the Cardiac Catheterization Oversight Committee in part to develop outcome standards for cardiac catheterization laboratories.
- Based on the Cardiac Catheterization Oversight Committee's review of the data submitted by cardiac catheterization laboratories share relevant information with the Department of Health licensure staff for appropriate follow-up.

The Department of Health has not formally convened a cardiac advisory committee. Recently, however, the Department did request to meet with representatives of the Pennsylvania Chapter of the American College of Cardiology.

During the course of this study, the Pennsylvania Medical Society convened a group of physicians to provide technical assistance to the Legislative Budget and Finance Committee, as called for in House Resolution 356. The Pennsylvania Chapter of the American College of Cardiology identified a group of members willing to assist the Commonwealth in reviewing technical clinical data associated with invasive and interventional cardiac procedures that is gathered by Commonwealth agencies. The Pennsylvania Chapter of the American College of Cardiology further volunteered members to assist the state should the Pennsylvania General Assembly enact legislation similar to that proposed in House Bill 2771. (Appendix B provides the Pennsylvania Chapter of the American College of Cardiology's correspondence identifying members willing to assist the Commonwealth.)

[29]The review was required by Act 1992-179 and a report issued in November 1996.

The General Assembly has provided the Department of Health with broad authority to establish health and safety standards for health care facilities. House Bill 2771 as introduced in 2004, in addition, specifically requires the Department of Health to promulgate regulations that include clinical quality indicators for specialized clinical services and a process for analyzing clinical quality indicator data, and to develop a system for clinical peer review and data-information analysis by state clinical advisory committees.

The state clinical advisory committees provided for in House Bill 2771 would further serve as an advisory board to the Secretary, conduct peer review consultations, and recommend licensure actions where there has been failure by a facility to meet key quality indicators and correct deficiencies. The proposed legislation further includes provisions for revocation-nonrenewal of a license, confidentiality and access to submitted materials and documents, and liability.

Other States' Cardiac Catheterization Requirements: Several major states similar to Pennsylvania currently rely on clinical advisory committees to assist in assuring patient safety and quality for specialized cardiac services. LB&FC staff reviewed requirements (licensure and/or CON) for cardiac catheterization service for eight comparison states (Florida, Maryland, Massachusetts, Michigan, New Jersey, New York, Ohio, West Virginia) selected because of their proximity to Pennsylvania and size. We found:

- Massachusetts and New York, and most recently Florida, have formally established ongoing cardiac service advisory committees to assist the state agency in establishing performance standards for cardiac service providers and other quality improvement matters. Other states, such as Maryland, New Jersey, and Ohio have formed ad hoc committees to provide the state agency with technical consultation.
- Massachusetts and New York cardiac service advisory committees are involved in provider performance reviews that are triggered when minimum volume proficiency standards are not met or when other relevant performance measures, such as mortality or complication rates, raise questions about quality of care.
- New Jersey utilizes an external organization approved by the state to conduct performance reviews and review plans of correction when minimum proficiency volumes are not met, and Michigan uses cardiologists for individual case reviews.
- Pennsylvania differs from the eight comparison states in that all eight states have established cardiac catheterization proficiency volume standards for health care facilities and/or physicians that are used to benchmark quality service provision. Such other state proficiency volumes are

equal to or greater than the minimum facility proficiency standards in the ACC/AHA practice guidelines.

Exhibit 2 provides information on Pennsylvania's and the eight comparison states' cardiac catheterization service requirements.

Exhibit 2

Cardiac Catheterization Requirements for Pennsylvania and Selected States

State	Annual Proficiency Volume(s)	Required Reporting	Ongoing External Advisory Committees
Pennsylvania	None	• Volume • Mortality/morbidity • Infection and complications • Patient risk factors	None
Florida	• Diagnostic: 300 • Level I Therapeutic: 300 • Level II Therapeutic: 1,100 with 400 therapeutic procedures	• Volume • Mortality • Infection rates • Nonfatal myocardial infarctions • Length of stay • Post operative bleeds • Same stay surgery • Others identified by a technical committee recently established in statute	Technical Advisory Committee: • Identifies standard data to be reported to the department • Identifies outcomes standards • Develops a risk adjustment methodology • Identifies specific steps to be taken by the department and individual hospitals that do not meet outcome standards within specified periods, including time periods for detailed case review and development and implementation of corrective action plans
Maryland	Therapeutic: 200	• Volume • Utilization • Access • Cost • Quality	Ad hoc committees formed.
Massachusetts	• Diagnostic: 300 (Performance of less than 150 results in delicensing) • Diagnostic and Therapeutic: 600, including 200 therapeutic • Physician minimum volumes also in place	• Mandatory National Cardiovascular Data Registry Reporting • Additional data submission to the state • Hospital quality assurance programs must perform assessments, including assessment of physician volumes, appropriateness of each procedure, all complications, any adverse outcomes, number of cases requiring transfer to tertiary facilities, and the technical quality of the catheterization studies, and provide a report of their findings and supporting data to the Department	• The state has data collection and interpretation technical advisory committee • The Invasive Cardiac Services Advisory Committee reviews the performance of diagnostic and diagnostic and therapeutic providers performing below established minimums (i.e., 300 and 600 procedures respectively), and the performance of physicians that do not meet minimum proficiency volumes. Based on the review of the Committee, the Department can permit a facility not meeting proficiency volumes to continue to offer service, and permit a hospital to continue to credential a physician.

Exhibit 2 (Continued)

State	Annual Minimum Proficiency Volume(s)	Required Reporting	Ongoing External Advisory Committees
Michigan	• 300 • Physician minimum volumes also in place.	• Procedure volume • Mortality and morbidity • Other procedure data requested by the state	Utilizes cardiologists in case reviews.
New Jersey	• Diagnostic: 350 • Diagnostic and selected therapeutic without cardiac surgery: 500 • Therapeutic with cardiac surgery center: 200 therapeutic • Physician volumes also in place.	• Audited procedure volumes • Mortality and complication rates • Normal study rates for specific laboratories and physicians • Percent of patients transferred to other facilities subsequent to diagnostic or therapeutic catheterizations • Number of right heart catheterization procedures	Independent external organization approved by the Department conducts a review and a plan of correction required when minimum proficiency volumes are not met.
New York	400	Coronary Angioplasty Reporting System includes: • demographic information; • patient, hospital, and cardiologist identifiers; • pre-procedural risk factors; post-PTCA complications; discharge date and disposition; • information on diseased vessels, including lesion location and type; • dilation attempt indicators; • pre-procedural and post procedural stenosis; and • bypass graft involvement in the angioplasty. State audits submitted data.	New York State Cardiac Advisory Committee developed the Coronary Angioplasty Reporting System. The committee also initiated efforts to measure risk-adjusted outcomes for CABG surgery in 1989 and has been in continuous operation ever since. In addition to reviewing state cardiac data, the committee has conducted site visits as part of departmental quality assurance efforts, and provided other assistance to the department.
Ohio	Diagnostic: 300 Therapeutic: 200	• Volume of procedures • Number of specific adverse outcomes identified in the National Cardiovascular Data Registry. • In hospital mortality • Mortality associated with reported adverse outcomes.	Ad hoc committees
West Virginia	300	• Requires Reporting to the National Cardiovascular Data Registry. • Certain providers must provide registry data reports to the state.	Utilizes an external quality assurance organization to review National Cardiovascular Data Registry data

Source: Developed by LB&FC staff.

Open Heart Surgery – Pennsylvania's 1998 Health Care Facility Licensure Standards and Standards in Other States.

The Department of Health's Work Group on Cardiac Surgical Services, after reviewing the existing regulations, concluded in 1997 that they were insufficient to ensure the quality of open heart surgery services. The group, therefore, recommended a new chapter to existing hospital regulations be developed to address open heart surgery program personnel requirements, support services, physical plants, and monitoring and oversight.

The open heart surgery work group did not recommend specific volume proficiency requirements be included in the regulations. It did, however, support the concept of a cardiac oversight committee to develop quality performance outcome measures.

When the Department of Health published final regulations for open heart surgery programs in 1998, it included many of the work group's recommendations, but not a peer oversight committee. The regulations included an expanded section on quality management and improvement and required that hospitals with open heart surgery programs maintain patient data on:

- Mortality/morbidity.
- Infections and complications.
- Patient risk factors.
- Volume of procedures performed.

The Department of Health's final open heart surgery regulations require hospitals to submit the data to the Department of Health on a quarterly basis and integrate the data into the hospital's quality assurance program. Similar to the cardiac catheterization regulations, the Department indicated it would review the data on open heart surgery to assess the quality of each hospital program. If concerns were identified as a result of such reviews, the Department would undertake a review of the program to determine if the concerns were valid.

Other States' Open Heart Surgery Requirements: LB&FC staff reviewed the open heart requirements of the other states shown in Exhibit 3. We found:

- Florida, Maryland, Massachusetts, Michigan, New Jersey, New York, Ohio, and West Virginia all have proficiency volume standards that facilities must meet. Typically, these states require that facilities perform 300 open heart surgeries annually. New York with its requirement of 500 surgeries per year has the highest facility proficiency volume.

- Massachusetts, Michigan, New Jersey, and West Virginia also have proficiency volume standards for surgeons performing open heart surgery. Ohio does not impose minimum proficiency volume standards on surgeons, but provides for quality reviews of their performance when low volumes are combined with high mortality.

Exhibit 3 provides additional information on other states' requirements for open heart surgery providers.

Organ Transplant Services – Pennsylvania's 1998 Health Care Facility Licensure Standards and Standards in Other States.

The Work Group on Organ Transplant Services[30] similarly found there was a gap in quality assurance in organ transplant services after the sunset of CON. The group stated that the federal Organ Procurement and Transplant Network (OPTN) by-laws and standards be adopted as the Pennsylvania standard, but went on to note:

> Even with the adoption of OPTN by-laws and standards, there is still a gap in quality assurance as it relates to organ transplant services. For example, the OPTN bylaws and standards do not address the need for a Medical Director and a Transplantation Coordinator.

The Work Group recommended state hospital licensure regulations be revised. It recommended the revised regulation incorporate standards from OPTN and the Medicare and Medicaid programs. The proposed regulations issued by the Department included such standards, including the requirement that programs meet volume proficiency standards where they had been identified for particular transplant types.

In general, the final regulations governing organ transplantation are similar to the Work Group's recommendations. The regulations require each transplant program to be a participating member of the OPTN and comply with its bylaws and standards and require a medical director and transplantation coordinator. The regulations also include provisions for nursing staff and other health care personnel.

The final regulations, however, differ from the Work Group's recommendations and the proposed regulations in that they do not include Medicare's proficiency volumes. The Department of Health in the preamble to its final regulation indicated it modified the Work Group's recommendation because the Department was unable to find an explanation for the selection of Medicare's proficiency volumes for liver, heart, and lung transplants.

[30]The Work Group on Organ Transplant Services was not asked to address tissue, bone marrow, and eye transplants. Such organ transplants were not addressed in the last State Health Services Plan.

Exhibit 3

Open Heart Surgery Requirements for Pennsylvania and Selected States

State	Annual Proficiency Volume(s)	Required Reporting	Ongoing External Advisory Committees
Pennsylvania	None	• Volume • Mortality/morbidity • Infections and complications • Patient risk factors	None
Florida	300	• Specific data to be collected shall be developed with the assistance of technical advisory panels.	Technical Advisory Panel to develop procedures and standards for measuring of outcomes.
Maryland	200	• Volume • Utilization • Access • Cost • Quality	Ad hoc committees formed.
Massachusetts	300 Physician minimum volumes also in place.	• Data collection system for assessment of patient selection protocols. • Data sufficient for case-by-case analysis of cardiac procedures, peer review, performance measurement and feedback, and analysis of outcomes.	Cardiac Care Quality Advisory Commission
Michigan	300 Physician minimum volumes also in place.	• Volume and source of payment • Complications/mobility/mortality • Budget and cost information • Operating schedules • Demographic information • Diagnostic information	Requires consulting agreement with a high volume existing program to: • Receive and make recommendation of surgical and support areas, staff, and training. • Work with medical staff to develop process to measure outcomes.
New Jersey	350 Physician minimum volumes also in place.	• Patient characteristics • Patient outcomes • Service to medically underserved population • Data audited at hospital expense	An independent external organization approved by the Department conducts a review and a plan of correction is developed when minimum volumes and standards are not met.

Exhibit 3 (Continued)

State	Annual Proficiency Volume(s)	Required Reporting	Ongoing External Advisory Committees
New York	500	Cardiac Surgery Reporting System (CRCS) collects cardiac surgery data, including: • Outcomes • Patient risk factors • Complication • Outcomes	New York State Cardiac Advisory Committee
Ohio	250 Quality assurance reviews for surgeons with low procedure volume and high mortality.	• Volumes of CABG and other Open Heart procedures • Length of stay • Mortality	None
West Virginia	250 Minimum surgeon volumes also in place.	Provider must participate in a national cardiovascular registry or databank.	None

Source: Developed by LB&FC staff from information obtained from other states

In place of Medicare's specified proficiency volumes, the Department's final regulation required that each program perform an "adequate number of procedures to maximize quality." It also required each transplantation program:

- Meet its expected survival rates as set forth by the national program.

When program survival rates are lower than expected, state regulations[31] provide for the Department:

- To review the program's performance to determine if the deviation can be accounted for by some unique aspect of the program, and
- Undertake a regulatory compliance review when the lower than expected patient survival rate cannot be explained.

Most of the comparison states we reviewed have some minimum volume standards for organ transplant providers. Of the eight states that we reviewed, only Pennsylvania has no proficiency volume standards, as shown in Table 1. Where states have not established minimum proficiency volumes, other restrictions may apply. West Virginia, for example, treats organ transplants as emerging technology and provides for imposition of a moratorium on their introduction. In New York, certain transplant programs without minimum proficiency volumes are limited to regional facilities involved in research.

Table 1

Minimum Volumes for Organ Transplants in Other States

	Liver	Heart	Kidney	Lung
Pennsylvania	0	0	0	0
Florida	5	12	15	2
Maryland	12	12	30	12
Massachusetts	15	12	NA	NA
Michigan	12	12	12	12
New Jersey	15	12	25	NA
New York	20	14	20	NA
Ohio	12	12	15	10
West Virginia	NA	NA	NA	NA

Source: Developed by LB&FC Staff from information provided by other states.

[31] 28 Pa. Code §158.19 (b) & (c).

Highly Specialized Clinical Services in Pennsylvania

F. After 1996, the number of Pennsylvania providers offering specialized cardiac services substantially increased.

As of mid-2002, as shown in Table2, 38 of Pennsylvania's 67 counties had health care providers with cardiac catheterization laboratories. As of June 2002,

- six more counties had labs than in 1996, and
- fifteen counties had more labs than they did in 1996.

Table 2 also shows 27 Pennsylvania counties had open heart surgery programs as of June 2002:

- Six more counties than had open heart surgery programs in 1996, and
- Nine counties with more open heart surgery programs than in 1996.

In some areas of the state, proliferation of cardiac services has occurred. Luzerne County, for example, went from having one open heart surgery program in 1996 to three by July 2002, and Chester County went from having no open heart program to three by July 2002.

Since the sunset of Pennsylvania's Certificate of Need Program in December 1996:

- 21 health care facilities established diagnostic cardiac catheterization programs,
- 31 health care facilities established therapeutic cardiac catheterization programs, and
- 23 health care facilities established open heart surgery programs.

Exhibits 4, 5, and 6 list programs that opened since CON sunset.

Table 2

Number of Facilities by County With Diagnostic and Therapeutic Cardiac Catheterization Labs and Open Heart Surgery Programs Pre and Post CON

County	Diagnostic Catheterization as of 6/30/96	Diagnostic Catheterization as of 6/30/02	Therapeutic Catheterization as of 6/30/96	Therapeutic Catheterization as of 6/30/02	Open Heart Surgery as of 6/30/96	Open Heart Surgery as of 6/30/02
Adams	0	1	0	0	0	0
Allegheny	18	18	9	11	9	11
Armstrong	1	0	0	0	0	0
Beaver	1	2	1	1	1	1
Berks	2	2	2	2	2	2
Blair	1	2	1	2	1	2
Bradford	1	1	1	1	1	1
Bucks	4	4	0	3	0	3
Butler	1	1	0	1	0	1
Cambria	2	2	1	2	1	2
Centre	0	1	0	0	0	0
Chester	4	4	0	3	0	3
Clearfield	2	2	0	1	0	1
Columbia	0	1	0	0	0	0
Cumberland	1	2	0	1	0	1
Dauphin	3	2	3	2	3	2
Delaware	5	3	1	2	1	2
Erie	2	3	2	2	2	2
Fayette	0	1	0	0	0	0
Franklin	1	1	0	0	0	0
Indiana	0	1	0	0	0	0
Lackawanna	2	2	1	2	1	2
Lancaster	3	3	2	2	2	2
Lawrence	1	1	0	0	0	0
Lebanon	1	1	0	0	0	0
Lehigh	5	4	3	4	3	4
Luzerne	1	3	1	3	1	3
Lycoming	1	1	1	1	1	1
McKean	0	1	0	1	0	0
Mercer	2	2	0	1	0	1
Montgomery	5	6	3	3	2	3
Montour	1	1	1	1	1	1
Northampton	1	1	1	1	1	1
Philadelphia	13	14	12	13	12	13
Schuylkill	0	1	0	0	0	0
Somerset	1	1	0	0	0	0
Washington	2	2	1	1	1	1
Westmoreland	4	3	1	1	1	1
York	1	3	1	1	1	1

Source: Developed by LB&FC staff from Department of Health Annual Hospital Questionnaire data.

Exhibit 4

Diagnostic Catheterization Programs Starting After 12/18/96

Year	Facility	Start Date
1997	Mercy Hospital/Wilkes-Barre	1/97
	Bon Secours Holy Family Regional Health System	8/97
	Uniontown Hospital	8/97
	Millcreek Community Hospital	10/97
1998	Frankford Hospital	3/98
	Canonsburg General Hospital	7/98
1999	Temple University Hospital	1/99
	Memorial Hospital York	6/99
2000	Mercy Providence Hospital	1/00
	Centre Community Hospital	4/00
	Chestnut Hill Hospital	4/00
	Bradford Regional Medical Center	12/00
	Warminster Hospital	12/00
2001	Hanover Hospital, Inc.	3/01
	Indiana Hospital	4/01
	Berwick Hospital Center	4/01
	Gettysburg Hospital	5/01
	Ohio Valley General Hospital	5/01
	Geisinger Wyoming Valley Medical Center	10/01
2002	Carlisle Regional Medical Center	1/02
2003	Meadville Medical Center	1/03

Source: Pennsylvania Health Care Cost Containment Council.

Exhibit 5

Therapeutic Catheterization Programs Starting After 12/18/96

Year	Facility	Start Date
1996	Abington Memorial Hospital	12/96
1997	Community Medical Center/Scranton	1/97
	Doylestown Hospital[a]	2/97
	St. Mary Medical Center	7/97
	Temple Lower Bucks Hospital	9/97
1998	Mercy Hospital/Wilkes-Barre	1/98
	Frankford Hospital	3/98
	St. Clair Memorial Hospital	4/98
	Butler Memorial Hospital	7/98
	Sacred Heart Hospital/Allentown	11/98
1999	UPMC Lee Regional Hospital	1/99
	Mercy Fitzgerald Hospital	6/99
2000	Bon Secours Holy Family Regional Health System	4/00
	Sharon Regional Health System	7/00
	Lehigh Valley Hospital/Muhlenberg	8/00
2001	DuBois Regional Medical Center	9/01
	Chester County Hospital	10/01
	Geisinger Wyoming Valley Medical Center	10/01
	Holy Spirit Hospital	10/01
2002	Main Line Hospital Paoli	1/02
	Jefferson Regional Medical Center	3/02
	Brandywine Hospital	7/02
2003	Somerset Hospital[a]	1/03
	Uniontown Hospital[b]	1/03
	Monongahela Valley Hospital[b]	2/03
	Phoenixville	7/03
	Chambersburg Hospital[b]	10/03
2004	Jameson Hospital[b]	2/04
	Montgomery Hospital[b]	7/04
	Jeannes[b]	7/04
	Holy Redeemer[b]	7/04

[a]Performed emergent PCI from 1997 through June 2000 as part of a national trial.
[b]Department of Health permits it to perform therapeutic catheterizations without onsite open-heart surgery.

Source: Developed by LB&FC staff from Pennsylvania Health Care Cost Containment Council data.

Exhibit 6

Open Heart Surgery Programs Starting After 12/18/96

Year	Facility	Start Date
1996	Abington Memorial Hospital	12/96
1997	Community Medical Center/Scranton	1/97
	Temple Lower Bucks Hospital	1/97
	St. Mary Medical Center	7/97
1998	Mercy Hospital/Wilkes-Barre	1/98
	Frankford Hospital	3/98
	St. Clair Memorial Hospital	4/98
	Butler Memorial Hospital	7/98
	Sacred Heart Hospital/Allentown	11/98
1999	UPMC Lee Regional Hospital	1/99
	Mercy Fitzgerald Hospital	5/99
2000	Bon Secours Holy Family Regional Health System	5/00
	Doylestown Hospital	7/00
	Sharon Regional Health System	7/00
2001	DuBois Regional Medical Center	4/01
	Chester County Hospital	9/01
	Geisinger Wyoming Valley Medical Center	10/01
	Holy Spirit Hospital	10/01
2002	Main Line Hospital Paoli	1/02
	Jefferson Regional Medical Center	3/02
	Lehigh Valley Hospital/Muhlenberg	6/02
	Brandywine Hospital	7/02
2003	Phoenixville	7/03

Source: Pennsylvania Health Care Cost Containment Council.

In the last half of 2003, Pennsylvania had 107 health care facilities providing diagnostic catheterization services, 68 providing therapeutic catheterizations, and 65 providing open heart surgery, according to data from the Pennsylvania Health Care Cost Containment Council. Appendices D and E provide lists of providers of cardiac catheterization services and open heart surgery during the period.

G. The number of hospitals offering organ transplants in Pennsylvania has remained relatively constant.

After the sunset of the CON program, one hospital (Pinnacle) established a kidney transplant program, though several hospitals approved to offer specific transplant programs under CON expanded their programs to cover additional types of transplants. In 1997, Pennsylvania had 16 hospitals performing solid organ transplants—the same number as in 2004. The 16 hospitals[32] include 3 offering children transplant programs and 13 hospitals offering adult programs. As shown in Exhibit 7, the 13 hospitals offering adult transplant programs include:

- 13 kidney transplant programs,
- 7 liver transplant programs,
- 6 heart transplant programs, and
- 3 lung transplant programs.

Exhibit 7

Hospital Transplant Programs

Hospital	Kidney	Liver	Heart	Lung
Albert Einstein	✓	✓	N/A	N/A
Allegheny General	✓	N/A	✓	N/A
Geisinger	✓	N/A	N/A	N/A
Hershey Medical Center	✓	✓	✓	N/A
Pinnacle Health	✓	N/A	N/A	N/A
Hahnemann	✓	✓	✓	N/A
Lankenau	✓	N/A	N/A	N/A
Lehigh Valley Hospital	✓	N/A	N/A	N/A
UPMC	✓	✓	✓	✓
Oakland VA Medical Center	✓	✓	N/A	N/A
Thomas Jefferson	✓	✓	N/A	N/A
Temple University	✓	N/A	✓	✓
Hospital of the University of Pennsylvania	✓	✓	✓	✓

Source: Developed by LB&FC staff from the OPTN/UNOS database.

[32]VA hospitals were not subject to CON. Until recently the Oakland VA Medical Center program was part of the UPMC program. In 2003, the VA hospital transplant program separated from the UPMC program.

Cardiac Services and Quality Benchmarks

H. Proliferation of cardiac catheterization services in the Commonwealth has resulted in many recently established programs not meeting the volume proficiency standards of national practice guidelines.

LB&FC staff utilized available data to assess the extent to which Commonwealth cardiac catheterization services facilities are meeting ACC/AHA's quality proficiency standards and the extent to which providers offering cardiac catheterization services under CON have had their ability to meet minimum proficiency standards compromised as a result of cardiac service proliferation. We utilized data from the Department of Health's Annual Hospital Questionnaire for FY 1995-96 and FY 2001-02 to analyze volumes of cardiac procedures performed by three distinct groups of facilities, those with:

- catheterization laboratories and CON-approved cardiac surgery programs,
- catheterization laboratories with post-CON cardiac surgery programs, and
- catheterization laboratories but without cardiac surgery programs.

Table 3 shows facilities providing therapeutic catheterizations under CON typically continued to meet ACC/AHA's minimum proficiency volumes. All of the facilities providing cardiac catheterization and cardiac surgery under CON, with the exception of two children's hospitals, met the minimum facility proficiency volumes of ACC/AHA, performing at least 200 therapeutic catheterizations in FY 2001-02, and most of these facilities are performing the recommended number of procedures (i.e., 400).

Table 3 also shows a much higher proportion of the facilities that started cardiac surgery programs after the CON program sunset are not meeting minimum facility proficiency volumes (i.e., 200) identified in the ACC/AHA minimum guidelines for therapeutic cardiac catheterization services and the quality benchmark of the federal Agency for Healthcare Research and Quality (AHRQ). A relatively smaller proportion of such facilities are meeting recommended proficiency volumes (i.e., 400) for therapeutic catheterization services. Seven[33] such programs performed fewer than 200 therapeutic procedures, and an additional six performed fewer than 400 procedures in FY 2001-2002. In other words:

- 13 of 21 facilities in this group in 2001-02, would not have met Florida or New York's volume proficiency standards (see Exhibit 2), and
- 7 would not have met Massachusetts, Maryland, New Jersey, or Ohio's volume proficiency standards.

[33]These counts and the analysis do not include two facilities that started cardiac surgery programs in FY 2001-02, and that did not report performing therapeutic catheterizations for the period.

Table 3

Comparison of Procedural Volumes for Selected Cardiac Catheterization Labs
(FY 1995-96 and FY 2001-02)

	Labs With Cardiac Surgery Programs Under CON		Labs With Cardiac Surgery Programs After CON		Labs Without Cardiac Surgery Programs	
	FY 1995-96	FY 2001-02	FY 1995-96	FY 2001-02	FY 1995-96	FY 2001-02
% of Facilities With at Least 400 PCI Procedures	73%	86%	NA	38%	NA	NA
% of Facilities With Fewer Than 200 PCI Procedures	7%	5%	NA	33%	NA	NA
Average Number of Therapeutic Procedures	767	949	NA	374	NA	NA
Average Number of Diagnostic & Therapeutic Procedures	2,952	3,357	388	1,524	315	250

Source: Developed by LB&FC staff from Department of Health Annual Hospital Questionnaire data.

In some states, such programs would be required to undergo state level quality assurance reviews.

As shown in Table 3, from FY 1995-96 through FY 2001-02, the average number of diagnostic and therapeutic catheterization procedures for facilities that started to offer cardiac surgery prior to and after the sunset of the CON program increased. The average number of catheterizations at facilities without surgery programs, however, declined.

In recent years, more cardiac catheterization providers without cardiac surgery programs are also encountering difficulty in meeting the minimum volume proficiency standards that were in effect in Pennsylvania's last State Health Services Plan. When we compared the individual facility volumes with the proficiency volumes in the state plan (i.e., 300 procedures annually), we found:

- Fourteen performed fewer than 300 procedures annually in FY 1995-96, including two performing fewer than 100.
- Twenty-seven performed fewer than 300 procedures annually in FY 2001-02, including seven performing fewer than 100.

In other words, in FY 2001-02,

- 75 percent (27 of 36) of the health care facilities in Pennsylvania providing cardiac catheterization services without cardiac surgery programs were not meeting the volume proficiency standards in place in the comparison states shown in Exhibit 2.
- Eleven of the 27 Pennsylvania providers would be "delicensed" if they were operating in Massachusetts and the remainder subject to quality assurance by the state licensure agency and its cardiac advisory committee.

I. Pennsylvania facilities are performing more therapeutic catheterizations than expected based on the federal Agency for Healthcare Research and Quality (AHRQ) quality utilization indicator.

While proficiency volume standards are important indicators of quality of care, they are not the only relevant indicators. The AHRQ has also identified other relevant quality of care indicators, such as area utilization rates. AHRQ has identified such an indicator for therapeutic catheterization services, noting that therapeutic catheterization is a potentially overused procedure, and rates vary widely with differences in procedure rates not accounted for by age or other clinical factors. More average procedure rates, therefore, represent better quality, according to AHRQ.

AHRQ reports that the expected rate of therapeutic catheterization is:

- 528.16 procedures per 100,000 population at risk (i.e., those 40 years and older).

Based on the AHRQ quality utilization indicator and state population data,[34] Pennsylvania would expect to have had approximately 30,000 therapeutic catheterizations performed in 2000. Significantly more (over 40,000 annually), however, were reported in the FY 1999-00 and FY 2000-01 Department of Health Annual Hospital Questionnaire Data.[35]

Such reported procedural volumes raise questions about the appropriateness of all therapeutic catheterization procedures performed in Pennsylvania. As noted in Finding D, in the past, the Department of Health has also raised questions about service appropriateness.

J. Pennsylvania facilities providing therapeutic catheterization services have observed mortality rates similar to reported national rates.

The federal Agency for Healthcare Research and Quality (AHRQ) has also identified procedural mortality rates as quality of care indicators. For therapeutic catheterization services, AHRQ has identified mortality greater than 1.46 percent as an indicator of a possible quality of care problem. The most recent observed mortality rate for the American College of Cardiology National Cardiovascular Data Registry (NCDR) is 1.4 percent, based on data from January 1998 through March 2001.[36]

LB&FC staff analyzed four years of data (calendar year 2000, 2001, 2002, and 2003) from patient discharges involving therapeutic catheterization procedures that hospitals report to the Pennsylvania Cost Containment Council. We found that Pennsylvania's average annual observed (in-hospital) mortality rate was 1.41 percent.

Pennsylvania facilities' performance was consistent with the literature--facilities with higher proficiency volumes had lower rates of mortality. Pennsylvania facilities with 400 or more therapeutic catheterization cases annually had an observed mortality rate of 1.35 percent. Eighty-seven percent of the approximately 155,000 therapeutic catheterizations in Pennsylvania from calendar years 2000 through 2003 were performed at health care facilities with more than 400 cases annually. Those with fewer than 400 had a 1.41 percent observed mortality rate, with

[34]2000 U.S. Census data for Pennsylvania.
[35]Higher than expected procedure volumes are also found in Pennsylvania Health Care Cost Containment data.
[36]The Journal of Invasive Cardiology 2003;15:578-580

six facilities performing fewer than 200 procedures annually having rates greater than AHRQ's 1.46 percent benchmark. For facilities with fewer than 100 procedures annually, their observed mortality rate was 1.78 percent.

K. Pennsylvania's mortality rate for therapeutic catheterizations, though similar to the national rate, is much higher than New York's.

Pennsylvania's overall mortality rate for therapeutic catheterization is comparable to reported national rates, but there appear to be opportunities for improvement. For example, the New York State Department of Health has taken an active role in helping to improve the quality of cardiac services, including therapeutic cardiac catheterizations. As noted in Finding B, New York requires all providers to submit procedure data to its cardiac registry that is overseen by the state's Cardiac Advisory Committee, which includes state and nationally recognized cardiologists and healthcare analysts.

New York health care facilities and the state health department have responded in various ways when state registry data have suggested quality problems. Such approaches include analysis of the systems of care to identify what led to adverse outcomes for patients and changes to health care processes that are faulty. In some cases, hospitals have reported improved outcomes by altering the processes of care for select groups of patients with particularly poor outcomes (i.e., emergency cases). Some facilities have altered their referral patterns to physicians, referring the most difficult cases to physicians with superior results. Some facilities have reduced the number of physicians on staff performing below minimum proficiency procedure volumes; and in some cases have withdrawn credentialing privileges. Some also completely reorganized their programs.

LB&FC staff compared the most recent publicly reported[37] observed mortality rates for New York therapeutic catheterization facilities with data for the same period for Pennsylvania facilities from the Pennsylvania Health Care Cost Containment Council.[38] As shown in Table 4, New York's observed mortality rate is roughly half that of Pennsylvania, and multi-year variation in mortality across facilities is greater in Pennsylvania than in New York. New York providers, moreover, performed roughly double the average number of procedures performed in Pennsylvania.

[37]New York State Department of Health, *Percutaneous Coronary Interventions (PCI) in New York State*, October 2004.
[38]New York is the only state that currently publishes facility and provider performance data for therapeutic catheterization services. Other states are working to implement similar reporting

Table 4

Pennsylvania and New York Therapeutic Catheterization Mortality Rates

	Number of Providers	Total Cases	Average Cases Per Provider	Observed Mortality Rate	Observed Mortality Range
Pennsylvania – 2002	66	39,490	598	1.28%	0.00—3.95%
Pennsylvania – 2000-2002	67	112,384	1,677	1.45%	0.51—5.48%
New York – 2002	41	46,090	1,124	0.70%	0.00—5.26%
New York – 2000-2002	41	128,230	3,128	0.72%	0.00—3.82%

Source: Developed by LB&FC staff from Pennsylvania Health Care Cost Containment data and published New York State Department of Health reports.

L. Other opportunities to improve the quality of Pennsylvania's cardiac catheterization services may be present.

Since 1998, the Pennsylvania Health Care Cost Containment Council, at the request of the Department of Health, has been providing the Department of Health with cardiac service reports to assist the Department in implementing hospital licensure regulations and assuring quality of care and patient safety. The requested data includes reports identifying in-hospital deaths of patients undergoing outpatient cardiac catheterizations and deaths of children receiving cardiac surgery at hospitals with adult cardiac surgery programs.

Outpatient Cardiac Catheterization Deaths

LB&FC staff reviewed all of the quarterly data provided to the Department of Health by the Council from the second half of calendar year 1998 through the fourth quarter of 2003. For each calendar year, we unduplicated the number of hospitals reporting deaths occurring for patients undergoing outpatient cardiac catheterization. As shown in Table 5, several hospitals have reported one or more deaths for patients undergoing outpatient cardiac diagnostic and therapeutic catheterizations. Some hospitals reported such deaths in multiple years. The reports do not identify if the outpatient catheterizations involved low or high risk patients.

Table 5

Number of Hospitals Reporting Deaths of Patients With Outpatient Catheterizations

Year	Number of Hospitals Performing Outpatient Diagnostic Catheterizations With Deaths (and Number of Reported Deaths)	Number of Hospitals Performing Outpatient Therapeutic Catheterizations With Deaths (and Number of Reported Deaths)
1998[a]	1 (1)	0 (0)
1999	8 (10)	5 (7)
2000	6 (12)	4 (4)
2001	8 (9)	4 (4)
2002	5 (5)	6 (6)
2003	9 (9)	5 (5)

[a]Partial year data.

Source: Developed by LB&FC staff from the Cardiovascular Reports prepared by the Pennsylvania Health Care Cost Containment Council for the Department of Health, and reporting data from July 1, 1998 through December 31, 2003.

The Department of Health's current hospital licensure regulations indicate outpatient catheterizations are only to be performed for low risk patients.[39] The Department of Health's last State Health Services Plan included a detailed definition of low risk patients for purposes of cardiac catheterization services. The Department of Health's 1998 licensure regulations, however, did not include a definition of a low risk patient for purposes of providing such services. When commenting on the Department's final regulations, the Pennsylvania Chapter of the American College of Cardiology noted the Department would need ongoing professional input to help define high risk catheterizations.

Adult Open Heart Surgery Programs With Child Deaths

The reports prepared by the Council and submitted to the Department of Health also highlight other possible opportunities for improvements. The Department of Health's licensure requirements recognize that cardiac services for children require specialized provisions. For this reason, the Council's report identifies all hospitals in which cardiac surgery is performed and a child's death occurs during such an admission. As shown in Table 6, Pennsylvania hospitals that do not have licensed pediatric cardiac surgery programs have reported child deaths during stays for open heart surgery.

[39]28 Pa. Code §138.14(b).

Table 6

Number of Adult Open Heart Surgery Programs Reporting In-Hospital Mortality for Children Following Open Heart Surgery

1998	3
1999	2
2000	2
2001	1
2002	0
2003	2

Source: Developed by LB&FC staff from the Cardiovascular Reports prepared by the Pennsylvania Health Care Cost Containment Council for the Department of Health and reporting data from July 1, 1998 through December 31, 2003.

In June 2004, the Department of Health advised the LB&FC staff that it had not used the cardiovascular reports prepared by the Council. It indicated that the reports "are not highly useful to survey process" as they cover previous year(s). The Pennsylvania Health Care Cost Containment Council advised the LB&FC that the Council prepares the reports based on the schedule requested by the Department in 1998.

In June 2004, the Department also advised the LB&FC staff that information concerning all of its investigations concerning cardiac (and other highly specialized clinical services) is found at the Department's website under Health Facility Locator and Survey Information. LB&FC staff reviewed the information at the website for all facilities reporting same stay deaths of patients that received catheterizations in an outpatient setting. We were unable to identify any report indicating the Department of Health had investigated such reported patient deaths.

M. In late 2002, the Department of Health officials started to waive key cardiac catheterization public health and safety licensure requirements with limited input and professional oversight.

Current Department of Health hospital licensure regulations require therapeutic catheterization services routinely be provided at hospitals with onsite open heart surgery programs. Similarly, the ACC/AHA guidelines recommend that such procedures be performed at hospitals with onsite open heart surgery.

The ACC/AHA guidelines allow an exception for some patients experiencing a "heart attack" and presenting at certain community hospital emergency rooms. Such therapeutic catheterization procedures are called "primary PCI," "primary angioplasty," or "emergent PCI." [40] Several important criteria for performance of

[40]"Emergent PCI" or "primary PCI" are PCIs (percutaneous coronary interventions) performed within 120 minutes for emergency acute myocardial infarction (AMI) patients seen in the emergency room with confirmed ST elevation or new left bundle branch block.

emergent or primary PCI are set forth in Tables 15 and 16 of the ACC/AHA's 2001 PCI guidelines. Exhibit 8 lists some of the key criteria.

As shown in Exhibit 8, the ACC/AHA criteria recognize the need for timely intervention to rapidly restore blood flow to the heart. The criteria, for example, indicate primary PCI procedures should be performed within 90 minutes (plus or minus 30 minutes) from arrival at the hospital. The ACC/AHA criteria also recognize operator and facility proficiency volumes are related to patient survival. They note practitioners should perform a minimum of 75 therapeutic catheterizations annually, and facilities should perform a minimum of 36 emergent PCIs annually.

Using New York's cardiac database, Babak and colleagues found low-volume physicians had a 7.1 percent observed mortality rate for primary angioplasty for acute myocardial infarction compared to a 3.8 percent rate for high volume physicians. Low volume hospitals had a 5.8 percent observed mortality rate compared to a 4.0 percent rate for high volume hospitals. Those patients treated by high volume physicians at high volume hospitals had a 49 percent lower in-hospital mortality rate than those treated at low volume hospitals. The researchers also noted the benefit of procedures performed by high volume physicians is muted when the procedure is performed at a low volume hospital.[41]

[41]*Circulation*, 2001;104:2171-2176

Exhibit 8

Criteria for the Performance of Primary Angioplasty at Hospitals Without Onsite Cardiac Surgery

Primary PCI procedures performed at facilities without onsite cardiac surgery must be performed:

- Within 90 ± 30 (i.e., not more than 120) minutes of admission,
- By a practitioner who performs 75 or more therapeutic catheterizations annually,
- At a facility that performs a minimum of 36 emergent PCIs annually,
- At a facility with a proven plan for appropriate hemodynamic[a] support capability for transfer with access within one hour to an open heart surgery operating room,
- At a facility with trained nursing and technical catheterization laboratory staff that participate in a 24 hour 365 day call schedule, and
- At a facility with rigorous case selection criteria.

Patient selected for such procedures should not include:

- Hemodynamically stable patients with:
  - Significant (greater than or equal to 60 percent) stenosis of an unprotected left main coronary artery upstream from an acute occlusion in the left coronary system that might be disrupted by the angioplasty catheter.
  - Extremely long or angulated infarct-related lesions with TIMI grade 3 flow.
  - Infarct-related lesions with TIMI grade 3 flow in stable patients with 3-vessel disease.
  - Infarct-related lesions of small or secondary vessels.
  - Lesions in other than the infarct artery.

Facilities should transfer for emergency by-pass surgery patients with:

- High-grade residual left main or multivessel coronary disease and clinical or hemodynamic instability
  - After angioplasty or occluded vessels,
  - Preferably with intraaortic balloon pump support.

[a]Movement involved in the circulation of the blood.

Source: Developed by LB&FC staff from the *ACC/AHA Percutaneous Coronary Intervention Guidelines*, JACC Vol. 37, No. 8, 2001, June 15, 2001:2239xxi.

The ACC/AHA guidelines specifically recommend non-emergent therapeutic catheterizations (also known as "elective PCI") be performed at facilities with onsite open heart surgery. Most therapeutic catheterizations are non-emergent/elective PCIs. Ninety percent of all therapeutic catheterizations performed in New York from 2000 through 2002 were non-emergent.

Starting in December 2002, the Department of Health granted exceptions to hospital licensure regulations and authorized eight hospitals to provide both emergent and elective therapeutic catheterization at facilities without onsite open heart surgery backup. Table 7 lists hospitals that received licensure exceptions. The Department advised the LB&FC that several more hospitals had submitted requests to provide emergent and elective therapeutic catheterization at facilities without onsite open heart surgery and that their requests were under review.

Table 7

Hospitals With DOH "Waivers" to Perform Emergent and Elective Therapeutic Catheterizations Without Onsite Open Heart Surgery Backup

Hospital	Date "Waiver" Authorized	Annual Number of Diagnostic Catheterizations Performed in FY 2001-02
Somerset	December 2002	28
Uniontown	January 2003	210
Monongahela Valley	February 2003	199
Jameson	February 2004	253
Chambersburg	January 2004	238
Montgomery	July 2004	251
Jeanes	July 2004	0
Holy Redeemer	July 2004	415

Source: Developed by LB&FC staff.

Department of Health Process for awarding cardiac service "waivers": The Department of Health utilized a committee of its career professional (medical, nursing, legal) staff to review requests for exceptions to hospital licensure regulations. Based on their review, the committee recommended denial[42] of the hospitals' requests to provide emergent and elective therapeutic catheterizations without onsite open heart surgery.[43] However, the then Secretary of Health subsequently determined[44] the Commonwealth would grant selected hospitals' requests to provide both emergent and elective therapeutic cardiac catheterization without onsite open heart surgery.[45] The Department did not in all cases publish notices of its subsequent reversal of its denials in the Pennsylvania Bulletin, even though its regulations require it to publish notice of its exception decisions.[46]

In June 2002, the Department first advised selected hospitals it would grant them waivers to perform:

[42]The Department advised the LB&FC the committee meetings are not open to the public and meeting notes are not prepared and maintained. The Department did, however, provide the LB&FC with copies of project denial notices issued following committee reviews.
[43]The Department of Health publishes notices of its receipt of exception requests and its approval or denial of such requests in the Pennsylvania Bulletin. From the data provided to the LB&FC, one acute care hospital listed in Table 7 did not specifically submit a formal waiver request to the Department, and notice of the hospital's request was not published in the Pennsylvania Bulletin. The Department of Health advised the LB&FC that a notice was not published in the Pennsylvania Bulletin as the Department considered the hospital as one of the "other hospitals" referred to in a related application.
[44]In some instances, such determinations occurred after providers appealed their exception denials. In other instances, the decisions were reached through discussions and development of agreements.
[45]In 1998, the Department of Health required a hospital that started performing emergency therapeutic catheterizations as part of a national clinical trial to cease performing the procedures. Subsequently, this hospital developed an open heart surgery program.
[46]28 Pa. Code §51.33(d).

- Emergent therapeutic catheterizations (emergent/primary PCI) by authorizing an exception to Pennsylvania hospital licensure regulations.[47]
- Non-emergent or elective therapeutic catheterizations (non-emergent/elective PCI) by granting an exception to hospital licensure regulations to conduct a two year "demonstration, or pilot, project" during which time such procedures could be performed without onsite open heart surgery backup.

The Department stated the demonstration would allow participants:

> . . . to provide better access to vital health services to members of their communities while establishing appropriate monitoring mechanisms to ensure that patient safety and quality assurance issues are identified and addressed.[48]

Current hospital regulations for cardiac services allow hospitals without onsite open heart surgery to perform therapeutic catheterization in emergency situations without obtaining an exception from the Department as long as the hospital reports the circumstances to the Department in writing within 72 hours.[49] By granting a hospital licensure exception for emergent or primary PCI, the Department, in effect, no longer required the hospital to promptly document the need for provision of an emergent PCI without onsite open heart surgery backup or to immediately alert the Department of the procedure for purposes of its quality assurance monitoring.

Earlier in 2002, Aversano and colleagues published results from the first randomized clinical trial highlighting the benefits of emergent or primary PCI for certain patients in certain hospitals without onsite open heart surgery backup. The researchers, however, stressed their result did not apply to all patients at all facilities. They also stressed their results did not apply to elective PCI. Specifically, they noted:

> . . . our results apply only to primary PCI for patients with acute MI with ST-segment elevation or left bundle-branch block on presenting ECG. They do not apply to rescue PCI after failed thrombolysis, to other unstable coronary syndromes such as unstable angina or MI associated with a nondiagnostic ECG, or to elective PCI.[50]

[47]The Department may grant exceptions to licensure regulations when the policy and objectives contained therein are otherwise met, or when compliance would create an unreasonable hardship and an exception would not impair or endanger the health, safety or welfare of a patient or resident. No exceptions or departures from licensure regulations will be granted if compliance with the requirement is provided for by statute. 28 Pa. Code §51.31.

[48]Department of Health correspondence June 7, 2002.

[49]See 28 Pa. Code §138.15 (restricting a hospital from performing high-risk cardiac catheterizations only if it has an open heart surgical program onsite); see also, 28 Pa. Code §138.2 (defining "high risk cardiac catheterization" to include PTCA procedures. 28 Pa. Code §138.17(c) provides that if a hospital that does not have an open heart surgery program onsite performs an emergent PTCA, the hospital shall report the circumstances to the Department in writing within 72 hours.

All medical researchers are not in agreement with the conclusion drawn from Aversano's research about the patient benefits to be gained from treating certain acute MI patients with primary PCI (rather than other available therapy) without onsite surgery backup. The randomized trial's findings have been questioned because the trial enrolled only 18 percent of the number of patients needed for statistical proof, and concerns about possible sample bias. Many initially randomized patients in the study sample were subsequently judged ineligible for the treatment to which they were assigned and were treated outside of the study's protocol. The ability of community emergency medical transport systems and community hospitals to routinely replicate the practices of the clinical trial have also been questioned.[51]

More recently, Wennberg and colleagues[52] utilized Medicare hospital data (from January 1, 1999, and December 1, 2001) to compare patient outcomes following PCI at facilities without and with onsite cardiac surgery. They found that mortality for patients with primary/rescue PCI was similar for facilities without (11.3 percent) and with (12.2 percent) cardiac surgery. For the larger non-primary/rescue PCI population, however, mortality was much higher at facilities without onsite cardiac surgery (4.6 percent vs. 2.8 percent). The odds of mortality at facilities without cardiac surgery were 38 percent higher, with increased mortality primarily confined to hospitals performing 50 or fewer Medicare PCIs per year. Wennberg and colleagues concluded:

> If PCI programs are allowed to develop in centers without on-site cardiac surgery, patients being treated by primary/rescue PCI will likely benefit. However, 78% of PCIs at institutions without cardiac surgery programs [in the study] were not primary/rescue PCIs and these patient outcomes were poorer than those in hospitals that had on-site cardiac surgery. Given that the absolute risk reduction in short-term mortality for primary PCI over thrombolysis (about 2%) is comparable with the increase in mortality for the non-primary/rescue PCI populations in hospitals without cardiac surgery, PCI performed at hospitals without cardiac surgery may be doing more harm than good.

The Wennberg study has also been critiqued. The Medicare database used in the study is limited to patients who are Medicare beneficiaries, and therefore does represent patients of all ages. The available Medicare data, moreover, has several more important limitations. It does not allow for researchers to statistically control for important patient and procedural risk factors, such as MI location, heart rate,

[50]Aversano, T. et al, JAMA, April 17, 2002, Vol 287, No 15, p. 1950

[51]See for example, *Mayo Clin Proc.* 2004;79:731-732.

[52]*JAMA*, October 27, 2004—Vol 292, No 16, 1961—1968.

blood pressure, and volume of patients presenting with shock. Without such important control data, it is not possible to determine if the reported observed differences in patient outcome are the result of patient differences or procedural and health system differences. Such differences among medical researchers highlight the need for a well designed national clinical trial with sufficient sample size from which to draw conclusions. As discussed below, such a study is currently being developed by nationally recognized medical researchers to provide the type of evidence-based research used by ACC/AHA committees in refining existing practice guidelines.

Department of Health Requirements for PCI without onsite open heart surgery: The Department of Health established certain requirements for the hospitals receiving exceptions to licensure regulations to perform primary and elective PCI without onsite open heart surgery backup, and indicated its Division of Acute and Ambulatory Care would monitor hospitals performance to ensure compliance with ACC/AHA guidelines. Exhibit 9 identifies requirements established by the Department of Health for hospitals providing therapeutic catheterizations without onsite open heart surgery.

Exhibit 9

Pennsylvania Department of Health Requirements for Selected Sites' Provision of Primary and Elective PCI Without Onsite Open Heart Surgery

Requirements for an Exception to Provide Emergent PCI

- Each hospital must comply with the standards and criteria set forth in the 2001 ACC Guidelines at Table 15 and 16. (See Exhibit 8.)

Requirements for an Exception to Provide Elective PCI as Part of a Pilot Project.

- Each hospital must identify and adopt standards and criteria that will be used in implementing non-emergent PCI. Such standards and criteria must address all relevant issues, including patient selection criteria, the criteria in Tables 15 and 16 of the ACC/AHA 2001 Guidelines, and other clinical issues raised in the guidelines (i.e., timely management of ischemic[a] complications, adequacy of specialized post-interventional care, logistics for managing cardiac surgical or vascular complications, and operator/laboratory volumes and accreditation).
- Each hospital must enlist a facility with expertise in the field to assist in the establishment of the standards and criteria, and provide required project monitoring.
- Each hospital must submit the proposed standards and criteria to the hospital institutional review board (IRB) for approval and, after the IRB has given its approval, to the Department of Health for review and approval.
- Each hospital must submit data as directed by the Department.
- Each hospital must provide evidence of how the project improves patient access to non-emergent PCI.

[a]Ischemia is a deficiency of blood in a part, usually due to functional constriction or actual obstruction of a blood vessel.

Source: Developed by LB&FC staff from correspondence signed by the Secretary of Health dated June 7, 2002.

As shown in Exhibit 9, the Department of Health did not:

- Establish minimum procedural volumes for both primary and elective PCIs for participating facilities,
- Require documentation of staff training and demonstrated ability for timely transfer of patients for emergency surgery, or
- Require 100 percent peer review of all procedures.

As a result, the Department of Health's criteria do not provide important patient safeguards used in other states.

Requirements in Other States: Several states that regulate cardiac services provide pathways for certain hospitals without onsite open heart surgery to perform emergent/ primary (but not elective) PCI for certain patients. Three of the states shown in Exhibit 2, Florida, Michigan, and New Jersey, have processes in place to allow hospitals without onsite open heart surgery backup that meet certain criteria to obtain permission to regularly perform emergent PCI for selected patients. Exhibit 10 provides key requirements used in such states.

Exhibit 10

Selected State Requirements for Emergent/Primary PCI Waivers

Florida

- Requires compliance with ACC/AHA guidelines, including operator and facility proficiency volumes
- Revokes its exemption for facilities failing to comply (within 18 months) with ACC/AHA proficiency volumes.
- Prohibits programs with revoked exemptions from reapplying for two years.
- Requires programs to review and test transfer and transport agreements.
- Requires facilities to document such transfer and transport agreements at least every three months.
- Requires compliance with the state's therapeutic catheterization reporting requirements.

Michigan

- Requires demonstrated performance of at least 400 diagnostic procedures annually.
- Requires documentation that at least 48 primary PCI will be performed annually based on submission of actual case records for patients transferred to other facilities, with the records reviewed by state staff and state-designated cardiologist to determine if primary PCI was appropriate for the patient.
- Assures compliance with ACC/AHA guidelines by requiring facilities seeking waivers to:
    - Have at least two interventional cardiologists performing primary PCI who have each performed 75 interventions annually as a primary operator at a facility with open heart surgery during the proceeding two years.
    - Have two interventional cardiologists who commit to functioning as a group willing and able to provide primary PCI at the community hospital 24/7, 365 days a year per a call schedule, and have the ability to be onsite and available to operate within 30 minutes of identifying the need for primary PCI.
    - Immediately report any changes in the interventional cardiologists who perform PCI to the state.
- Requires written agreements between a community hospital and an open heart surgery center before it will consider an application. The written agreement must include:
    - Involvement of the open heart surgery facility in the development of credentialing criteria and recommending physicians approved to perform primary PCI.
    - Provision for ongoing cross-training for professional and technical staff involved in the provision of primary PCI, along with annual documentation of competency.
    - Provision for ongoing cross training for emergency department, catheterization laboratory and critical care unit staff to ensure experience in handling the high acuity status of primary PCI patient candidates, along with annual documentation of competency.
    - Regularly held joint cardiology/cardiac surgery conferences to review all primary PCI cases.
    - Development and ongoing review of patient selection criteria for primary PCI patients, and implementation of those criteria.
    - A mechanism to provide for appropriate transfer between facilities and an agreed plan for prompt care.
    - Written protocols, signed by the community hospital and the open heart surgery facility, for provision for immediate and efficient transfer.
    - Quarterly review and testing of written protocols for patient transfer and transport.
    - Consultation on facilities, equipment, staffing, ancillary services, and policies and procedures for the provision of interventional procedures.
    - A written protocol for case selection for the performance of primary PCI consistent with ACC/AHA guidelines.
    - A written protocol to ensure primary PCI is provided within 120 minutes of the patient presenting at the community hospital emergency room.
- Requires participation in a data registry, with the hospital requesting state permission to perform primary PCI liable for the cost of data submission and of onsite reviews required for the state to verify and monitor volumes and assure quality.

New Jersey

- Requires documentation of performance of 500 diagnostic catheterizations per year and transfer of 36 primary PCI cases per year based on actual AMI cases from the prior two years.
- Requires documentation that physicians performing primary PCI have performed at least 75 interventions annually and continue to do so.
- Requires compliance with ACC/AHA guidelines.
- Requires compliance with reporting requirements.

Source: Developed by LB&FC staff.

In addition, several of the states listed in Exhibit 2, have authorized selected hospitals to perform emergent/primary PCI as part of national research trials. New York, Maryland, Massachusetts, and Ohio authorized selected hospitals to perform emergent PCI as part of national research trials conducted by Aversano and other Johns Hopkins Medical Institution researchers. In addition to the criteria established by the national trial, New York developed additional criteria for facilities receiving waivers to provide primary PCI without onsite surgery. For example, waiver applicants were required to have performed a minimum of 400 diagnostic catheterization cases a year for the previous three years, and have had good results as judged by their mortality and major complication rates. New York, moreover, required facilities with waivers to report data to its cardiac registries and it includes data for such facilities and participating physicians in its published PCI performance reports.

Typically, states that regulate cardiac services do not authorize provision of elective PCI at hospitals without onsite open heart surgery.[53] Pennsylvania and West Virginia are the only states in Exhibit 2 that have authorized certain hospitals to perform emergent and elective PCI without onsite open heart surgery.

In West Virginia, the state's certificate of need program is conducting a demonstration pilot project. West Virginia published the criteria facilities had to meet to qualify to participate in the demonstration pilot project and selected three hospitals for its demonstration. Exhibit 11 provides West Virginia's selection criteria.

[53]LB&FC staff reviewed lists of hospitals that report providing elective PCI in states that regulate cardiac services. When we contacted relevant state officials in states such as Iowa, New Hampshire, North Carolina, Tennessee, and Washington, we were advised the state does not permit elective PCI at facilities without onsite open heart surgery programs. We were further advised the hospital "should not be doing it." In the case of a facility in New Hampshire, state officials indicated the hospital started its program prior to state regulation and, therefore, was exempt from the state regulation. Other hospitals on the lists are in western states that do not regulate cardiac services. Dr. Wharton from New Hampshire reported in late 2000 that 68 sites in the United States performed PCI without onsite open heart surgery (out of a total of approximately 800 sites), but only 22 of the 68 sites performed elective PCI, and many of these sites had low volumes.

Exhibit 11

West Virginia's Requirements to Participate in a Pilot Project to Provide Emergent and Non-Emergent/Elective PCI Without Onsite Open Heart Surgery

Pilot demonstration applicant must:

- Have provided diagnostic cardiac catheterization services for a period of not less than three years.
- Have performed a minimum of 600 diagnostic catheterization procedures annually for the most recent three year period.
- Have capacity to perform a minimum of 200 therapeutic catheterizations annually within 24 months of initiating services.
- Have at least two Board certified physicians who will actively participate in the Demonstration Pilot Project.
- Demonstrate each participating physician has performed a minimum of 75 therapeutic cardiac catheterizations annually for each of the most recent three years.
- Document patients have been informed that cardiac surgery is not available onsite, are aware of the associated risks, and have consented to have the procedure performed.
- Document provisions for joint quality review, to include 100 percent peer review of all procedures.
- Document proposed unit staffing meets ACC/AHA guidelines.
- Document staff has training in advanced life-saving procedures, including but not limited to, Intra-Aortic Balloon Pump Assist and sealing of perforated vessels using Stents.
- Document services will be available 24 hours a day, seven days a week.
- Provide a current copy of a collaborative agreement with one or more tertiary facility(ies) within 30 minutes air travel time of the demonstration facility and must possess the ability to transfer patients by air. The cooperative agreement must include:
    - Guidelines for selection of patients.
    - Provisions for emergency and routine transfer of patients, including transfer of patient information, and for agreed-upon cardiac catheterization imaging standards to avoid redundant catheterizations.
    - Provisions that specify cardiac surgery staff and facilities shall be immediately available to the patient upon notification of an emergency.
    - Explicit description of the responsibilities of each party.
- Participate in a national cardiovascular registry or databank, and report outcome results to the state.

Source: West Virginia Health Care Authority.

The LB&FC staff analyzed available data to assess the extent to which Pennsylvania hospitals providing primary and elective PCI without onsite open heart surgery meet West Virginia's criteria to participate in its demonstration. We found:

- None of the eight facilities selected by the Department performed at least 600 diagnostic catheterizations annually (see Table 7).
- Two of the eight facilities did not have the experience of performing diagnostic catheterizations for three years prior to receiving the waiver.
- None of the eight facilities documented that all physicians performing emergent PCI at demonstration sites had performed at least 75 interventions annually.
- None of the eight facilities documented call schedules showing availability of primary PCI 24/7, 365 days a year.
- Two of the three facilities operating in 2002 and 2003, including one that advised the Department it would perform over 300 PCI procedures annually (i.e., 25 per month), performed only four therapeutic catheterizations monthly during that period, based on data reported to the PHC4.
- Only one of the three facilities performing emergent and elective PCI in 2002 and 2003 performed an average of 15 procedures monthly and was on path to meet West Virginia's standard of at least 200 therapeutic catheterizations annually after 24 months of operations.

Both West Virginia and Pennsylvania require patients provide informed consent to participate in the state's demonstration or pilot projects. LB&FC staff reviewed the available patient consent forms approved for use at Pennsylvania's demonstration sites and provided to us by the Department.[54] We found patient consent forms are not standard across the demonstration sites, and Pennsylvania patients in the demonstration are not given important information about the risk associated with their participation. Exhibit 12 provides selected language from patient consent forms used in the Department of Health's demonstration.

As shown in Exhibit 12, Hospital 1 advises the patient there is less than 0.1 percent risk of death associated with therapeutic catheterizations. The American College of Cardiology National Cardiovascular Data Registry's observed in-hospital mortality rates for emergent PCI on stable patients is 5.4 percent, and for emergent salvage PCI 42.6 percent.[55] The New York cardiac data reports an observed mortality rate of 3.73 percent for "emergency cases" for 2000 through 2002 PCI discharges, and 0.37 percent for non-emergency cases.

[54]Consent forms were not included in the information provided by the Department of Health for all projects.
[55]Observed mortality rates also differ by age groups. The NCDR observed mortality rate for those less than 50 is 0.6 percent, and for those greater than 80, it is 3.8 percent.

The language in Hospital 1 and Hospital 2's informed consent forms acknowledges complications associated with the procedure can trigger the need for emergency open heart surgery. Hospital 2 advises the patient there is "minimal risk" the patient might need to be transferred to a hospital for open heart surgery if certain complications arise during the procedure. Hospital 1 advises that there is less than a 2 percent risk of blood vessel damage, closure, or severe bleeding associated with the procedure. Neither consent form, however, explicitly advises the patient about differences in the likelihood of survival related to time to surgery should the patient experience serious complications (i.e., the shorter the time to surgery, the greater the likelihood of patient survival). Hospital 1 only implies such differences by noting on the consent form that if transferred, "emergency surgery . . . might be performed more quickly and thus possibly more safely. . . ."

As shown in Exhibit 12, several of the consent forms approved by the Department do not advise the patient that the American College of Cardiology recommends against elective PCI at facilities without open heart surgery onsite. The language in some forms, moreover, could be interpreted by a patient to mean that the Pennsylvania Department of Health endorses the quality and the safety of the procedure being performed at a hospital without onsite open heart surgery backup. Such an interpretation could easily be drawn by laypersons since several of the hospitals were reported by local newspapers as having "received state approval to perform the life-saving procedure."[56]

Starting in 2004, the Department of Health has required facilities with licensure exceptions to include specific language in their informed consent forms indicating the Pennsylvania Department of Health and the American College of Cardiology recommend that patients undergo non-emergent therapeutic catheterizations in a hospital with open heart surgery onsite (see Exhibit 12, Hospital 4). The Department, however, has not required hospitals that received exceptions in 2002 and 2003 to modify their patient consent forms to include similar language.

In 2004, the Department of Health also started to require hospitals participating in its demonstration to advise their medical malpractice insurers they were providing therapeutic catheterizations as part of a demonstration without onsite open heart surgery backup and required documentation of such notice to the medical malpractice insurer.[57] To date, the Department has not required similar notice and submission of documentation from previously approved facilities.

[56]See, for example, Herald-Standard, 2/14/03

[57]Medical malpractice lawsuits are generally based on tort law, which includes both statutes and court decisions. A tort is a wrongful act or omission that causes harm Typically, a malpractice tort would be based on the claim that the health care provider was negligent, had failed to meet the acceptable standard of care owed to the patient, and thus caused injury to the patient

Exhibit 12

Selected Excerpts From Informed Consent Forms Used in Programs Performing Emergent and Elective Therapeutic Cardiac Catheterization Without Onsite Open Heart Surgery Backup

***Hospital 1*:** For catheterization/angiography, there is less than 1% risk of heart attack or stroke, and less than 0.1% risk of death or major allergic reaction. Blood vessel damage, closure, or severe bleeding occurs in less than 2%. For balloon PTCA/stenting there is generally less than 3% risk of major heart attack and less than 1% risk of death or need for emergency transfer for coronary bypass surgery. There is less than 2% risk of major blood vessel problems requiring blood transfusion or surgery. . . . Other treatment options include bypass surgery, or transfer to a cardiac surgical hospital before balloon PTCA/stenting. If I am transferred first, emergency surgery (in the rare event that I need it after the PTCA/stenting) might be performed more quickly and thus possibly more safely, but I will need a second procedure and often a longer hospital stay with this option.

***Hospital 2*:** My doctor has explained to me what these procedures are and the possible risks of these procedures. These risks include: (a) heart attack, (b) major vascular damage (puncture or injury of a blood vessel), (c) allergy to the contrast (or dye) that is injected into the vessel, (d) death, and (e) arrhythmia. . . . My doctor has explained that . . . hospital does not have an open heart surgery service It also has been explained that angioplasty procedures have usually been performed in a hospital with open heart surgery, but that . hospital has been approved by the Pennsylvania Department of Health to offer this service at . . . as part of a demonstration project. The demonstration project is intended to make angioplasty procedures more accessible in community hospitals qualified to provide the service. My doctor has explained that there is minimal risk that I might need to be transferred to a hospital with an open heart surgery service if certain complications arise during the procedure. If that happens, I have been told that I would be transferred immediately to a hospital with open heart surgery. I also understand that as part of the demonstration project, [the] hospital may be reporting data about my case to the Department of Health and to another teaching hospital.

***Hospital 3*:** My doctor has explained that . . . hospital does not have an open heart surgery service. My doctor also has explained that in Pennsylvania angioplasty procedures have usually been performed in a hospital with open heart surgery, but that . . . hospital has been granted an exception to this requirement by the Pennsylvania Department of Health to participate in a demonstration project. The demonstration project is intended to make angioplasty procedures more accessible in community hospitals that qualify to provide the service. My doctor has explained that there is a minimal risk that I might need to be transferred to a hospital with an open heart surgery service if certain complications arise during the procedure. If that happens, I have been told that I would be transferred urgently using strict policies and procedures already developed to a hospital with open heart surgery. Guidelines of the American College of Cardiology recommend that elective angioplasty be performed in hospitals with open heart surgery on site.

***Hospital 4*:** In Pennsylvania, angioplasty and stenting procedures have usually been performed in hospitals offering open heart surgical services. The Pennsylvania Department of Health and the American College of Cardiology recommend that patients undergo elective angioplasty procedures in a hospital with onsite open heart surgery services. A list of hospitals in the . . . area with open heart surgery services is attached to this consent form. The Department has granted an exception to certain community hospitals in order to make angioplasty procedures more available to patients located in areas served by those community hospitals.

Source: Developed by LB&FC staff from documents provided by the Department of Health.

In 2004, the Department of Health also started to require new demonstration projects to identify nearby facilities that provide therapeutic catheterizations with onsite open heart surgery backup. As shown in Table 8, four of the eight facilities in the Department's pilot projects are in counties that did not have open heart surgery programs. All demonstration sites, however, had hospitals providing therapeutic catheterization with onsite open heart surgery backup in at least one county. Neighboring programs[58] providing therapeutic catheterization with onsite open heart surgery backup appear to have capacity to serve additional patients given the number of available programs. Five of the eight pilot programs operate in areas where not all of the existing programs are meeting ACC/AHA's minimum proficiency volume standards.

Table 8

Waiver Facilities and Number of Nearby Hospitals With Open Heart Surgery Programs

Hospital	Number of Open Heart Surgery Programs Within County	Number of Open Heart Surgery Programs in Surrounding Counties
Somerset	None	3
Uniontown	None	2
Monongahela Valley	1	13
Jameson	None	3
Chambersburg	None	1
Montgomery	3	24
Jeanes	10	8
Holy Redeemer	3	24

Source: Developed by LB&FC staff from Department of Health data.

Department of Health Monitoring of Waiver Sites: The Department of Health advised hospitals that received exceptions to hospital licensure regulations to provide PCI without onsite open heart surgery that it would monitor their performance for compliance with the ACC/AHA guidelines. LB&FC staff met with Department of Health staff to become familiar with their monitoring procedures. They advised us projects are monitored using American College of Cardiology National Cardiovascular Data Registry reports for individual sites and that Department staff first received such reports for calendar year 2003 in June 2004.

LB&FC staff reviewed the data (for the three demonstration sites operating in 2003) available to the Department of Health through the national registry. The national registry lends itself to a variety of reports. The reports presented to the Department have been designed by the sites themselves, according to national registry officials with whom we spoke.

[58]All but one of the demonstration programs have neighboring programs within one hour or less travel time, and the one program where the neighboring program is over one hour relies on physicians from the neighboring program to provide coverage.

The national registry reports provided to the Department do not provide the Department with information required to assess compliance with the ACC/AHA requirements adopted by the Department (see Exhibit 8). They, for example, do not provide information on:

- number of primary PCI performed at the facility during the year, and
- number of such therapeutic catheterizations performed by each physician during the year.

The reports submitted to the Department also do not:

- Demonstrate relevant patient selection criteria are being followed.
- Demonstrate the procedures were subject to peer review, including procedures involving patient death.

One area where information relevant to the ACC/AHA guidelines is provided is the time from when a patient arrives at the hospitals to the time of the emergent PCI. ACC/AHA guidelines indicate emergent PCI should be performed within 120 minutes of arrival at the hospital.

- One of the three hospitals (operating in 2003) did not meet the criteria for any of its patients.
- Two of the three hospitals did not meet the criteria for 60 percent or more of their patients.

In addition, LB&FC staff identified certain key discrepancies in the procedure volumes reported voluntarily to the national registry and those reported to the Pennsylvania Health Care Cost Containment Council for one of the three hospitals. The facility reported performing 47 PCI to the national registry (and the Department of Health) with one patient death in the catheterization laboratory, and 35 therapeutic catheterizations to the Council with no patient deaths.

We contacted the hospital, and after researching the data, the hospital informed us that they had conducted 52 PCI in calendar year 2003, including nine unsuccessful attempts, and had two patient deaths. Based on our discussions with other states, we understand attempted and unsuccessful PCI and associated patient outcomes are to be reported to the national registry. It is also our understanding that attempted and unsuccessful PCI should be rare events.

Differences in the number of reported procedures were due to the way in which unsuccessful PCI were recorded in the different data systems, and the hospital failing to report outpatient procedures to the PHC4. In the case of the PHC4 data, the unsuccessful PCIs, including two in which patient deaths occurred, were not reported as therapeutic catheterizations. Instead, they were captured as inpatient deaths with diagnostic catheterizations.

The problems with the data for one demonstration site highlight the significant challenge facing the Department of Health staff and the staff of tertiary care hospitals working with the demonstration sites to assure quality of care and patient safety. They have no way of assuring all procedures relevant to quality of care and patient safety in the demonstration come to their attention. To begin to assure that all procedures with adverse patient outcomes are identified, they would need to review all diagnostic and therapeutic catheterizations billed and reported to the PHC4.

In 2003, the Pennsylvania Chapter of the American College of Cardiology advised the Department of Health of its concerns for patient safety with the demonstration pilot project. The Chapter noted:

> . . . the recent waivers granted to hospitals to perform elective [PCI] without onsite cardiac surgical back-up are potentially hazardous. All angioplasty procedures carry a small and unpredictable risk for major complications, including death. Recent data available from the NCDR database would suggest that urgent bypass surgery is needed in 1 of 300 patients undergoing elective PCI. For this reason, the expert committee of cardiologists that revised the guidelines for PTCA stated: 'at this time, the Committee, therefore continues to support the recommendation that elective PCI should not be performed in facilities without onsite cardiac surgery (Table 17 [in the ACC/AHA guidelines]).' (J Am Coll Cardiol 2001;37:2239xxi)[59]

In December 2004, the Department of Health requested to meet with representatives from the Pennsylvania Chapter. It sought Chapter input as the two year demonstration period for the initial sites is coming to a close.

Proposed National Elective PCI Clinical Trial: When the Department of Health initiated its demonstration program allowing performance of elective PCI, a national clinical trial was not available to hospitals interested in evaluating the safety and efficacy of elective PCI provision without onsite open heart surgery backup to improve the availability of cardiac services in their communities. Currently, medical researchers at Johns Hopkins Medical Institutions are in the process of finalizing the design for an elective angioplasty study. This national trial requires random of assignment of 12,000 patients to PCI at a facility with onsite open heart surgery or a facility without such surgical backup.

[59]May 5, 2003 correspondence

Hospitals seeking to participate in the proposed national trial must meet certain criteria. They must:

- have the capability to perform 200 therapeutic catheterizations in an existing laboratory;
- agree to complete a primary and elective PCI development program, abide by the trial's physician, patient, and devise selection criteria; collect and transmit study data in a timely manner; perform certain therapeutic catheterizations via a defined study protocol;
- develop and maintain a quality and error management program, including a weekly interventional conference and monthly QE review;
- perform PCI 24/7; and
- report outcomes to a clinical trial registry.

The national trial physician inclusion criteria require that physicians:

- meet the ACC/AHA standards for competency (minimum of 75 cases per year),
- agree to practice in accordance with defined study device and patient selection criteria,
- obtain necessary informed consent from patient participants,
- complete necessary data forms, and
- participate in required QE programs and competency review and training.

The principal researcher for the proposed national trial advised the LB&FC that several states that regulate cardiac services and have requirements for onsite open heart surgery backup for therapeutic catheterizations (e.g., Massachusetts, New Jersey, Michigan, and Maryland) are considering granting waivers to their regulations to allow selected facilities to participate in the proposed national trial. We were also advised that Pennsylvania facilities that meet project selection criteria would be welcomed to participate in the national trial.

N. The volume of open heart procedures performed has been declining at the same time as many new programs opened.

In 1995, Pennsylvania providers performed over 19,000 CABG procedures—the primary type of open heart surgery—according to published reports from the Pennsylvania Health Care Cost Containment Council (PHC4). By 2002 just over 16,000 procedures were performed. Despite the 15 percent drop in reported CABG cases, 18 new open heart surgery programs were included in the Council's 2002 published report.[60]

The decline in procedure volume and the increase in the number of open heart surgery programs have resulted in a sharp drop in the average volume of procedures performed by Pennsylvania open heart surgery programs. In 1995, they averaged about 450 procedures annually—the facility volume required in Pennsylvania's last State Health Services Plan. By 2002, Pennsylvania programs had dropped to just under 270 procedures.

When we compared Pennsylvania cardiac surgery providers' average volume of procedures with surrounding states for whom data were available, we found Pennsylvania providers perform fewer CABG procedures on average than providers in New York and New Jersey. As shown in Table 9, the average number of procedures performed by providers in New York and New Jersey is over 50 percent greater than the average for Pennsylvania's providers.

Table 9

Calendar Year 2000 CABG Volumes for Pennsylvania and Selected States

State	Total Providers	Total Procedures	Average Procedures Per Provider
Pennsylvania	55	19,281	350
New York	34	18,121	533
New Jersey	15	8,220	548

Source: Developed by LB&FC staff from published CABG reports.

In 2003, many Pennsylvania cardiac surgery programs were not meeting facility proficiency volumes that are in place in other states. Table 10 provides the cardiac service facility proficiency volumes used in selected states.[61] Failure to meet proficiency volumes in many of the states triggers a quality assurance review to assure patient safety.

[60]PHC4 published CABG reports do not include all programs that are in operation at a particular point in time. From December 1996 through December 2003, Pennsylvania had 23 new open heart surgery programs.
[61]Massachusetts, Michigan, and West Virginia also have minimum proficiency volumes for physicians.

Table 10

Cardiac Surgery Annual Proficiency Volumes for Selected States

State	Annual Proficiency Volumes
Pennsylvania	None
Florida	300
Maryland	200
Massachusetts	300
Michigan	300
New Jersey	350
New York	500
Ohio	250
West Virginia	250

Source: Developed by LB&FC staff from relevant state regulations and policies.

In calendar year 2003,

- 19 of Pennsylvania's 63 adult open heart surgery programs did not meet facility volume proficiency standards of any of the other states listed in Table 10.
- 14 met New York's facility proficiency volume standard.
- 28 met New Jersey's standard.
- 34 met Florida's, Massachusetts', and Michigan's standard.
- 39 met Ohio's and West Virginia's standard.
- 44 met Maryland's standard.

Five of the 19 programs that did not meet the volume proficiency standards of the other states had observed mortality rates greater than the AHRQ's quality benchmark for CABG.

O. More open heart surgeons were performing fewer than 100 CABG in 2002 than in 1995, and such surgeons have mortality rates 30 percent higher than the statewide average.

Over time the number of open heart surgeons in Pennsylvania has remained fairly stable. An increasing number and proportion of such surgeons, however, performed fewer than 100 surgeries, as shown in Table 11.

Table 11

Surgeons Performing Fewer Than 100 CABG Procedures
(In 1995 and 2002)

Year	Total Surgeons	Surgeons Performing Fewer Than 100 CABG Procedures
1995	189	88 (47%)
2002	190	102 (54%)

Source: Pennsylvania Health Care Cost Containment.

The PHC4's CABG-procedure-only mortality rate declined for all surgeons from 1995 to 2002, as shown in Table 12. Surgeons performing more than 200 cases had the lowest CABG mortality rates in 1995 and 2002. They also had the most improvement over the period. As a result, by 2002, surgeons performing more than 200 cases had CABG mortality rates in 2002 that were 34 percent less than the rate for all CABG surgeons in the state.

The mortality rates for surgeons performing fewer than 100 cases also improved from 1995 to 2002. Nonetheless, their CABG mortality rates remained roughly 30 percent higher than the average for all surgeons over the period.

Table 12

Surgeon CABG Mortality Rates by Procedure Volume
(1995 and 2002)

Year	CABG Mortality-All Surgeons	CABG Mortality-Surgeons Performing Fewer Than 100 Procedures	CABG Mortality-Surgeons Performing 200 or More Procedures
1995........	3.3%	4.4%	2.7%
2002........	2.4	3.1	1.6

Source: Pennsylvania Health Care Cost Containment Council.

Organ Transplant Services and Quality Benchmarks

P. Some Pennsylvania transplant programs have not met Medicare's proficiency volumes.

Several Pennsylvania transplant programs have not met Medicare's volume standards in recent years.[62] As shown in Table 13:

- One (Oakland VA Medical Center) of the 13 adult kidney transplant programs did not met Medicare's standard.
- Two (Hershey Medical Center and Hahnemann) of the seven liver transplant programs did not meet Medicare's standard.
- One (Allegheny General Hospital) of the six heart transplant programs did not meet Medicare's standard.
- One (Temple University) of the three lung transplant programs did not meet Medicare's standard.

Table 13

Average Annual Transplant Volumes

Hospital	Kidney	Liver	Heart	Lung
Albert Einstein	45.2	41.6	N/A	N/A
Allegheny General	72.8	N/A	5.2	N/A
Geisinger	36.0	N/A	N/A	N/A
Hershey Medical Center	62.0	6.8	13.2	N/A
Pinnacle Health	58.8	N/A	N/A	N/A
Hahnemann	92.8	6.0	17.2	N/A
Lankenau	18.0	N/A	N/A	N/A
Lehigh Valley Hospital	29.6	N/A	N/A	N/A
UPMC	126.0	157.2	33.6	48.0
Oakland VA Medical Center	2.0	18.8	N/A	N/A
Thomas Jefferson	95.2	30.0	N/A	N/A
Temple University	17.2	N/A	41.6	7.6
Hospital of the University of Pennsylvania	130.4	94.4	46.0	28.8

Note: Annualized volumes for kidney and liver transplants are based on data for the period 1/1/01 to 6/30/03. Annualized volumes for heart and lung transplants are based on data for the period 7/1/00 to 12/31/02.
Source: Developed by LB&FC staff from the Scientific Registry of Transplant Recipients database.

[62]Transplant programs are not required to participate in the Medicare program; 93 percent of programs nationwide, however, do participate.

In part, the problems providers experience in meeting Medicare's volume standards for heart and lung transplants may be due to the decline in available organs for such transplants in Pennsylvania from 1995 through 2003. In 1995, there were 211 heart transplants in Pennsylvania, according to the database of the Scientific Registry of Transplant Recipients. By 2003, there were only 169. In 1995, there were 118 lung transplants in Pennsylvania. By 2003, they were just 93.

Only kidney and liver transplants increased during the period—mirroring the recent increase in such transplants nationwide. Kidney transplants in Pennsylvania increased from just over 700 in 1995 to over 1,000 in 2003, with the number of liver transplants increasing from 400 to over 500.

On February 4, 2005, moreover, the federal Department of Health and Human Services published proposed changes to its Medicare conditions of participation for transplant hospitals. The proposal would replace Medicare's current standards of 12 transplants over a 12-month period for heart, and liver transplant programs, and 10 transplants for lung transplant programs. In their place, Medicare would require centers to achieve specified one-year patient and graft survival rates over a 2.5 year period based on a minimum of 9 patients. Medicare's proposed outcome measures for centers seeking initial approval and subsequent re-approval mirror the current approach taken by the National Organ Procurement Transplant Network (OPTN) discussed below.

Q. Over one-half of Pennsylvania transplant programs have one-year patient survival rates lower than their expected rates, though the difference is not significantly lower for most programs.

In addition to volume, patient survival rates[63] historically have been considered indicators of quality of care for transplant programs. In the case of major organ transplants, Medicare has established initial patient survival rates, which it currently considers too low since medical technology and pharmacology have significantly increased transplant patient and graft survival. In early February 2005, therefore, Medicare proposed to adopt center-specific outcome standards based on those of the Organ Procurement and Transplant Network (OPTN).

The national Organ Procurement and Transplant Network (OPTN),[64] in conjunction with the Scientific Registry of Transplant Recipients (SRTR), establishes survival rates for individual programs based on the characteristics (such as age, disease, blood type, and relevant clinical data) of those served and the experience of similar patients nationwide during specific periods of time. According to

[63]These rates represent patients and may include patients whose transplants have failed, but the patient continues to survive though such means as a subsequent transplant, or in the case of kidney patients through dialysis.
[64]See, 42 C.F.R. §§121.1-121.12.

Pennsylvania Department of Health licensure regulations and as discussed below, quality assurance reviews are to be conducted when transplant programs are not meeting their Organ Procurement and Transplant Network (OPTN) expected survival rates.[65]

Federal OPTN regulations require ongoing and periodic review and evaluation of transplant programs that are part of OPTN. [66] They also require transplant centers to submit significant data, including clinical data, to the Scientific Registry for all patients receiving organ transplants in the United States.[67] In the United States, transplant programs are required to participate in the OPTN in order to match patients in need of organ transplants with organs available for transplant.

The OPTN bylaws state:

> Survival rates. In the distribution of survival rates of all OPTN members a center with a low (as defined below) survival rate would be subject to evaluation to determine if the low survival rate may be accounted for by patient mix or some other unique clinical aspect of the transplant program in question.
>
> Those programs whose actual observed patient and/or graft survival rates fall below their expected rates by more than a threshold will be reviewed . . .
>
> While the precise numerical criteria may be selected by the MPSC (Membership and Professional Standards Committee), the initial criteria employed to identify programs with low patient and/or graft survival rates will include the finding that the observed events minus expected events is greater than 3 and the observed event divided by the expected events is greater than 1.5; and there exists an one sided p value of less than 0.05.
>
> Observed events[68] represent deaths or graft loss as reported in the OPTN database. Expected events represent deaths or grafts as calculated utilizing organ specific transplant models. Incomplete follow-up data will be treated as a graft loss or patient death in the context of this analysis.

[65]§158.19
[66]42 C.F.R. §121.10 (b) (iii).
[67]See, 42 C.F.R. §121.11 (b) (2).
[68]Observed and expected events are referring to numbers of patient deaths and numbers of graft failures. Observed events are the actual numbers reported by the program to the Registry, and expected events are the numbers expected based on the model used by the Scientific Registry of Transplant Recipients to arrive at a center specific survival rate.

> If a program's performance cannot be explained by patient mix or some other unique clinical aspect of the transplant program in question, it will be considered for appropriate action in accordance with Appendix A of [the OPTN] bylaws.[69]

On February 4, 2005, Medicare proposed one-year patient (and also graft) survival rates over a 2.5 year period based on OPTN's three thresholds.

The OPTN/UNOS[70] board of directors had designated responsibility for monitoring transplant programs to its membership and professional standards committee. The OPTN/UNOS staff regularly provide the committee with various reports to help identify if relevant criteria[71] established for transplant centers are being followed.

Such reports include quarterly reports of risk-adjusted center specific patient mortality using statistical models developed by the Scientific Registry. The committee uses these reports (without the names of centers identified) to identify transplant programs that should be reviewed because of possible poor performance. The reports, which focus on one-year survival rates adjusted for patient characteristics, are used to flag programs that fall below the thresholds specified in the bylaws.

Transplant programs that are "flagged" by the OPTN/UNOS membership and professional standards committee are regularly monitored to see if their performance improves. They are also engaged in a quality assurance process. The process involves:

- Requesting programs to verify the data they reported to the Scientific Registry and providing complete data when all required data has not been submitted. Programs that may not have reported complete data to the Registry may have different survival results based on more complete reporting.

- Assessing to determine if the program's expected survival rate is accurate, or if the program includes patients or performs procedures that are not accounted for in the model the Scientific Registry uses to identify each program's expected survival rate. Based on the additional information provided by the program, the committee may decide that the lower than expected survival for the program is due to its serving patients who have characteristics that are not included in the statistical model.

[69]OPTN bylaws, Appendix B-2 at www.optn.org. The exact same language can be found in the UNOS bylaws Appendix B Attachment 1-designated transplant program criteria, xii transplant programs.
[70]OPTN bylaws state: The OPTN board of directors shall be elected in parallel with and using the same processes as the OPTN contractor's board of directors, resulting in identical membership, if the OPTN contract provides for such an arrangement." The bylaws go on to state: "this will enable the OPTN contractor to perform tasks required by the OPTN contract under the governance of the OPTN board of directors.
[71]The reader should note that survival rates are not the only criteria that are monitored.

- Requesting and reviewing information from the program based on its own self-assessment and on the steps the program is taking to improve performance.

- Reviewing independent consulting reports and recommended plans for improvement that have been initiated by the program itself.

- Contracting with transplant experts to conduct onsite reviews and offer consultation when requested or where indicated.

Ultimately, the committee may recommend to the OPTN board that a process begin to declare the program not to be a member in good standing. Remaining a member in good standing is important to programs since such membership is required to receive donor organs for transplant. If the committee should recommend and the board concur that the program's designated transplant program status be changed, the program has rights to appeal to the Secretary of the Department of Health and Human Services. OPTN staff with whom we spoke, however, advised that programs "flagged" for monitoring typically have identified relevant program issues and are taking steps to implement improvements. In some cases, they decide to voluntarily change their program status and make their program inactive. In other words, they stop performing transplants.

In addition to supporting the work of OPTN and its board, the Scientific Registry of Transplant Recipients (SRTR) is required by federal regulations[72] and its federal contract to post on the Internet center-specific outcome data for every transplant center in the United States. Twice a year, the SRTR website posts significant performance outcome data at its website including one month, one year, and three-year expected and actual survival rates for specific cohorts of patients served by each center.

The SRTR website (and the OPTN membership and standards committee's) reported survival data are based on a specific group of transplant patients served during specific timeframes. The time frames and characteristics of the patients served by the center continually change. A particular program's expected survival rate, therefore, is not constant and continually changes.

The Scientific Registry's website notes that because of differences in patients served across programs, individual program survival rates cannot be compared. It also notes that specific circumstances at each center may affect many of the measures included in the report and advises the public to contact the program for further information.

[72]42 C F.R. §121.11 (b) (1) (iv)

The reports posted by the Scientific Registry at its website are based on the same patient and center database used by the OPTN membership and professional standards committee to review and evaluate programs. The website semi-annual reports are similar, though not the same, as the committee's quarterly reports. The Scientific Registry's website reports, however, can be used to "flag" programs with possible performance issues and monitor their performance over time for quality assurance follow up, or to determine if the program is involved with the OPTN in quality assurance processes.

LB&FC staff reviewed the Scientific Registry's website (www.ustranplant.org) reports for Pennsylvania transplant programs. Specifically, we reviewed the one-year patient expected and actual survival rates for kidney, liver, heart and lung transplant programs for each center for two groups (or cohorts) of patients:

- patients receiving kidney and liver transplants from January 1, 2001 through June 30, 2003, and patients receiving heart and lung transplants from July 1, 2000 through December 31, 2002, and
- patients receiving kidney and liver transplants from July 1, 2001 through December 31, 2003, and patients receiving heart and lung transplants from January 1, 2001 through June 30, 2003.

We found:

For kidney transplant patients:

- From January 1, 2001 through June 30, 2003, 6 of the 13 kidney transplant programs had actual one-year patient survival below their expected rates. For 1 of the 6 programs, the lower than expected rate was significantly different.

- From July 1, 2001 through December 31, 2003, 7 of the 13 kidney transplant programs had actual one-year patient survival below their expected rates. For 1 of the 7 programs, the lower than expected rate was significantly different.

For liver transplant patients:

- From January 1, 2001 through June 30, 2003, 5 of the 7 liver transplant programs had actual one-year patient survival below their expected rates. For 1 of the 5 programs the lower than expected rate was significantly different.

- From July 1, 2001 through December 31, 2003, 5 of the 7 liver transplant programs had actual one-year patient survival below their expected rates.

- From July 1, 2001 through December 31, 2003, 5 of the 7 liver transplant programs had actual one-year patient survival below their expected rates. For 2 of the 5 programs, the lower than expected rate was significantly different.

For heart transplant patients:

- From July 1, 2000 through December 31, 2002, 4 of the 6 heart transplant programs had actual one-year patient survival below their expected rates, though none of the 4 programs had rates that were significantly different from their expected rates.

- From January 1, 2001 through June 30, 2003, 4 of the 6 heart transplant programs had actual one-year patient survival below their expected rates, though none of the 4 programs had rates that were significantly different from their expected rates.

For lung transplant patients

- From July 1, 2000 through December 31, 2002, 3 of the 3 lung transplant programs had actual one year patient survival below their expected rates, though none of the 3 programs had rates that were significantly different from their expected rates.

- From January 1, 2001 through June 30, 2003, 3 of the 3 lung transplant programs had actual one year patient survival below their expected rates, though none of the 3 programs had rates that were significantly different from their expected rates.

Those programs with actual one-year patient survival rates significantly lower than their expected rates appear[73] to meet the two additional criteria in OPTN bylaws that would "flag" them for OPTN monitoring of performance trends and quality assurance efforts on the part of the programs to address problems that may be identified.

The federal Department of Health and Human Services, in the February 4, 2005, proposed Medicare regulations, stated that based on the Scientific Registry data from July 2004, nationwide 10 percent of all adult kidney, liver, heart and lung programs had lower than expected one-year patient and graft survival and met all three OPTN thresholds that would "flag" their performance. LB&FC staff reviewed

[73]The Scientific Registry's website does not list the actual number of deaths to determine if the difference in observed events versus expected events is greater than 3. The number, however, can be inferred from the reported data (i.e., the actual number of transplant patients and the difference between the actual and expected survival rates), according to staff from the Scientific Registry with whom we spoke.

Pennsylvania adult patient programs' patient and graft one-year survival rates, using the Scientific Registry data from January 2005. We found:

- Only 8.62 percent of Pennsylvania's adult kidney, liver, heart, and lung programs had lower than expected one-year patient and graft survival rates that met all three OPTN thresholds that would trigger performance review.

This suggests that Pennsylvania organ transplant programs as a group perform as well, possibly somewhat better, than programs nationally.

In addition to the OPTN review, the Pennsylvania Department of Health is also to monitor the performance of Commonwealth transplant programs. The Department of Health's vital organ transplant regulations at §158.19 state as follows:

> (a) Each transplantation program shall perform an adequate number of procedures to maximize quality.
>
> (b) Each transplantation program shall meet the expected survival rate as set forth by the Organ Procurement and Transplantation Network in its bylaws. Those programs whose actual survival rates fall below their expected survival rates will be reviewed by the Department to determine if this deviation can be accounted for by patient mix or some other unique clinical aspect of the transplantation program.
>
> (c) If the transplantation program is unable to provide an explanation for its failure to meet the expected survival rate, the Department will undertake a review of that program to determine if it is in compliance with the criteria in this chapter. The hospital shall cooperate with the Department in this review.

In June 2004, the Department advised the LB&FC staff that information on all of its investigations and reviews of licensed facilities could be found at its website. We reviewed the information available at its website for all facilities with actual organ transplant survival rates lower than their expected rates, including those where the difference is lower and significant. We were unable to identify any such reviews having been undertaken by the Department of Health.

III. Appendices

APPENDIX A

House Resolution 356 of 2003

PRINTER'S NO. 2400

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE RESOLUTION

No. 356 Session of 2003

INTRODUCED BY MUNDY, DAILEY, BIANCUCCI, DeLUCA, D. EVANS, BEBKO-JONES, BROWNE, COY, CRUZ, CURRY, EACHUS, FRANKEL, FREEMAN, GEORGE, GERGELY, GOODMAN, GRUCELA, HARHAI, HERSHEY, LEACH, LEDERER, LEVDANSKY, MANDERINO, PETRI, READSHAW, ROONEY, SURRA, TANGRETTI, TIGUE, WASHINGTON, WHEATLEY, YOUNGBLOOD AND VANCE, JULY 8, 2003

REFERRED TO COMMITTEE ON AGING AND OLDER ADULT SERVICES, JULY 8, 2003

A RESOLUTION

Directing the Legislative Budget and Finance Committee to study certain issues related to health care facilities.

WHEREAS, The House of Representatives recognizes the need for quality assurance in providing health care services which involve specialized technical medical procedures and require extraordinary expertise and resources to be effective, including, but not limited to, organ transplant, cardiac catheterization and open-heart surgery; and

WHEREAS, The Department of Health currently licenses health care facilities in this Commonwealth and focuses primarily on basic safety standards for facility structures; and

WHEREAS, Since the sunset of the certificate of need program in the mid-1990s, there has been no statutory authority that requires health care facilities to prove they are providing needed services to the communities in which they operate; and

WHEREAS, The result has been an increase in the number of ambulatory surgical facilities and similar nonhospital health care facilities in this Commonwealth; and

WHEREAS, The quality of health care declines when fewer procedures and treatments are performed at each facility; and

WHEREAS, The cost of health care rises as duplicate medical equipment and staff are needed at each facility; therefore be it

RESOLVED, That the House of Representatives direct the Legislative Budget and Finance Committee, in consultation with health care experts and specialists, to conduct a study to examine and identify:

(1) Health care services that require extraordinary expertise and resources, such as organ transplant, cardiac catheterization and open-heart surgery.

(2) Types of health care facilities that provide these health care services.

(3) Standards for clinically effective care developed by national accreditation and specialty organizations for health care facilities that offer these services, including volume standards on the minimum number of cases a health care facility must treat in order to ensure clinical proficiency.

(4) Ways to ensure that health care facilities performing these services have sufficient volume to meet recognized professional standards for clinically effective care.

(5) Ways to ensure that health care facilities performing these services have appropriate staff and backup resources that deal with emergency circumstances to meet recognized professional standards for clinically effective care.

Appendix A (Continued)

(6) Standards for clinically effective care and licensing procedures for health care facilities in other states;

and be it further

RESOLVED, That the Legislative Budget and Finance Committee make a report of its findings and recommendations to the Speaker of the House of Representatives, the Aging and Older Adult Services Committee and the Health and Human Services Committee within one year of adoption of this resolution.

G7L82BIL/20030H0356R2400 - 3 -

APPENDIX B

Correspondence From the Pennsylvania Chapter of the American College of Cardiology

Pennsylvania
CHAPTER

RECEIVED OCT 1 2 2004

Chapter Administrator Office
Maria B. Elias
777 East Park Drive
PO Box 8820
Harrisburg, PA 17105-8820
(888) 633-5784
(717) 558-7750
(FAX) 558-7841
melias@pamedsoc.org
www.paacc.org

October 7, 2004

Mrs Mary Anne Nardone
Legislative Budget and Finance Committee
Finance Building
Room 400A
PO Box 8737
Harrisburg, PA 17105

Dear Mrs. Nardone:

Enclosed is a list of practicing physicians who are members of the Pennsylvania Chapter of the American College of Cardiology. Each cardiologist has expressed a willingness and commitment to volunteer his service in working with the state as it relates to HB2771.

As per our telephone conversation, our state chapter is very interested in working with you and the legislature in reviewing data submitted to PHC4 and NCDR as it pertains to the practice of invasive and interventional cardiology in Pennsylvania.

The physicians listed below are in good standing in the PaACC and possess the clinical expertise necessary to critically review the practice records submitted to these monitoring agencies.

If we can be of any further assistance please do not hesitate to contact us individually or our Chapter administrator, Maria Elias [telephone: 558-7850 ext.1475; fax: 717-558-7841; e-mail: melias@pamedsoc.org].

Again, thank you for your time

Steven M. Ettinger

Steven Ettinger
ACC Governorship Eastern Pennsylvania

Dr Donald C Durbeck
Dr. Howard C Herrmann
Dr Ancil A. Jones
Dr. Steven M. Ettinger
Dr Paul N Casale
Dr A.J Conrad Smith
Dr. Joseph G Cacchione
Dr David M. Lasorda
Dr Michael A Rossi

Copy: Dr A.J Conrad Smith
Chapter File

Source: American College of Cardiology, Eastern Pennsylvania Governorship.

APPENDIX C

Hospitals Providing Diagnostic Catheterizations
(As of 12/31/03)

Alle-Kiski
Berwick
Bradford Regional
Brookville
Canonsburg General
Carlisle Regional
Chambersburg
Chestnut Hill
Clearfield
Community Lancaster
Ellwood City
Ephrata Community
Forbes Regional
Frick
Gettysburg
Good Samaritan/Lebanon
Grant View
Hanover
Holy Redeemer
Indiana Regional
Jameson Memorial
Latrobe Area
Meadville
Memorial York
Mercy Philadelphia
Mercy Providence
Millcreek Community
Montgomery
Moses Taylor
Mount Nittany
Ohio Valley General
Pottstown Memorial
Riddle Memorial
Sewickley Valley
Suburban General/Pittsburgh
UPMC Horizon
UPMC McKeesport
UPMC Passavant Cranberry
UPMC St. Margaret
Warminster

Source: PA Health Care Cost Containment Council.

APPENDIX D

Hospitals Providing Diagnostic and Therapeutic Catheterizations
(As of 12/31/03)

Abington Memorial
Albert Einstein
Allegheny General
Altoona
Bon Secours Holy Family
Brandywine
Butler Memorial
Chester County
Children's Hosp Pgh
Children's Hosp Phila
Community/Scranton
Conemaugh Valley Memorial
Crozer-Chester
Doylestown
DuBois Regional
Easton
Frankford
Geisinger Wyoming Valley
Geisinger/Danville
Graduate
Hahnemann University
Hamot
Holy Spirit
Hospital University PA
Jefferson Regional
Lancaster General
Lancaster Regional
Lehigh Valley
Lehigh Valley/Muhlenberg
Main Line Bryn Mawr
Main Line Lankenau
Main Line Paoli
Medical Center Beaver
Medical College PA
Mercy Fitzgerald
Mercy Pittsburgh
Mercy/Scranton
Mercy/Wilkes-Barre
Milton S Hershey
Monongahela Valley
Pennsylvania
Phoenixville
Pinnacle Health
Reading
Robert Packer
Sacred Heart/Allentown
Saint Vincent Health
Sharon Regional
Somerset Center Health
St Christopher's Children
St Clair Memorial
St Francis Central
St Joseph/Reading
St Luke's/Bethlehem
St Mary
Temple Lower Bucks
Temple University
Thomas Jefferson Univ
Uniontown
Univ PA/Presbyterian
UPMC Lee Regional
UPMC Passavant
UPMC Presby Shadyside
Washington
Western Pennsylvania
Westmoreland Regional
Williamsport
WVHCS
York

Source: PA Health Care Cost Containment Council.

APPENDIX E

Hospitals Providing Open Heart Surgery
(As of 12/31/03)

Abington Memorial
Albert Einstein
Allegheny General
Altoona
Bon Secours Holy Family
Brandywine
Butler Memorial
Chester County
Children's Hosp Pgh
Children's Hosp Phila
Community Medical Center/Scranton
Conemaugh Valley Memorial
Crozer-Chester
Doylestown
DuBois Regional
Easton
Frankford
Geisinger Wyoming Valley
Geisinger/Danville
Graduate
Hahnemann University
Hamot
Holy Spirit
Hospital University PA
Jefferson Regional
Lancaster General
Lancaster Regional
Lehigh Valley
Lehigh Valley/Muhlenberg
Main Line Bryn Mawr
Main Line Lankenau
Main Line Paoli
Medical Center Beaver
Medical College PA
Mercy Fitzgerald
Mercy Pittsburgh
Mercy/Scranton
Mercy/Wilkes-Barre
Milton S Hershey
Pennsylvania
Phoenixville
Pinnacle Health
Presbyterian (U of PA)
Reading
Robert Packer
Sacred Heart/Allentown
St Christopher's Children
St Clair Memorial
St Joseph/Reading
St Luke's/Bethlehem
St Mary
St Vincent Health
Sharon Regional
Temple University
Temple Lower Bucks
Thomas Jefferson Univ
Uniontown
UPMC Presbyterian
UPMC Lee Regional
UPMC Passavant
UPMC Shadyside
Washington
Western Pennsylvania
Westmoreland Regional
Williamsport
WVHCS
York

Source: PA Health Care Cost Containment Council.

APPENDIX F

Hospitals Providing Major Organ Transplants
(As of June 2004)

Albert Einstein Medical Center
Allegheny General
Children's Hosp Pgh
Children's Hosp Phila
Geisinger Medical Center/Danville
Hahnemann University
Hamot
Hospital University PA
Lehigh Valley
Main Line Lankenau
Milton S Hershey
Pennsylvania
Pinnacle Health
St Christopher's Children
Temple University
Thomas Jefferson University Hospital
UPMC Presbyterian/Shadyside
Western Pennsylvania

Source: PA Health Care Cost Containment Council.

APPENDIX G

Response to This Report

Commonwealth of Pennsylvania

DEPARTMENT OF HEALTH

HARRISBURG

THE SECRETARY

April 8, 2005

Mr. Philip R. Durgin, Executive Director
Legislative Budget and Finance Committee
Room 400, Finance Building
Harrisburg, Pennsylvania 17107

Dear Mr. Durgin:

Thank you for the opportunity to comment on the draft report entitled Quality Assurance for Specialized Clinical Services.

Our comments fall into four general categories: Recommendations, Process, General, and Specific.

RECOMMENDATIONS:
The Department's comments on the report recommendations follow:

1. The Department of Health should routinely review the cardiac data hospitals submit as part of state licensure requirements. The Department agrees. We currently use the hospital data provided to us by PHC4 in two ways. The detailed cardiac catheterization reports that we receive periodically are used as a resource for our regular survey process if we find a problem at a facility. We also obtain quarterly sample reports that are used to structure our patient chart sample. Since much of our clinical work is based on individual patient chart review, this tool allows us to focus our attention on the services offered at a particular hospital.

2. The Department of Health, working with the Pennsylvania Chapter of the American College of Cardiology, should take steps to form a cardiac oversight committee to assist the Department. The Department agrees. We have had several discussions with the PA chapter of the ACC regarding their recommendations and advice. The Deputy Secretary for Quality Assurance was invited to present to their annual conference. Most recently, we asked the ACC to make recommendations to us regarding the use of exceptions, and methods of evaluation. We are currently waiting to receive these recommendations.

3. The Department of Health should institute a moratorium on approval of additional hospital licensure exceptions for provision of PCI without cardiac surgery on site. The Department agrees, and we will cease approvals once all outstanding litigation is resolved.

4. The Department of Health should require all current PCI demonstration sites to join a national clinical trial and comply with all requirements and protocols of the national clinical trial. The Department agrees, and we will make it a condition of exception renewal after the initial two-year exception is completed. We also require this as a condition of any new exceptions that result from litigation.

5. The Department of Health should routinely review survival data for individual transplant programs and follow-up with programs with lower than expected survival rates. The Department agrees. We currently use the organ transplant web site data in cases where the survey identifies problems with the transplant program.

PROCESS:
As we expressed to you at our transmittal meeting on January 24, 2005, the Department believes that the process LB&FC uses for obtaining agency feedback does not provide a good opportunity to incorporate all subjects' observations into the final report.

The Department requested (copy attached) that we be permitted to share copies of the confidential report with the entities that were the focus of the report. As of the date of this letter, we have not received a response from you, so we have honored your request to keep the report confidential. However, several entities that are the subject of specific recommendations have not had an opportunity to comment. By issuing a confidential document that is not sent to all the parties being studied, we believe that the accuracy and depth of the report is compromised. The entities in question include the hospitals that are currently providing percutaneous coronary intervention (PCI) services under the demonstration project.

The Department also requested a listing of the facilities that your staff believes provide care that does not meet benchmark standards. As of the date of this letter, we have not received this list and as a result, have not been able to evaluate your findings as accurately as we would like.

GENERAL:
Our general observations focus on three areas: Policy Analysis, PCI Exceptions, and Regulation Enforcement.

Policy Analysis
The issue of how to control and improve quality in health care facilities is very complex. Legislators, regulators and policy analysts have not yet developed a national consensus on the best policy framework to use. There are three generally accepted policy approaches:

1. CERTIFICATE OF NEED (CON) MODEL: This model uses a set of non-marketplace supply restriction regulations and a highly complex quantitative analysis of outcome benchmarks.
2. REGULATORY MODEL: This model relies on rigorous compliance regulations and a robust consumer complaint system.
3. LEARNING MODEL: This model adopts a facility self-reporting and education model in which the reported data are analyzed for quality problem patterns, and the results are fed back to the reporting facilities, so they may implement policies and protocols that will prevent recurrence of these problems.

The Pennsylvania General Assembly has explicitly changed Commonwealth policy away from the CON model toward the regulatory and learning models. The Department has made every effort to comply with the changes required by the General Assembly.

The CERTIFICATE OF NEED statute sunset in 1996. That statutory sunset removed any legal authority that the Department had for establishing or enforcing quality benchmarks or limiting facility growth before a hospital could commence the provision of a service. The Department, under a prior administration, adopted compromise regulations that retained some very limited ability to use service data as one of the regulatory tools that could be incorporated into our traditional licensing survey. These regulations did not have explicit facility performance requirements, so even though the Department enforced these standards, the outcomes are not as effective as originally hoped.

The REGULATORY MODEL is embodied in the Health Care Facility Act (HCFA) and Department regulations. These requirements spell out in considerable detail the expectations the General Assembly and the Department have for facility performance, and the methods that the Department may use in enforcing those expectations in health care facilities. The legislation and regulation combine to establish minimum acceptable quality standards with which all facilities must comply. During the last several years the Department has improved our survey activity to substantially increase the amount of oversight in health care facilities. At the same time the Department has substantially increased our capacity to receive and manage consumer complaints.

The LEARNING MODEL is represented in the MCARE Act (Act 13 of 2002). This forward-looking statute moved Pennsylvania (PA) substantially ahead of other states by forming the Patient Safety Authority (PSA), along with very detailed requirements for reporting. There are three types of things that facilities must report to the Commonwealth: incidents, serious events, and infrastructure failures. The Department is now beginning to collect enough data to begin evaluating problem areas. In addition to reporting, Act 13 requires facilities to develop patient safety plans, establish patient safety committees, and designate patient safety officers.

The interplay of these three policy approaches and an analysis of the PA legislative history should be the foundation for any serious discussion of health care quality in the Commonwealth. Unfortunately, the report, Quality Assurance for Specialized Clinical Services, devotes all its attention to the CON model.

Even if this was the intended focus, the Department believes that your report would have been well served by a more balanced review of the literature and analysis of the consequences of the various policy options. For example, several notable organizations such as the U.S. Department of Justice and the World Health Organization have raised serious questions about the validity of the supply restriction, or CON model. Given the stature of these organizations, their position certainly warrants consideration. We believe that it is legitimate to periodically debate how best to control and monitor the operation of health care facilities in the Commonwealth. However, the issues incumbent to licensing health care facilities are complex and certainly warrant a more thorough debate.

PCI Exceptions

In looking at the issue of the appropriateness of hospitals without open-heart surgical services providing PCI services, the report notes the recommendation of the ACC on this issue. While it is correct that the ACC Guidelines of 2001 recommend that elective PCI be provided only in hospitals with open-heart surgical services, the report does not recognize that there are other studies and literature that have found that PCI services can be safely provided in hospitals without open-heart surgical services. Any comprehensive study of this issue should show that there is ongoing discussion in this area and that it is far from settled. The Department's discussions with hospital representatives, cardiac surgeons and cardiologists confirm that there is a wide variance of opinion on this matter. When Department representatives participated in a discussion of this issue at a meeting last year of the Pennsylvania Chapter of the American College of Cardiology, there was an acknowledgement that the issue of PCI services is unsettled and that data can be reviewed which suggest that the provision of certain PCI services in hospitals without open heart surgery is feasible.

In grappling with this issue and recognizing that this is an ever developing and changing area of medicine, the Department determined that it would balance the potential risk of providing PCI in a hospital without open heart surgical services with the benefits of making this service available to more Pennsylvania citizens. Those hospitals that are participating in the demonstration projects were able to show that they would be providing PCI services to individuals who otherwise would have to travel substantial additional distances to access this service. In the case of elective PCI services, the geographical distances involved could mean that the patient would not receive this vital service at all.

All of the above is not to suggest that the Department agrees that all hospitals should be permitted to provide PCI services. However, this Committee must realize that this is a complex issue with many diverse viewpoints and the subject of ongoing research and discussion. In being responsive to the direction of the General Assembly "to encourage innovation and continuous development of improved methods of health care" (35 P.S. §448.102) the Department must consider these viewpoints and accommodate them where possible.

Regulation Enforcement
The Department is particularly concerned that the report implies that we failed to properly implement our regulations. We disagree with that implication and question whether the research examined how the survey process uses Pennsylvania Health Care Cost Containment Council (PHC4) data as part of that process.

A summary of that process follows:

The Department conducts full license surveys in each hospital at least every two years. In addition, we investigate any complaints received, and any serious events reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS) system. Our survey method is based on two techniques.

First, we walk through the facility to identify any obvious regulatory non-compliance. Second, we obtain a sample of patient care charts that will be investigated in detail for compliance with our regulations. To the extent that organ transplant, cardiac catheterization and open-heart surgery services are provided at the facility, we include those services as part of the patient chart review. We routinely receive reports from PHC4 that are used to select our sample of patient charts. We believe that this approach satisfies the requirements of our regulations, without being unduly burdensome to providers, or consume inordinate amounts of staff time trying to evaluate complex data reports. If either our walk through, or chart review indicates a quality problem in organ transplant, cardiac catheterization and open-heart surgery services, we expand the number of charts reviewed, and look at facility clinical procedures for these services. If we need additional information, we look at national benchmark data such as the national organ transplant database.

SPECIFIC:

The Department would also like to call your attention to several specific concerns regarding the accuracy of portions of the report. The comments are arranged by page number.

1. **Page S-1** The statement that PA is one of 14 states without CON is inaccurate and misleading to the reader. For example, since much of the discussion relates to Percutaneous Coronary Intervention it should be noted that, according to 2004 data from the American Health Planning Association, an <u>additional</u> 14 states (including Virginia, Ohio, Delaware, Oregon) have limited CON programs. Of these, only 3 regulate PCI, and only 3 regulate open-heart. Thus 25, not 14 states do not regulate PCI through CON, and 24 do not regulate open heart, at least through CON.

2. **Page S-5** This section overstates the pre-CON sunset "after-the-fact" evaluation authority of the Department. After the initial volume projections were reviewed during the application process; no further monitoring or remediation was conducted. Therefore, suggestions that CON somehow provided a tighter monitoring process are inaccurate.
3. **Page S-6** First bullet. There is no normative data presented regarding the number of hospitals offering specialized services. For example, is the number of Pennsylvania programs per 100,000 population high or low compared to the U.S.?
4. **Page S-7** First bullet. The statistic as stated distorts the dimension of the issue. For example, when compared to the total number of cardiac catheterization programs not in compliance, it should be noted that those seven hospitals represent only 6.5% of the total number of programs.
5. **Page S-7** Third bullet. To be meaningful, the data should be normalized for acuity. For example, PA also has the third-largest population over the age of 65. Additionally, according to the Bureau of Health Statistics and Research, PA has a significantly higher age-adjusted rate of cardiovascular disease and coronary heart disease per 100,000 population than the U.S. Therefore, a higher rate of PCI may be explainable.
6. **Page S-8** First bullet. Is this an age-adjusted mortality rate? What is the statistical significance of this comparison? Why was New York selected as the baseline comparison as opposed to U.S. data?
7. **Page 14** The 1994 State Health Services Plan is 11 years old, and is based on data several years older than that. It is invalid to compare these data to the 2005 health services market place. The authority and basis for the plan sunset in1996 and it no longer reflects Commonwealth policy.
8. **Page 24-25** The report includes charts comparing PA standards to other states. According to the report, states were selected according to populations and proximity to Pennsylvania. Only 8 states are included in the comparison. This leaves this reviewer wondering if any bias crept into the selection of the comparison states.
9. **Page 38** The tables are presented in a manner that may possibly distort the magnitude of the problems. Without providing the Department with the names of the facilities, it is impossible to evaluate the allegations.

Thank you for the opportunity to review and provide comments on the draft report, Quality Assurance for Specialized Clinical Services. If we can be any further assistance, please feel free to contact me.

Sincerely,

Calvin B. Johnson, M.D., M.P.H
Secretary of Health

Enclosure

Commonwealth of Pennsylvania
DEPARTMENT OF HEALTH
P. O. BOX 90
HARRISBURG 17108-0090

CORRECTED COPY

January 27, 2005

DEPUTY SECRETARY FOR
QUALITY ASSURANCE

(717) 783-1078

Mr. Philip R. Durgin, Executive Director
Legislative Budget and Finance Committee
Room 400, Finance Building
Harrisburg, Pennsylvania 17105

Dear Mr. Durgin:

Thank you for sharing a draft copy of your study entitled Quality Assurance for Specialized Clinical Services. We have begun our review, and we believe that we can improve the quality of our response by obtaining thoughts directly from several of the organizations you mention in your confidential draft.

First, the recommendations in the report specifically address a variety of hospital issues. In order to provide a thorough review of the document, we respectfully request permission to share the draft report with the Hospital and Health Systems Association of PA (HAP). We believe that they may have useful observations to suggest regarding your findings.

Second, you make two specific recommendations regarding the PCI demonstration sites. We would like your permission to share your draft with those sites so that we could incorporate their opinions into our response. We believe that they may be in a better position to directly comment on your recommendations.

Third, I would like to formally restate the written request that I gave you at the meeting. Your staff made specific reference to hospitals that provide care that does not meet benchmark standards. Please provide us with a list of those facilities so that we can review our files to determine whether we concur with your findings. It is my understanding that there is no data confidentiality restriction on sharing your detailed analysis since we are the ones that originally provided the data to your staff.

Thank you for your consideration of these three requests.

Sincerely,

Richard H. Lee

cc: Dr. Johnson
Ms. Matio
Ms. Wolf
bcc: Mr. Lee
File

REPORT | JANUARY 2024

Tracking Virginia's 2022 Health Care Spending and Employment Trends

Samuel Obbin, MS
Corwin (Corey) Rhyan, MPP
Matt Daly, PhD

Contents

Report Highlights

Virginia Health Sector Spending

- Total annual personal health care (PHC) spending in Virginia increased from a revised estimate of $78.6 billion in 2021 to $83.5 billion in 2022 (an increase of 6.3%). This is a continuation of the growth in 2021 after the decline in 2020.
- Total health spending as a percent of the state Gross Domestic Product for Virginia fell to an estimated 14.9% in 2022, the smallest share since 2011. The percentage of the economy going to health care in Virginia is well below the national average of 17.1%.
- PHC spending increased in Virginia by an average year-over-year rate of 6.3% in 2022, slightly below last year's growth rate of 7.6%. Average national PHC spending increased by 6.0% in 2022, slower than Virginia's rate.
- If Virginia had spent the same portion of its GDP on health care as the U.S. average (17.1%), spending would have been $14.9 billion dollars more in 2022.
- Health spending per capita in Virginia in 2022 was about $1,800 lower than the national average, with all major spending categories lower than their national comparators. This $1,800 per capita health care spending gap between Virginia and the U.S. has increased from 2021, when it was $1,600 per person.
- Virginians in 2022, on average, spent $570 less per capita on hospital services, $260 less per capita on professional services, $340 less on prescription drugs, $130 less on nursing home and home health care, and $510 less on other types of care.
- The largest payer for PHC products and services in Virginia is private health insurance, spending an estimated $27.3 billion on personal health care in 2022, followed by Medicare at $18.5 billion, and Medicaid $15.3 billion, although Medicaid has been the fastest-growing payer in spending and enrollment since 2015.

Virginia Private Health Insurance Trends

- For individuals with health insurance coverage through a private-sector employer, the average single premium in 2022 was $7,400 and the average family premium was $21,400.
- Including average deductibles, the sum of average premiums and deductibles was $9,400 for single coverage and $25,200 for family coverage. Virginia's average single premium plus deductible was nearly the same as the national average ($9,600), while the average family premium plus deductible was slightly lower than the national average ($25,700).
- These annual single and family premiums have increased 24.2% and 21.8%, respectively, between 2015 and 2022, while combined premium and deductible totals have increased even faster (31.2% for single coverage and 26.2% for family coverage).
- Since 2008, per-enrollee private insurance personal health care spending has increased by 51.6%, while single annual premiums have increased by 76.6%, and family premiums have increased 79.3%. Growth in the combination of premiums and deductibles has been even faster over this period, rising 89.1%.

Virginia Health Sector Government Assistance

- Federal government financial assistance for the health care sector in Virginia declined substantially in 2022. After receiving $800 million in assistance in 2021, this support fell to $235 million in 2022.
- The Provider Relief Funds Virginia received decreased by 19.8% in 2022 from a year prior, while the Paycheck Protection Program ended nationwide. The combined pandemic-related federal government assistance received decreased significantly (68%) in 2022.

Virginia Health Sector Employment

- In the fourth quarter (Q4) of 2022, 389,000 individuals were employed by the health care sector in Virginia, about 11.5% of the total private sector employed population. This is up 5.2% from Q4 2021 and is now above the pre-pandemic peak of 381,000 workers.
- Employment rose across the major health care sectors; ambulatory settings gained an estimated 10,000 workers between 2021 and 2022, hospitals gained 5,000 workers, and nursing homes and residential settings gained 4,000 workers.
- As of Q4 2022, total health sector employment in Virginia was 4.7% above the beginning of 2019, with hospital employment up 3.0% and ambulatory employment up 10.4%. Nursing and residential employment remained below 2019 levels, down 6.6%.
- A tight labor market for health care workers continued in 2022 in Virginia, driving up the costs for providers. Average annual wages for healthcare practitioners (e.g., physicians, nurses, and technicians) were up 2.8% year over year in 2022, while annual wages for health care support roles (aides and assistants) were up 6.6%. Since 2019, these annual wages were up 12.1% and 11.0%, respectively.
- The overall unemployment rate for health care jobs remained very low in Virginia in 2022, at 2.7% across health care industry roles and 2.1% among health care occupations.

Data Source Updates and Revisions

This document follows and updates previous reports that have been published (2019, 2020, 2021). Those works provided a comprehensive look at health sector trends for the Commonwealth of Virginia, including measures of health care spending, employment, and insurance costs from 2015 to 2021, using data from the Center for Medicare & Medicaid Services (CMS) National and State Health Expenditure Accounts (NHEA), data from the Commonwealth's All-Payer Claims Database (APCD), and a variety of other government sources.

Similar to last year, this report incorporates data on NHEA personal health care spending by state of residence that was released in the fall of 2022 by CMS. Those state-specific data include estimates of health spending, by category and by payer, from 1991 through 2020. We continue to benchmark all state data sources to the CMS state health spending levels for all years through 2020 and apply other state data sources to estimate growth in spending between the final benchmark year (2020) and 2022. National health spending data from CMS are available through 2022 and are included as comparisons to Virginia's trends in this report.

These reports differentiate between spending trends in PHC categories, non-PHC categories, and total health care spending in Virginia. PHC spending is the subset of health care expenditures that includes the direct use of health care goods and services, including hospital care, physician and clinical services, nursing home and home health care, prescription drugs, and durable medical equipment. Non-PHC health expenditures are components of health spending not directly tied to health care utilization, such as the administration costs of Medicare and Medicaid, the net cost of private health insurance, research and development, public health expenditures, and other expenses on infrastructure and equipment.

While prior reports have primarily assessed trends in total health spending, the varying impacts of the COVID-19 pandemic have caused some of the underlying PHC and non-PHC spending trends to diverge, such that greater clarity in this report is required. As such some data and charts previously reporting "total health spending," may now report PHC spending or vice versa.

We continue our methodology from last year's report by using the Bureau of Economic Analysis (BEA) personal consumption expenditure (PCE) data by health sector components, allowing us to update BEA estimates of the Virginia health sector that previously relied only on personal income, a subset of PCE. Due to updates to 2021 BEA data and other sources, total Virginia PHC spending for 2021 was revised downward slightly from $78.5 billion to $77.2 billion.

Similar to last year, the CMS Geographic Variation File for 2022 was not available at the time of analysis. Instead, this year we again used BEA data on state gross domestic product (GDP) government transfer components, which detail the value of Medicare benefits provided to Virginia residents as the approach to estimate the most recent year of Medicare spending trends.

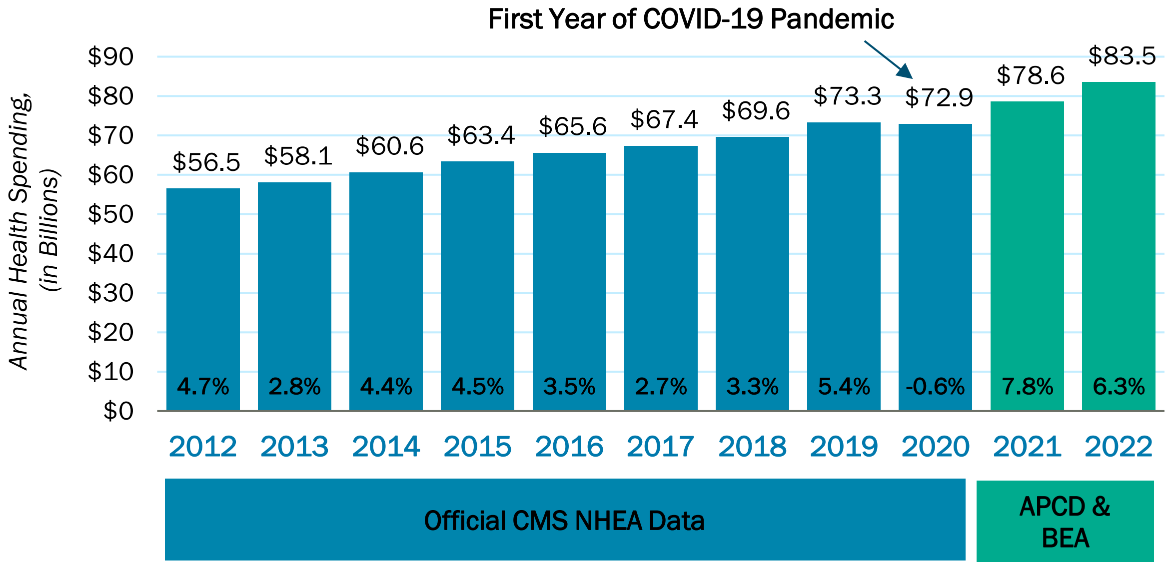
It is essential to note the 2020–2022 estimates of PHC spending in Virginia takes the estimates of total CMS state health expenditure data and subtracts one-time federal government financial assistance to providers—Paycheck Protection Program (PPP) and Provider Relief Funds (PRF)—to estimate the true health spending used on the receipt of care in all years. We then separately assessed trends in government assistance between 2020 and 2022 in a subsequent section. In recent releases of the official NHEA for the U.S. for 2020 and 2022, CMS includes these payments in their health spending estimates; therefore, to be consistent with our analyses of Virginia health spending trends, we omitted the PPP and PRF data from the national health spending findings in all comparisons.

Additional key data sources used in this report include the Virginia APCD, from which we used data on Medicaid and commercial health insurance claims; CMS Form-64 data on state Medicaid expenditures; Altarum's Health Sector Economic Indicators (HSEI) data; Agency for Health Research and Quality's (AHRQ) Medical Expenditure Panel Survey—Insurance/Employer Component (MEPS-IC) data; and BEA state-level PCE for the health sector. We used these data, blended and combined with data on health insurance enrollment statistics from the American Community Survey and official CMS Medicare and Medicaid enrollment files, to estimate by component and payer Virginia health spending trends through 2022.

We have designed all estimates to benchmark the existing CMS state-level health spending data, while extending those data through the most recent period available. We standardize most data in this report to be quarterly, using cubic splines to interpolate data when annual sources are used and averages to roll up monthly-level data. More detail on the specific data used in our analyses and the methodologies used to process and standardize the data are detailed in the methods appendix.

Overall Virginia Health Sector Spending

Figure 1: Virginia Annual Personal Health Care Spending (in Billions) and Growth Rate from Prior Year (Percent)



Virginia PHC spending in 2022 was $83.5 billion,[1] increasing 6.3% ($4.9 billion) from the prior year's spending level of $78.6 billion (**Figure 1**). This 6.3% increase in PHC spending was the second fastest increase since 2012, but slightly below last year's revised growth rate of 7.8%.[2] Growth in PHC spending since 2020 has been above the average seen in Virginia since 2012 (4.1%), primarily because the COVID-19 pandemic resulted in significant reductions in utilization for many types of health care services and led to a negative growth rate in PHC spending (-0.6% year-over-year) from 2019 to 2020.

Adding in the non-PHC spending categories, total health care spending in Virginia in 2022 was an estimated $98.8 billion, a 5.4% increase over the 2021 total spending estimate of $93.8 billion. PHC spending in 2022 continued the rebound observed in 2021. Spending on non-PHC spending categories (e.g., public insurance administration costs, net cost of private insurance, public health care spending, and research and development) increased by 0.4% year over year in 2022, slowing somewhat from last year's change (1.5%) and following the 2019 to 2020 rapid increase of 11.0% that was the largest since at least 2008.

Figure 2 shows the quarterly trend in Virginia's PHC spending relative to national growth in the last twelve quarters, showing that after an initial slump in cumulative health spending growth in the Commonwealth and nationwide (-12.1% versus -10.6%) in Q2 2020 (the peak of initial COVID-19

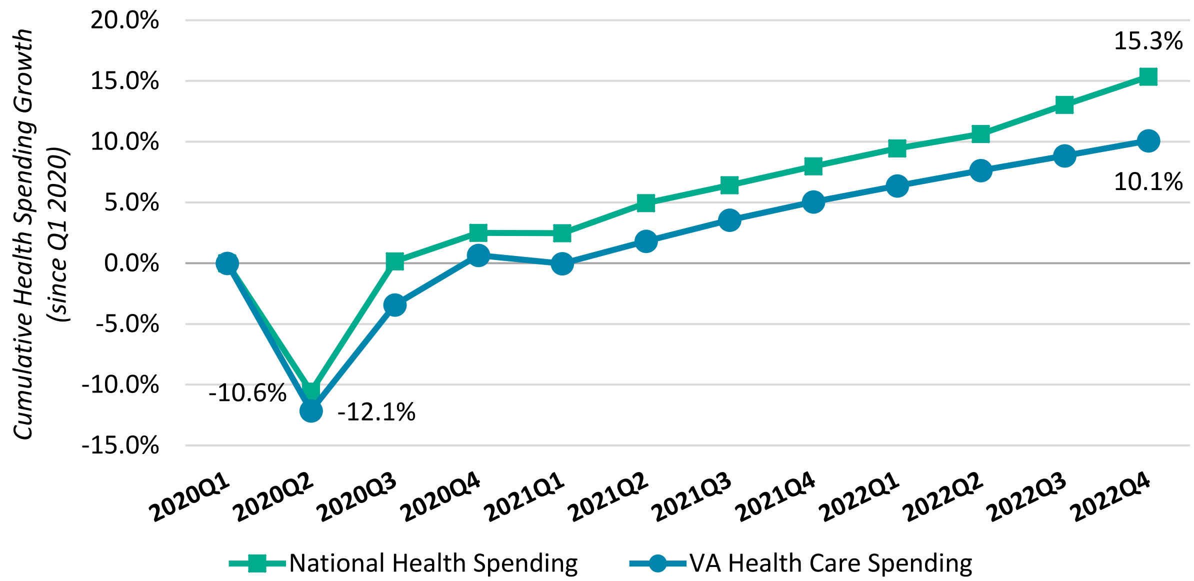
---

[1] In this report we show personal health care (PHC) spending as the amount spent on the traditional CMS-defined PHC categories, while excluding supplemental federal government support for health providers, such as Paycheck Protection Program (PPP) forgivable loans or Provider Relief Fund (PRF) provider payments. PHC spending includes direct spending on health care products and services (e.g., hospital, physician, and prescription drug spending), while non-PHC spending includes other expenditures such as: the administration of public health insurance, the net cost of private insurance, public health spending, and research and development. We differentiate between the underlying growth trends in PHC vs. non-PHC categories. More details on PHC vs. non-PHC definitions are here.
[2] Unless otherwise noted, health spending and growth rates in this report are shown as nominal, annualized values to be consistent with the way CMS reports spending in its NHEA. This means these spending data are not adjusted for inflation, and this report instead uses measures such as spending as a percent of GDP or per-capita spending values when assessing changes over time.

infections and a period of significant economic lockdowns), there has been a gradual recovery of health spending through Q4 2022. By Q4 2022, total national health care spending was 15.3% higher than it was in Q1 2020; yet, for Virginia, health care spending was only 10.1% greater over the same period. The gap in this health spending recovery could be due to differences in how the pandemic lockdowns and health care utilization reductions impacted Virginia or the willingness of residents to go back to seeking care as the pandemic continued into 2021 and 2022.

Nationally, much of the growth in health spending in 2021 and 2022 has been attributable mostly to increases in utilization rather than price increases; however, state-specific, sector-wide health care price and utilization trends are not readily available to assess differences Virginia's underlying utilization vs. price factors on total spending.

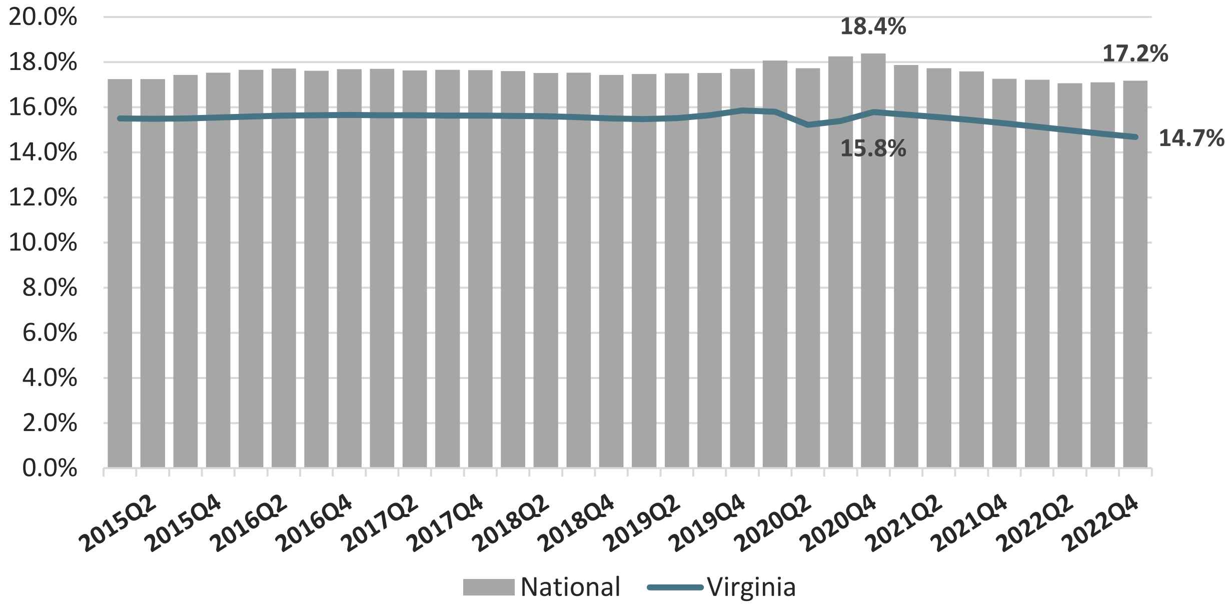
Figure 2: Virginia and National Quarterly Health Care Cumulative Spending Growth (since Q1 2020)



As a percent of Gross Domestic Product (GDP), Virginia's total health spending (including both PHC and non-PHC) mainly stayed constant between 2015 and 2020 but has been declining in 2021 and 2022. Both total health care spending and state GDP fell slightly in 2020, before each rebounded significantly in 2021 through to 2022. Due in part to faster inflation in economywide products relative to price increases for health care products and services, GDP increased faster than overall health spending in the Commonwealth in 2021 and 2022. Between 2020 and 2022, nominal state GDP increased at an annualized average rate of 5.9%, whereas health spending increased at an annualized rate of only 4.4%. As a result, the percentage of state GDP spent on health care fell from an estimated 15.8% in 2020 Q4 to 14.7% in 2022 Q4 (**Figure 3**). The 14.7% of GDP spent on health care in Virginia is the lowest since 2011 and well below the national average.

Figure 3 shows quarterly data on how Virginia's total health care spending as a percent of the economy has been consistently less than the national average since 2015. National health spending as a percent of GDP peaked in Q4 2020, at 18.4%, while Virginia health spending as a percent of GDP peaked at 15.9% in Q4 2019 and then at 15.8% in Q4 2020. Since that local maximum in 2020, Virginia's health care spending as a percent of GDP has been falling steadily to 14.7% in Q4 of 2022. While this 2022 trend is notable and represents significant reductions in the relative size of the Virginia health sector over this period, given a rebound in nationwide health spending as a percent of GDP throughout 2023, we expect there to be a rebound in health spending as a share of Virginia's economy in next year's data.

Figure 3: Virginia and National Health Spending as a Percent of GDP (2015–2022)

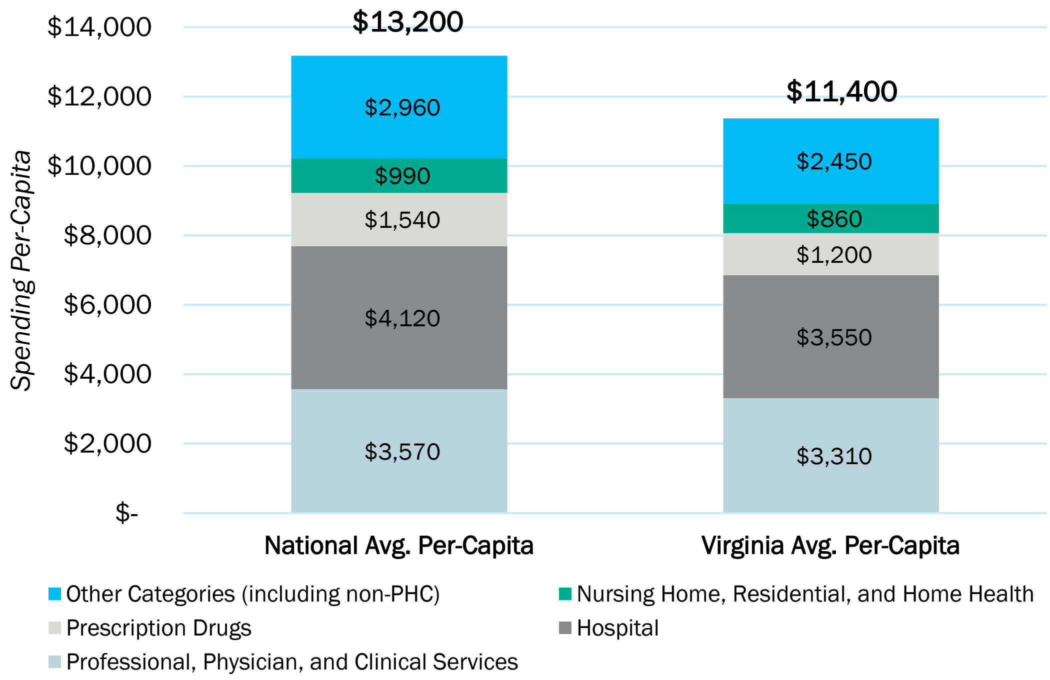


In 2022, if Virginia had spent the same proportion of its state GDP as the national average on health care, health care spending would have been $14.9 billion dollars more ($113.7 billion versus the actual $98.8 billion). The gap in the percentage of GDP relative to the national average going to health care declined slightly in 2022, resulting in small reduction in the difference compared to last year's reported difference of $15.8 billion between actual spending and the hypothetical total spending based on the national GDP share (data not shown).

As a result of the recovery in total health care spending following the pandemic, health spending on goods and services increased on a per capita basis in Virginia between 2021 and 2022, from $10,800 per person in 2021 to $11,400 in 2022. Despite this increase, Virginia's per capita health spending remains below the national average, which increased from $12,400 in 2021 to $13,200 per capita in 2022.[3] As a result, Virginia's estimated health spending per capita in 2022 was over $1,800 less than the national average (**Figure 4**). Among the major health spending components, residents on average in Virginia spent less per capita in 2022 than the national average on professional, physician, and clinical services ($260 less per capita); hospital care ($570 less per capita); nursing home, residential, and home health ($130 less per capita); prescription drugs ($340 less per capita) and other care ($510 less per capita) (*differences may not match chart values exactly due to rounding*).

[3] Note that both national and Virginia total and per-capita spending estimates for 2021 are revised slightly from last year's report due to incorporating data revisions from some spending input sources.

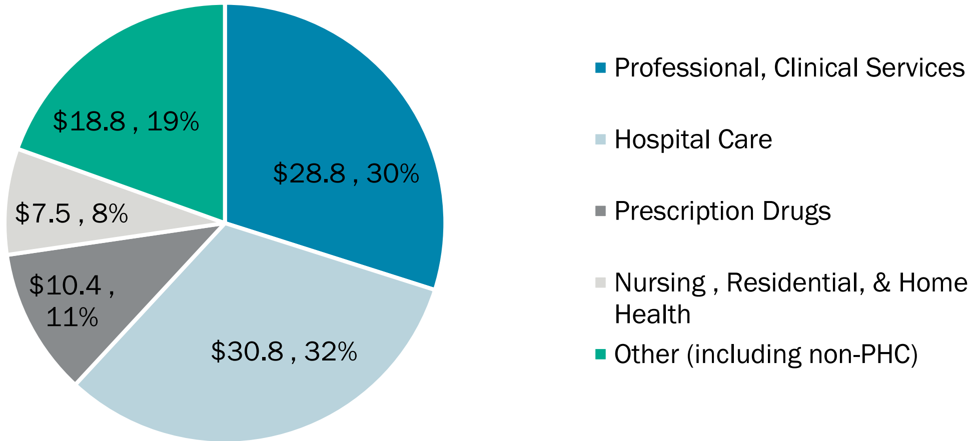
Figure 4: Average Total Health Spending Per Capita, by Category, 2022



This means, relative to the national average spending per capita, Virginia residents spend 7.3% less on professional and physician care, 13.8% less on hospital care, 13.1% less on nursing home, residential and home health care, and 22.1% less on prescription drugs (*values may not match chart exactly due to rounding*). These differences do not account for differences in the population (age, demographics, economic factors, or health status); however, a recent analysis in Health Affairs Forefront that did adjust for these factors found Virginia to be 4th lowest spending state in the country in "standardized health spending."

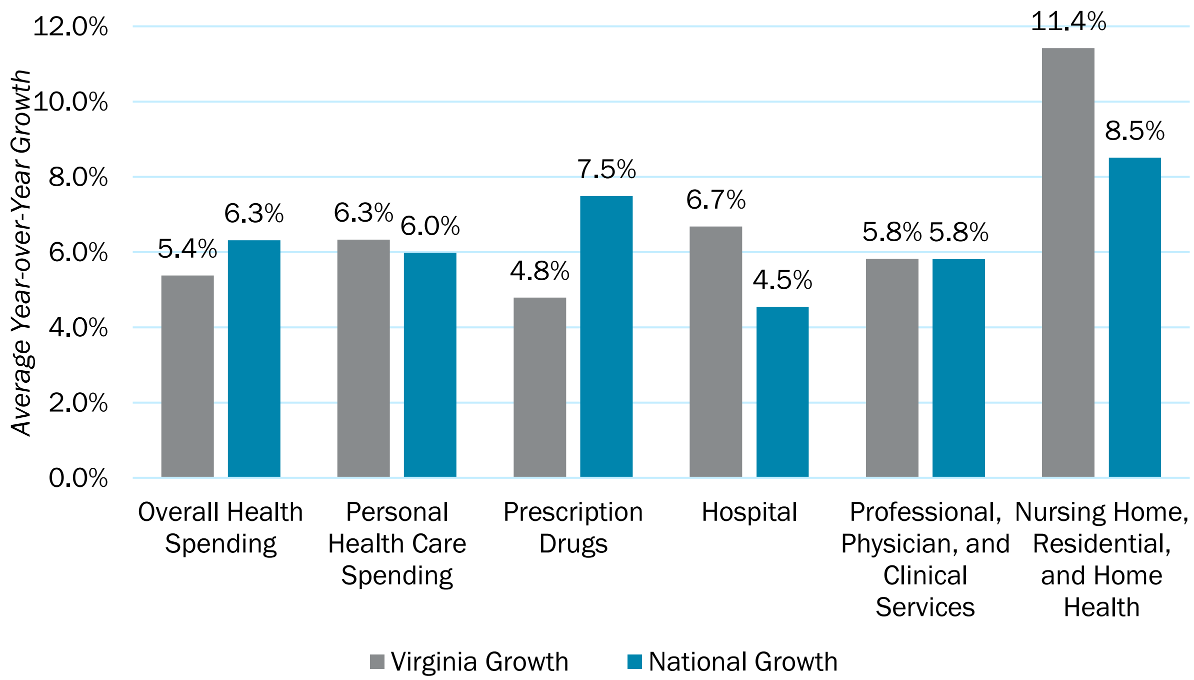
As a percentage of total health spending in Virginia, hospital spending was the largest major category of spending in 2022, accounting for $30.8 billion (32%) of spending (**Figure 5**). Professional, physician, and clinical services were the next largest category at $28.8 billion (30%), followed by other care and non-PHC categories at $18.8 billion (19%). The smallest two categories for the year were prescription drug spending and nursing home, residential, and home health spending, which accounted for $10.4 billion (11%) and $7.5 billion (7%), respectively in 2022. These proportions of total spending are broadly similar to the national averages. Hospital spending accounts for 31% of total health, professional and physician services is 27%, nursing home and home health care comprises 8%, and prescription drug spending is 12% of 2022 health spending.

Figure 5: Virginia Health Care Spending by Category (in Billions), 2022



Virginia's fastest-growing health spending category is nursing home, residential, and home health care with a growth rate of 11.4% year-over-year (**Figure 6**). The next fastest-growing categories of spending are hospital care (6.7%); professional, physician, and clinical services (5.8%) and prescription drug spending (4.8%). Of note, spending growth on prescription drugs has been slower in Virginia than the national average over this period while spending growth in the other categories have either been at par or higher the national average.

Figure 6: Average Spending Growth Rates (2021–2022), by Major Personal Health Care Category

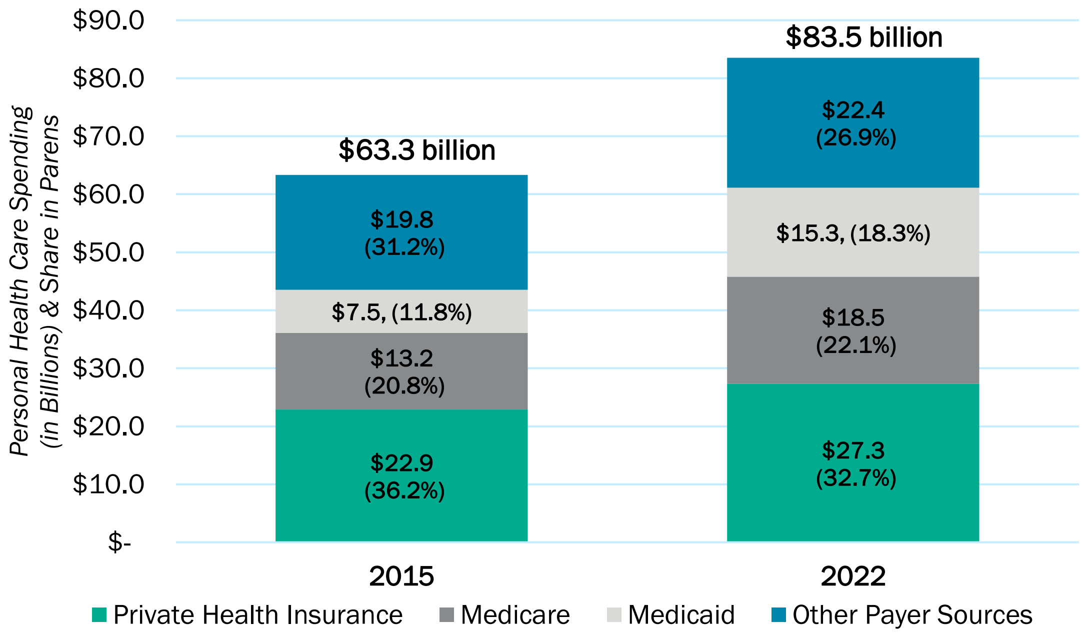


Virginia Health Sector Payers

The largest payer (by dollars spent) for health care products and services in Virginia in 2022 was private health insurance, spending an estimated $27.3 billion in PHC spending,[4] followed by Medicare ($18.5 billion), and Medicaid ($15.3 billion) (**Figure 7**). As a share of total PHC spending, the proportion of health care dollars covered under private insurance fell from 36.2% in 2015 to an estimated 32.7% in 2022. Conversely, the percentage of PHC paid by Medicare increased from 20.8% to 22.1% in 2022, and spending covered through Medicaid increased from 11.8% in 2015 to 18.3% in 2022, an increase from $7.8 billion in total spending to over $15 billion.

Compared to 2021, private health insurance spending increased by 2.6% year over year, Medicare spending increased by 4.4%, and Medicaid spending grew by 12.4%. Some 2021 spending estimates by payer were updated in this new data series, with a notable reduction in the estimate of private insurance spending from $28.0 billion last year to $26.6 billion in the new data due to updated BEA data and smoothing new private insurance spending estimates through 2022. Spending from other payer sources reached $22.4 billion in Virginia or 26.9% of all health spending. Included in this "other" category is out-of-pocket spending, other third-party payer spending, Department of Defense and Department of Veterans Affairs spending, school health spending, and worker's compensation. Nationally, the largest subcomponent of the "other" category is out-of-pocket spending.

Figure 7: Virginia Personal Health Care Spending Levels by Major Payer, 2015 & 2022



[4] CMS NHE state spending by payer estimates only include PHC spending. Public health spending, investment, research and development, net cost of insurance, and government administration of public insurance costs that are included in "total health spending" are not included in the "other payer" PHC data in this section.

The enrollment in each of these major payer types follows the spending trends, with the largest number enrolled in private health insurance (5.8 million), Medicaid (2.0 million), and Medicare (1.6 million).[5] An estimated 875,000 individuals were uninsured in Virginia in 2022.

Since 2020, Medicaid enrollment has exceeded enrollment in Medicare in Virginia, although the gap in enrollment between the two public programs is expected to close in 2023 as the public health emergency ends, likely resulting in fewer Medicaid enrollees. Growth in personal health care spending and enrollment for public payers has been inversely proportional to their starting size as Medicaid enrollment and spending growth has been the fastest of the three payers since 2015—enrollment growth averaging 8.5% year over year since 2015 and spending growth averaging 9.3% (**Figure 8**). Medicare is the second fastest-growing payer, with enrollment growth averaging 2.2% and spending 4.4% through 2022. Lastly, private insurance enrollment is growing very slowly, with only 0.7% year-over-year average growth since 2015 and a 2.8% average increase in spending growth.

The dramatic rise in Medicaid spending growth between 2015 and 2022 is primarily due to the growth in enrollment and Medicaid expansion for the Commonwealth. As of Q4 2022, there were an estimated 2.0 million people covered by Medicaid, up from 1.4 million just three years before. The rate of this growth remained high in 2022, increasing 10.0% from the year before, and continuing the fast growth period of initial Medicaid expansion. Medicaid remains by far the fastest-growing payer population in the Commonwealth.

Figure 8: Virginia Personal Health Care Spending and Enrollment Growth by Major Payer, 2015–2022

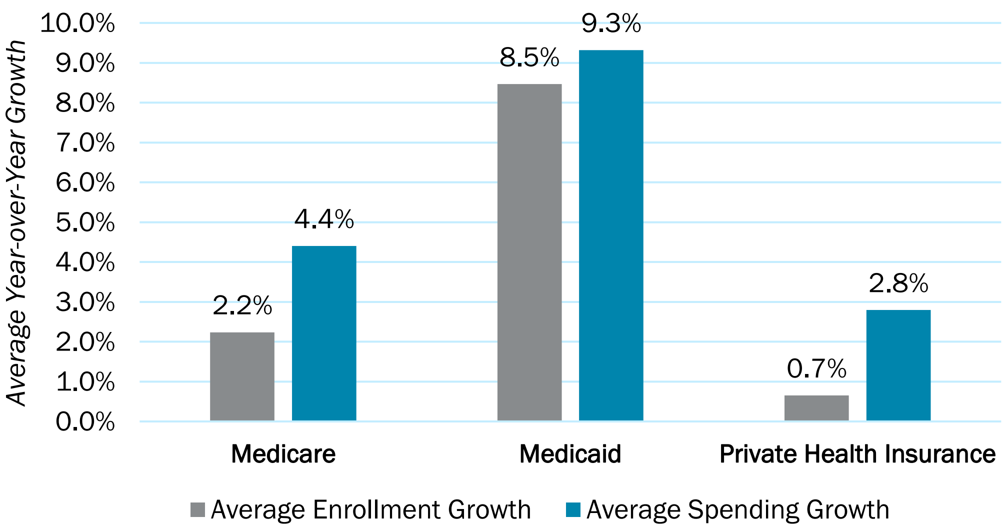
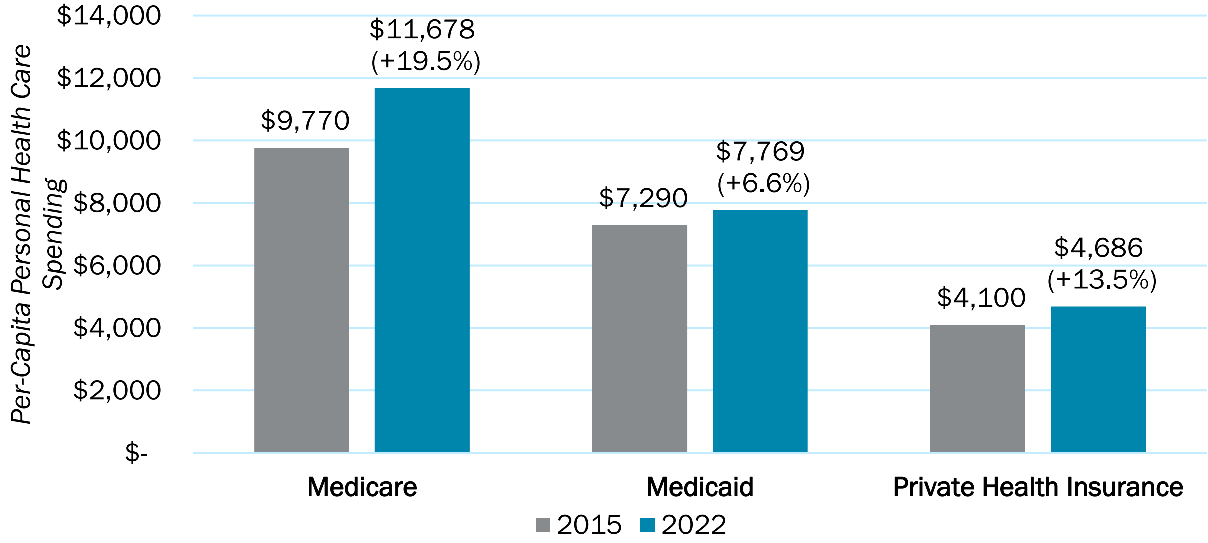


Figure 9 shows spending per capita changes by payer between 2015 and 2022 for Virginia, where per capita Medicare spending has grown the most (19.5%), then private health insurance health spending per capita (13.5%), and lastly Medicaid per capita spending growth (6.6%).

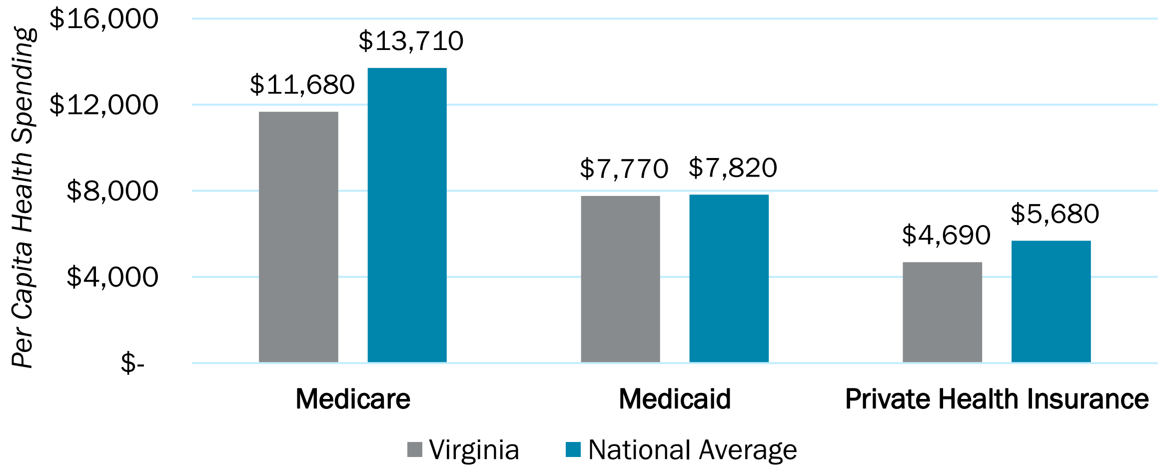
[5] The sum of these insurance counts will exceed the total number of Virginia residents, due to the fact individuals can report multiple types of insurance within a single year. In this report, we benchmark to CMS NHEA enrollment estimates through 2020 and then use KFF data to estimate the total private insurance through 2022 and direct enrollment data from CMS to estimate Medicare and Medicaid enrollment.

Figure 9: Virginia Per Capita Personal Health Care Spending by Major Payers, 2015 & 2022



For 2022, this equates to $11,700 of PHC spending per Medicare enrollee, $7,800 per Medicaid enrollee, and $4,700 per private health insurance enrollee (note this spending is estimated only for the personal health care spending component of total health expenditures and does not include out-of-pocket costs, as this is the CMS NHEA state data standard). When compared to the national average in 2021, annual personal health care spending per enrollee in Virginia is below average for private insurance enrollees ($4,700 vs. $5,700) and Medicare enrollees ($11,700 vs. $13,700) and is also slightly lower for Medicaid enrollees ($7,770 vs. $7,800) (**Figure 10**).

Figure 10: 2022 Virginia and National Per Capita Personal Health Care Spending, by Major Payers

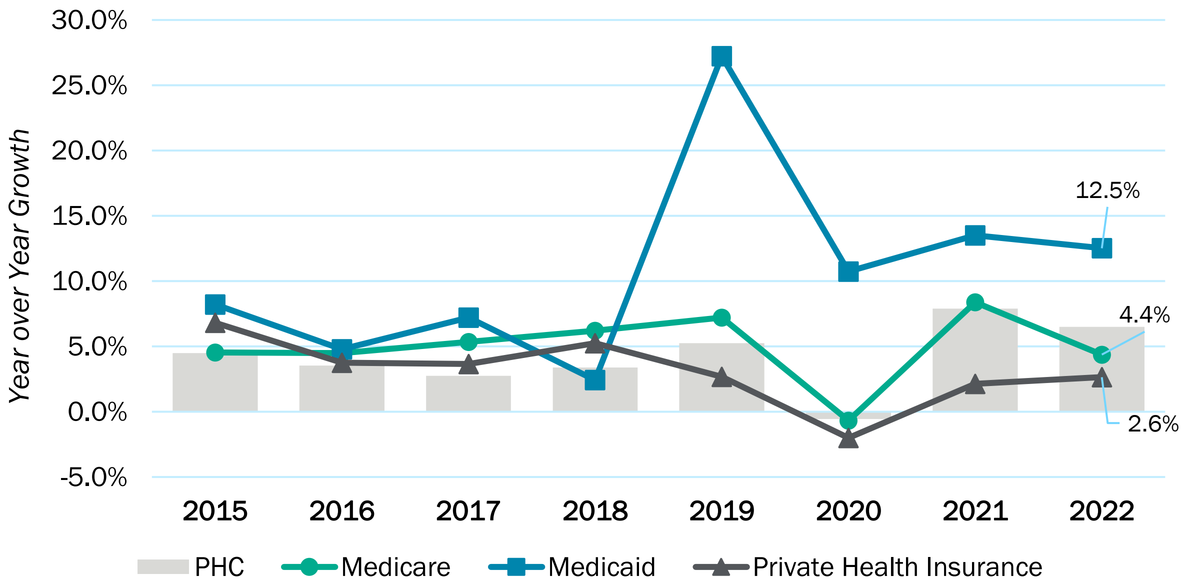


Between 2015 and 2019, growth in total health spending in Virginia remained relatively constant at about 4.0% (**Figure 11**). Nationally, total health spending also grew at a relatively constant rate of about 5.0% between the same period. In 2020, when the COVID-19 pandemic emerged, total health spending (including PHC and non-PHC components) grew by only 1.2% and 1.5% in Virginia and nationally respectively. Health spending growth rebounded to 6.7% in 2021 and 5.4% in 2022, above the pre-pandemic average in Virginia.

Since 2015, Medicaid spending has been the biggest contributor to the growth in health spending in Virginia, growing at an average rate of 10.8% (10.0% and 12.3% on average before and after the pandemic began respectively). The pre-pandemic growth average for Medicaid spending is strongly impacted by the 2019 outlier, due to the first year of Medicaid expansion in the state. The second biggest contributor has been Medicare spending with an average growth rate of 5.0% (5.6% and 4.0% on average before and after the pandemic began respectively); the least contributor has been private health insurance, growing on average by 3.1% since 2015 (4.4% before the emergence of the pandemic and 0.9% after the pandemic).

Nationally, while Medicare spending contributed the most to growth in national health spending before the pandemic emerged, with an average growth of 5.1%, Medicaid spending contributed the least to national health spending with an average growth rate of 4.4%. However, since the pandemic began, Medicaid has been the biggest contributor to growth in national health spending, growing at an average rate of 8.8%; private health insurance spending has contributed the least since the pandemic emerged with an average growth rate of 4.6%.

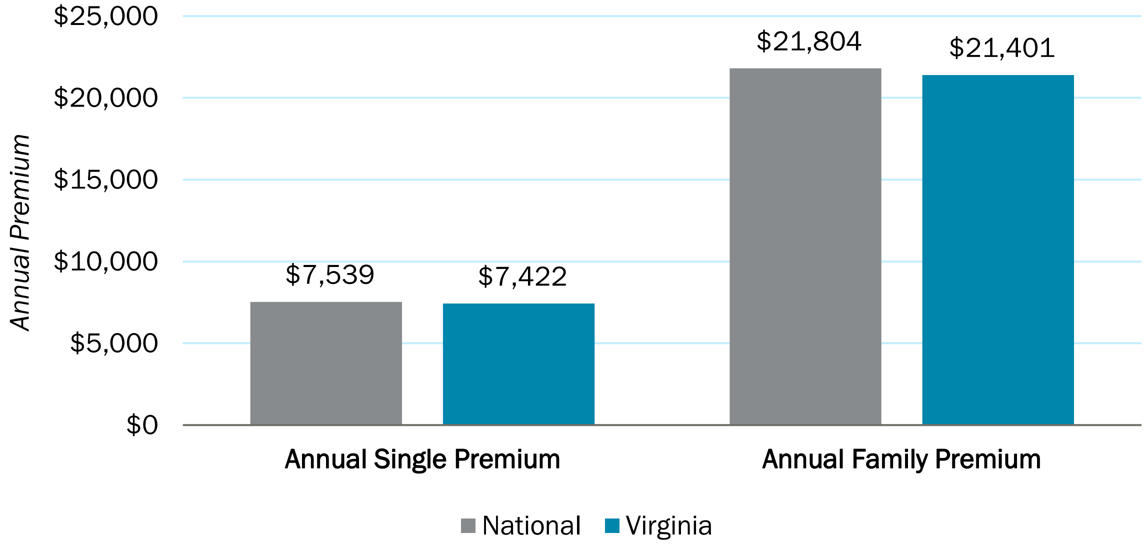
Figure 11: Virginia Personal Health Care Spending Growth by Major Payers, 2022



Virginia Private Health Insurance Cost Trends

For individuals with single coverage from a private-sector employer, annual average premiums were $7,420, about $100 less than the national average of $7,540. For those with family plans, annual premiums from a private-sector employer were $21,400 compared to $21,800 nationally, a slightly larger difference (**Figure 12**).

Figure 12: Virginia and National Private Insurance Single and Family Premiums, 2022

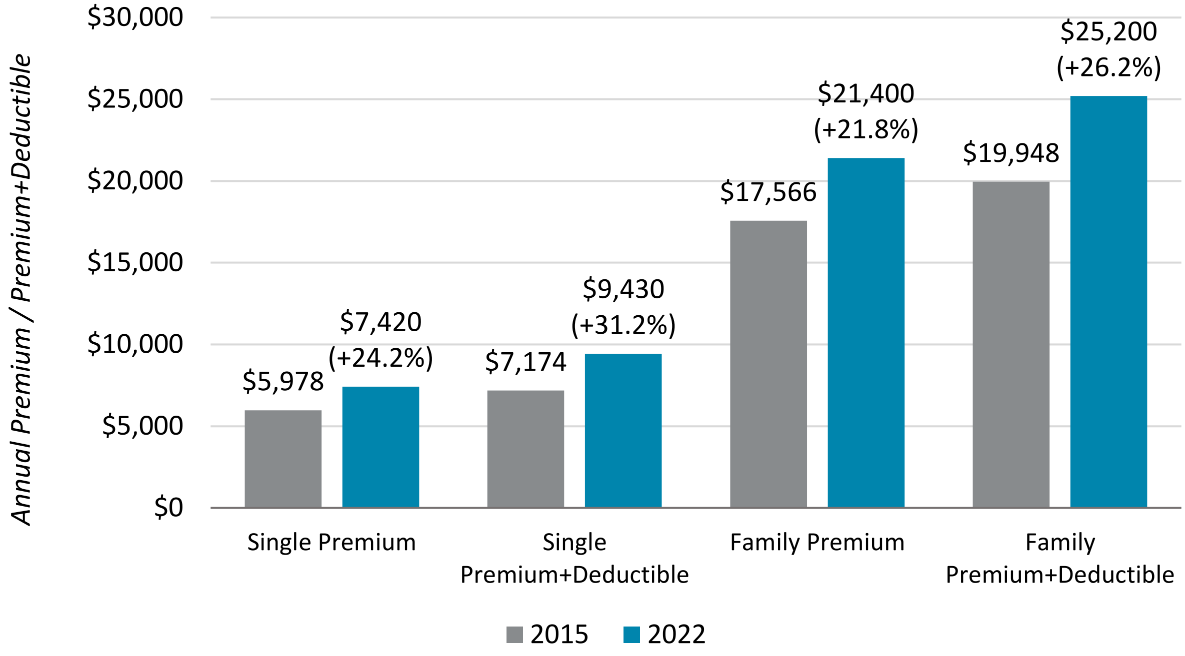


Virginia's private health insurance spending (not including out-of-pocket costs) per capita in 2022 is approximately $1,000 (17.5%) less than the national average ($4,700 vs. $5,700); however, the accompanying private insurance premium in Virginia for family coverage, is only 1.8% below national average and 2.1% below the national average when combined premiums and average deductibles are considered in 2022.[6] Furthermore, average single premiums and premiums + deductibles are only lower in Virginia by 1.6%, despite much lower per-enrollee private insurance spending.

Since 2015, private insurance premiums for individual coverage have increased 24.2%, while premiums for family coverage have increased 21.8%. Even greater has been the increases in estimates of total health care insurance payments computed based on total premiums plus average deductibles for each plan type. When rising deductibles are included in the calculations, single private insurance coverage became 31.2% more expensive over the past 7 years, while family coverage became 26.2% more costly (**Figure 13**).

[6] These reports have typically relied exclusively on Medical Panel Expenditure Survey – Insurance Component (MEPS-IC), estimates of Virginia health insurance premiums and deductibles. However, due to greater than normal disparate response values for the 2022, we have alternatively used KFF Employer Health Benefits Annual Survey data to estimate Virginia's 2022 insurance premiums.

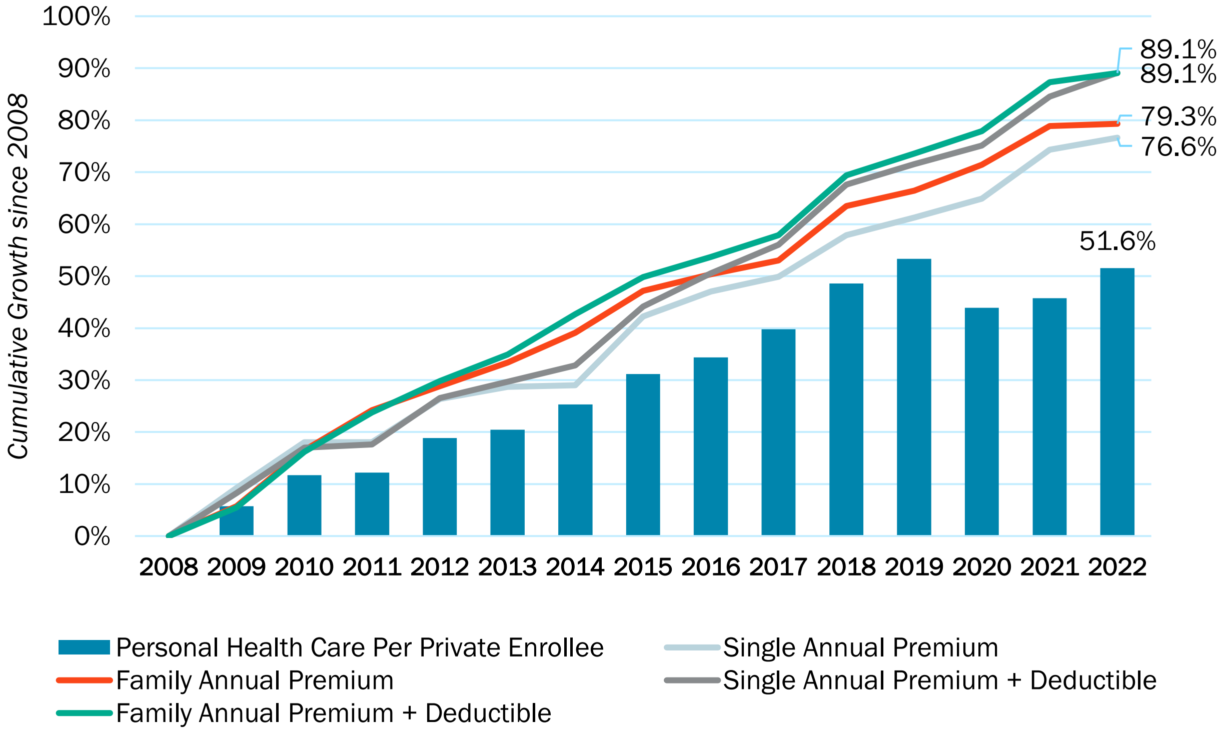
Figure 13: Virginia Private-Sector Employee Health Insurance Premiums, 2015 & 2022



When assessing the impact of these growth differences over a longer period, it is clear that, for Virginia, the cumulative growth in both single and family annual premiums has outpaced underlying spending on personal health care services by private insurance plans. Since 2008, personal health care expenditures per private insurance enrollee are up 51.6%, while the premiums for single coverage of a private-sector employee are up 76.6%, and family premiums are 79.3% higher (**Figure 14**). Furthermore, over this period, other types of cost-sharing have also increased—average deductibles are substantially higher, as are many types of co-payments for specific services. If the annual deductible were added to each of the single and family plan annual premiums, total plan costs would be 89.1% and 89.1% higher, respectively, in 2022 (**Figure 14**).

Separately, for individual coverage purchased on the marketplace, monthly premiums in Virginia in 2022 were higher than the national average, by 2.7% ($450 versus $438, *data not shown*). These individual premiums in Virginia have decreased slightly from the prior year ($479 in 2021), but are up significantly from 2015, when the benchmark single premium in Virginia was $281. 2022 insurance premiums in Virginia could have been impacted in part due to expectations of the 2023 reinsurance program. In a bid to lower prices, the state, with federal approval, passed a reinsurance program to cover a portion of the most expensive claims by insurers. The program operates as a traditional reinsurance program by reimbursing ACA individual market health insurers for a percentage of an enrollee's claims costs that exceed a specified threshold and up to a specified ceiling. Consequently, it is expected that private premiums for single residents in both the individual market and from private insurance could fall in 2023 and in the years that the program is in operation.

Figure 14: Cumulative Growth in Private Insurance Personal Health Care Expenditures, Single Premiums, and Family Premiums, Virginia, 2008-2022



Indications from experts are that health insurance costs for private employers are increasingly unaffordable, particularly for small employers. In assessing the net cost of insurance component of insurance premiums, there are a variety of sources that can be used, although they are not available annually at the state level. To calculate national totals, we used the CMS National Health Expenditure Accounts (NHEA) data to find that the net cost of insurance expenditures increased from $235 billion in 2019 to $297 billion in 2020 and remained high through 2022 at $279 billion.

Federal Government Direct Pandemic Financial Assistance

In this section, we analyze Virginia's health care sector details of the direct financial support from the federal government to health care systems and providers in the Commonwealth to help providers cope with the adverse impacts of the COVID-19 pandemic. These funds came mostly from two major programs: the Provider Relief Funds (PRF) and the Paycheck Protection Program (PPP).

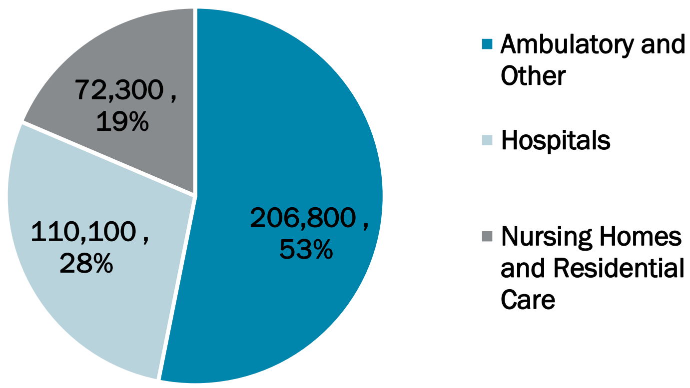
PRF was federal financial support specific to health care entities and was primarily provided to large hospital and health care systems to assist with additional costs required to treat COVID patients and make up for lost revenues due to delayed and forgone care during the pandemic. PRF funds were typically direct payments that would not be expected to be repaid. PPP was, conversely, a program that offered financial assistance to businesses in all industries (although health care was one of the largest recipients of these funds) and support in health care settings mostly went to small- or medium-sized practices and these dollars were offered as forgivable loans as long as conditions such as maintaining staff employment levels were met. PPP ended in May of 2021. Consequently, federal financial support came only from the PRF in 2022.

Compared to other states, Virginia received just 1.6% of the total PRF provided nationally in 2022. Virginia's health care providers received $235 million in PRF financial support from the federal government in 2022, which is 19.8% down from 2021, and representing 0.3% of total health care spending (down from 0.8% of total health care spending a year ago). This is a similar percentage to the 0.3% of national health care spending that was offered nationwide, representing nearly $15.5 billion in financial COVID relief.

Virginia Health Sector Employment

As of the fourth quarter of 2022, the Commonwealth's private sector employed more than 3.4 million Virginians, with 389,000, or about 11.5% of the privately employed population working in the health sector.[7] Health sector employees had steadily increased over time, growing from 338,000 individuals in early 2015 to 381,000 in Q1 2020. This then fell dramatically at the start of the pandemic due to furloughed health workers (to a bottom of 350,000) before bouncing back to the current 389,000. Among those employees, 207,000 (53.1%) work in ambulatory care settings, 110,000 in hospital settings (28.3%), and 72,000 (18.6%) in nursing homes and residential care settings (**Figure 15**).

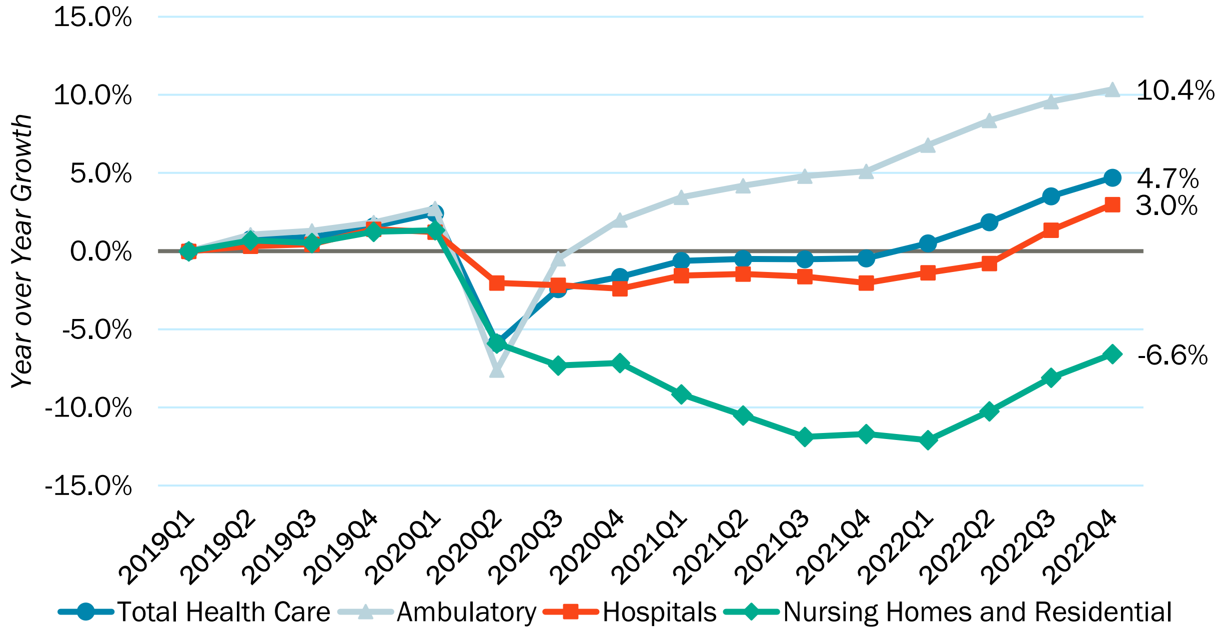
Figure 15: Virginia Health Sector Employment, Q4 2022



By the end of 2022, employment in hospitals returned to their pre-pandemic levels of employment (up by 3.0% from Q1 2019). However, nursing home and residential care facilities were still down nearly 7.0% in total employment over the same period (**Figure 16**). These trends were similar to the national health care employment situation, where nursing homes and residential care facilities employment went down while employment in hospitals and ambulatory settings have returned to their pre-pandemic levels. Hospitals and nursing home employment rebounded in 2022, with year-over-year growth rates of 5.1% and 5.8% respectively. This was also the case nationally, with employment in both sectors growing at a rate of 2.1% and 3.1% year-over-year by the end of Q4 of 2022.

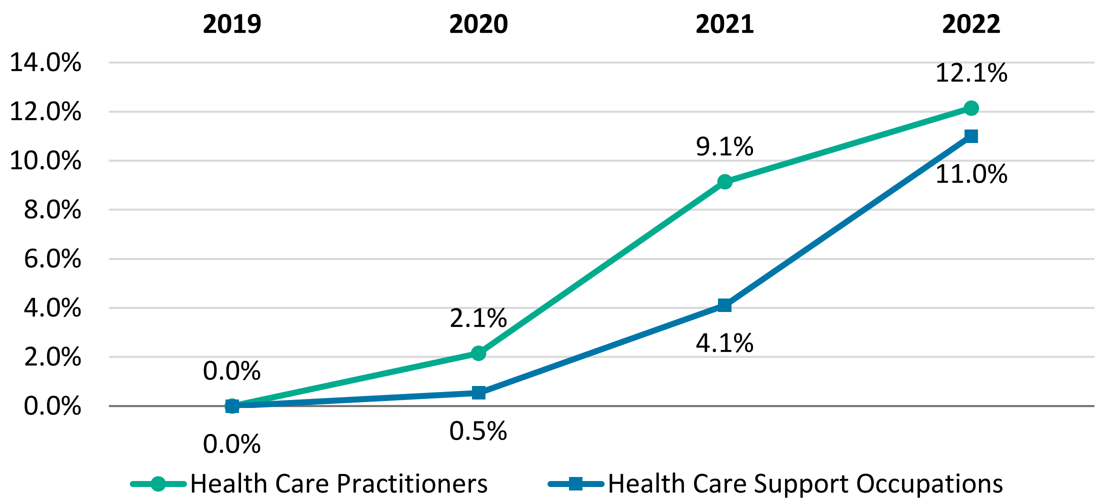
[7] Note that this 370,000 and other employment estimates come from the BLS Current Employment Statistics (CES) and a survey of Virginia business and government establishments. As a result, temporary and contract employees and self-employed health care workers are not included in these statistics.

Figure 16: Virginia Health Sector Employment Cumulative Growth, by Major Category



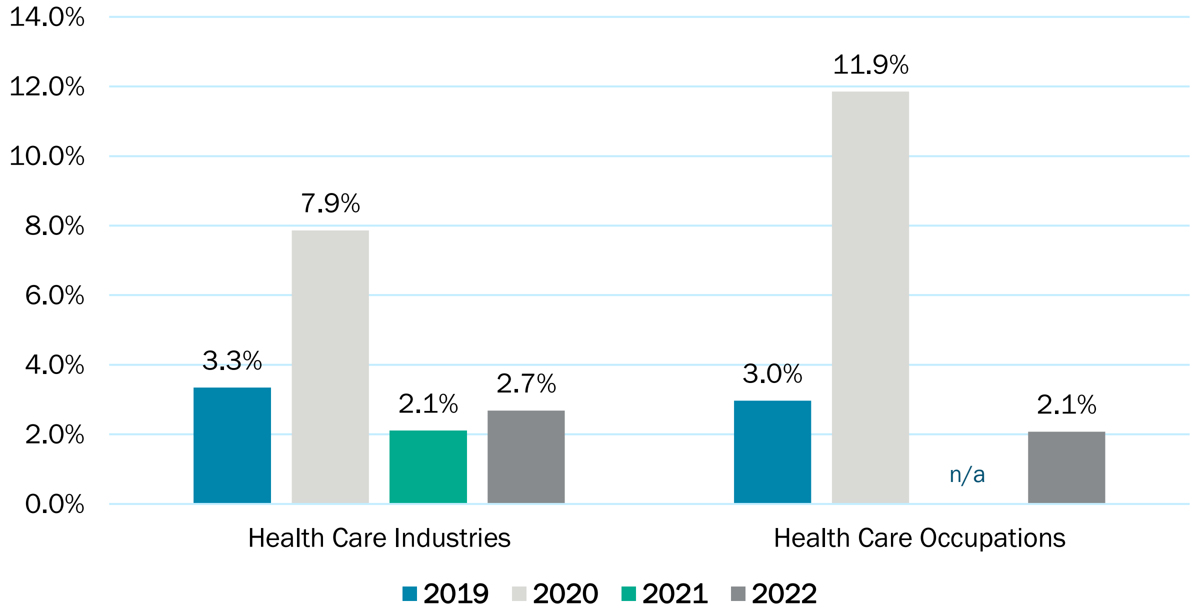
While health care employment totals recovered in 2022 and for the majority of settings exceeded counts of employees in Virginia prior to the pandemic, there remained signficant evidence that the labor market for health care employees was very tight, driving up costs of providing care. Wages continued to increase in 2022 after above average increases in 2021 and since 2019 in Virginia, annual wages for health care practitioners (e.g., physicians, nurses, and technitions) were up 12.1% cumulatively, while wages for health care support (e.g., aides and asssitants) employees were up 11.0% (**Figure 17**). Growth in 2022 for the support employees (6.6%) exceeded the growth in wages for practitioners (2.8%), after the opposite ocurred in 2021. As a result, cumulative growth of the support employee's annual wages nearly caught up to practitioners between 2019 and 2022.

Figure 17: Virginia Cumulative Health Sector Year-Over-Year Wage Growth (2019-2022), by Occupation Category



Moreover, assessing the unemployment rate among Virginia's health care industries and occupations, we see that the labor market has remained very tight in 2022. Among all health care industry jobs, unemployment rates averaged 2.7% in 2022, while among health care specific occupations, unemployment averaged and even lower 2.1% (**Figure 18**).

Figure 18: Virginia Unemployment Rates in 2022, by Occupation and Industry Category



Higher labor costs likely contributed to greater overall costs for providing care for many health care entities. Labor and capital costs in 2022 increased for health care as economywide inflation continued to increase significantly, while health spending (and revenues for many providers) likely increased at a slower rate in Virginia. Evidence from regional data sources (such as the KaufmanHall National Hospital Flash Report), found that total hospital expenses in the "Northeast/Mid-Atlantic" region increased by 7% year-over-year in 2022 and 17% between 2019 and 2022, while the labor expenses increased by 8% year-over-year and 16% from 2019. Compared to volume and operating revenue trends that either saw either negative or very slow growth between 2021 and 2022, many hospital financial metrics were signficantly worse in 2022. KaufmanHall reports for the Northeast/Mid-Atlantic regions that hospital operating margins were down 44% year-over-year in 2022 and down 12% from 2019 to 2022. Newer data for 2023 show that these trends began to reverse this year as labor cost growth and other inflation pressures have slowed and revenues have increased, but 2022 was a year of particuarly difficult financial performance for many health care providers due to higher costs.

Conclusion

The Virginia health care sector continued to stabilize in 2022 after the dramatic impacts of the pandemic that hit in 2020. The return to moderate health spending growth that we saw in last year's report has continued into 2022, although this health spending growth has been somewhat overshadowed by much larger increases in statewide GDP increases and economywide inflation. After PHC spending declined in Virginia in 2020, we found that with updated data it increased 5.8% in 2021 and 5.6% in 2022. These growth rates are above recent historical averages. However, even with above average growth, the relative size of the health care sector compared to statewide GDP shrunk in 2022, falling from an average of 15.2% in 2021 to 14.3% in Q4 2022. This 14.3% of the economy is the smallest share of the Virginia's GDP since 2011.

Overall trends in Virginia health spending continue to show that total health spending per capita in Virginia is lower than nationwide averages, and that less was spent per person in 2022 on hospital care ($500 per capita), professional services ($300 per capita), prescription drugs ($300 per capita), and nursing home care ($100 per capita). While average health spending per capita and private health insurance spending on care per enrollee in Virginia are well below national averages, premiums for many types of private health insurance remain higher than what might be expected given the differences in spending (continuing a finding we've discussed in previous years). Growth in private-sector employee premiums and combined premiums and deductibles have increased between 13.3% and 35.0% since 2015.

Lastly, while 2022 data show that hiring picked up for health care employment categories in Virginia, the labor market remained tight and growth in labor costs likely remained elevated, affecting provider financials. Annual wage increases for both health care practitioners and health care support operations were positive in 2022, putting upward pressure on costs for providers and systems. These higher costs included the observed changes in health care wages, but also higher costs due to economywide inflation in 2022. Looking ahead to the data for 2023, we expect that as new health spending information becomes available, we will see health spending growth continue to rebound from the pandemic, and that total health care as a share of the overall economy will likely bounce back from the ten-year low seen in 2022. We will continue to track trends in Virginia's health sector employment data and expect robust hiring to continue, while private insurance premium trends relative to underlying health care spending are more likely to slowly adjust in future years given early 2023 indications.

Appendix A: Report Methodology

Virginia Health Sector Spending

CMS National Health Expenditure Accounts Benchmarking

Analyses in this report follow strategy of Altarum's national-level Health Sector Economic Indicators (HSEI) briefs and data, at the state level. HSEI spending analyses are designed to provide the most up-to-date possible estimates of health expenditures that are consistent with and build upon the CMS National Health Expenditure Accounts (NHEA). Among health economists and health sector experts, these data are among the most frequently cited and most trusted estimates of health sector spending and provide robust, consistent, and understandable estimates of health sector expenditure trends. The NHEA accounts contain data at the national level (updated annually) and state level (updated every 4 or 5 years), data by payer, data by spending category, and data for specific demographic groups (age and gender). Also included in the NHEA are projections of future health national health sector expenditures, which are updated annually. Despite their reliability, official NHEA data are released with a significant time lag, particularly at the state level (the most recent data at the time of writing are available through the year 2020).

Therefore, this work directly incorporates and benchmarks to CMS NHEA data whenever it is available, and then subsequently builds on those data to generate estimates of spending for periods that are not yet available in the NHEA data: in this report the quarterly data for 2022. When subsequent releases of NHEA data become available, this approach makes it possible to re-benchmark our findings for the years provided and continue estimating for new periods not yet available from CMS. All category definitions, populations, and spending estimates in this report match directly with the CMS definitions used in the NHEA. Details on the NHEA methodology and how it compares to other health sector spending estimates, for example those in GDP accounting, are available on the NHEA homepage. In the case of the state health spending trends, we benchmark to the data available from 2008 through 2020 in the state-level NHEA accounts, using data on total spending by health category, spending by payer, and spending per enrollee for each of the three major insurance types. Data on state health spending trends come in two variants, based on residence and provider location; we use data by residence as the source for this report.

In some cases, data from CMS (which are reported annually), need to be portioned into quarterly or monthly estimates to support the estimates of future periods and to ensure consistent reporting over time. In the national HSEI, within-year trends are estimated using the underlying health spending estimates from Bureau of Economic Analysis (BEA) National Income and Product Accounts (NIPA) data, while splined to ensure that the national annual HSEI totals match with the CMS NHEA totals. In the state-level work, we follow a similar approach, yet often do not have the same historical data in our underlying series to generate intra-year trends. Therefore, in this work, we instead use a simple cubic spline for intra-year trends of the state-level CMS total spending, spending by category, and spending by payer data from 2008 to 2020. As a result, averages of quarterly data in the final workbooks may differ very slightly from the annual data reported by CMS, due to the cubic spline methodology. Generally, our approach is to report on annualized data, which estimates spending quarterly based on what an annual total of spending would be for that period if it continued for an entire year.

In order to estimate future periods of data, while benchmarking to the CMS NHEA state-level data through 2020, we use the same approach as in the national-level HSEI analyses. We calculate from other data year-over-year growth rates for subsequent periods in categories and series that are comparable to the official NHEA statistics. For example, data from the Virginia APCD and data from state-level GDP and NIPA sources are used to calculate year-over-year growth rates and those are then applied directly to the base year (2020) CMS NHEA estimates. This approach is made separately and independently for total state spending category spending, spending by payer, and enrollment by payer. This approach ensures that future period estimates are consistent with the CMS NHEA data and that there are no discontinuities between the official CMS NHEA data and the more recent periods in this report and the underlying data. We specifically highlight this in Figure 1 of this report, showing the official and estimated periods in different colors.

Some estimates of health expenditures that are available at the national level are not available in the CMS state-level data (or differ slightly from the national data). For example, state NHEA data do not include estimates of spending beyond personal health care expenditures (PHC), nor do they directly contain estimates of total spending or spending per enrollee from minor insurance types (like military health systems or the Indian Health Service) or for the uninsured. Generally, when CMS spending data are not available to be used as benchmarks, we do not include estimates of those components in this report. The exception to that is our estimate of total health expenditures for Virginia (in addition to the PHC expenditure data). We estimate this by applying the ratio of national total health spending to national PHC expenditures to the state-level estimates of PHC to estimate state-level total health spending. This statistic is then used in our comparison of total health spending as a percent of GDP nationally to health spending as a percent of state GDP.

The benchmarking approach discussed above also applies to estimates of enrollment by major insurance types in the state, using CMS data through 2020. We attempt to remain consistent with NHEA population data, including the way that individuals are reported with multiple insurance types, and do not specifically report on the number of individuals uninsured at the state level. Details on data used to estimate enrollment in subsequent periods is described below, primarily relying on U.S. Census American Community Survey data.

Population and Health Insurance Enrollment Estimates

Data used to estimate enrollment by insurance type in Virginia for 2022 incorporate data from the U.S. Census American Community Survey (ACS) and official Medicaid enrollment data. 1-year ACS data on health insurance status by type were obtained from the Kaiser Family Foundation State Health Facts, and 2022 data were used for individuals residing in Virginia, using growth rates to estimate the change in those insured with private health insurance and Medicare. Note that despite the fact the ACS data allow for respondents to flag multiple insurance types, this approach does not double-count enrollees, because only the growth rate from ACS is applied to the benchmark CMS enrollment data. Individuals with private insurance include both those that reported receiving insurance directly from their employer and those who purchased insurance directly from an insurance company during the year.

For Medicaid enrollment, we used data on enrollment by state from the Kaiser Family Foundation, again applying the year-over-year growth rate from this data to the benchmark CMS NHEA Medicaid enrollment counts. This yielded what we believe to be a more accurate count of Medicaid enrollment growth statistic, particularly for the years 2019-2022, where enrollment expanded greatly due to the state passing Medicaid expansion in the prior year.

Private Health Insurance Personal Health Care (PHC) Spending Estimates

Total health spending and spending per enrollee for those with private health insurance in this report benchmark to CMS NHEA estimates of spending from private health insurance sources. The primary data source used to build on the CMS NHEA data (which ends in the year 2020) is data on private health insurance spending captured in medical claims contained within the Virginia All-Payer Claims Database. Importantly, we use this data only in combination with the enrollment data described above to estimate trends in health sector private insurance spending. We do this by estimating trends in the APCD for health spending per private insurance enrollee over time and then multiply this data on spending per enrollee by the enrollment data from ACS above to estimate total year-over-year growth trends for Virginia's private health insurance funded spending. Spending per enrollee is calculated from the APCD on a monthly basis based on data using the sum of health expenditures in the four major claim types (Inpatient-IP, Outpatient-OP, Prescription Drug-RX, and Professional-PB) and then dividing by the number of enrollees in that month in the APCD enrollment tables.

We use this approach to incorporate the APCD data into our health spending estimates, rather than simply using total spending from private insurers directly from the APCD because the APCD does not cover all individuals with private insurance in Virginia. Those covered by a self-insured employer are potentially missing from this data, due to the fact that those entities are not required to submit their claims to the APCD. This is particularly an issue during periods following March 2016, when the Gobeille v. Liberty Mutual Insurance Co. case was decided by the U.S. Supreme Court. Moreover, the number of submitters and enrollees covered by the APCD are not consistent over time. Therefore, the approach of using monthly computations of total spending and enrollment compensates for changes in enrollment over the year and also for potential loss of submitters over time in a way that does not bias our estimates of total spending.

The monthly data on per enrollee spending were then combined via averaging into quarterly data and annual data and applied to the enrollment counts discussed in the prior section to estimate total spending. Some monthly data series derived from the APCD, such as commercial prescription drug spending in later periods, required smoothing to estimate year-over-year spending growth trends, where necessary this was done using an 18-month trailing average.

Medicaid Personal Health Care (PHC) Spending Estimates

An identical approach to the one used in the private insurance personal health care spending data was applied to estimate spending by Medicaid in Virginia for the periods building on the 2020 CMS benchmark data. Although the concerns about total spending computed in the APCD for Medicaid are less significant, because it is likely all Medicaid enrollees are covered by the APCD submitters (unlike those with private insurance), we chose to use the same approach to ensure consistency between the Medicaid and private health insurance methodology. However, for Medicaid, an additional step was taken to also include additionally available data on spending trends from CMS State Expenditure Reporting for Medicaid & CHIP data collected via CMS-64 forms for each state. We believe that this data, which measures trends in total spending by the Virginia Medicaid program in each state over time is also likely to be strongly predictive of the official CMS reported health sector spending (separately from the underlying claims data reported to the APCD).

Therefore, to estimate final Medicaid PHC spending and spending per enrollee, we blend two separate estimates of Virginia Medicaid spending over time, one generated from the APCD approach described above and one directly from estimates in spending growth by the Medicaid program from the Form-64 data. These data are blended by computing annual growth rates and then using a simple average of the two approaches to estimate Virginia health spending from the NHEA 2020 benchmark year.

Medicare Personal Health Care (PHC) Spending Estimates

Estimates of total personal health care expenditures for Medicare differ from the above approaches, due to the fact that comprehensive Medicare claims were not available in the APCD for all necessary time periods at the time of analysis. We therefore use data from the BEA State Gross Domestic Product data, which details the size of government transfer payments to state residents for Medicare benefits. This varies from prior works where we used Medicare Geographic Variation Public Use File and the Medicare Part D Provider Utilization and Payment Data: Part D Prescriber file to estimate per enrollee spending trends for Virginia and multiply those data with the enrollment counts from the ACS to estimate year-over-year growth in Medicare spending. At the time of analysis, the 2022 Medicare Geographic Public Use file was unfortunately available, leading to our use of the alternate BEA source. Data for 2022 were updated from the prior report using the Geographic Public Use File for that year.

Spending by Personal Health Care Category

Independent of the spending estimates by payer, we also estimate spending by the major NHEA health expenditure categories for Virginia, including physician and professional services, hospital services, nursing home and residential care services, and prescription drug expenditures. These results by category are generated using the underlying year-over-year growth trends in the data for each payer attributable to each NHEA category (and mixed using weighted averages, weighted by the enrollment in each insurance type). The categories in the underlying data are attributed in varying ways, depending on the category and data source. For example, data from the APCD for private insurance and Medicaid are attributed based on claim type (Inpatient claims attributed to hospital spending, professional claims to physician and clinical spending, and prescription drug claims to prescription drug spending) and data from the Medicaid Form-64 data are attributed based on the category of spending listed. The overall state of Virginia growth rate from these combined data for each category is then applied to the base year (2020) CMS NHEA spending by category to calculate the 2021 and 2022 spending estimates.

Also incorporated into the health spending category estimates are data from BEA state-level personal consumption expenditures data for the following settings: hospitals, nursing and residential, and ambulatory services. A simple average is used to combine the year-over-year growth rate estimate derived from the state-level BEA data and the data directly from the APCD, Medicaid, and Medicare sources. The blended growth rate is then applied to the CMS NHEA data. Details on the differences between spending category estimates derived from the blended payer data and growth estimated directly from the BEA personal consumption expenditures data are available upon request.

Lastly, to generate estimates of total PHC expenditures for the state for 2022, data on growth in spending for those not covered by the three major insurance types was required. An estimate of this aggregate PHC spending was computed directly from Virginia personal consumption expenditure data for health care services and then blended with the data described above on the three major payers. This "other" category is used to estimate spending both from other sources and on categories not described above.

Virginia Health Sector Employment

Data on health care employment is taken directly from the Bureau of Labor Statistics (BLS) Current Employment Statistics (CES) data for Virginia. These data are available directly for all categories used in this report. Monthly data are collected and then combined via an average to generate quarterly and annual data. State-level data are only available in the "Not Seasonally Adjusted" data series; however, this has a minimal impact, as seasonal trends in health care employment are very slight. Health employment as a percent of total employment is calculated in two ways (described in the report), using both a base of total nonfarm employment and total private sector employment (also not seasonally adjusted). The difference between these two series is that private sector employment excludes those employed by public state and federal government entities.

In this year's report, we added data on health employment and wage trends by occupation from the BLS Occupational Employment and Wage Statistics (OEWS) and findings from the Current Population Survey (CPS). These data were processed to reveal findings for the Commonwealth of Virginia for specific health employment statistics, while analyzing the underlying microdata such that findings were consistent with aggregate, publicly-available findings.

Virginia Private Health Insurance Costs

Data on private employer health insurance premiums are calculated based on the Agency for Health Research and Quality's (AHRQ) Medical Expenditure Panel Survey— Insurance/Employer Component (MEPS-IC) and KFF Employer Health Benefits Annual Survey Data. MEPS-IC data track and allow for the comparison of private health insurance premiums and plan characteristics, such as deductibles, for individuals with coverage from a private-sector employer across the U.S. and for specific states. The data were curated using the MEPSnet/I.C. Trend Query online portal, and data for private-sector establishments were taken for Virginia to include all plan types (single, family, and employee+1) separately, all provider types (HMO, PPO, any-provider plans) combined, for all firm types combined, and all firm sizes combined for the Commonwealth. In 2022, data from the MEPS-IC Virginia survey respondents showed abnormally disparate survey response values and data that did not align with national or regional trends. As a result, for 2022 individual and family premiums, data from the KFF Employer Health Benefits survey were supplemented to estimate 2022 premiums. Data on the "South" region for all insurance types (Figure 1.4) in the KFF report were applied to 2021 data to estimate Virginia's 2022 premiums.

MEPS-IC data for national premiums and deductibles were obtained using the above approach. We collected additional data on insurance coverage purchased directly by individuals (not through an employer) from the Healthcare.gov marketplace, specifically trends in the state's average "benchmark" premium—the second-lowest-cost silver plan for a 40-year-old. These data are compiled by the Kaiser Family Foundation and made publicly available in the State Health Facts: Marketplace Average Benchmark Premiums tables.

Virginia Federal Government Pandemic Financial Support Analyses

Direct financial support for health care systems and providers was calculated using data on the Provider Relief Fund payments (Health Resources & Services Administration) and Paycheck Protection Program (U.S. Small Business Association) from their respective agencies. Data were collected by year, state, and (when possible) type of provider receiving the funds. These spending totals by program were aggregated together and then contrasted with the total health care spending by health sector category. In order to identify the quantity of Provider Relief Fund payments allocations among the seven health care service categories, the Paycheck Protection Program allocations were subtracted from the total allocations reported by CMS in the 2020, 2021, and 2022 NHEA.

SENATE OF VIRGINIA

GHAZALA F. HASHMI
15TH SENATORIAL DISTRICT
PART OF CHESTERFIELD COUNTY; AND
PART OF THE CITY OF RICHMOND

P.O. BOX 396
RICHMOND, VA 23218

COMMITTEE ASSIGNMENTS:
EDUCATION AND HEALTH, CHAIR
AGRICULTURE, CONSERVATION AND
NATURAL RESOURCES
FINANCE AND APPROPRIATIONS
TRANSPORTATION
RULES

June 17, 2024

Karen Shelton, MD, State Health Commissioner
Virginia Department of Health
James Madison Building,
109 Governor Street, 13th Floor,
Richmond, VA 23219

VIA EMAIL

Dear Dr. Shelton,

I write regarding the work of the State Health Services Task Force as directed by Senate Bill 277. As the Chair of the Senate Education and Health Committee, as well as the patron of the bill, I am reviewing the work of the task force with interest. I understand that the task force has begun its work to meet the obligations identified by SB 277.

The legislative language outlines that the task force is responsible for providing recommendations for the following three areas:

- Identifying which of the facilities and projects listed in § 32.1-102.1:3 of the Code of Virginia should be added to the expedited review process
- Defining the criteria applicable to any projects subject to expedited review
- Establishing the framework for the application and approval process of projects

It seems that the task force has not begun to fully address these issues, and I am concerned that the necessary recommendations will not be delivered to the General Assembly by the November deadline. I am hopeful that you can provide reassurances that the task force is on track to deliver the full scope of recommendations by the deadline so that the next legislative actions can be determined for the 2025 Session.

Thank you again for your leadership on these critical issues.

Sincerely yours,

Ghazala F. Hashmi, PhD
Chair, Senate Education and Health Committee
Member, Virginia Senate

VIRGINIA HOSPITAL
& HEALTHCARE
ASSOCIATION

4200 INNSLAKE DRIVE, SUITE 203, GLEN ALLEN, VIRGINIA 23060-6772
P.O. BOX 31394, RICHMOND, VIRGINIA 23294-1394
(804) 965-1227 FAX (804) 965-0475

June 24, 2024

Karen Shelton, MD
State Health Commissioner
Virginia Department of Health
P.O. Box 2448
Richmond, Virginia 23218-2448

Re: State Health Services Plan Task Force

Dear Commissioner Shelton,

We are grateful that the work of the State Health Services Plan Task Force is underway. The Task Force plays an important role in the COPN Program, including completing a number of activities required by statute. The most notable of these required activities is the development of a comprehensive State Health Services Plan (SHSP, formerly the "State Medical Facilities Plan" or "SMFP") for adoption by the Board of Health. As we have conveyed to you in previous correspondence, we remain concerned that this requirement of the law has not yet been implemented, and the current SHSP/SMFP plan has not been updated since 2009, about 15 years.

The Task Force has conducted three meetings thus far, with a fourth meeting scheduled for July 12, 2024. The agenda for each of these meetings has been dominated by efforts to develop recommendations for expedited review pursuant to Senator Hashmi's 2024 SB 277. We understand the Senator's concerns stated in her letter to you on June 17th and we wholeheartedly respect the obligation to fulfill that statutory requirement. However, other statutory requirements that have not yet been fulfilled, particularly the requirements under Va. Code § 32.1-102.2:1 for the Task Force to develop recommendations for a comprehensive SHSP for adoption by the Board by November 1, 2022, should not be disregarded.

Furthermore, having an updated SHSP is a necessary precursor to making decisions about which projects could be moved towards expedited review. For example, in the context of psychiatric beds, if the relevant sections of the SHSP were updated to indicate that there is a severe shortage of psychiatric beds in a given health planning district and that determinations of need would thus be noncontested or noncontroversial, then that would be insightful for determining whether expedited review would be appropriate for such projects and the limitations or conditions that should apply.

Accordingly, we urge you to direct the Task Force to commence its work on developing recommendations for a comprehensive SHSP prior to, or at least in parallel, with any work on expedited review. VHHA remains committed to assisting with this important effort, including contributing resources, data, and subject matter experts that can assist with the technical aspects of updating the SHSP.

As it relates to expedited review, we have been working closely with our members to explore a reasonable path forward for considering application of expedited review to certain psychiatric projects that are typically non-contested and/or raise comparatively few health planning concerns. So, we similarly want to support the Task Force's efforts in this area, but the work on expedited review is, in our mind, subsequent to updating the SHSP.

Again, we are grateful for the work that you and the Task Force are undertaking to improve Virginia's COPN Program and we urge you to take steps to establish a higher priority for making updates to the SHSP.

Sincerely,

Sean T. Connaughton
President & CEO

VIRGINIA HOSPITAL & HEALTHCARE ASSOCIATION

4200 INNSLAKE DRIVE, SUITE 203, GLEN ALLEN, VIRGINIA 23060-6772
P.O. BOX 31394, RICHMOND, VIRGINIA 23294-1394
(804) 965-1227 FAX (804) 965-0475

SUBMITTED ELECTRONICALLY AT: regulatory.comment@vdh.virginia.gov
karen.shelton@vdh.virginia.gov; Allyson.Flinn@vdh.virginia.gov

June 28, 2024

Karen Shelton, MD
State Health Commissioner
Virginia Department of Health
P.O. Box 2448
Richmond, Virginia 23218-2448

Re: Public Comment to State Health Services Plan Task Force, July 12, 2024, Meeting

Dear Commissioner Shelton,

Thank you for the opportunity to submit this public comment to the State Health Services Plan Task Force in advance of its July 12, 2024, meeting. At the conclusion of the May 30, 2024, meeting of the Task Force, members of the Task Force were asked to submit in writing their preferences on each of thirteen options presented in the Virginia Department of Health's (VDH's) Analysis on Potential Expedited and Psychiatric Process, including any additionally discussed alternatives or options. This public comment is submitted in response to VDH's Analysis for consideration by the SHSP Task Force as it seeks to develop its recommendations.

Based upon discussions at the May 30, 2024, meeting of the SHSP Task Force, it does not appear that there is complete consensus for moving psychiatric *facilities* or psychiatric *services* from standard review to expedited review, but that there may be some grounds for consensus among Task Force members regarding moving from standard review to expedited review the *addition, relocation, or conversion* of psychiatric beds at an existing facility that has obtained a COPN to provide psychiatric services or to establish a psychiatric facility.

VHHA submits that if the Task Force is going to recommend expedited review, it should be limited to addition, relocation, or conversion of a limited number or percent of psychiatric beds over some period of time at an existing facility that has obtained a COPN to provide psychiatric services or to establish a psychiatric facility, and should include several safeguards as described in this public comment.

Psychiatric Projects Eligible for Expedited Review

If expedited review is expanded to include psychiatric bed additions, conversions, and relocations, it should be limited to existing medical care facilities that have a COPN to provide psychiatric services or for a hospital licensed as a provider by the Department of Behavioral Health and Developmental Services (DBHDS) and limited to:

- Addition of up to lesser of 10 or 10% of psychiatric beds.
- Conversion of up to lesser of 10 or 10% of non-psychiatric beds to psychiatric beds.
- Relocation of up to lesser of 10 or 10% of psychiatric beds within the same health planning district to another existing medical care facility owned or controlled by the same person or under common ownership with the same person.

Clarifications to existing law are also needed to prevent psychiatric beds approved under expedited review from being converted to non-psychiatric beds without a standard COPN (similar to the current requirement on psych beds obtained pursuant to an RFA – See 32.1-102.1:3(B)(9)).

Eligibility for Expedited Review of such psychiatric projects should be contingent upon the following:

- Neither the Commissioner nor any member of the public, to include a competing applicant, has contested the proposed project;
- The Commissioner determines that the proposed project is consistent with the provisions of the State Health Services Plan applicable to acute psychiatric and acute substance abuse disorder treatment services in effect at the time of application;
- The medical care facility has not added, converted, or relocated psychiatric beds under expedited review in the previous two years;
- The medical care facility certifies that it has not been cited for a federal or state certification or licensure deficiency related to psychiatric services or beds within the twelve (12) months prior to submission of the application, or if it has been cited, that a plan of correction has been submitted to and approved by the appropriate federal and state agency(ies);
- The beds will be Medicare and Medicaid certified, as appropriate to the ages of the bed types/patients served; and
- The medical care facility has maintained an average annual occupancy rate of 80% for existing licensed psychiatric beds[1], or
- The beds added are dedicated for use in treating geriatric patients, patients with neurocognitive disorders, including dementia, or a neurodevelopmental disability, including a developmental disability or intellectual disability, such as autism spectrum disorder, or patients with complex medical or other high acuity needs.

Expedited Review Process for Psychiatric Projects

The existing expedited review process set forth in 12VAC5-220-280 *et seq*. should apply to psychiatric bed projects, with the following modifications:

[1] Most psychiatric beds (roughly 47,000) are in semi-private rooms compared to a smaller portion (roughly 8,800) in private rooms. In many cases, even though a bed may be available or unoccupied in a semi-private room, it cannot be used because, for clinical or safety reasons, it is necessary for the patient to be confined to a room without another occupant. Any calculation of occupancy rates should take this into account in evaluating capacity.

- Submission of applications for expedited review should be limited to the applicable batch cycle for the project or at scheduled intervals throughout the calendar year to help contain the costs of managing the notice, objection, and approval process.
- The Department should be required to post at a dedicated page on its website notice of the proposed project within seven (7) days of receipt of an application that has been deemed complete and for which the application fee has been paid to the Department. This would serve as notice to persons of their ability to submit an objection to the Commissioner contesting the project.
- The timeframe for the decision by the Commissioner to render a decision should run from the date of the posting of notice by the Department (as opposed to the date of receipt under current regulations) to allow ample time for a person to submit an objection to the Commissioner contesting the project and for the Commissioner to have time to review such objection. Regulations should allow a reasonable period of time from the date of posting notice for persons to file objections (*e.g.*, 15 days) as well as a reasonable period of time for review by the Commissioner (*e.g.*, 30 days). Following an objection to a project, standard review will apply.
- If the Commissioner determines the project does not meet the criteria for expedited review, including the additional requirements established above, the applicant will be notified and standard review will apply.

<u>Application and Implementation of Law</u>

Unless otherwise expressly stated herein, these recommendations assume that all other provisions of COPN law and regulations applicable to COPN application and approvals under standard review would likewise apply to expedited review (*e.g.*, calculation and application of fee amounts, capital expenditure requirements, etc.).

Implementing law required to authorize expedited review for these services should include a sunset provision causing the law to expire after five years. This would allow ample time for the outcomes of this policy change to be objectively evaluated and to determine if the policy should be continued.

<u>Expedited Review Should be Limited to Projects that Are Non-Contested and/or Raise Comparatively Few Health Planning Concerns</u>

VHHA support for expedited review is limited to certain projects that are non-contested and/or raise comparatively few health planning concerns. With the exception of the limited addition, relocation, or conversion of psychiatric beds (subject to additional requirements described herein) all other projects listed in the VDH Analysis are highly competitive and not regarded as non-contested and/or raising comparatively few health planning concerns. Further, as reflected in its legislative mandate, the SHSP Task Force is to develop recommendations on expedited review of project types "that are generally non contested and present limited health planning impacts" and it is submitted that including additional project types at this time goes well beyond the scope of that mandate.

We believe this presents a reasonable path forward for considering application of expedited review to certain psychiatric projects that are typically non-contested and/or raise comparatively few health planning concerns and includes appropriate safeguards to prevent a negative impact on the ability of existing acute psychiatric providers to continue to provide historic levels of services to patients in the community, including Medicaid or other indigent patients.

Again, we are grateful for the work that you and the Task Force are undertaking to improve Virginia's COPN Program. The COPN Program is a critical policy function of the Commonwealth and reforms to modernize this program present a great opportunity to produce greater efficiencies and generate even better outcomes.

Thank you for your consideration of this public comment.

Sincerely,

R. Brent Rawlings
Senior Vice President & General Counsel

cc: Dr. Thomas Eppes, Chair, SHSP Task Force
Karen Cameron, Vice Chair, SHSP Task Force

COPN Decisions 2003 - 2024 YTD

Based on COPN Project Definition and Project Sub-Type Within the Definition

Grouped by Service Type	Chapt 1271	Average	Total			HPR I		HPR II		HPR III		HPR IV		HPR V	
	Recommendation?	Capital Value	Total	Approve	Deny	Approve	Deny	Approve	Deny	Approve	Deny	Approve	Deny	Approve	Deny
Hospital															
Add Hospital Beds by Relocation of existing hospital beds	when not competing	$ 2,075,019	2	2	0	0	0	0	0	0	0	1	0	1	0
Add new Hospital Beds	when not competing	$ 60,301,785	39	36	3	4	0	14	0	3	0	6	0	9	3
Establish a Hospital		$ 101,767,945	16	12	4	2	0	3	1	1	0	3	1	3	2
Establish a long term acute care hospital		$ 16,121,983	11	8	3	1	0	2	0	2	0	2	1	4	2
Neonatal Intensive Care															
Introduce Neonatal Specialty Care Intermediate Level		$ 18,024,042	7	6	1	2	0	2	0	1	0	0	0	1	1
Introduce Neonatal Specialty Care Specialty Level		$ 36,000,953	8	4	4	0	0	0	0	1	3	1	0	2	1
Imaging															
Add a CT scanner by relocating an existing CT in the planning district	when not competing	$ 1,006,590	1	1	0	0	0	0	0	0	0	1	0	0	0
Add a CT scanner in an existing hospital with existing CT services	when not competing	$ 2,292,228	96	95	1	21	0	15	1	21	0	16	0	22	0
Add a CT scanner in an existing imaging center	when not competing	$ 2,340,147	15	11	4	3	1	4	0	1	1	1	2	2	0
Add a CT scanner in an existing outpatient surgical hospital with existing CT services	when not competing	$ 1,166,266	1	1	0	0	0	1	0	0	0	0	0	0	0
Establish an imaging center for CT imaging		$ 3,161,678	82	65	17	5	2	23	9	9	1	19	5	9	0
Introduce a new CT for radiation therapy simulation in an existing center for radiation therapy		$ 906,405	23	23	0	3	0	4	0	4	0	6	0	6	0
Introduce a new CT service in an existing hospital		$ 552,795	4	4	0	0	0	0	0	1	0	1	0	2	0
Introduce a new CT service in an existing imaging center		$ 979,819	9	9	0	2	0	3	0	0	0	3	0	1	0
Introduce CT by relocating an existing CT in the planning district		$ 1,567,124	1	1	0	0	0	1	0	0	0	0	0	0	0
Establish an imaging center for MRI imaging		$ 1,887,957	42	30	12	4	0	7	3	1	2	8	3	10	4
Add an MRI scanner by relocating an existing MRI in the planning district	when not competing	$ 3,334,548	5	5	0	0	0	0	0	0	0	3	0	2	0
Add an MRI scanner in an existing hospital with existing MRI services	when not competing	$ 3,662,739	62	61	1	14	1	11	0	12	0	11	0	13	0
Add an MRI scanner in an existing imaging center	when not competing	$ 2,684,190	36	26	10	7	0	9	3	3	1	1	6	6	0
Introduce a new MRI service in an existing hospital		$ 1,553,251	6	6	0	0	0	3	0	2	0	0	0	1	0
Introduce a new MRI service in an existing imaging center		$ 2,078,211	6	5	1	0	0	3	1	1	0	1	0	0	0
Add a PET scanner in an existing hospital with existing PET services	when not competing	$ 3,642,552	12	11	1	1	0	2	0	5	1	2	0	1	0
Add a PET scanner in an existing imaging center	when not competing	$ 1,669,058	6	6	0	1	0	3	0	2	0	0	0	0	0
Establish an imaging center for PET imaging		$ 1,577,840	19	18	1	2	0	10	1	1	0	4	0	1	0
Introduce a new PET service in an existing hospital		$ 740,599	18	18	0	0	0	2	0	5	0	2	0	9	0
Introduce a new PET service in an existing imaging center		$ 1,985,079	2	2	0	1	0	0	0	0	0	1	0	0	0
Introduce a new PET service in an existing radiation therapy center		$ 1,206,934	2	2	0	0	0	1	0	0	0	0	0	1	0
Add a scanner by converting a mobile site to a fixed unit (CT and/or PET and/or MRI)	when not competing	$ 1,984,575	17	17	0	2	0	1	0	4	0	2	0	8	0
Establish an imaging center for 2 or more regulated modalities (Other than Cancer Treatment)		$ 6,073,176	27	20	7	3	2	2	2	1	1	10	2	4	0
Intermediate Care Facility for Individuals with Intellectual Disability															
Establish an intermediate care facility with 13 or more beds for individuals with intellectual disability[5]		$ 107,370	2	2	0	0	0	0	0	0	0	0	0	2	0
Long Term Care															
Add a distinct part nursing home unit in an existing hospital		$ 39,316	1	1	0	0	0	0	0	0	0	0	0	1	0
Add new nursing home beds in an existing nursing home		$ 3,962,474	24	21	3	8	0	3	0	1	0	6	2	3	1
Add nursing home beds in an existing nursing home by relocating beds from outside the PD		$ 5,278,762	10	10	0	2	0	2	0	1	0	2	0	3	0
Add nursing home beds in an existing nursing home by relocating beds within the PD		$ 3,853,049	20	20	0	1	0	5	0	4	0	6	0	4	0
Add nursing home beds in an existing nursing home in a CCRC		$ 6,440,253	6	6	0	0	0	0	0	1	0	3	0	2	0
Establish a new nursing home		$ 13,753,743	15	14	1	4	1	3	0	5	0	1	0	1	0
Establish a new nursing home by relocation		$ 20,897,582	14	13	1	2	0	0	0	3	1	3	0	5	0
Establish a new nursing home in a CCRC		$ 10,339,216	6	6	0	1	0	2	0	1	0	0	0	2	0
Cardiac Catheterization															
Add a cardiac catheterization lab in an existing hospital with cardiac catheterization services	when not competing	$ 2,749,928	29	29	0	9	0	5	0	2	0	8	0	5	0
Establish a freestanding cardiac catheterization laboratory		$ 6,337,687	4	4	0	0	0	1	0	0	0	2	0	1	0

Introduce a new cardiac catheterization service in an existing hospital		$ 1,828,087	13	12	1	3	0	2	0	3	0	3	0	1	1
Surgical															
Add new operating rooms in an existing hospital	when not competing	$ 17,151,511	62	59	3	10	0	14	0	6	2	6	0	23	1
Add new operating rooms in an existing outpatient surgical hospital	when not competing	$ 1,721,201	22	21	1	3	1	7	0	0	0	4	0	7	0
Add new operating rooms in an existing outpatient surgical hospital by relocating existing ORs from another hospital	when not competing	$ 1,813,954	5	4	1	0	0	0	0	1	0	2	0	1	1
Introduce a new kidney transplant service in an existing hospital		$ 27,562	1	1	0	0	0	0	0	0	0	0	0	1	0
Introduce a new lung transplant service in an existing hospital		$ 150,000	1	1	0	0	0	0	0	0	0	1	0	0	0
Introduce a new pancreas transplant service in an existing hospital		$ -	1	1	0	0	0	0	0	0	0	0	0	1	0
Introduce a new open heart surgery service in an existing hospital		$ 3,318,210	8	4	4	1	0	1	1	0	1	1	1	1	1
Establish a new outpatient surgical hospital		$ 6,572,159	79	64	15	7	1	15	4	5	1	17	2	20	7
Psychiatric															
Add new psychiatric beds in an existing hospital	when not competing	$ 6,653,261	35	31	4	5	0	8	1	4	0	6	0	8	3
Add new psychiatric beds in an existing hospital with an existing psychiatric unit by converting beds to psychiatric beds	when not competing	$ 2,318,036	5	5	0	0	0	0	0	1	0	4	0	0	0
Establish a new inpatient psychiatric hospital		$ 16,349,458	8	6	2	0	1	1	1	0	0	1	0	4	0
Introduce a new psychiatric service in an existing hospital by adding new beds		$ 4,080,161	7	7	0	0	0	0	0	2	0	2	0	3	0
Introduce a new psychiatric service in an existing hospital by converting existing beds		$ 2,229,632	3	3	0	0	0	0	0	3	0	0	0	0	0
Introduce a new psychiatric service in an existing hospital by transfering existing psychiatric beds from another hospital		$ 1,467,450	2	2	0	1	0	0	0	1	0	0	0	0	0
Medical Rehabilitation															
Add new rehabilitation beds in a hospital with existing rehabilitation services	when not competing	$ 6,532,828	13	12	1	3	0	4	0	0	0	4	1	1	0
Add rehabilitation beds in a hospital with existing rehabilitation services by converting Med/surg beds	when not competing	$ 100,000	1	1	0	0	0	0	0	1	0	0	0	0	0
Establish a new rehabilitation hospital		$ 21,060,203	13	8	5	2	1	1	1	3	0	2	1	0	2
Introduce a new medical rehabilitation service in an existing hospital		$ 8,217,575	4	4	0	0	0	2	0	2	0	0	0	0	0
Radiation Theapy / Cancer Treatment															
Establish a center for radiation therapy service (brachytherapy)		$ 551,619	3	3	0	1	0	1	0	0	0	1	0	0	0
Introduce a new radiation therapy service (brachytherapy) in an existing hospital		$ 302,296	14	14	0	3	0	8	0	0	0	3	0	0	0
Add a linear accelerator by relocating an existing linear accelerator to a hospital with an existing linear accelerator	when not competing	$ 285,000	1	1	0	0	0	1	0	0	0	0	0	0	0
Add a linear accelerator in an existing hospital with an existing linear accelerator	when not competing	$ 8,694,135	16	15	1	3	0	2	0	2	0	3	0	5	1
Add a linear accelerator in an existing outpatient surgical hospital with an existing linear accelerator	when not competing	$ 6,793,811	1	1	0	0	0	1	0	0	0	0	0	0	0
Add a linear accelerator in an existing radiation treatment center with a linear accelerator	when not competing	$ 269,157	2	2	0	0	0	0	0	0	0	0	0	2	0
Establish a center for radiation therapy service (linear accelerator)		$ 6,035,584	10	6	4	0	0	2	0	0	3	2	1	2	0
Introduce a new radiation therapy service (linear accelerator) in an existing hospital		$ 8,334,559	6	3	3	1	0	0	1	1	2	1	0	0	0
Introduce a new radiation therapy service (linear accelerator) in an existing outpatient surgical hospital		$ 6,650	1	1	0	0	0	0	0	0	0	0	0	1	0
Establish a center for proton beam therapy		$ 132,620,000	1	1	0	0	0	0	0	0	0	0	0	1	0
Introduce new proton beam therapy in an existing hospital		$ 93,239,505	1	1	0	0	0	1	0	0	0	0	0	0	0
Add SRS equipment in an existing radiation treatment center with with existing SRS		$ 5,923,940	1	1	0	0	0	1	0	0	0	0	0	0	0
Establish an cancer treatment center for 2 or more regulated modalities		$ 6,383,046	9	4	5	0	0	0	0	1	2	0	0	3	3
Introduce a new SRS in an existing hospital		$ 3,946,145	44	35	9	9	2	9	5	4	0	4	1	9	1
Introduce a new SRS in an existing radiation therapy center		$ 687,867	5	5	0	0	0	2	0	0	0	2	0	1	0
Relocation															
Establish a medical care facility that is the relocation of existing regulated modality(ies), other than beds, within the PD		$ 40,907,407	95	89	6	13	0	24	1	13	0	15	1	24	4
			526	461	65	74	6	113	15	55	11	94	8	125	25
		HPR Approval Rate		87.6%		92.5%		88.3%		83.3%		92.2%		83.3%	

Other Potential Project Types for Which No Requests Have Been Made
Introduce a new heart transplant service in an existing hospital
Introduce a new liver transplant service in an existing hospital
Introduce a new multi-organ transplant service in an existing hospital
Introduce Neonatal Specialty Care Sub Specialty Specialty Level
Introduce a new CT service in an existing outpatient surgical hospital
Introduce a new CT service in an existing freestanding cardiac catheterization laboratory

Introduce a new MRI service in an existing outpatient surgical hospital
Introduce a new MRI service in an existing PET imaging center
Introduce a new MRI service in an existing freestanding cardiac catheterization laboratory
Introduce a new PET service in an existing freestanding cardiac catheterization laboratory
Introduce a new PET service in an existing outpatient surgical hospital
Add an MRI scanner in an existing outpatient surgical hospital with existing MRI services
Add a PET scanner in an existing outpatient surgical hospital with existing PET services
Add SRS equipment in an existing hospital with existing SRS
Add SRS equipment in an existing outpatient surgical hospital with with existing SRS

COPN Decisions 2003 - 2024 YTD

Based on COPN Project Definition and Project Sub-Type Within the Definition

	Chapt 1271	Average	Total			HPR I		HPR II		HPR III		HPR IV		HPR V	
Sorted by Action Type (Establish, Introduce, Add...)	**Recommendation?**	**Capital Value**	**Total**	**Approve**	**Deny**	**Approve**	**Deny**	**Approve**	**Deny**	**Approve**	**Deny**	**Approve**	**Deny**	**Approve**	**Deny**
Establish a Hospital		$ 101,767,945	16	12	4	2	0	3	1	1	0	3	1	3	2
Establish a long term acute care hospital		$ 16,121,983	11	8	3	1	0	2	0	2	0	2	1	4	2
Establish a new rehabilitation hospital		$ 21,060,203	13	8	5	2	1	1	1	3	0	2	1	0	2
Establish a new inpatient psychiatric hospital		$ 16,349,458	8	6	2	0	1	1	1	0	0	1	0	4	0
Establish a new outpatient surgical hospital		$ 6,572,159	79	64	15	7	1	15	4	5	1	17	2	20	7
Establish an intermediate care facility with 13 or more beds for individuals with		$ 107,370	2	2	0	0	0	0	0	0	0	0	0	2	0
Establish a new nursing home		$ 13,753,743	15	14	1	4	1	3	0	5	0	1	0	1	0
Establish a new nursing home by relocation		$ 20,897,582	14	13	1	2	0	0	0	3	1	3	0	5	0
Establish a new nursing home in a CCRC		$ 10,339,216	6	6	0	1	0	2	0	1	0	0	0	2	0
Establish a freestanding cardiac catheterization laboratory		$ 6,337,687	4	4	0	0	0	1	0	0	0	2	0	1	0
Establish an imaging center for CT imaging		$ 3,161,678	82	65	17	5	2	23	9	9	1	19	5	9	0
Establish an imaging center for MRI imaging		$ 1,887,957	42	30	12	4	0	7	3	1	2	8	3	10	4
Establish an imaging center for PET imaging		$ 1,577,840	19	18	1	2	0	10	1	1	0	4	0	1	0
Establish a center for proton beam therapy		$ 132,620,000	1	1	0	0	0	0	0	0	0	0	0	1	0
Establish a center for radiation therapy service (brachytherapy)		$ 551,619	3	3	0	1	0	1	0	0	0	1	0	0	0
Establish a center for radiation therapy service (linear accelerator)		$ 6,035,584	10	6	4	0	0	2	0	0	3	2	1	2	0
Establish an cancer treatment center for 2 or more regulated modalities		$ 6,383,046	9	4	5	0	0	0	0	1	2	0	0	3	3
Establish an imaging center for 2 or more regulated modalities (Other than Cancer Treatment)		$ 6,073,176	27	20	7	3	2	2	2	1	1	10	2	4	0
Establish a medical care facility that is the relocation of existing regulated modality(ies), other than beds, within the PD		$ 40,907,407	95	89	6	13	0	24	1	13	0	15	1	24	4
Introduce a new psychiatric service in an existing hospital by adding new beds		$ 4,080,161	7	7	0	0	0	0	0	2	0	2	0	3	0
Introduce a new psychiatric service in an existing hospital by converting existing beds		$ 2,229,632	3	3	0	0	0	0	0	3	0	0	0	0	0
Introduce a new psychiatric service in an existing hospital by transfering existing psychiatric beds from another hospital		$ 1,467,450	2	2	0	1	0	0	0	1	0	0	0	0	0
Introduce a new kidney transplant service in an existing hospital		$ 27,562	1	1	0	0	0	0	0	0	0	0	0	1	0
Introduce a new lung transplant service in an existing hospital		$ 150,000	1	1	0	0	0	0	0	0	0	1	0	0	0
Introduce a new pancreas transplant service in an existing hospital		$ -	1	1	0	0	0	0	0	0	0	0	0	1	0
Introduce a new medical rehabilitation service in an existing hospital		$ 8,217,575	4	4	0	0	0	2	0	2	0	0	0	0	0
Introduce a new open heart surgery service in an existing hospital		$ 3,318,210	8	4	4	1	0	1	1	0	1	1	1	1	1
Introduce a new cardiac catheterization service in an existing hospital		$ 1,828,087	13	12	1	3	0	2	0	3	0	3	0	1	1
Introduce a new radiation therapy service (brachytherapy) in an existing hospital		$ 302,296	14	14	0	3	0	8	0	0	0	3	0	0	0
Introduce a new radiation therapy service (linear accelerator) in an existing hospital		$ 8,334,559	6	3	3	1	0	0	1	1	2	1	0	0	0
Introduce a new radiation therapy service (linear accelerator) in an existing outpatient surgical hospital		$ 6,650	1	1	0	0	0	0	0	0	0	0	0	1	0
Introduce a new SRS in an existing hospital		$ 3,946,145	44	35	9	9	2	9	5	4	0	4	1	9	1
Introduce a new SRS in an existing radiation therapy center		$ 687,867	5	5	0	0	0	2	0	0	0	2	0	1	0
Introduce new proton beam therapy in an existing hospital		$ 93,239,505	1	1	0	0	0	1	0	0	0	0	0	0	0
Introduce Neonatal Specialty Care Intermediate Level		$ 18,024,042	7	6	1	2	0	2	0	1	0	0	0	1	1
Introduce Neonatal Specialty Care Specialty Level		$ 36,000,953	8	4	4	0	0	0	0	1	3	1	0	2	1
Introduce a new CT service in an existing hospital		$ 552,795	4	4	0	0	0	0	0	1	0	1	0	2	0
Introduce a new CT service in an existing imaging center		$ 979,819	9	9	0	2	0	3	0	0	0	3	0	1	0
Introduce a new CT for radiation therapy simulation in an existing center for radiation therapy		$ 906,405	23	23	0	3	0	4	0	4	0	6	0	6	0
Introduce CT by relocating an existing CT in the planning district		$ 1,567,124	1	1	0	0	0	1	0	0	0	0	0	0	0
Introduce a new MRI service in an existing hospital		$ 1,553,251	6	6	0	0	0	3	0	2	0	0	0	1	0
Introduce a new MRI service in an existing imaging center		$ 2,078,211	6	5	1	0	0	3	1	1	0	1	0	0	0
Introduce a new PET service in an existing hospital		$ 740,599	18	18	0	0	0	2	0	5	0	2	0	9	0
Introduce a new PET service in an existing imaging center		$ 1,985,079	2	2	0	1	0	0	0	0	0	1	0	0	0
Introduce a new PET service in an existing radiation therapy center		$ 1,206,934	2	2	0	0	0	1	0	0	0	0	0	1	0

Add new Hospital Beds	when not competing	$ 60,301,785	39	36	3	4	0	14	0	3	0	6	0	9	3
Add Hospital Beds by Relocation of existing hospital beds	when not competing	$ 2,075,019	2	2	0	0	0	0	0	0	0	1	0	1	0
Add new psychiatric beds in an existing hospital	when not competing	$ 6,653,261	35	31	4	5	0	8	1	4	0	6	0	8	3
Add new psychiatric beds in an existing hospital with an existing psychiatric unit by converting beds to psychiatric beds	when not competing	$ 2,318,036	5	5	0	0	0	0	0	1	0	4	0	0	0
Add new rehabilitation beds in a hospital with existing rehabilitation services	when not competing	$ 6,532,828	13	12	1	3	0	4	0	0	0	4	1	1	0
Add rehabilitation beds in a hospital with existing rehabilitation services by converting Med/surg beds	when not competing	$ 100,000	1	1	0	0	0	0	0	1	0	0	0	0	0
Add new operating rooms in an existing hospital	when not competing	$ 17,151,511	62	59	3	10	0	14	0	6	2	6	0	23	1
Add new operating rooms in an existing outpatient surgical hospital	when not competing	$ 1,721,201	22	21	1	3	1	7	0	0	0	4	0	7	0
Add new operating rooms in an existing outpatient surgical hospital by relocating existing ORs from another hospital	when not competing	$ 1,813,954	5	4	1	0	0	0	0	1	0	2	0	1	1
Add a distinct part nursing home unit in an existing hospital		$ 39,316	1	1	0	0	0	0	0	0	0	0	0	1	0
Add new nursing home beds in an existing nursing home		$ 3,962,474	24	21	3	8	0	3	0	1	0	6	2	3	1
Add nursing home beds in an existing nursing home by relocating beds from outside the PD		$ 5,278,762	10	10	0	2	0	2	0	1	0	2	0	3	0
Add nursing home beds in an existing nursing home by relocating beds within the PD		$ 3,853,049	20	20	0	1	0	5	0	4	0	6	0	4	0
Add nursing home beds in an existing nursing home in a CCRC		$ 6,440,253	6	6	0	0	0	0	0	1	0	3	0	2	0
Add a cardiac catheterization lab in an existing hospital with cardiac catheterization services	when not competing	$ 2,749,928	29	29	0	9	0	5	0	2	0	8	0	5	0
Add a CT scanner in an existing hospital with existing CT services	when not competing	$ 2,292,228	96	95	1	21	0	15	1	21	0	16	0	22	0
Add a CT scanner by relocating an existing CT in the planning district	when not competing	$ 1,006,590	1	1	0	0	0	0	0	0	0	1	0	0	0
Add a CT scanner in an existing outpatient surgical hospital with existing CT services	when not competing	$ 1,166,266	1	1	0	0	0	1	0	0	0	0	0	0	0
Add a CT scanner in an existing imaging center	when not competing	$ 2,340,147	15	11	4	3	1	4	0	1	1	1	2	2	0
Add a scanner by converting a mobile site to a fixed unit (CT and/or PET and/or MRI)	when not competing	$ 1,984,575	17	17	0	2	0	1	0	4	0	2	0	8	0
Add an MRI scanner in an existing hospital with existing MRI services	when not competing	$ 3,662,739	62	61	1	14	1	11	0	12	0	11	0	13	0
Add an MRI scanner in an existing imaging center	when not competing	$ 2,684,190	36	26	10	7	0	9	3	3	1	1	6	6	0
Add an MRI scanner by relocating an existing MRI in the planning district	when not competing	$ 3,334,548	5	5	0	0	0	0	0	0	0	3	0	2	0
Add a PET scanner in an existing hospital with existing PET services	when not competing	$ 3,642,552	12	11	1	1	0	2	0	5	1	2	0	1	0
Add a PET scanner in an existing imaging center	when not competing	$ 1,669,058	6	6	0	1	0	3	0	2	0	0	0	0	0
Add a linear accelerator in an existing hospital with an existing linear accelerator	when not competing	$ 8,694,135	16	15	1	3	0	2	0	2	0	3	0	5	1
Add a linear accelerator by relocating an existing linear accelerator to a hospital with an existing linear accelerator	when not competing	$ 285,000	1	1	0	0	0	1	0	0	0	0	0	0	0
Add a linear accelerator in an existing outpatient surgical hospital with an existing linear accelerator	when not competing	$ 6,793,811	1	1	0	0	0	1	0	0	0	0	0	0	0
Add a linear accelerator in an existing radiation treatment center with a linear accelerator	when not competing	$ 269,157	2	2	0	0	0	0	0	0	0	0	0	2	0
Add SRS equipment in an existing radiation treatment center with with existing SRS		$ 5,923,940	1	1	0	0	0	1	0	0	0	0	0	0	0
			1,199	1,059	140	170	13	254	36	152	22	220	30	266	39
		HPR Approval Rate		88.3%		92.9%		87.6%		87.4%		88.0%		87.2%	

Other Potential Project Types for Which No Requests Have Been Made	
Introduce a new heart transplant service in an existing hospital	
Introduce a new liver transplant service in an existing hospital	
Introduce a new multi-organ transplant service in an existing hospital	
Introduce Neonatal Specialty Care Sub Specialty Specialty Level	
Introduce a new CT service in an existing outpatient surgical hospital	
Introduce a new CT service in an existing freestanding cardiac catheterization laboratory	
Introduce a new MRI service in an existing outpatient surgical hospital	
Introduce a new MRI service in an existing PET imaging center	
Introduce a new MRI service in an existing freestanding cardiac catheterization laboratory	
Introduce a new PET service in an existing freestanding cardiac catheterization laboratory	
Introduce a new PET service in an existing outpatient surgical hospital	
Add an MRI scanner in an existing outpatient surgical hospital with existing MRI services	
Add a PET scanner in an existing outpatient surgical hospital with existing PET services	
Add SRS equipment in an existing hospital with existing SRS	
Add SRS equipment in an existing outpatient surgical hospital with with existing SRS	