Agenda

September 6, 2024 at 9:00 a.m.
Board Room 4, Perimeter Center
9960 Mayland Drive, Henrico, VA 23233

1. Call to Order and Welcome – Dr. Thomas Eppes, Jr., Chair
2. Roll Call
3. Review of § 32.1-102.2:1 of the Code of Virginia
4. Review of Agenda – Allyson Flinn, Policy Analyst
5. Review of Meeting Materials
6. Approval of Prior Meeting Minutes
7. Public Comment Period

Break

8. The State Health Services Plan
    a. Review of the projects currently within the State Medical Facilities Plan – Erik Bodin, DCOPN Director
    b. Planning to address the mandate within § 32.1-102.2:1 of the Code of Virginia
    c. Discussion
9. Wrap-Up and Next Steps
    a. Selection of Future Meeting Dates & Cadence
10. Meeting Adjournment

CT Scanners		2022								
		Hospital			Freestanding			Combined			
		Average	Min	Max	Average	Min	Max	Average	Min	Max	Average
	SMFP							7,400			
	I	8,376	1,107	14,714	5,287	3	14,583	7,604	3	14,714	
	II	12,694	3,738	24,722	4,922	-	9,697	9,309	-	24,722	
	III	7,889	2,228	13,275	3,329	578	6,789	7,142	578	13,275	
	IV	10,226	4,297	14,905	3,813	235	7,344	8,591	235	14,905	
	V	10,543	1,283	24,478	3,450	-	10,846	7,790	0	24,478	
	State	9,822	1,107	24,722	4,214	-	14,583	8,103	0	24,722	

MRI Scanners		2022								
		Hospital			Freestanding			Combined			
		Average	Min	Max	Average	Min	Max	Average	Min	Max	Average
	SMFP							5,000			
	I	331	608	4,878	4,356	4	7,992	3,703	4	7,992	
	II	4,136	870	6,461	4,992	870	7,185	4,656	870	7,185	
	III	2,432	436	4,551	4,188	2,650	6,019	2,783	436	6,019	
	IV	3,003	403	5,325	3,179	736	5,792	3,063	403	5,792	
	V	3,599	793	8,164	3,194	83	5,766	3,400	83	8,164	
	State	3,230	403	8,164	4,048	4	7,992	3,575	4	8,164	

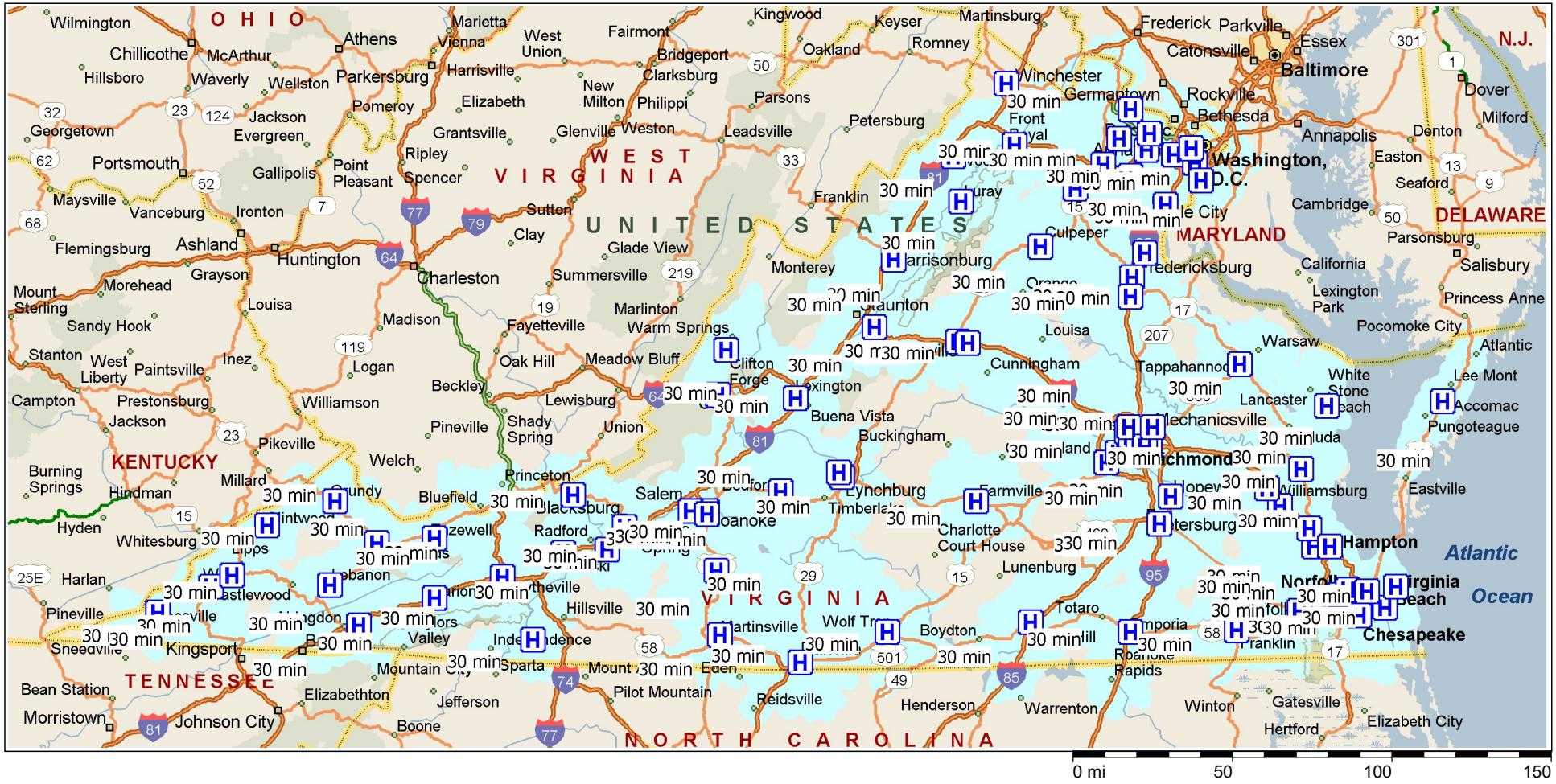
PET Scanners		2022								
		Hospital			Freestanding			Combined			
		Average	Min	Max	Average	Min	Max	Average	Min	Max	Average
	SMFP							6,000			
	I	1,111	114	2,975	1,949	1,949	1,949	1,231	114	2,975	
	II	556	43	1,063	2,068	356	3,802	1,564	43	3,802	
	III	880	31	5,882	-	-	-	880	3	5,882	
	IV	1,141	2	2,849	2,187	2,187	2,187	1,257	2	2,849	
	V	1,282	53	3,597	146	27	200	1,029	27	3,597	
	State	1,037	2	5,882	1,588	27	3,802	1,137	2	5,882	

COPN Project Types (Sorted by Total Number of Decisions)
Based on COPN Project Definition and Project Sub-Type Within the Definition

Grouped by Service Type	Reason	Total Decisions	Units	Utilization Volume SMFP Volume	SMFP 2nd Yr	Average 2022	Average 2018-2022	Travel
Imaging								
Add a CT scanner by relocating an existing CT in the planning district		1	Procedures	7,400				
Add a CT scanner in an existing hospital with existing CT services		96	Procedures	7,400				
Add a CT scanner in an existing imaging center		15	Procedures	7,400				
Add a CT scanner in an existing outpatient surgical hospital with existing CT services		1	Procedures	7,400				
Establish an imaging center for CT imaging		82	Procedures	7,400				
Introduce a new CT for radiation therapy simulation in an existing center for radiation therapy		23		Exempt				
Introduce a new CT service in an existing hospital		4	Procedures	7,400				
Introduce a new CT service in an existing imaging center		9	Procedures	7,400				
Introduce CT by relocating an existing CT in the planning district		1	Procedures	7,400				
	CT	232	Minutes					30
Establish an imaging center for MRI imaging		44	Procedures	5,000				
Add an MRI scanner by relocating an existing MRI in the planning district		5	Procedures	5,000				
Add an MRI scanner in an existing hospital with existing MRI services		62	Procedures	5,000				
Add an MRI scanner in an existing imaging center		36	Procedures	5,000				
Introduce a new MRI service in an existing hospital		6	Procedures	5,000				
Introduce a new MRI service in an existing imaging center		6	Procedures	5,000				
	MRI	159	Minutes					30
Add a PET scanner in an existing hospital with existing PET services		12	Procedures	6,000				
Add a PET scanner in an existing imaging center		6	Procedures	6,000				
Establish an imaging center for PET imaging		18	Procedures	6,000				
Introduce a new PET service in an existing hospital		18	Procedures	6,000				
Introduce a new PET service in an existing imaging center		2	Procedures	6,000				
Introduce a new PET service in an existing radiation therapy center		2	Procedures	6,000				
	PET	58	Minutes					60
Add a scanner by converting a mobile site to a fixed unit (CT ~~and/or PET and/or MRI~~)				6,000				
Add a scanner by converting a mobile site to a fixed unit (~~CT and/or~~ PET ~~and/or MRI~~)		17		1,400				
Add a scanner by converting a mobile site to a fixed unit (~~CT and/or PET and/or~~ MRI)				3,000				
Establish an imaging center for 2 or more regulated modalities (Other than Cancer Treatment)		27						
	Other	44						
	All Imaging	**493**						
Surgical								
Add new operating rooms in an existing hospital		62	Hours	1,600				
	Inpatient Hospital Operating Rooms	62	Minutes					30
Establish a new outpatient surgical hospital		79	Hours	1,600				
Add new operating rooms in an existing outpatient surgical hospital		22	Hours	1,600				
Add new operating rooms in an existing outpatient surgical hospital by relocating existing ORs from another hospital		5	Hours	1,600				
	Outpatient Surgical Hospital	106	Minutes					30
Introduce a new kidney transplant service in an existing hospital		1			30			
Introduce a new lung transplant service in an existing hospital		1			12			
Introduce a new pancreas transplant service in an existing hospital		1			12			
Introduce a new heart transplant service in an existing hospital		0			17			
Introduce a new liver transplant service in an existing hospital		0			21			
	Transplant	3	Minutes					120
Introduce a new open heart surgery service in an existing hospital		8	Procedures	400	250			
Introduce a new PEDIATRIC open heart surgery service in an existing hospital								
	Open Heart Surgery	8	Minutes					60
	All Surgery	**179**						
Radiation Therapy / Cancer Treatment								
Establish a center for radiation therapy service (brachytherapy)		3	Procedures	8,000	5,000			
Introduce a new radiation therapy service (brachytherapy) in an existing hospital		14	Procedures	8,000	5,000			
	Brachytherapy	17						
Add a linear accelerator by relocating an existing linear accelerator to a hospital with an existing linear accelerator		1	Procedures	8,000				
Add a linear accelerator in an existing hospital with an existing linear accelerator		16	Procedures	8,000				
Add a linear accelerator in an existing outpatient surgical hospital with an existing linear accelerator		1	Procedures	8,000				
Add a linear accelerator in an existing radiation treatment center with a linear accelerator		2	Procedures	8,000				
Establish a center for radiation therapy service (linear accelerator)		9	Procedures	8,000	5,000			
Introduce a new radiation therapy service (linear accelerator) in an existing hospital		6	Procedures	8,000	5,000			
Introduce a new radiation therapy service (linear accelerator) in an existing outpatient surgical hospital		1	Procedures	8,000	5,000			
	Linear Accelerator	36						
Establish a center for proton beam therapy		1						
Introduce new proton beam therapy in an existing hospital		1						
	Proton Beam Therapy	2						
Add SRS equipment in an existing radiation treatment center with with existing SRS		1	Procedures	350				
Introduce a new SRS in an existing hospital		44	Procedures	350	250			
Introduce a new SRS in an existing radiation therapy center		5	Procedures	350	250			
	Stereotactic Radiosurgery	50						
Establish an cancer treatment center for 2 or more regulated modalities		9						
	Multiservice Center	9						
	Radiation Therapy	**114**	Minutes					60
Long Term Care								
Add a distinct part nursing home unit in an existing hospital		1						
Add new nursing home beds in an existing nursing home		24	Avg Occupancy	90%				
Add nursing home beds in an existing nursing home by relocating beds from outside the PD		10	Avg Occupancy	90%				
Add nursing home beds in an existing nursing home by relocating beds within the PD		20	Avg Occupancy	90%				
Establish a new nursing home		15	Avg Occupancy	90%				
Establish a new nursing home by relocation		14						
	Nursing Home	84	Minutes					30
Establish a new nursing home in a CCRC	SMFP Standard is NF beds < 21% of non-NF beds, not > 60 NF beds	6						

Add nursing home beds in an existing nursing home in a CCRC	SMFP Standard is NF beds < 21% of non-NF beds, not > 60 NF beds		6						
	CCRC		12						
	All Long Term Care		**96**						
Relocation									
Establish a medical care facility that is the relocation of existing regulated modality(ies), other than beds, within the PD			96						
	Relocation		**96**						
Hospital									
Add Hospital Beds by Relocation of existing hospital beds	ICU beds at 65%		2	Occupancy	80%				
Add new Hospital Beds			39	Occupancy	80%				
Establish a Hospital			16	Occupancy	80%				
Establish a long term acute care hospital			11						
	Inpatient Hospital		**68**	Minutes					30
Psychiatric									
Add new psychiatric beds in an existing hospital			35	Occupancy	75%				
Add new psychiatric beds in an existing hospital with an existing psychiatric unit by converting beds to psychiatric beds			5	Occupancy	75%				
Establish a new inpatient psychiatric hospital			8	Occupancy	75%				
Introduce a new psychiatric service in an existing hospital by adding new beds			7	Occupancy	75%				
Introduce a new psychiatric service in an existing hospital by converting existing beds			3	Occupancy	75%				
Introduce a new psychiatric service in an existing hospital by transfering existing psychiatric beds from another hospital			2	Occupancy	75%				
	Psychiatric Services		**60**	Minutes					60
Cardiac Catheterization									
Add a cardiac catheterization lab in an existing hospital with cardiac catheterization services			29	Procedures	1,200	400			
Introduce a new cardiac catheterization service in an existing hospital			13	Procedures	1,200	500			
Introduce or add PEDIATRIC cardiac catheterization				Procedures		200			
	Hospital Based Cardiac Catheterization		42						
Establish a freestanding cardiac catheterization laboratory			4		1,200				
	Freestanding Cardiac Catheterization		4						
	All Cardiac Catheterization		**46**	Minutes					60
Medical Rehabilitation									
Add new rehabilitation beds in a hospital with existing rehabilitation services			13	Occupancy	80%				
Add rehabilitation beds in a hospital with existing rehabilitation services by converting Med/surg beds			1	Occupancy	80%				
Establish a new rehabilitation hospital			13	Occupancy	80%				
Introduce a new medical rehabilitation service in an existing hospital			4	Occupancy	80%				
	Medical Rehabilitation		**31**	Minutes					60
Neonatal Intensive Care									
Introduce Neonatal Specialty Care Intermediate Level			7	Occupancy	85%				30
Introduce Neonatal Specialty Care Specialty Level			8	Occupancy	85%				90
Introduce Neonatal Specialty Care Sub-Specialty Level			0	Occupancy	85%				
	NICU		**15**	Minutes					30 / 90
Intermediate Care Facility for Individuals with Intellectual Disability									
Establish an intermediate care facility with 13 or more beds for individuals with intellectual disability[5]			2						
	ICF/IID		**2**						

Virginia within 30 minute drive of a CT scanner



9/4/2024

Virginia Administrative Code

Chapter 230. State Medical Facilities Plan

Part I
Definitions and General Information

12VAC5-230-10. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Acute psychiatric services" means hospital-based inpatient psychiatric services provided in distinct inpatient units in general hospitals or freestanding psychiatric hospitals.

"Acute substance abuse disorder treatment services" means short-term hospital-based inpatient treatment services with access to the resources of (i) a general hospital, (ii) a psychiatric unit in a general hospital, (iii) an acute care addiction treatment unit in a general hospital licensed by the Department of Health, or (iv) a chemical dependency specialty hospital with acute care medical and nursing staff and life support equipment licensed by the Department of Behavioral Health and Developmental Services.

"Bassinet" means an infant care station, including warming stations and isolettes.

"Bed" means that unit, within the complement of a medical care facility, subject to COPN review as required by Article 1.1 (§ 32.1-102.1 et seq.) of the Code of Virginia and designated for use by patients of the facility or service. For the purposes of this chapter, bed does include cribs and bassinets used for pediatric patients but does not include cribs and bassinets in the newborn nursery or neonatal special care setting.

"Cardiac catheterization" means an invasive procedure where a flexible tube is inserted into the patient through an extremity blood vessel and advanced under fluoroscopic guidance into the heart chambers or coronary arteries. A cardiac catheterization may be conducted for diagnostic or therapeutic purposes but does not include a simple right heart catheterization for monitoring purposes as might be performed in an electrophysiology laboratory, pulmonary angiography as an isolated procedure, or cardiac pacing through a right electrode catheter.

"Commissioner" means the State Health Commissioner.

"Competing applications" means applications for the same or similar services and facilities that are proposed for the same health planning district, or same health planning region for projects reviewed on a regional basis, and are in the same batch review cycle.

"Complex therapeutic cardiac catheterization" means the performance of cardiac catheterization for the purpose of correcting or improving certain conditions that have been determined to exist in the heart or great arteries or veins of the heart, specifically catheter-based procedures for structural treatment to correct congenital or acquired structural or valvular abnormalities.

"Computed tomography" or "CT" means a noninvasive diagnostic technology that uses computer analysis of a series of cross-sectional scans made along a single axis of a bodily structure or tissue to construct an image of that structure.

"Continuing care retirement community" or "CCRC" means a retirement community consistent with the requirements of Chapter 49 (§ 38.2-4900 et seq.) of Title 38.2 of the Code of Virginia.

"COPN" means a Medical Care Facilities Certificate of Public Need for a project as required in Article 1.1 (§ 32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia.

"COPN program" means the Medical Care Facilities Certificate of Public Need Program implementing Article 1.1 (§ 32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia.

"DEP" means diagnostic equivalent procedure, a method for weighing the relative value of various cardiac catheterization procedures as follows: a diagnostic cardiac catheterization equals 1 DEP, a simple therapeutic cardiac catheterization equals 2 DEPs, a same session procedure (diagnostic and simple therapeutic) equals 3 DEPs, and a complex therapeutic cardiac catheterization equals 5 DEPs. A multiplier of 2 will be applied for a pediatric procedure (i.e., a pediatric diagnostic cardiac catheterization equals 2 DEPs, a pediatric simple therapeutic cardiac catheterization equals 4 DEPs, and a pediatric complex therapeutic cardiac catheterization equals 10 DEPs.)

"Diagnostic cardiac catheterization" means the performance of cardiac catheterization for the purpose of detecting and identifying defects in the great arteries or veins of the heart or abnormalities in the heart structure, whether congenital or acquired.

"Direction" means guidance, supervision, or management of a function or activity.

"Gamma knife®" means the name of a specific instrument used in stereotactic radiosurgery.

"Health planning district" means the same contiguous areas designated as planning districts by the Virginia Department of Housing and Community Development or its successor.

"Health planning region" means a contiguous geographic area of the Commonwealth as designated by the State Board of Health with a population base of at least 500,000 persons, characterized by the availability of multiple levels of medical care services, reasonable travel time for tertiary care, and congruence with planning districts.

"Health system" means an organization of two or more medical care facilities, including hospitals, that are under common ownership or control and are located within the same health planning district, or health planning region for projects reviewed on a regional basis.

"Hospital" means a medical care facility licensed as an inpatient hospital or outpatient surgical center by the Department of Health or as a psychiatric hospital by the Department of Behavioral Health, and Developmental Services.

"ICF/MR" means an intermediate care facility for the mentally retarded.

"Indigent" means any person whose gross family income is equal to or less than 200% of the federal Nonfarm Poverty Level or income levels A through E of 12VAC5-200-10 and who is uninsured.

"Inpatient" means a patient who is hospitalized longer than 24 hours for health or health related services.

"Intensive care beds" or "ICU" means inpatient beds located in the following units or categories:

1. General intensive care units are those units where patients are concentrated by reason of serious illness or injury regardless of diagnosis. Special lifesaving techniques and equipment are immediately available and patients are under continuous observation by nursing staff;

2. Cardiac care units, also known as Coronary Care Units or CCUs, are units staffed and equipped solely for the intensive care of cardiac patients; and

3. Specialized intensive care units are any units with specialized staff and equipment for the purpose of providing care to seriously ill or injured patients based on age selected categories of diagnoses, including units established for burn care, trauma care, neurological care, pediatric care, and cardiac surgery recovery but does not include bassinets in neonatal special care units.

"Lithotripsy" means a noninvasive therapeutic procedure to (i) crush renal and biliary stones using shock waves (i.e., renal lithotripsy) or (ii) treat certain musculoskeletal conditions and relieve the pain associated with tendonitis (i.e., orthopedic lithotripsy).

"Long-term acute care hospital" or "LTACH" means an inpatient hospital that provides care for patients who require a length of stay greater than 25 days and is, or proposes to be, certified by the Centers for Medicare and Medicaid Services as a long-term care inpatient hospital pursuant to 42 CFR Part 412. An LTACH may be either a freestanding facility or located within an existing or host hospital.

"Magnetic resonance imaging" or "MRI" means a noninvasive diagnostic technology using a nuclear spectrometer to produce electronic images of specific atoms and molecular structures in solids, especially human cells, tissues and organs.

"Medical rehabilitation" means those services provided consistent with 42 CFR 412.23 nd 412.24.

"Medical/surgical" means those services available for the care and treatment of patients not requiring specialized services.

"Minimum survival rates" means the base percentage of transplant recipients who survive at least one year or for such other period of time as specified by the United Network for Organ Sharing (UNOS).

"Neonatal special care" means care for infants in one or more of the higher service levels designated in 12VAC5-410-443 .

"Nursing facility" means those facilities or components thereof licensed to provide long-term nursing care.

"Obstetrical services" means the distinct organized program, equipment and care related to pregnancy and the delivery of newborns in inpatient facilities.

"Off-site replacement" means the relocation of existing beds or services from an existing medical care facility site to another location within the same health planning district.

"Open heart surgery" means a surgical procedure requiring the use or immediate availability of a heart-lung bypass machine or "pump." The use of the pump during the procedure distinguishes "open heart" from "closed heart" surgery.

"Operating room" means a room used solely or principally for the provision of surgical procedures involving the administration of anesthesia, multiple personnel, recovery room access, and a fully controlled environment.

"Operating room use" means the amount of time a patient occupies an operating room and includes room preparation and cleanup time.

"Operating room visit" means one session in one operating room in an inpatient hospital or outpatient surgical center, which may involve several procedures. Operating room visit may be used interchangeably with "operation" or "case."

"Outpatient" means a patient who visits a hospital, clinic, or associated medical care facility for diagnosis or treatment, but is not hospitalized 24 hours or longer.

"Pediatric" means patients younger than 18 years of age. Newborns in nurseries are excluded from this definition.

"Perinatal services" means those resources and capabilities that all hospitals offering general level newborn services as described in 12VAC5-410-443 must provide routinely to newborns.

"PET/CT scanner" means a single machine capable of producing a PET image with a concurrently produced CT image overlay to provide anatomic definition to the PET image. For the purpose of granting a COPN, the State Board of Health pursuant to § 32.1-102.2 A 6 of the Code of Virginia has designated PET/CT as a specialty clinical service. A PET/CT scanner shall be reviewed under the PET criteria as an enhanced PET scanner unless the CT unit will be used independently. In such cases, a PET/CT scanner that will be used to take independent PET and CT images will be reviewed under the applicable PET and CT services criteria.

"Planning horizon year" means the particular year for which bed or service needs are projected.

"Population" means the census figures shown in the most current series of projections published by a demographic entity as determined by the commissioner.

"Positron emission tomography" or "PET" means a noninvasive diagnostic or imaging modality using the computer-generated image of local metabolic and physiological functions in tissues produced through the detection of gamma rays emitted when introduced radionuclides decay and release positrons. A PET device or scanner may include an integrated CT to provide anatomic structure definition.

"Primary service area" means the geographic territory from which 75% of the patients of an existing medical care facility originate with respect to a particular service being sought in an application.

"Procedure" means a study or treatment or a combination of studies and treatments identified by a distinct ICD-10 or CPT code performed in a single session on a single patient.

"Qualified" means meeting current legal requirements of licensure, registration, or certification in Virginia or having appropriate training, including competency testing, and experience commensurate with assigned responsibilities.

"Radiation therapy" means treatment using ionizing radiation to destroy diseased cells and for the relief of symptoms. Radiation therapy may be used alone or in combination with surgery or chemotherapy.

"Relevant reporting period" means the most recent 12-month period, prior to the beginning of the applicable batch review cycle, for which data is available from VHI or a demographic entity as determined by the commissioner.

"Rural" means territory, population, and housing units that are classified as "rural" by the Bureau of the Census of the U.S. Department of Commerce, Economic and Statistics Administration.

"Simple therapeutic cardiac catheterization" means the performance of cardiac catheterization for the purpose of correcting or improving certain conditions that have been determined to exist in the heart, specifically catheter-based treatment procedures for relieving coronary artery narrowing.

"SMFP" means the state medical facilities plan as contained in Article 1.1 (§ 32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia used to make medical care facilities and services needs decisions.

"Stereotactic radiosurgery" or "SRS" means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume. SRS may be delivered in a single session or in a fractionated course of treatment up to five sessions.

"Stereotactic radiotherapy" or "SRT" means more than one session of stereotactic radiosurgery.

"Substance abuse disorder treatment services" means services provided to individuals for the prevention, diagnosis, treatment, or palliation of chemical dependency, which may include attendant medical and psychiatric complications of chemical dependency. Substance abuse disorder treatment services are licensed by the Department of Behavioral Health, and Developmental Services.

"Supervision" means to direct and watch over the work and performance of others.

"Use rate" means the rate at which an age cohort or the population uses medical facilities and services. The rates are determined from periodic patient origin surveys conducted for the department by the regional health planning agencies or other health statistical reports authorized by Chapter 7.2 (§ 32.1-276.2 et seq.) of Title 32.1 of the Code of Virginia.

"VHI" means the health data organization defined in § 32.1-276.4 of the Code of Virginia and under contract with the Virginia Department of Health.

Statutory Authority

§§ 32.1-12 and 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from VR355-30-100 § 1, eff. July 1, 1993; amended, Virginia Register Volume 19, Issue 8, eff. February 3, 2003; Volume 25, Issue 9, eff. February 15, 2009; Errata, 25:11 VA.R. 2018 February 2, 2009; amended, Virginia Register Volume 37, Issue 14, eff. March 31, 2021.

12VAC5-230-20. (Repealed.)

Historical Notes

Derived from VR355-30-100 § 2, eff. July 1, 1993; amended, Virginia Register Volume 19, Issue 8, eff. February 3, 2003; repealed, Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-30. Guiding principles in the development of project review criteria and standards.

The following general principles serve as the basis for the development of the review criteria and standards for specific medical care facilities and services contained in this document:

1. The COPN program is based on the understanding that excess capacity or underutilization of medical facilities are detrimental to both cost effectiveness and quality of medical services in Virginia.

2. The COPN program seeks the geographical distribution of medical facilities and to promote the availability and accessibility of proven technologies.

3. The COPN program seeks to promote the development and maintenance of services and access to those services by every person who needs them without respect to their ability to pay.

4. The COPN program seeks to encourage the conversion of facilities to new and efficient uses and the reallocation of resources to meet evolving community needs.

5. The COPN program discourages the proliferation of services that would undermine the ability of essential community providers to maintain their financial viability.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from VR355-30-100 § 3, eff. July 1, 1993; amended, Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-40. General application filing criteria.

A. In addition to meeting the applicable requirements of this chapter, applicants for a Certificate of Public Need shall include documentation in their application that their project addresses the applicable requirements listed in § 32.1-102.3 of the Code of Virginia.

B. The burden of proof shall be on the applicant to produce information and evidence that the project is consistent with the applicable requirements and review policies as required under Article 1.1 (§ 32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia.

C. The commissioner may condition the approval of a COPN by requiring an applicant to: (i) provide a level of care at a reduced rate to indigents, (ii) accept patients requiring specialized care, or (iii) facilitate the development and operation of primary medical care services in designated medically underserved areas of the applicant's service area. The applicant must actively seek to comply with the conditions place on any granted COPN.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-50. Project costs.

The capital development costs of a facility and the operating expenses of providing the authorized services should be comparable to the costs and expenses of similar facilities with the health planning region.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-60. When competing applications received.

In reviewing competing applications, preference may be given to an applicant who:

1. Has an established performance record in completing projects on time and within the authorized operating expenses and capital costs;

2. Has both lower capital costs and operating expenses than his competitors and can demonstrate that his estimates are credible;

3. Can demonstrate a consistent compliance with state licensure and federal certification regulations and a consistent history of few documented complaints, where applicable; or

4. Can demonstrate a commitment to serving his community or service area as evidenced by unreimbursed services to the indigent and providing needed but unprofitable services, taking into account the demands of the particular service area.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009; Errata, 25:11 VA.R. 2018 February 2, 2009.

12VAC5-230-70. Calculation of utilization of services provided with mobile equipment.

A. The minimum service volume of a mobile unit shall be prorated on a site-by-site basis reflecting the amount of time that proposed mobile units will be used, and existing mobile units have been used, during the relevant reporting period, at each site using the following formula:

Required full-time minimum service volume	X	Number of days the service will be on site each week	X 0.2 =	Prorated minimum services volume (not to exceed the required full-time minimum service volume)

B. The average annual utilization of existing and approved CT, MRI, PET, lithotripsy, and catheterization services in a health planning district shall be calculated for such services as follows:

$$\left(\frac{\text{Total volume of all units of the relevant service in the reporting period}}{\left(\text{\# of existing or approved fixed units} \times \text{Fixed unit minimum service volume}\right) + Y \text{ Utilization}}\right) \times 100 = \%\ \text{Average Utilization}$$

Y = the sum of the minimum service volume of each mobile site in the health planning district with the minimum services volume for each such site prorated according to subsection A of this section.

C. This section does not prohibit an applicant from seeking to obtain a COPN for a fixed site service provided capacity for the services has been achieved as described in the applicable service section.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009; Errata, 25:11 VA.R. 2018 February 2, 2009.

12VAC5-230-80. When institutional expansion needed.

A. Notwithstanding any other provisions of this chapter, the commissioner may grant approval for the expansion of services at an existing medical care facility in a health planning district with an excess supply of such services when the proposed expansion can be justified on the basis of a facility's need having exceeded its current service capacity to provide such service or on the geographic remoteness of the facility.

B. If a facility with an institutional need to expand is part of a health system, the underutilized services at other facilities within the health system should be reallocated, when appropriate, to the facility with the institutional need to expand before additional services are approved for the applicant. However, underutilized services located at a health system's geographically remote facility may be disregarded when determining institutional need for the proposed project.

C. This section is not applicable to nursing facilities pursuant to § 32.1-102.3:2 of the Code of Virginia.

D. Applicants shall not use this section to justify a need to establish new services.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009; Errata, 25:11 VA.R. 2018 February 2, 2009.

12VAC5-230-90. Travel time.

Article 1
Criteria and Standards for Computed Tomography

CT services should be within 30 minutes driving time one way under normal conditions of 95% of the population of the health planning district using a mapping software as determined by the commissioner.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-100. Need for new fixed site or mobile service.

A. No new fixed site or mobile CT service should be approved unless fixed site CT services in the health planning district performed an average of 7,400 procedures per existing and approved CT scanner during the relevant reporting period and the proposed new service would not significantly reduce the utilization of existing

providers in the health planning district. The utilization of existing scanners operated by a hospital and serving an area distinct from the proposed new service site may be disregarded in computing the average utilization of CT scanners in such health planning district.

B. Existing CT scanners used solely for simulation with radiation therapy treatment shall be exempt from the utilization criteria of this article when applying for a COPN. In addition, existing CT scanners used solely for simulation with radiation therapy treatment may be disregarded in computing the average utilization of CT scanners in such health planning district.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-110. Expansion of fixed site service.

Proposals to expand an existing medical care facility's CT service through the addition of a CT scanner should be approved when the existing services performed an average of 7,400 procedures per scanner for the relevant reporting period. The commissioner may authorize placement of a new unit at the applicant's existing medical care facility or at a separate location within the applicant's primary service area for CT services, provided the proposed expansion is not likely to significantly reduce the utilization of existing providers in the health planning district.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009; Errata, 25:11 VA.R. 2018 February 2, 2009.

12VAC5-230-120. Adding or expanding mobile CT services.

A. Proposals for mobile CT scanners shall demonstrate that, for the relevant reporting period, at least 4,800 procedures were performed and that the proposed mobile unit will not significantly reduce the utilization of existing CT providers in the health planning district.

B. Proposals to convert authorized mobile CT scanners to fixed site scanners shall demonstrate that, for the relevant reporting period, at least 6,000 procedures were performed by the mobile scanner and that the proposed conversion will not significantly reduce the utilization of existing CT providers in the health planning district.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-130. Staffing.

CT services should be under the direction or supervision of one or more qualified physicians.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

Article 2
Criteria and Standards for Magnetic Resonance Imaging

12VAC5-230-140. Travel time.

Article 2
Criteria and Standards for Magnetic Resonance Imaging

MRI services should be within 30 minutes driving time one way under normal conditions of 95% of the population of the health planning district using a mapping software as determined by the commissioner.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-150. Need for new fixed site service.

No new fixed site MRI services should be approved unless fixed site MRI services in the health planning district performed an average of 5,000 procedures per existing and approved fixed site MRI scanner during the relevant reporting period and the proposed new service would not significantly reduce the utilization of existing fixed site MRI providers in the health planning district. The utilization of existing scanners operated by a hospital and serving an area distinct from the proposed new service site may be disregarded in computing the average utilization of MRI scanners in such health planning district.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-160. Expansion of fixed site service.

Proposals to expand an existing medical care facility's MRI services through the addition of an MRI scanner may be approved when the existing service performed an average of 5,000 MRI procedures per scanner during the relevant reporting period. The commissioner may authorize placement of the new unit at the applicant's existing medical care facility, or at a separate location within the applicant's primary service area for MRI services, provided the proposed expansion is not likely to significantly reduce the utilization of existing providers in the health planning district.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-170. Adding or expanding mobile MRI services.

A. Proposals for mobile MRI scanners shall demonstrate that, for the relevant reporting period, at least 2,400 procedures were performed and that the proposed mobile unit will not significantly reduce the utilization of existing MRI providers in the health planning district.

B. Proposals to convert authorized mobile MRI scanners to fixed site scanners shall demonstrate that, for the relevant reporting period, 3,000 procedures were performed by the mobile scanner and that the proposed conversion will not significantly reduce the utilization of existing MRI providers in the health planning district.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-180. Staffing.

MRI services should be under the direct supervision of one or more qualified physicians.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

Article 3
Magnetic Source Imaging

12VAC5-230-190. Policy for the development of MSI services.

Article 3
Magnetic Source Imaging

Because Magnetic Source Imaging (MSI) scanning systems are still in the clinical research stage of development with no third-party payment available for clinical applications, and because it is uncertain as to how rapidly this technology will reach a point where it is shown to be clinically suitable for widespread use and distribution on a cost-effective basis, it is preferred that the entry and development of this technology in Virginia should initially occur at or in affiliation with, the academic medical centers in the state.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

Article 4
Positron Emission Tomography

12VAC5-230-200. Travel time.

Article 4
Positron Emission Tomography

PET services should be within 60 minutes driving time one way under normal conditions of 95% of the health planning district using a mapping software as determined by the commissioner.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-210. Need for new fixed site service.

A. If the applicant is a hospital, whether free-standing or within a hospital system, 850 new PET appropriate cases shall have been diagnosed and the hospital shall have provided radiation therapy services with specific ancillary services suitable for the equipment before a new fixed site PET service should be approved for the health planning district.

B. No new fixed site PET services should be approved unless an average of 6,000 procedures per existing and approved fixed site PET scanner were performed in the health planning district during the relevant reporting period and the proposed new service would not significantly reduce the utilization of existing fixed site PET providers in the health planning district . The utilization of existing scanners operated by a hospital and serving an area distinct from the proposed new service site may be disregarded in computing the average utilization of PET units in such health planning district.

Note: For the purposes of tracking volume utilization, an image taken with a PET/CT scanner that takes concurrent PET/CT images shall be counted as one PET procedure. Images made with PET/CT scanners that can take PET or CT images independently shall be counted as individual PET procedures and CT procedures respectively, unless those images are made concurrently.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-220. Expansion of fixed site services.

Proposals to increase the number of PET scanners in an existing PET service should be approved only when the existing scanners performed an average of 6,000 procedures for the relevant reporting period and the proposed expansion would not significantly reduce the utilization of existing fixed site providers in the health planning district.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-230. Adding or expansing mobile PET or PET/CT services.

A. Proposals for mobile PET or PET/CT scanners should demonstrate that, for the relevant reporting period, at least 230 PET or PET/CT appropriate patients were seen and that the proposed mobile unit will not significantly reduce the utilization of existing providers in the health planning district.

B. Proposals to convert authorized mobile PET or PET/CT scanners to fixed site scanners should demonstrate that, for the relevant reporting period, at least 1,400 procedures were performed by the mobile scanner and that the proposed conversion will not significantly reduce the utilization of existing providers in the health planning district .

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-240. Staffing.

PET services should be under the direction or supervision of one or more qualified physicians. Such physicians shall be designated or authorized by the Nuclear Regulatory Commission or licensed by the Division of Radiologic Health of the Virginia Department of Health, as applicable.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

Article 5
Noncardiac Nuclear Imaging Criteria and Standards

12VAC5-230-250. Travel time.

Article 5
Noncardiac Nuclear Imaging Criteria and Standards

Noncardiac nuclear imaging services should be available within 30 minutes driving time one way under normal driving conditions of 95% of the population of the health planning district using a mapping software as determined by the commissioner.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-260. Need for new service.

No new noncardiac imaging services should be approved unless the service can achieve a minimum utilization level of:

1. 650 procedures in the first 12 months of operation;

2. 1,000 procedures in the second 12 months of service; and

3. The proposed new service would not significantly reduce the utilization of existing providers in the health planning district.

Note: The utilization of an existing service operated by a hospital and serving an area distinct from the proposed new service site may be disregarded in computing the average utilization of noncardiac nuclear imaging services in such health planning district.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-270. Staffing.

The proposed new or expanded noncardiac nuclear imaging service should be under the direction or supervision of one or more qualified physicians designated or authorized by the Nuclear Regulatory Commission or the Division of Radiologic Health of the Virginia Department of Health, as applicable.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

Part III
Radiation Therapy Services

Article 1
Radiation Therapy Services

12VAC5-230-280. Travel time.

Article 1
Radiation Therapy Services

Radiation therapy services should be available within 60 minutes driving time one way under normal conditions of 95% of the population of the health planning district using a mapping software as determined by the commissioner.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-290. Need for new service.

A. No new radiation therapy service should be approved unless:

1. Existing radiation therapy machines located in the health planning district performed an average of 8,000 procedures per existing and approved radiation therapy machine in the relevant reporting period; and

2. The new service will perform at least 5,000 procedures by the second year of operation without significantly reducing the utilization of existing providers in the health planning district.

B. The number of radiation therapy machines needed in a health planning district will be determined as follows:

$$\frac{\text{Population x Cancer Incidence Rate x 60\%}}{320}$$

where:

1. The population is projected to be at least 150,000 people three years from the current year as reported in the most current projections of a demographic entity as determined by the commissioner;

2. The cancer incidence rate as determined by data from the Statewide Cancer Registry;

3. 60% is the estimated number of new cancer cases in a health planning district that are treatable with radiation therapy; and

4. 320 is 100% utilization of a radiation therapy machine based upon an anticipated average of 25 procedures per case.

C. Proposals for new radiation therapy services located less than 60 minutes driving time one way, under normal conditions, from any site that radiation therapy services are available shall demonstrate that the proposed new

services will perform an average of 4,500 procedures annually by the second year of operation, without significantly reducing the utilization of existing services in the health planning district.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-300. Expansion of service.

Proposals to expand radiation therapy services should be approved only when all existing radiation therapy services operated by the applicant in the health planning district have performed an average of 8,000 procedures for the relevant reporting period and the proposed expansion would not significantly reduce the utilization of existing providers.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-310. Statewide Cancer Registry.

Facilities with radiation therapy services shall participate in the Statewide Cancer Registry as required by Article 9 (§ 32.1-70 et seq.) of Chapter 2 of Title 32.1 of the Code of Virginia.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-320. Staffing.

Radiation therapy services should be under the direction or supervision of one or more qualified physicians designated or authorized by the Nuclear Regulatory Commission or the Division of Radiologic Health of the Virginia Department of Health, as applicable.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

Article 2
Criteria and Standards for Stereotactic Radiosurgery

12VAC5-230-330. Travel time.

Article 2
Criteria and Standards for Stereotactic Radiosurgery

Stereotactic radiosurgery services should be available within 60 minutes driving time one way under normal conditions of 95% of the population of a health planning region using a mapping software as determined by the commissioner.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-340. Need for new service.

A. No new stereotactic radiosurgery services should be approved unless:

1. The number of procedures performed with existing units in the health planning region averaged more than 350 per year in the relevant reporting period; and

2. The proposed new service will perform at least 250 procedures in the second year of operation without significantly reducing the utilization of existing providers in the health planning region.

B. Preference may be given to a project that incorporates stereotactic radiosurgery service incorporated within an existing standard radiation therapy service using a linear accelerator when an average of 8,000 procedures during the relevant reporting period and utilization of existing services in the health planning region will not be significantly reduced.

C. Preference may be given to a project that incorporates a dedicated Gamma Knife® within an existing radiation therapy service when:

1. At least 350 Gamma Knife® appropriate cases were referred out of the region in the relevant reporting period; and

2. The applicant can demonstrate that:

a. An average of 250 procedures will be preformed in the second year of operation; and

b. Utilization of existing services in the health planning region will not be significantly reduced.

D. Preference may be given to a project that incorporates non-Gamma Knife® SRS technology within an existing radiation therapy service when:

1. The unit is not part of a linear accelerator;

2. An average of 8,000 radiation procedures per year were performed by the existing radiation therapy services;

3. At least 250 procedures will be performed within the second year of operation; and

4. Utilization of existing services in the health planning region will not be significantly reduced.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009; Errata, 25:11 VA.R. 2018 February 2, 2009.

12VAC5-230-350. Expansion of service.

Proposals to increase the number of stereotactic radiosurgery services should be approved only when all existing stereotactic radiosurgery machines in the health planning region have performed an average of 350 procedures per existing and approved unit for the relevant reporting period and the proposed expansion would not significantly reduce the utilization of existing providers in the health planning region.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-360. Statewide Cancer Registry.

Facilities with stereotactic radiosurgery services shall participate in the Statewide Cancer Registry as required by Article 9 (§ 32.1-70 et seq.) of Chapter 2 of Title 32.1 of the Code of Virginia.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-370. Staffing.

Stereotactic radiosurgery services should be under the direction or supervision of one or more qualified physicians.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

Part IV
Cardiac Services

Article 1
Criteria and Standards for Cardiac Catheterization Services

12VAC5-230-380. Travel time.

Article 1
Criteria and Standards for Cardiac Catheterization Services

Cardiac catheterization services should be within 60 minutes driving time one way under normal conditions of 95% of the population of the health planning district using mapping software as determined by the commissioner.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-390. Need for new service.

A. No new fixed site cardiac catheterization service should be approved for a health planning district unless:

1. Existing fixed site cardiac catheterization services located in the health planning district performed an average of 1,200 cardiac catheterization DEPs per existing and approved laboratory for the relevant reporting period;

2. The proposed new service will perform an average of 200 DEPs in the first year of operation and 500 DEPs in the second year of operation; and

3. The utilization of existing services in the health planning district will not be significantly reduced.

B. Proposals for mobile cardiac catheterization laboratories should be approved only if such laboratories will be provided at a site located on the campus of an inpatient hospital. Additionally, applicants for proposed mobile cardiac catheterization laboratories shall be able to project that they will perform an average of 200 DEPs in the first year of operation and 350 DEPs in the second year of operation without significantly reducing the utilization of existing laboratories in the health planning district below 1,200 procedures.

C. Preference may be given to a project that locates new cardiac catheterization services at an inpatient hospital that is 60 minutes or more driving time one way under normal conditions from existing services if the applicant can demonstrate that the proposed new laboratory will perform an average of 200 DEPs in the first year of operation and 400 DEPs in the second year of operation without significantly reducing the utilization of existing laboratories in the health planning district.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-400. Expansion of services.

Proposals to increase cardiac catheterization services should be approved only when:

1. All existing cardiac catheterization laboratories operated by the applicant's facilities where the proposed expansion is to occur have performed an average of 1,200 DEPs per existing and approved laboratory for the relevant reporting period; and

2. The applicant can demonstrate that the expanded service will achieve an average of 200 DEPs per laboratory in the first 12 months of operation and 400 DEPs in the second 12 months of operation without significantly reducing the utilization of existing cardiac catheterization laboratories in the health planning district.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-410. Pediatric cardiac catheterization.

No new or expanded pediatric cardiac catheterization services should be approved unless:

1. The proposed service will be provided at an inpatient hospital with open heart surgery services, pediatric tertiary care services or specialty or subspecialty level neonatal special care;

2. The applicant can demonstrate that the proposed laboratory will perform at least 100 pediatric cardiac catheterization procedures in the first year of operation and 200 pediatric cardiac catheterization procedures in the second year of operation; and

3. The utilization of existing pediatric cardiac catheterization laboratories in the health planning district will not be reduced below 100 procedures per year.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-420. Nonemergent cardiac catheterization.

A. Simple therapeutic cardiac catheterization. Proposals to provide simple therapeutic cardiac catheterization are not required to offer open heart surgery service available on-site in the same hospital in which the proposed simple therapeutic service will be located. However, these programs shall adhere to the requirements described in subdivisions 1 through 9 of this subsection.

The programs shall:

1. Participate in the Virginia Heart Attack Coalition, the Virginia Cardiac Services Quality Initiative, and the Action Registry-Get with the Guidelines or National Cardiovascular Data Registry to monitor quality and outcomes;

2. Adhere to strict patient-selection criteria;

3. Perform annual institutional volumes of 300 cardiac catheterization procedures, of which at least 75 should be percutaneous coronary intervention (PCI) or as dictated by American College of Cardiology (ACC)/American Heart Association (AHA) Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories effective 1991;

4. Use only AHA/ACC-qualified operators who meet the standards for training and competency;

5. Demonstrate appropriate planning for program development and complete both a primary PCI development program and an elective PCI development program that includes routine care process and case selection review;

6. Develop and maintain a quality and error management program;

7. Provide PCI 24 hours a day, seven days a week;

8. Develop and maintain necessary agreements with a tertiary facility that must agree to accept emergent and nonemergent transfers for additional medical care, cardiac surgery, or intervention; and

9. Develop and maintain agreements with an ambulance service capable of advanced life support and intra-aortic balloon pump transfer that guarantees a 30-minute or less response time.

B. Complex therapeutic cardiac catheterization. Proposals to provide complex therapeutic cardiac catheterization should be approved only when open heart surgery services are available on-site in the same hospital in which the proposed complex therapeutic service will be located. Additionally, these complex therapeutic cardiac catheterization programs will be required to participate in the Virginia Cardiac Services Quality Initiative and the Virginia Heart Attack Coalition.

Statutory Authority

§§ 32.1-12 and 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009; amended, Virginia Register Volume 37, Issue 14, eff. March 31, 2021.

12VAC5-230-430. Staffing.

A. Cardiac catheterization services should have a medical director who is board certified in cardiology and has clinical experience in performing physiologic and angiographic procedures.

In the case of pediatric cardiac catheterization services, the medical director should be board-certified in pediatric cardiology and have clinical experience in performing physiologic and angiographic procedures.

B. Cardiac catheterization services should be under the direct supervision or one or more qualified physicians. Such physicians should have clinical experience in performing physiologic and angiographic procedures.

Pediatric catheterization services should be under the direct supervision of one or more qualified physicians. Such physicians should have clinical experience in performing pediatric physiologic and angiographic procedures.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-440. Travel time.

Article 2
Criteria and Standards for Open Heart Surgery

A. Open heart surgery services should be within 60 minutes driving time one way under normal conditions of 95% of the population of the health planning district using mapping software as determined by the commissioner.

B. Such services shall be available 24 hours a day, seven days a week.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-450. Need for new service.

A. No new open heart services should be approved unless:

1. The service will be available in an inpatient hospital with an established cardiac catheterization service that has performed an average of 1,200 DEPs for the relevant reporting period and has been in operation for at least 30 months;

2. Open heart surgery services located in the health planning district performed an average of 400 open heart and closed heart surgical procedures for the relevant reporting period; and

3. The proposed new service will perform at least 150 procedures per room in the first year of operation and 250 procedures per room in the second year of operation without significantly reducing the utilization of existing open heart surgery services in the health planning district.

B. Preference may be given to a project that locates new open heart surgery services at an inpatient hospital more than 60 minutes driving time one way under normal condition from any site in which open heart surgery services are currently available and:

1. The proposed new service will perform an average of 150 open heart procedures in the first year of operation and 200 procedures in the second year of operation without significantly reducing the utilization of existing open heart surgery rooms within two hours driving time one way under normal conditions from the proposed new service location below 400 procedures per room; and

2. The hospital provided an average of 1,200 cardiac catheterization DEPs during the relevant reporting period in a service that has been in operation at least 30 months.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-460. Expansion of service.

Proposals to expand open heart surgery services shall demonstrate that existing open heart surgery rooms operated by the applicant have performed an average of:

1. 400 adult equivalent open heart surgery procedures in the relevant reporting period if the proposed increase is within one hour driving time one way under normal conditions of an existing open heart surgery service; or

2. 300 adult equivalent open heart surgery procedures in the relevant reporting period if the proposed service is in excess of one hour driving time one way under normal conditions of an existing open heart surgery service in the health planning district.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-470. Pediatric open heart surgery services.

No new pediatric open heart surgery service should be approved unless the proposed new service is provided at an inpatient hospital that:

1. Has pediatric cardiac catheterization services that have been in operation for 30 months and have performed an average of 200 pediatric cardiac catheterization procedures for the relevant reporting period; and

2. Has pediatric intensive care services and provides specialty or subspecialty neonatal special care.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-480. Staffing.

A. Open heart surgery services should have a medical director who is board certified in cardiovascular or cardiothoracic surgery by the appropriate board of the American Board of Medical Specialists.

In the case of pediatric cardiac surgery, the medical director should be board certified in cardiovascular or cardiothoracic surgery, with special qualifications and experience in pediatric cardiac surgery and congenital heart disease, by the appropriate board of the American Board of Medical Specialists.

B. Cardiac surgery should be under the direct supervision of one or more qualified physicians.

Pediatric cardiac surgery services should be under the direct supervision of one or more qualified physicians.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

Part V
General Surgical Services

12VAC5-230-490. Travel time.

Surgical services should be available within 30 minutes driving time one way under normal conditions for 95% of the population of the health planning district using mapping software as determined by the commissioner.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-500. Need for new service.

A. The combined number of inpatient and outpatient general purpose surgical operating rooms needed in a health planning district, exclusive of procedure rooms, dedicated cesarean section rooms, operating rooms designated exclusively for cardiac surgery, procedures rooms or VDH-designated trauma services, shall be determined as follows:

$$\frac{\text{FOR} = ((\text{ORV}/\text{POP}) \times (\text{PROPOP})) \times \text{AHORV}}{1600}$$

Where:

ORV = the sum of total inpatient and outpatient general purpose operating room visits in the health planning district in the most recent five years for which general purpose operating room utilization data has been reported by VHI; and

POP = the sum of total population in the health planning district as reported by a demographic entity as determined by the commissioner, for the same five-year period as used in determining ORV.

PROPOP = the projected population of the health planning district five years from the current year as reported by a demographic program as determined by the commissioner.

AHORV = the average hours per general purpose operating room visit in the health planning district for the most recent year for which average hours per general purpose operating room visits have been calculated as reported

by VHI.

FOR = future general purpose operating rooms needed in the health planning district five years from the current year.

1600 = available service hours per operating room per year based on 80% utilization of an operating room available 40 hours per week, 50 weeks per year.

B. Projects involving the relocation of existing operating rooms within a health planning district may be authorized when it can be reasonably documented that such relocation will: (i) improve the distribution of surgical services within a health planning district ; (ii) result in the provision of the same surgical services at a lower cost to surgical patients in the health planning district; or (iii) optimize the number of operations in the health planning district that are performed on an outpatient basis.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-510. Staffing.

Surgical services should be under the direction or supervision of one or more qualified physicians.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

Part VI
Inpatient Bed Requirements

12VAC5-230-520. Travel time.

Inpatient beds should be within 30 minutes driving time one way under normal conditions of 95% of the population of a health planning district using a mapping software as determined by the commissioner.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-530. Need for new service.

A. No new inpatient beds should be approved in any health planning district unless:

1. The resulting number of beds for each bed category contained in this article does not exceed the number of beds projected to be needed for that health planning district for the fifth planning horizon year; and

2. The average annual occupancy based on the number of beds in the health planning district for the relevant reporting period is:

a. 80% at midnight census for medical/surgical or pediatric beds;

b. 65% at midnight census for intensive care beds.

B. For proposals to convert under-utilized beds that require a capital expenditure with an expenditure exceeding the threshold amount as determined using the formula contained in subsection C of this section, consideration may be given to such proposal if:

1. There is a projected need in the applicable category of inpatient beds; and

2. The applicant can demonstrate that the average annual occupancy of the converted beds would meet the utilization standard for the applicable bed category by the first year of operation.

For the purposes of this part, "underutilized" means less than 80% average annual occupancy for medical/surgical or pediatric beds, when the relocation involves such beds and less than 65% average annual occupancy for intensive care beds when relocation involves such beds.

C. The capital expenditure threshold referenced in subsection B of this section shall be adjusted annually using the percentage increase listed in the Consumer Price Index for All Urban Consumers (CPI-U) for the most recent year as follows:

A x (1+B)

where:

A = the capital expenditure threshold amount for the previous year

and

B = the percent increase for the expense category "Medical Care" listed in the most recent year available of the CPI-U of the U.S. Bureau of Labor Statistics.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009; amended, Virginia Register Volume 30, Issue 8, eff. February 4, 2014.

12VAC5-230-540. Need for medical/surgical beds.

The number of medical/surgical beds projected to be needed in a health planning district shall be computed as follows:

1. Determine the use rate for the medical/surgical beds for the health planning district using the formula:

BUR = (IPD/PoP)

Where:

BUR = the bed use rate for the health planning district.

IPD = the sum of total inpatient days in the health planning district for the most recent five years for which inpatient day data has been reported by VHI; and

PoP = the sum of total population 18 years of age and older in the health planning district for the same five years used to determine IPD as reported by a demographic program as determined by the commissioner.

2. Determine the total number of medical/surgical beds needed for the health planning district in five years from the current year using the formula:

ProBed = ((BUR x ProPop)/365)/0.80

Where:

ProBed = The projected number of medical/surgical beds needed in the health planning district for five years from the current year.

BUR = the bed use rate for the health planning district determined in subdivision 1 of this section.

ProPop = the projected population 18 years of age and older of the health planning district five years from the current year as reported by a demographic program as determined by the commissioner.

3. Determine the number of medical/surgical beds that are needed in the health planning district for the five planning horizon years as follows:

NewBed = ProBed – CurrentBed

Where:

NewBed = the number of new medical/surgical beds that can be established in a health planning district, if the number is positive. If NewBed is a negative number, no additional medical/surgical beds should be authorized for the health planning district.

ProBed = the projected number of medical/surgical beds needed in the health planning district for five years from the current year determined in subdivision 2 of this section.

CurrentBed = the current inventory of licensed and authorized medical/surgical beds in the health planning district.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009; amended, Virginia Register Volume 25, Issue 13, eff. April 1, 2009.

12VAC5-230-550. Need for pediatric beds.

The number of pediatric beds projected to be needed in a health planning district shall be computed as follows:

1. Determine the use rate for pediatric beds for the health planning district using the formula:

PBUR = (PIPD/PedPop)

Where:

PBUR = The pediatric bed use rate for the health planning district.

PIPD = The sum of total pediatric inpatient days in the health planning district for the most recent five years for which inpatient days data has been reported by VHI; and

PedPop = The sum of population under 18 years of age in the health planning district for the same five years used to determine PIPD as reported by a demographic program as determined by the commissioner.

2. Determine the total number of pediatric beds needed to the health planning district in five years from the current year using the formula:

ProPedBed = ((PBUR x ProPedPop)/365)/0.80

Where:

ProPedBed = The projected number of pediatric beds needed in the health planning district for five years from the current year.

PBUR = The pediatric bed use rate for the health planning district determined in subdivision 1 of this section.

ProPedPop = The projected population under 18 years of age of the health planning district five years from the current year as reported by a demographic program as determined by the commissioner.

3. Determine the number of pediatric beds needed within the health planning district for the fifth planning horizon year as follows:

NewPedBed – ProPedBed – CurrentPedBed

Where:

NewPedBed = the number of new pediatric beds that can be established in a health planning district, if the number is positive. If NewPedBed is a negative number, no additional pediatric beds should be authorized for the health planning district.

ProPedBed = the projected number of pediatric beds needed in the health planning district for five years from the current year determined in subdivision 2 of this section.

CurrentPedBed = the current inventory of licensed and authorized pediatric beds in the health planning district.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009; amended, Virginia Register Volume 25, Issue 13, eff. April 1, 2009.

12VAC5-230-560. Need for intensive care beds.

The projected need for intensive care beds in a health planning district shall be computed as follows:

1. Determine the use rate for ICU beds for the health planning district using the formula:

ICUBUR = (ICUPD/Pop)

Where:

ICUBUR = The ICU bed use rate for the health planning district.

ICUPD = The sum of total ICU inpatient days in the health planning district for the most recent five years for which inpatient day data has been reported by VHI; and

Pop = The sum of population 18 years of age or older for adults or under 18 for pediatric patients in the health planning district for the same five years used to determine ICUPD as reported by a demographic program as determined by the commissioner.

2. Determine the total number of ICU beds needed for the health planning district, including bed availability for unscheduled admissions, five years from the current year using the formula:

ProICUBed = ((ICUBUR x ProPop)/365)/0.65

Where:

ProICUBed = The projected number of ICU beds needed in the health planning district for five years from the current year;

ICUBUR = The ICU bed use rate for the health planning district as determine in subdivision 1 of this section;

ProPop = The projected population 18 years of age or older for adults or under 18 for pediatric patients of the health planning district five years from the current year as reported by a demographic program as determined by the commissioner.

3. Determine the number of ICU beds that may be established or relocated within the health planning district for the fifth planning horizon planning year as follows:

NewICUB = ProICUBed – CurrentICUBed

Where:

NewICUBed = The number of new ICU beds that can be established in a health planning district, if the number is positive. If NewICUBed is a negative number, no additional ICU beds should be authorized for the health planning district.

ProICUBed = The projected number of ICU beds needed in the health planning district for five years from the current year as determined in subdivision 2 of this section.

CurrentICUBed = The current inventory of licensed and authorized ICU beds in the health planning district.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009; amended, Virginia Register Volume 25, Issue 13, eff. April 1, 2009.

12VAC5-230-570. Expansion or relocation of services.

A. Proposals to relocate beds to a location not contiguous to the existing site should be approved only when:

1. Off-site replacement is necessary to correct life safety or building code deficiencies;

2. The population currently served by the beds to be moved will have reasonable access to the beds at the new site, or to neighboring inpatient facilities;

3. The number of beds to be moved off-site is taken out of service at the existing facility;

4. The off-site replacement of beds results in:

a. A decrease in the licensed bed capacity;

b. A substantial cost savings, cost avoidance, or consolidation of underutilized facilities; or

c. Generally improved operating efficiency in the applicant's facility or facilities; and

5. The relocation results in improved distribution of existing resources to meet community needs.

B. Proposals to relocate beds within a health planning district where underutilized beds are within 30 minutes driving time one way under normal conditions of the site of the proposed relocation should be approved only when the applicant can demonstrate that the proposed relocation will not materially harm existing providers.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-580. Long-term acute care hospitals (LTACHs).

A. LTACHs will not be considered as a separate category for planning or licensing purposes. All LTACH beds remain part of the inventory of inpatient hospital beds.

B. A LTACH shall only be approved if an existing hospital converts existing medical/surgical beds to LTACH beds or if there is an identified need for LTACH beds within a health planning district. New LTACH beds that would result in an increase in total licensed beds above 165% of the average daily census for the health planning district will not be approved. Excess inpatient beds within an applicant's existing acute care facilities must be converted to fill any unmet need for additional LTACH beds.

C. If an existing or host hospital converts existing beds for use as LTACH beds, those beds must be delicensed from the bed inventory of the existing hospital. If the LTACH ceases to exist, terminates its services, or does not offer services for a period of 12 months within its first year of operation, the beds delicensed by the host hospital to establish the LTACH shall revert back to that host hospital.

If the LTACH ceases operation in subsequent years of operation, the host hospital may reacquire the LTACH beds by obtaining a COPN, provided the beds are to be used exclusively for their original intended purpose and the application meets all other applicable project delivery requirements. Such an application shall not be subject to the standard batch review cycle and shall be processed as allowed under Part VI (12VAC5-220-280 et seq.) of the Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations.

D. The application shall delineate the service area for the LTACH by documenting the expected areas from which it is expected to draw patients.

E. A LTACH shall be established for 10 or more beds.

F. A LTACH shall become certified by the Centers for Medicare and Medicaid Services (CMS) as a long-term acute care hospital and shall not convert to a hospital for patients needing a length of stay of less than 25 days without obtaining a certificate of public need.

1. If the LTACH fails to meet the CMS requirements as a LTACH within 12 months after beginning operation, it may apply for a six-month extension of its COPN.

2. If the LTACH fails to meet the CMS requirements as a LTACH within the extension period, then the COPN granted pursuant to this section shall expire automatically.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-590. Staffing.

Inpatient services should be under the direction or supervision of one or more qualified physicians.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

Part VII
Nursing Facilities

12VAC5-230-600. Travel time.

A. Nursing facility beds should be accessible within 30 minutes driving time one way under normal conditions to 95% of the population in a health planning district using mapping software as determined by the commissioner.

B. Nursing facilities should be accessible by public transportation when such systems exist in an area.

C. Preference may be given to proposals that improve geographic access and reduce travel time to nursing facilities within a health planning district.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-610. Need for new service.

A. A health planning district should be considered to have a need for additional nursing facility beds when:

1. The bed need forecast exceeds the current inventory of existing and authorized beds for the health planning district; and

2. The median annual occupancy of all existing and authorized Medicaid-certified nursing facility beds in the health planning district was at least 93%, and the average annual occupancy of all existing and authorized Medicaid-certified nursing facility beds in the health planning district was at least 90%, excluding the bed inventory and utilization of the Virginia Veterans Care Centers.

Exception: When there are facilities that have been in operation less than one year in the health planning district, their occupancy can be excluded from the calculation of average occupancy .

B. No health planning district should be considered in need of additional beds if there are unconstructed beds designated as Medicaid certified. This presumption of "no need" for additional beds extends for three years from the issuance date of the certificate.

C. The bed need forecast will be computed as follows:

PDBN = (UR64 x PP64) + (UR69 x PP69) + (UR74 x PP74) + (UR79 x PP79) + (UR84 x PP84) + (UR85 x PP85)

Where:

PDBN = Planning district bed need.

UR64 = The nursing home bed use rate of the population aged 0 to 64 in the health planning district as determined in the most recent nursing home patient origin study authorized by VHI.

PP64 = The population aged 0 to 64 projected for the health planning district three years from the current year as most recently published by a demographic program as determined by the commissioner.

UR69 = The nursing home bed use rate of the population aged 65 to 69 in the health planning district as determined in the most recent nursing home patient origin study authorized by VHI.

PP69 = The population aged 65 to 69 projected for the health planning district three years from the current year as most recently published by a demographic program as determined by the commissioner.

UR74 = The nursing home bed use rate of the population aged 70 to 74 in the health planning district as determined in the most recent nursing home patient origin study authorized by VHI.

PP74 = The population aged 70 to 74 projected for the health planning district three years from the current year as most recently published by a demographic program as determined by the commissioner.

UR79 = The nursing home bed use rate of the population aged 75 to 79 in the health planning district as determined in the most recent nursing home patient origin study authorized by VHI.

PP79 = The population aged 75 to 79 projected for the health planning district three years from the current year as most recently published by a demographic program as determined by the commissioner.

UR84 = The nursing home bed use rate of the population aged 80 to 84 in the health planning district as determined in the most recent nursing home patient origin study authorized by VHI.

PP84 = The population aged 80 to 84 projected for the health planning district three years from the current year as most recently published by a demographic program as determined by the commissioner.

UR85+ = The nursing home bed use rate of the population aged 85 and older in the health planning district as determined in the most recent nursing home patient origin study authorized by VHI.

PP85+ = The population aged 85 and older projected for the health planning district three years from the current year as most recently published by a demographic program as determined by the commissioner.

Health planning district bed need forecasts will be rounded as follows:

Health Planning District Bed Need	Rounded Bed Need
1–29	0
30–44	30
45–84	60
85–104	90
105–134	120
135–164	150
165–194	180
195–224	210
225+	240

Exception: When a health planning district has:

1. Two or more nursing facilities;

2. Had a median annual occupancy rate of 93% of all existing and authorized Medicaid-certified nursing facility beds and an annual average occupancy rate of at least 90% of all existing and authorized Medicaid-certified nursing facility beds for each of the most recent two years for which bed utilization has been reported to VHI; and

3. Has a forecasted bed need of 15 to 29 beds, then the bed need for this health planning district will be rounded to 30.

D. No new freestanding nursing facilities of less than 90 beds should be authorized. However, consideration may be given to a new freestanding facility with fewer than 90 nursing facility beds when the applicant can

demonstrate that such a facility is justified based on a locality's preference for such smaller facility and there is a documented poor distribution of nursing facility beds within the health planning district.

E. When evaluating the capital cost of a project, consideration may be given to projects that use the current methodology as determined by the Department of Medical Assistance Services.

F. Preference may be given to projects that replace outdated and functionally obsolete facilities with modern facilities that result in the more cost-efficient resident services in a more aesthetically pleasing and comfortable environment.

Statutory Authority

§§ 32.1-12 and 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009; amended, Virginia Register Volume 37, Issue 14, eff. March 31, 2021.

12VAC5-230-620. Expansion of services.

Proposals to increase an existing nursing facility's bed capacity should not be approved unless the facility has operated for at least two years and the average annual occupancy of the facility's existing beds was at least 90% in the relevant reporting period as reported to VHI.

Note: Exceptions will be considered for facilities that operated at less than 90% average annual occupancy in the most recent year for which bed utilization has been reported when the facility offers short stay services causing an average annual occupancy lower than 90% for the facility.

Statutory Authority

§§ 32.1-12 and 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009; amended, Virginia Register Volume 37, Issue 14, eff. March 31, 2021.

12VAC5-230-630. Continuing care retirement communities.

Proposals for the development of new nursing facilities or the expansion of existing facilities by continuing care retirement communities (CCRC) will be considered when:

1. The facility is registered with the State Corporation Commission as a continuing care provider pursuant to Chapter 49 (§ 38.2-4900 et seq.) of Title 38.2 of the Code of Virginia;

2. The number of nursing facility beds requested in the initial application does not exceed the lesser of 20% of the continuing care retirement community's total number of beds that are not nursing home beds or 60 beds;

3. The number of new nursing facility beds requested in any subsequent application does not cause the continuing care retirement community's total number of nursing home beds to exceed 20% of its total number of beds that are not nursing facility beds; and

4. The continuing care retirement community has established a qualified resident assistance policy.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-640. Staffing.

Nursing facilities shall be under the direction or supervision of a licensed nursing home administrator and staffed by licensed and certified nursing personnel qualified as required by law.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

Part VIII
Lithotripsy Service

12VAC5-230-650. Travel time.

Lithotripsy services should be available within 30 minutes driving time one way under normal conditions for 95% of the population of the health planning region using mapping software as determined by the commissioner.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-660. Need for new service.

A. Preference may be given to a project that establishes new renal or orthopedic lithotripsy services at a new facility through contract with, or by lease of equipment from, an existing service provider authorized to operate in Virginia, and the facility has referred at least two appropriate patients per week, or 100 appropriate patients annually, for the relevant reporting period to other facilities for either renal or orthopedic lithotripsy services.

B. A new renal lithotripsy service may be approved if the applicant can demonstrate that the proposed service can provide at least 750 renal lithotripsy procedures annually.

C. A new orthopedic lithotripsy service may be approved if the applicant can demonstrate that the proposed service can provide at least 500 orthopedic lithotripsy procedures annually.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-670. Expansion of services.

A. Proposals to expand renal lithotripsy services should demonstrate that each existing unit owned or operated by that vendor or provider has provided at least 750 procedures annually at all sites served by the vendor or provider.

B. Proposals to expand orthopedic lithotripsy services should demonstrate that each existing unit owned or operated by that vendor or provider has provided at least 500 procedures annually at all sites served by the vendor or provider.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-680. Adding or expanding mobile lithotripsy services.

A. Proposals for mobile lithotripsy services should demonstrate that, for the relevant reporting period, at least 125 procedures were performed and that the proposed mobile unit will not reduce the utilization of existing machines in the health planning region.

B. Proposals to convert a mobile lithotripsy service to a fixed site lithotripsy service should demonstrate that, for the relevant reporting period, at least 430 procedures were performed and the proposed conversion will not reduce the utilization of existing providers in the health planning district.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-690. Staffing.

Lithotripsy services should be under the direction or supervision of one or more qualified physicians.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

Part IX
Organ Transplant

12VAC5-230-700. Travel time.

A. Organ transplantation services should be accessible within two hours driving time one way under normal conditions of 95% of Virginia's population using mapping software as determined by the commissioner.

B. Providers of organ transplantation services should facilitate access to pre and post transplantation services needed by patients residing in rural locations be establishing part-time satellite clinics.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-710. Need for new service.

A. There should be no more than one program for each transplantable organ in a health planning region.

B. Performance of minimum transplantation volumes as cited in 12VAC5-230-720 does not indicate a need for additional transplantation capacity or programs.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-720. Transplant volumes; survival rates; service proficiency; systems operations.

A. Proposals to establish organ transplantation services should demonstrate that the minimum number of transplants would be performed annually. The minimum number transplants of required by organ system is:

Kidney	30
Pancreas or kidney/pancreas	12
Heart	17
Heart/Lung	12
Lung	12
Liver	21
Intestine	2

Note: Any proposed pancreas transplant program must be a part of a kidney transplant program that has achieved a minimum volume standard of 30 cases per year for kidney transplants as well as the minimum transplant survival rates stated in subsection B of this section.

B. Applicants shall demonstrate that they will achieve and maintain at least the minimum transplant patient survival rates. Minimum one-year survival rates listed by organ system are:

Kidney	95%
Pancreas or kidney/pancreas	90%

Heart	85%
Heart/Lung	70%
Lung	77%
Liver	86%
Intestine	77%

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-730. Expansion of transplant services.

A. Proposals to expand organ transplantation services shall demonstrate at least two years successful experience with all existing organ transplantation systems at the hospital.

B. Preference may be given to a project expanding the number of organ systems being transplanted at a successful existing service rather than developing new programs that could reduce existing program volumes.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-740. Staffing.

Organ transplant services should be under the direct supervision of one or more qualified physicians.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

Part X
Miscellaneous Capital Expenditures

12VAC5-230-750. Purpose.

This part of the SMFP is intended to provide general guidance in the review of projects that require COPN authorization by virtue of their expense but do not involve changes in the bed or service capacity of a medical care facility addressed elsewhere in this chapter. This part may be used in coordination with other service specific parts addressed elsewhere in this chapter.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-760. Project need.

12VAC5-230-760. Project need.

A. All applications involving a capital expenditure with an expenditure exceeding the threshold amount as determined using the formula contained in subsection B of this section by a medical care facility should include documentation that the expenditure is necessary in order for the facility to meet the identified medical care needs of the public it serves. Such documentation should clearly identify that the expenditure:

1. Represents the most cost-effective approach to meeting the identified need; and

2. The ongoing operational costs will not result in unreasonable increases in the cost of delivering the services provided.

B. The capital expenditure threshold referenced in subsection A of this section shall be adjusted annually using the percentage increase listed in the Consumer Price Index for All Urban Consumers (CPI-U) for the most recent year as follows:

A x (1+B)

where:

A = the capital expenditure threshold amount for the previous year

and

B = the percent increase for the expense category "Medical Care" listed in the most recent year available of the CPI-U of the U.S. Bureau of Labor Statistics.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009; amended, Virginia Register Volume 30, Issue 8, eff. February 4, 2014.

12VAC5-230-770. Facilities expansion.

Applications for the expansion of medical care facilities should document that the current space provided in the facility for the areas or departments proposed for expansion is inadequate. Such documentation should include:

1. An analysis of the historical volume of work activity or other activity performed in the area or department;

2. The projected volume of work activity or other activity to be performed in the area or department; and

3. Evidence that contemporary design guidelines for space in the relevant areas or departments, based on levels of work activity or other activity, are consistent with the proposal.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-780. Renovation or modernization.

A. Applications for the renovation or modernization of medical care facilities should provide documentation that:

1. The timing of the renovation or modernization expenditure is appropriate within the life cycle of the affected building or buildings; and

2. The benefits of the proposed renovation or modernization will exceed the costs of the renovation or modernization over the life cycle of the affected building or buildings to be renovated or modernized.

B. Such documentation should include a history of the affected building or buildings, including a chronology of major renovation and modernization expenses.

C. Applications for the general renovation or modernization of medical care facilities should include downsizing of beds or other service capacity when such capacity has not operated at a reasonable level of efficiency as identified in the relevant sections of this chapter during the most recent five-year period.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-790. Equipment.

Applications for the purchase and installation of equipment by medical care facilities that are not addressed elsewhere in this chapter should document that the equipment is needed. Such documentation should clearly indicate that the (i) proposed equipment is needed to maintain the current level of service provided, or (ii) benefits of the change in service resulting from the new equipment exceed the costs of purchasing or leasing and operating the equipment over its useful life.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

Part XI
Medical Rehabilitation

12VAC5-230-800. Travel time.

Medical rehabilitation services should be available within 60 minutes driving time one way under normal conditions of 95% of the population of the health planning district using mapping software as determined by the commissioner.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-810. Need for new service.

A. The number of comprehensive and specialized rehabilitation beds shall be determined as follows:

((UR x PROPOP)/365)/.80

Where:

UR = the use rate expressed as rehabilitation patient days per population in the health planning district as reported by VHI; and

PROPOP = the most recent projected population of the health planning district five years from the current year as published by a demographic entity as determined by the commissioner.

B. Proposals for new medical rehabilitation beds should be considered when the applicant can demonstrate that:

1. The rehabilitation specialty proposed is not currently offered in the health planning district; and

2. There is a documented need for the service or beds in the health planning district.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-820. Expansion of services.

No additional rehabilitation beds should be authorized for a health planning district in which existing rehabilitation beds were utilized with an average annual occupancy of less than 80% in the most recently reported year.

Preference may be given to a project to expand rehabilitation beds by converting underutilized medical/surgical beds.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-830. Staffing.

Medical rehabilitation facilities should be under the direction or supervision of one or more qualified physicians.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

Part XII
Mental Health Services

Article 1
Acute Psychiatric and Acute Substance Abuse Disorder Treatment Services

12VAC5-230-840. Travel time.

Article 1
Acute Psychiatric and Acute Substance Abuse Disorder Treatment Services

Acute psychiatric and acute substance abuse disorder treatment services should be available within 60 minutes driving time one way under normal conditions of 95% of the population using mapping software as determined by the commissioner.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-850. Continuity; integration.

A. Existing and proposed acute psychiatric and acute substance abuse disorder treatment providers shall have established plans for the provision of services to indigent patients that include:

1. The minimum number of unreimbursed patient days to be provided to indigent patients who are not Medicaid recipients;

2. The minimum number of Medicaid-reimbursed patient days to be provided, unless the existing or proposed facility is ineligible for Medicaid participation;

3. The minimum number of unreimbursed patient days to be provided to local community services boards; and

4. A description of the methods to be utilized in implementing the indigent patient service plan and assuring the provision of the projected levels of unreimbursed and Medicaid-reimbursed patient days.

B. Proposed acute psychiatric and acute substance abuse disorder treatment providers shall have formal agreements with the appropriate local community services boards or behavioral health authority that:

1. Specify the number of patient days that will be provided to the community service board;

2. Describe the mechanisms to monitor compliance with charity care provisions;

3. Provide for effective discharge planning for all patients, including return to the patient's place of origin or home state if not Virginia; and

4. Consider admission priorities based on relative medical necessity.

C. Providers of acute psychiatric and acute substance abuse disorder treatment serving large geographic areas should establish satellite outpatient facilities to improve patient access where appropriate and feasible.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-860. Need for new service.

A. The combined number of acute psychiatric and acute substance abuse disorder treatment beds needed in a health planning district with existing acute psychiatric or acute substance abuse disorder treatment beds or both will be determined as follows:

((UR x PROPOP)/365)/.75

Where:

UR = the use rate of the health planning district expressed as the average acute psychiatric and acute substance abuse disorder treatment patient days per population reported for the most recent five-year period; and

PROPOP = the projected population of the health planning district five years from the current year as reported in the most recent published projections by a demographic entity as determined by the Commissioner of the Department of Mental Health, Mental Retardation and Substance Abuse Services.

For purposes of this methodology, no beds shall be included in the inventory of psychiatric or substance abuse disorder beds when these beds (i) are in facilities operated by the Department of Mental Health, Mental Retardation and Substance Abuse Services; (ii) have been converted to other uses; (iii) have been vacant for six months or more; or (iv) are not currently staffed and cannot be staffed for acute psychiatric or substance abuse disorder patient admissions within 24 hours.

B. Subject to the provisions of 12VAC5-230-70, no additional acute psychiatric or acute substance abuse disorder treatment beds should be authorized for a health planning district with existing acute psychiatric or acute substance abuse disorder treatment beds or both if the existing inventory of such beds is greater than the need identified using the above methodology.

Preference may also be given to the addition of acute psychiatric or acute substance abuse beds dedicated for the treatment of geriatric patients in health planning districts with an excess supply of beds when such additions are

justified on the basis of the specialized treatment needs of geriatric patients.

C. No existing acute psychiatric or acute substance disorder abuse treatment beds should be relocated unless it can be reasonably projected that the relocation will not have a negative impact on the ability of existing acute psychiatric or substance abuse disorder treatment providers or both to continue to provide historic levels of service to Medicaid or other indigent patients.

D. The combined number of acute psychiatric and acute substance abuse disorder treatment beds needed in a health planning district without existing acute psychiatric or acute substance abuse disorder treatment beds will be determined as follows:

((UR x PROPOP)/365)/.75

Where:

UR = the use rate of the health planning region in which the health planning district is located expressed as the average acute psychiatric and acute substance abuse disorder treatment patient days per population reported for the most recent five-year period;

PROPOP = the projected population of the health planning district five years from the current year as reported in the most recent published projections by a demographic entity as determined by the Commissioner of the Department of Mental Health, Mental Retardation and Substance Abuse Services.

E. Preference may be given to the development of needed acute psychiatric beds through the conversion of unused general hospital beds. Preference will also be given to proposals for acute psychiatric and substance abuse beds demonstrating a willingness to accept persons under temporary detention orders (TDO) and that have contractual agreements to serve populations served by community services boards, whether through conversion of underutilized general hospital beds or development of new beds.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

Article 2
Mental Retardation

12VAC5-230-870. Need for new service.

Article 2
Mental Retardation

The establishment of new ICF/MR facilities with more than 12 beds shall not be authorized unless the following conditions are met:

1. Alternatives to the proposed service are not available in the area to be served by the new facility;

2. There is a documented source of referrals for the proposed new facility;

3. The manner in which the proposed new facility fits into the continuum of care for the mentally retarded is identified;

4. There are distinct and unique geographic, socioeconomic, cultural, transportation, or other factors affecting access to care that require development of a new ICF/MR;

5. Alternatives to the development of a new ICF/MR consistent with the Medicaid waiver program have been considered and can be reasonably discounted in evaluating the need for the new facility;

6. The proposed new facility will have a maximum of 20 beds and is consistent with any plan of the Department of Mental Health, Mental Retardation and Substance Abuse Services and the mental retardation service priorities for the catchment area identified in the plan;

7. Ancillary and supportive services needed for the new facility are available; and

8. Service alternatives for residents of the proposed new facility who are ready for discharge from the ICF/MR setting are available.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009; Errata, 25:11 VA.R. 2018 February 2, 2009.

12VAC5-230-880. Continuity; integration.

Each facility should have a written transfer agreement with one or more hospitals for the transfer of emergency cases if such hospitalization becomes necessary.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-890. Compliance with licensure standards.

Mental retardation facilities should meet all applicable licensure standards as specified in 12VAC35-105, Rules and Regulations for the Licensing of Providers of Mental Health, Mental Retardation and Substance Abuse Services.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

Part XIII
Perinatal and Obstetrical Services

Article 1
Criteria and Standards for Obstetrical Services

12VAC5-230-900. Travel time.

Article 1
Criteria and Standards for Obstetrical Services

Obstetrical services should be located within 30 minutes driving time one way under normal conditions of 95% of the population of the health planning district using mapping software as determined by the commissioner.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-910. Need for new service.

No new obstetrical services should be approved unless the applicant can demonstrate that, based on the population and utilization of current services, there is a need for such services in the health planning district without significantly reducing the utilization of existing providers in the health planning district.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-920. Continuity.

A. Perinatal service capacity, including service availability for unscheduled admissions, should be developed to provide routine newborn care to infants delivered in the associated obstetrics service, and shall be able to stabilize and prepare for transport those infants requiring the care of a neonatal special care services unit.

B. The proposal shall identify the primary and secondary neonatal special care center nearest the proposed service shall provide transport one-way to those centers.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-930. Staffing.

Obstetric services should be under the direction or supervision of one or more qualified physicians.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

Article 2
Neonatal Special Care Services

12VAC5-230-940. Travel time.

Article 2
Neonatal Special Care Services

A. Intermediate level neonatal special care services should be located within 30 minutes driving time one way under normal conditions of hospitals providing general level new born services using mapping software as determined by the commissioner.

B. Specialty and subspecialty neonatal special care services should be located within 90 minutes driving time one way under normal conditions of hospitals providing general or intermediate level newborn services using mapping software as determined by the commissioner.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-950. Need for new service.

No new level of neonatal service shall be offered by a hospital unless that hospital has first obtained a COPN granting approval to provide each such level of service.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-960. Intermediate level newborn services.

A. Existing intermediate level newborn services as designated in 12VAC5-410-443 should achieve 85% average annual occupancy before new intermediate level newborn services can be added to the health planning region.

B. Intermediate level newborn services as designated in 12VAC5-410-443 should contain a minimum of six bassinets.

C. No more than four bassinets for intermediate level newborn services as designated in 12VAC5-410-443 per 1,000 live births should be established in each health planning region.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-970. Specialty level newborn services.

A. Existing specialty level newborn services as designated in 12VAC5-410-443 should achieve 85% average annual occupancy before new specialty level newborn services can be added to the health planning region.

B. Specialty level newborn services as designated in 12VAC5-410-443 should contain a minimum of 18 bassinets .

C. No more than four bassinets for specialty level newborn services as designated in 12VAC5-410-443 per 1,000 live births should be established in each health planning region.

D. Proposals to establish specialty level services as designated in 12VAC5-410-443 shall demonstrate that service volumes of existing specialty level newborn service providers located within the travel time listed in 12VAC5-230-940 will not be significantly reduced.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-980. Subspecialty level newborn services.

A. Existing subspecialty level newborn services as designated in 12VAC5-410-443 should achieve 85% average annual occupancy before new subspecialty level newborn services can be added to the health planning region.

B. Subspecialty level newborn services as designated in 12VAC5-410-443 should contain a minimum of 18 bassinets .

C. No more than four bassinets for subspecialty level newborn services as designated in 12VAC5-410-443 per 1,000 live births should be established in each health planning region.

D. Proposals to establish subspecialty level newborn services as designated in 12VAC5-410-443 shall demonstrate that service volumes of existing subspecialty level newborn providers located within the travel time listed in 12VAC5-230-940 will not be significantly reduced.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-990. Neonatal services.

The application shall identify the service area and the levels of service of all the hospitals to be served by the proposed service.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

12VAC5-230-1000. Staffing.

All levels of neonatal special care services should be under the direction or supervision of one or more qualified physicians as described in 12VAC5-410-443.

Statutory Authority

§ 32.1-102.2 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 25, Issue 9, eff. February 15, 2009.

Documents Incorporated by Reference (12VAC5-230)

ACC/AHA Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories, American College of Cardiology/American Heart Association Ad Hoc Task Force on Cardiac Catheterization, JACC Vol. 18 No. 5, November 1, 1991: 1149-82

Website addresses provided in the Virginia Administrative Code to documents incorporated by reference are for the reader's convenience only, may not necessarily be active or current, and should not be relied upon. To ensure the information incorporated by reference is accurate, the reader is encouraged to use the source document described in the regulation.

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September 4, 2024

Karen Shelton, MD
State Health Commissioner
Virginia Department of Health
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Re: Public Comment to State Health Services Plan Task Force, September 6, 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 September 6, 2024, meeting. At the August 23, 2024, Task Force meeting, members of the Task Force approved a series of recommendations for additional project types, other than various psychiatric services projects already considered, that should be moved from full COPN review to Expedited Review. These recommendations were derived from an analysis and recommendations prepared by the Virginia Department of Health (VDH). This public comment is submitted in response to those recommendations approved by the Task Force.

As we have stated in previous public comment, VHHA support for expedited review is limited to certain project types that are non contested and present limited health planning impacts. Further, as reflected in its legislative mandate, the scope of 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."

The recommendation approved by the Task Force in the August 23, 2024, meeting to move all imaging services project types to Expedited Review includes projects that are *not* non contested and present *significant* health planning impacts that go well beyond the scope of its mandate. VHHA is opposed to this recommendation and respectfully requests that the Task Force reconsider its motion and remove this recommendation.

In addition, we respectfully request that the Task Force take steps to align all of its recommendations to be consistent across project type categories. In particular, the qualifier "when not competing" should apply to all project types moved to Expedited Review, Expedited Review should not be available for new services, and all project types that involve addition or relocation of beds should include limitations on the number and frequency of beds and be confined to the same planning district, as applicable, similar to those applied to psychiatric bed

project types previously approved for Expedited Review by the Task Force. The rationale for each of these requests is provided below.

Imaging Services

The Task Force approved a motion, on a vote of 6 Yes and 5 No, to recommend all imaging services project types included in the block of imaging services project types listed in the VDH Recommendations. The block that the Task Force approved included 11 project types for imaging services that VDH did not recommend including as discussion for Expedited Review. This is the only instance where there was a motion considered to include *all* project types included in the block, regardless of whether or not they were recommended by VDH to be included as discussion for Expedited Review. In all other motions, only those project types recommended by VDH to be included as discussion for Expedited Review were included in the motion, making this an anomaly that is entirely inconsistent with all other recommendations of the Task Force and is without any sufficient evidence to support it.

The project types included are not "generally non contested"

The project types included are not "generally non contested." In particular, among the project types included in the block are applications for several new services, *i.e.*, applications for project types that the applicant has not been previously approved to provide. Of all of the other categories included in recommendations adopted by the Task Force, the project types involve expansion of an existing service, not the introduction or establishment of a new service. Imaging Services is the only category where this was considered. VHHA submits that under no circumstance should an application for a new service that the applicant has not been previously approved to provide should be considered non contested, and thus should not be eligible for Expedited Review.

Further, the Task Force had information before it that clearly demonstrates these project types *are* highly contested. A majority of the project types for imaging services having a VDH recommendation of "No" had IFFC rates above 30%, several of which had an IFFC rate above 50%. Such project types cannot be considered "non contested" and should be subject to full COPN review, not Expedited Review.

The project types included do not "present limited health planning impacts"

Imaging services present significant health planning impacts:

- Imaging services involve large capital expenditures, that if undertaken without adequate capacity demands, can result in higher costs, unsustainable operations, and/or improper utilization.
- The capacity and utilization requirements that apply to imaging services under the State Health Services Plan are needed to ensure that there is broad geographical access to these services across the health planning region to prevent clustering in more densely populated areas with more lucrative commercial markets.
- Imaging services require specialized accreditation or other approvals.

- The location of imaging services can negatively impact the ability of existing providers to provide historic levels of services to patients in the community, including Medicaid or other indigent patients
- The location of imaging services can have a negative staffing impact on other facilities in the service area, such that approval does not create a net increase in access and capacity.

All of these concerns indicate that the imaging services included in the Task Force recommendation, particularly those involving new services, do have significant health planning impacts, such that they should be subject to full COPN review, not Expedited Review.

Accordingly, VHHA is opposed to this recommendation by the Task Force, and we respectfully ask the Task Force to reconsider its motion and remove from Expedited Review these imaging services project types that are not generally non contested and do not present limited health planning impacts.

Not Competing

As stated above, for all project types, the Expedited Review process should be limited to projects "when not competing." Most, but not all of the project types included in recommendations approved by the Task Force based upon a recommendation by VDH included this qualifier. VHHA respectfully requests that the Task Force apply this qualifier to all project types it approves for Expedited Review. This will require the Task Force to also consider recommendations for how to determine when a project is "not competing." VHHA submits that this determination should include any or all of the following circumstances:

- Within a batch cycle, there are multiple applications from different applicants for the same project type in the same planning district. Alternatively or in addition, where one of those applicants files a written opinion with the Commissioner objecting to the application.
- The Commissioner receives a written opinion from a person directly affected objecting to the application.
- A public hearing is requested or the Commissioner determines that a public hearing is in the public interest.

New Services

No project types that involve the introduction or establishment of new services that the applicant has not previously received a COPN to provide should be included in Expedited Review. This principle is reflected in those project types included in VDH "Yes" options, which did not include any project types for the introduction or establishment of new services. There can be no basis for concluding that any such services could be regarded as generally non contested and present limited health planning impacts and we submit that this should be adopted as a baseline standard for excluding projects types that involve the introduction or establishment of a new services from being eligible for Expedited Review.

Limitations on Number and Frequency and Planning District

For any project types involving the addition of beds, a limit of 10 beds or 10% of beds, whichever is greater, in any two year period, should apply in order to be eligible for Expedited Review. Similarly, for any project types involving the relocation of beds, relocation should be confined to the same planning district. These limitations were included in Task Force recommendations to move certain psychiatric bed project types to Expedited Review, and the same rationale for including those limitations on psychiatric bed project types should equally apply to non-psychiatric bed project types.

In conclusion, we again respectfully request the Task Force to:

- Reconsider its motion on imaging services and remove from Expedited Review these project types that are not generally non contested and do not present limited health planning impacts.
- Align all of its recommendations to be consistent across project type categories:
    - The qualifier "when not competing" should apply to all project types moved to Expedited Review.
    - Expedited Review should not be available for new services.
    - All project types that involve addition or relocation of beds should include limitations on the number and frequency of beds and be confined to the same planning district, as applicable.

Lastly, as a more general comment, the legislative mandate instructs the Task Force to develop a "framework for the application and approval of [projects for Expedited Review]." The Task Force previously adopted recommendations to extend Expedited Review from 45 days to 90 days; to include Expedited Review projects in batch cycles; and to allow members of the public to request a hearing for a project under Expedited Review. Aside from these recommendations, there has not been other deliberation on the framework for the application and approval of projects for Expedited Review. We submit that further consideration is needed by the Task Force in order to complete this directive. Particularly given that the framework for the application and approval of projects is part and parcel to what project types may be appropriate for Expedited Review.

We hope that this public comment is useful to the SHSP Task Force as it seeks to develop its framework for Expedited Review. 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

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September 4, 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, September 6, 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 upcoming September 6, 2024 meeting regarding recommendations approved at the August 23, 2024 meeting.

VHC Health has served the Northern Virginia market for over 75 years. We are the only independent hospital system in the region and one of three in the Commonwealth of Virginia. Our continued independence, supported by our Board of Directors, has allowed VHC to build a reputation as a high-quality provider known for its extraordinary patient experience. We have also built a reputation within the payer community as a low-cost, high-quality provider and, as a result, recognized by Kaiser Permanente as one of their "core" hospitals. As a testament to our high quality care, we are one of the few institutions to receive the CMS's Overall Hospital Quality 5-Star Hospital designation.

For reasons stated in the public comment letter submitted by the Virginia Hospital & Healthcare Association, VHC Health is strongly opposed to the recommendation approved by the Task Force at the August 23, 2024, meeting to include all imaging services project types in Expedited Review. We respectfully request that the Task Force remove this motion from its recommendations. Imaging services are typically highly contested and involve significant health planning. As such, we believe they should remain in full COPN review.

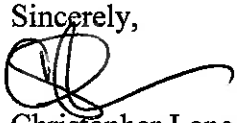
The COPN process is a vital component of Virginia's complex healthcare delivery system. It serves an important function to help control healthcare costs, promote access to care and prevent selective over-expansion that could threaten our healthcare safety net. That foundation is critical to VHC Health's ability to provide the quality care and patient experience that sets us apart and allows us to meet all the health care needs of all the communities we serve. It also allows VHC to provide the over $60 million per year in charity care and financial assistance to the communities we serve. The proliferation of imaging and lack of full COPN review and sound

health planning would be detrimental to VHC Health's ability to continue to provide these essential health services to our community.

For these reasons, we again respectfully ask the Task Force to retract its motion on imaging services and remove from Expedited Review these imaging services project types that are not generally non-contested and do not present limited health planning impacts. Regarding all other recommendations of the Task Force on project types that should be considered for Expedited Review and the process for Expedited Review, we associate our organization with the previous public comments submitted by the Virginia Hospital & Healthcare Association and support its recommendations on these matters.

Thank you for your consideration of this public comment and for the ongoing work of the Task Force.

Sincerely,



Christopher Lane
President & CEO
VHC Health

Augusta Health

Care that makes a lifetime.

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September 4, 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, September 6, 2024, Meeting

Dear Commissioner Shelton,

Thank you for providing Augusta Health the opportunity to submit this public comment to the State Health Services Plan Task Force in advance of its upcoming September 6, 2024, meeting regarding recommendations approved at the August 23, 2024, meeting.

Augusta Health is a community hospital nestled in the Shenandoah Valley in Augusta County, Virginia. It has been providing services to the residents of the Shenandoah Valley and surrounding areas for over thirty years. Augusta Health provides an array of acute-care services, operates Augusta Medical Group, sponsors Graduate Medical Education for the Internal Medicine Residency Program, and provides several outpatient and ancillary services. Augusta Health not only provides high quality care, but it is also debt free, and provides over $15,000,000, annually in community benefit.

As an independent community hospital with a strong financial standing and a history of providing quality care for over thirty years, Augusta Health strongly relies on the COPN review. The COPN review process is an important regulatory tool to ensure that new healthcare services are necessary for the relevant planning district. The COPN process prevents overbuilding of healthcare facilities and prevents the duplication of services. The COPN process also provides appropriate government oversight by requiring hospitals to demonstrate the necessity of the services, impose charity care requirements, and in turn controls costs for the consumer. Augusta Health has been able to maintain is strong financial position and provide the community with all necessary services, in great part, because of the COPN review's ability to prohibit saturation of the market.

For reasons stated in the public comment letter submitted by the Virginia Hospital & Healthcare Association, Augusta Health is strongly opposed to the recommendation approved by the Task Force at the August 23, 2024, meeting to include all imaging services project types in Expedited Review. We respectfully request that the Task Force remove this motion from its recommendations. Imaging services project types are typically highly contested and involve significant health planning impacts such that they should remain in full COPN review.

Imaging is often pursued by competitors of Augusta Health as it is a highly generating revenue source. And in more rural communities, such as the one served by Augusta Health, there is limited demand for imaging services. These types of services are also the underpinning for sustainability for Augusta Health and provides the financial backbone for Augusta Health's ability to provide community benefit and

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Augusta Health

Care that makes a lifetime.

charity care. Failure to maintain the full review COPN process on imaging services project types that are not generally non contested and do not present limited health planning impacts would detrimentally

impact Augusta Health's ability, in the short term, to: (1) provide necessary community services at its community clinics, which are in vulnerable communities; (2) continue to invest in behavioral health services, which are a necessity in the community served by Augusta Health; and (3) continue running its Graduate Medical Education program, thereby impacting the future pipeline of primary care for the region. In the long term, it may impact Augusta Health's complete sustainability as an independent, community-governed Health System.

For these reasons, we again respectfully ask the Task Force to retract its motion on imaging services and remove from Expedited Review these imaging services project types that are not generally non contested and do not present limited health planning impacts. Regarding all other recommendations of the Task Force on project types that should be considered for Expedited Review and the process for Expedited Review, we associate our organization with the previous public comments submitted by the Virginia Hospital & Healthcare Association and support its recommendations on these matters. Thank you for your consideration of this public comment and for the ongoing work of the Task Force.

Sincerely,

Crystal Farmer

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CARILION CLINIC

September 4, 2024

Karen Shelton, MD
State Health Commissioner
Virginia Department of Health
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Richmond, Virginia 23218-2448

Re: Public Comment to State Health Services Plan Task Force, September 6, 2024, Meeting

Dear Commissioner Shelton,

As you prepare for the upcoming September 6th State Health Services Plan Task Force meeting, I would like to take this opportunity to share our public comment. Carilion Clinic, Southwest Virginia's leading non-profit healthcare system, provides care to the most people in Southwest Virginia, with more than 1.5 million annual patient encounters. Our commitment to comprehensive care, which extends across our inpatient, emergency, and ambulatory care sites, is a testament to our unwavering dedication to ensuring equitable access to healthcare for all patients, regardless of payer.

I am expressing Carilion's strong opposition to the Task Force's recent recommendation, made during the August 23, 2024 meeting to include all imaging services project types in Expedited Review. Our primary concern lies in the potential ramifications of including imaging services project types in Expedited Review, as these cases are often highly contested and can significantly impact health planning. We believe that doing so may adversely affect the equitable distribution of health services in Southwest Virginia, potentially resulting in increased regional health spending and the unnecessary proliferation of high-cost services. We are concerned that this decision could disproportionately impact uninsured or underinsured patients and cause health equity issues.

We respectfully urge the Task Force to reconsider its decision and remove the inclusion of imaging services project types from Expedited Review. Furthermore, we support the recommendations the Virginia Hospital & Healthcare Association put forth on other project types and the process for Expedited Review.

We appreciate your attention to this public comment and dedication to the Task Force's ongoing work. Your efforts are crucial in shaping the future of healthcare in Virginia, and we are grateful for your service. Thank you.

Sincerely,

Tracy Clouser,
Vice President, Communications, Marketing, and Planning
Carilion Clinic

HCA Healthcare | Capital Division

September 4, 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, September 6, 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 upcoming September 6, 2024 meeting regarding recommendations approved at the August 23, 2024 meeting.

For reasons stated in the public comment letter submitted by the Virginia Hospital & Healthcare Association, HCA Virginia Health System is strongly opposed to the recommendation approved by the Task Force at the August 23, 2024 meeting to include all imaging services project types in Expedited Review. We respectfully request that the Task Force remove this motion from its recommendations. Imaging services project types are typically highly contested and involve significant health planning impacts such that they should remain in full COPN review.

Imaging services represent one of the few positive revenue streams for hospitals in contrast to the many other services that hospitals provide at a loss as we care for Virginians 24/7, 365 days a year. As such, HCA has been on record in past COPN work groups against cherry-picking reforms that would be akin to removing this service from the COPN regulations. Doing so would place hospitals at a disadvantage that would be detrimental to fiscal health at a time when many systems are still struggling.

For these reasons, we respectfully ask the Task Force to retract its motion on imaging services and remove from Expedited Review these imaging services project types that are not generally non-contested and do not present limited health planning impacts. Regarding all other recommendations of the Task Force on project types that should be considered for Expedited Review and the process for Expedited Review, we associate our organization with the previous public comments submitted by the Virginia Hospital & Healthcare Association and support its recommendations on these matters. Thank you for your consideration of this public comment and for the ongoing work of the Task Force.

Sincerely,

William Lunn, MD
President, HCA Healthcare Capital Division

901 E. Cary Street, Suite 2100
Richmond, VA 23219
O. 804-327.7600
HCAHealthcare.com

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karen.shelton@vdh.virginia.gov; Allyson.Flinn@vdh.virginia.gov

September 4, 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, September 6, 2024, Meeting

Dear Commissioner Shelton,

UVA Health appreciates the opportunity to submit this public comment to the State Health Services Plan (SHSP) Task Force in advance of its upcoming September 6, 2024, meeting regarding recommendations approved at the August 23, 2024, meeting.

UVA Health serves the people of the Commonwealth by providing exceptional patient care, educating future healthcare leaders, pursuing innovative and life-enhancing discoveries, and supporting the communities we serve. Our mission and purpose as an institution is "*Transforming Health and Inspiring Hope for All Virginians & Beyond*". As a public academic health system and safety net provider, UVA Health has the privilege of caring for Virginians across our clinical enterprise including a multi-specialty physician group, a Level 1 Trauma Center, a nationally recognized NCI-designated Comprehensive Cancer Center, UVA Children's Hospital – including a Level IV NICU and a Pediatric Intensive Care Unit, Virginia's only comprehensive adult and pediatric transplant program, three community hospitals, a specialty rehabilitation hospital, and an integrated network of primary and specialty care ambulatory clinics throughout Virginia.

UVA Health ("UVAH") appreciates the important role that the Virginia Department of Health's ("VDH") Certificate of Public Need Program ("COPN") plays in ensuring high quality and cost-effective care is available for Virginians throughout the Commonwealth. We welcome the opportunity to provide input to the SHSP Task Force regarding the COPN recommendations approved at the August 23, 2024 meeting. Our initial concern regarding the comments and recommended changes to the COPN process is that UVAH does not have a clear understanding of what the "Expedited Review process" proposed by the Task Force will entail as compared to the current full review process that has been in place for many years.

In the absence of any clarity regarding the parameters around a new Expedited Review process, we are concerned that some significant questions surrounding the Task Force recommendations remain unanswered: for example, would the expedited review process reduce the time line for review of COPN applications but not change the review criteria? Or would an expedited review process change review criteria currently used for COPN applications? Would it result in a process that is so significantly truncated that expedited review applications will essentially receive automatic approvals? If the underlying concern is that the full COPN review process takes too long, then we would support first

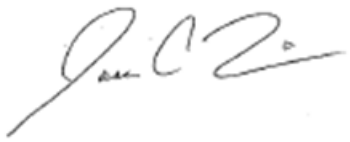
exploring opportunities to shorten the current full review process before carving out exceptions to that process.

Because of these and other concerns, UVAH wishes to align itself with the public comment letter submitted by the Virginia Hospital & Healthcare Association ("VHHA"). In particular, because imaging services project types are often highly contested and involve significant health planning impacts, UVA Health strongly opposes the recommendation approved by the Task Force at the August 23, 2024, meeting to include all imaging services project types in Expedited Review. UVA Health respectfully urges the Task Force to remove this motion from its recommendations.

Full COPN review of imaging projects takes a number of critically important health planning factors into account, such as present and future community need, costs of a proposed project, viability of the provider, the demand for services in the planning area, patient origins, projected population growth, and projected utilization of the services. This level of review helps to ensure that services are well balanced and distributed. It discourages both underutilization and overutilization and the detrimental impacts of such imbalances in the health care system of Virginia. Elimination of this level of assessment of public need for imaging services would hurt patients and providers alike.

For these reasons, we again respectfully ask the Task Force to retract its motion on imaging services and remove from Expedited Review these imaging services project types that are not generally non contested and do not present limited health planning impacts. Regarding all other recommendations of the Task Force on project types that should be considered for Expedited Review and the process for Expedited Review, we associate UVAH with the previous public comments submitted by the VHHA and support its recommendations on these matters. Thank you for your consideration of UVA Health's public comment and for the ongoing work of the Task Force.

Sincerely,



Jason C. Lineen, MBA
Chief Strategy Officer, UVA Health

Colin P. Derdeyn, MD, FAHA, FACR
Theodore E. Keats Professor and Chair, Department of Radiology and Medical Imaging
Professor of Neurology and Neurological Surgery
University of Virginia School of Medicine

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karen.shelton@vdh.virginia.gov; Allyson.Flinn@vdh.virginia.gov

September 4, 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, September 6, 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 upcoming September 6, 2024, meeting regarding recommendations approved at the August 23, 2024, meeting.

Bon Secours Richmond Health System operates seven acute-care hospitals in the Richmond metro, the Northern Neck, Petersburg and Emporia which support a full-range of services, including Centers of Excellence in cardiac surgery, women's and children's services, orthopedics, bariatrics, general surgery, oncology, emergency care, and ambulatory services. Bon Secours is committed to help bring people and communities to health and wholeness. Through Community Needs Assessments and strategic planning processes, Bon Secours thoroughly researches and creates comprehensive plans to address each community's most significant needs. Alignment with Virginia's Certificate of Public Need (COPN) ensures Bon Secours can provide cost effective access to health care for our communities, consistent with our mission "to bring good help to those in need, especially people who are poor, dying and underserved."

For reasons stated in the public comment letter submitted by the Virginia Hospital & Healthcare Association, Bon Secours Richmond is strongly opposed to the recommendation approved by the Task Force at the August 23, 2024, meeting to include all imaging services project types in Expedited Review. We respectfully request that the Task Force remove this motion from its recommendations. Imaging services project types are typically highly contested and involve significant health planning impacts such that they should remain in full COPN review.

In 2023, DCOPN granted approval for Bon Secours Memorial Regional Medical Center to expand CT and MRI Services by establishing a free-standing emergency department to include CT and MRI imaging (VA-04864). The project was approved based on its consistency with the State Medical Facilities Plan (SMFP); history of service to area, financial accessibility, and higher than average charity care; increasing financial and geographic access in a growing planning district; established institution-specific need; and benefit beyond status quo. Two additional applications for advanced imaging were included in the same batch cycle and all three projects were subject to opposition, indicating that imaging projects are both competitive and contested. In this instance, both competing projects were recommended for denial based on lack of increasing geographic access, inconsistency with SMFP due to surplus of CT and MRIs in the planning district, and/or duplication of proposed projects. In this instance, DCOPN's thorough review of

these applications led to a prudent decision to accomplish the stated goals to "contain health care costs while ensuring financial viability and access to health care for all Virginia at a reasonable cost."

For these reasons, we again respectfully ask the Task Force to retract its motion on imaging services and remove from Expedited Review these imaging services project types that are not generally non contested and do not present limited health planning impacts. Regarding all other recommendations of the Task Force on project types that should be considered for Expedited Review and the process for Expedited Review, we associate our organization with the previous public comments submitted by the Virginia Hospital & Healthcare Association and support its recommendations on these matters. Thank you for your consideration of this public comment and for the ongoing work of the Task Force.

Sincerely,

Michael Lutes
Market President
Bon Secours Richmond Health System

Sentara Health
Office of Government & Community Relations
1300 Sentara Way
Virginia Beach, VA 23464

SUBMITTED ELECTRONICALLY AT: regulatorycomment@vdh.virginia.gov karen.shelton@vdh.virginia.gov; Allyson.Flinn@vdh.virginia.gov

September 4, 2024

Karen Shelton, M.D.
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, September 6, 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 upcoming September 6, 2024, meeting regarding recommendations approved at the August 23, 2024, meeting.

For reasons stated in the public comment letter submitted by the Virginia Hospital & Healthcare Association, Sentara Health is opposed to the recommendation approved by the Task Force at the August 23, 2024, meeting to include all imaging services project types in Expedited Review. We respectfully request that the Task Force remove this motion from its recommendations. Imaging services project types are typically highly contested and involve significant health planning impacts such that they should remain in full COPN review.

COPN's purpose is to constrain the development of excess capacity and underutilization by validating public need prior to approval. Without proper review, imaging services are particularly vulnerable for proliferation and unnecessary utilization due to the potential financial return associated with these services and ability to provide them in an outpatient environment.

Regarding all other recommendations of the Task Force on project types that should be considered for Expedited Review and the process for Expedited Review, we associate our organization with the public comments submitted by the Virginia Hospital & Healthcare Association and support its recommendations on these matters.

Thank you for your consideration of this public comment and for the ongoing work of the Task Force.

Sincerely,

Anna James
Senior Vice President, Government & Community Relations
Sentara Health

Riverside Health

701 Town Center Drive, Suite 1000
Newport News, VA 23606-4286
Phone: 757-534-7000

riversideonline.com

September 4, 2024

Via Electronic Mail (karen.shelton@vdh.virginia.gov, allyson.Flinn@vdh.virginia.gov, and regulatorycomment@vdh.virginia.gov)
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, September 6, 2024, Meeting

Dear Commissioner Shelton:

Thank you for the opportunity to submit public comment to the State Health Services Plan Task Force in advance of its upcoming September 6, 2024, meeting regarding recommendations approved at the August 23, 2024, meeting.

Virginia's Certificate of Need Program ("COPN") is an important health planning tool and is essential for Riverside Health to maintain financial stability, to ensure access to health services for all regardless of ability to pay, to promote high quality care, and to provide a full range of essential health services.

As outlined in statute, the role of the State Health Services Task Force is to provide recommendations on "project types that are generally non-contested and present limited health planning impacts." Imaging COPN projects are both routinely contested and have significant impacts to health planning. For example, Bon Secours Hampton Roads Imaging, LLC and Maryview Hospital LLC's recently submitted COPN Req. No. VA-8770 seeking COPN approval to establish a specialized imaging center in Isle of Wight County with one CT and one MRI ("Bon Secours' Project"). This project is highly contested. Three separate health systems, including Riverside, Sentara and Chesapeake Regional Healthcare, have submitted letters of opposition to this imaging COPN project.

Additionally, imaging COPN projects present a significant impact to health planning. The guiding principles in the development of COPN project review criteria discourage "the proliferation of services that would undermine the ability of essential community providers to maintain their financial viability." Riverside's community hospitals, including one now under construction in Isle of Wight County, rely on anticipated revenues from diagnostic imaging services to support many essential health services that are or will be provided at a loss.

Riverside faces escalating operational costs and economic pressures in the communities we serve, yet we continue to invest to expand access. The decisions to invest are based on the principles of COPN project review criteria that are grounded in health planning. Without a careful and thorough review of proposed imaging COPN projects, this presents a serious threat to thoughtful health planning.

For these reasons and reasons stated in the public comment letter submitted by the Virginia Hospital & Healthcare Association, **Riverside Health is strongly opposed to the recommendation approved by the Task Force at the August 23, 2024, meeting to include all imaging services project types in Expedited Review**. We respectfully request the Task Force remove this motion from its recommendations. Imaging services project types are typically highly contested and involve significant health planning impacts and should remain in full COPN review.

Accordingly, Riverside respectfully requests the Task Force to retract its motion on imaging services and remove from Expedited Review these imaging services project types that are not generally non contested and do not present limited health planning impacts. Regarding all other recommendations of the Task Force on project types that should be considered for Expedited Review and the process for Expedited Review, we associate our organization with the previous public comments submitted by the Virginia Hospital & Healthcare Association and support its recommendations on these matters.

Thank you for your consideration of this public comment and for the ongoing work of the Task Force.

Sincerely,

Michael J. Dacey, MD
President and CEO, Riverside Health

August 30, 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, September 6, 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 upcoming September 6, 2024, meeting regarding recommendations approved at the August 23, 2024, meeting.

Sovah Health offers comprehensive quality care where people need it most – close to home. We are part of Lifepoint Health, a national network of hospitals, with six community hospitals right here in Virginia. We are known for our expertise and leadership in hospital operations and are continually focused on growing markets that can build and sustain diverse services to meet the evolving needs of our rural communities. Virginia's Certificate of Public Need (COPN) program is critical to keeping rural hospitals open and preserving access to essential service lines and in-patient care.

For reasons stated in the public comment letter submitted by the Virginia Hospital & Healthcare Association, Sovah Health and Lifepoint Health are strongly opposed to the recommendation approved by the Task Force at the August 23, 2024, meeting to include all imaging services project types in Expedited Review. We respectfully request that the Task Force remove this motion from its recommendations. Imaging services projects are typically highly contested and involve significant health planning impacts such that they should remain in full COPN review.

As the sole healthcare provider for many Virginians, weakening or removing COPN puts access to quality care at risk in rural communities. When COPN is reformed, rural communities and patients pay the price. Sovah Health works to maintain delivery of critical in-patient service lines in our two Virginia hospitals. Our community hospitals rely on revenues from diagnostic imaging services to subsidize many services provided to the community at a loss. Allowing imaging service projects to utilize the Expedited Review process will potentially lead to redundant imaging centers within hospital catchment areas and will negatively impact other vital service lines within hospitals that already have narrow operating margins.

For these reasons, we again respectfully ask the Task Force to retract its motion on imaging services and remove from Expedited Review these imaging services project types that are not generally non contested and do not present limited health planning impacts. Regarding all other recommendations of the Task Force on project types that should be considered for Expedited Review and the process for Expedited Review, we associate our organization with the previous public comments submitted by the Virginia Hospital & Healthcare Association and support its recommendations on these matters. Thank you for your consideration of this public comment and for the ongoing work of the Task Force.

Sincerely,

Steve Heatherly
Market President – Sovah Health

BalladHealth
It's your story. We're listening.

303 Med Tech Parkway
Suite 300
Johnson City, TN 37604

balladhealth.org

SUBMITTED ELECTRONICALLY AT: regulatorycomment@vdh.virginia.gov karen.shelton@vdh.virginia.gov; Allyson.Flinn@vdh.virginia.gov

September 3, 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, September 6, 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 upcoming September 6, 2024, meeting regarding recommendations approved at the August 23, 2024, meeting.

Ballad Health is a not-for-profit system serving residents of Southwest Virginia. Within the Lenowisco, Cumberland Plateau, and Mount Rogers Health Planning Districts, we operate 7 acute care hospitals and one freestanding urgent care center. Between those entities, there are 10 CT units, 6 fixed MRI units, 1 mobile MRI unit and 2 mobile PET sites. Outpatient diagnostic services are critical to the financial well-being of these rural hospitals. Just as many other not-for-profit hospitals and systems do, Ballad Health relies on revenues from more profitable service lines, such as outpatient CT, MRI and PET to subsidize less profitable essential hospital services (such as emergency department services, ob/gyn and lab, just to name a few).

For reasons stated in the public comment letter submitted by the Virginia Hospital & Healthcare Association, Ballad Health is strongly opposed to the recommendation approved by the Task Force at the August 23, 2024, meeting to include all imaging services project types in Expedited Review. We respectfully request that the Task Force remove this motion from its recommendations. Imaging services project types are typically highly contested and involve significant health planning impacts such that they should remain in full COPN review.

Ballad Health has experience with new providers seeking to initiate imaging services in the community. In 2022, Holston Medical Group submitted a COPN (Request No. VA-8669) to open an imaging center in Duffield, Virginia (Scott County) and provide CT services. The financial viability of the project was dependent on redirecting CT volumes (and related revenues) away from the newly opened Lee County Community Hospital and Lonesome Pine Hospital, which operate underutilized services for residents of Planning District 1. The COPN process enabled both Ballad and members from the local community to better understand the potential ramifications and voice their concern through the public hearing and additional letters of opposition. Such letters highlighted that when rural hospitals and health systems are facing significant economic challenges, every revenue dollar is meaningful to our ability to continue delivering essential healthcare services to the communities we serve. Despite many arguments presented

through the review process and the IFFC which followed, this project was ultimately approved. As it has not yet opened, the ultimate impact to the hospitals is not yet known. However, this change would have removed the voice that the community and these hospitals had throughout the process as well as the ability of Ballad Health to better understand the impending ramifications of the project.

For these reasons, we again respectfully ask the Task Force to retract its motion on imaging services and remove from Expedited Review these imaging services project types that are not generally non contested and do not present limited health planning impacts. Regarding all other recommendations of the Task Force on project types that should be considered for Expedited Review and the process for Expedited Review, we associate our organization with the previous public comments submitted by the Virginia Hospital & Healthcare Association and support its recommendations on these matters. Thank you for your consideration of this public comment and for the ongoing work of the Task Force.

Sincerely,

Eric Deaton
Chief Operating Officer
Ballad Health

TWIN COUNTY
Regional Healthcare

Duke LifePoint Healthcare

August 30, 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, September 6, 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 upcoming September 6, 2024, meeting regarding recommendations approved at the August 23, 2024, meeting.

Twin County Regional Healthcare offers comprehensive quality care where people need it most – close to home. We are part of Lifepoint Health, a national network of hospitals, with six community hospitals right here in Virginia. We are known for our expertise and leadership in hospital operations and are continually focused on growing markets that can build and sustain diverse services to meet the evolving needs of our rural communities. Virginia's Certificate of Public Need (COPN) program is critical to keeping rural hospitals open and preserving access to essential service lines and in-patient care.

For reasons stated in the public comment letter submitted by the Virginia Hospital & Healthcare Association, Twin County Regional Healthcare and Lifepoint Health are strongly opposed to the recommendation approved by the Task Force at the August 23, 2024, meeting to include all imaging services project types in Expedited Review. We respectfully request that the Task Force remove this motion from its recommendations. Imaging services projects are typically highly contested and involve significant health planning impacts such that they should remain in full COPN review.

As the sole healthcare provider for many Virginians, weakening or removing COPN puts access to quality care at risk in rural communities. When COPN is reformed, rural communities and patients pay the price. Twin County Regional Healthcare works to maintain delivery of critical in-patient service lines. Our community hospitals rely on revenues from diagnostic imaging services to subsidize many services provided to the community at a loss. Allowing imaging service projects to utilize the Expedited Review process will potentially lead to redundant imaging centers within hospital catchment areas and will negatively impact other vital service lines within hospitals that already have narrow operating margins.

TWIN COUNTY
Regional Healthcare

Duke LifePoint Healthcare

For these reasons, we again respectfully ask the Task Force to retract its motion on imaging services and remove from Expedited Review these imaging services project types that are not generally non contested and do not present limited health planning impacts. Regarding all other recommendations of the Task Force on project types that should be considered for Expedited Review and the process for Expedited Review, we associate our organization with the previous public comments submitted by the Virginia Hospital & Healthcare Association and support its recommendations on these matters. Thank you for your consideration of this public comment and for the ongoing work of the Task Force.

Sincerely,

Sudandra Ratnasamy
Chief Executive Officer
Twin County Regional Healthcare

ValleyHealth
Healthier, together.

August 30, 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, September 6, 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 upcoming September 6, 2024 meeting regarding recommendations approved at the August 23, 2024 meeting.

Valley Health is a not-for-profit health system serving a population of more than 500,000 in the Northern Shenandoah Valley of Virginia, the Eastern Panhandle and Potomac Highlands of West Virginia. As a healthcare provider, employer, and community partner, Valley Health is committed to improving the health of the region. The system includes six hospitals and more than 100 outpatient locations, including 70 medical practices and Urgent Care centers, outpatient rehabilitation, medical transport, long-term care, and home health.

For reasons stated in the public comment letter submitted by the Virginia Hospital & Healthcare Association, Valley Health System is strongly opposed to the recommendation approved by the Task Force at the August 23, 2024 meeting to include all imaging services project types in Expedited Review. We respectfully request that the Task Force remove this motion from its recommendations. Imaging services project types are typically highly contested and involve significant health planning impacts such that they should remain in full certificate of public need (COPN) review.

Virginia's COPN program is needed to control overall healthcare costs and ensure the availability of essential healthcare services. It does not regulate services most frequently used by consumers, such as primary care, but rather focuses on more complex, specialized services. Most states maintain some form of COPN law because COPN laws help hospitals maintain a full line of essential health services for their communities. The COPN laws in Virginia have long ensured that the Commonwealth remains one of the best states for healthcare quality and access and this includes avoiding an overabundance of imaging services. Piecemeal changes or targeted exemptions such as those proposed could lead to a decrease in

access for patients on lower-margin government health insurance, moving of services to more lucrative demographic areas, and threaten the financial viability of many Virginia healthcare providers.

With regard to the specific question of regulatory review for establishment of imaging services, hospital systems generally have a much more rigorous oversight process to ensure quality of imaging. Removal or weakening of COPN requirements for advanced imaging services creates a pathway for provision of lower quality service and can facilitate market entry by providers who "cherry-pick" high margin services for insured patients. This type of siphoning off of high margin services can have significant and detrimental financial impact on not-for-profit health systems like Valley Health who provide care and service to all patient types, including those who are uninsured, underinsured and/or are unable to pay.

For these reasons, we again respectfully ask the Task Force to retract its motion on imaging services and remove from Expedited Review these imaging services project types that could be easily exploited by opportunistic investors with no regard for the entirety of the healthcare ecosystem. Regarding all other recommendations of the Task Force on project types that should be considered for Expedited Review and the process for Expedited Review, we associate our organization with the previous public comments submitted by the Virginia Hospital & Healthcare Association and support its recommendations on these matters. Thank you for your consideration of this public comment and for the ongoing work of the Task Force.

Sincerely,

Mark Nantz
President and CEO
Valley Health System

Clinch Valley Health

August 30, 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, September 6, 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 upcoming September 6, 2024, meeting regarding recommendations approved at the August 23, 2024, meeting.

Clinch Valley Health offers comprehensive quality care where people need it most – close to home. We are part of Lifepoint Health, a national network of hospitals, with six community hospitals right here in Virginia. We are known for our expertise and leadership in hospital operations and are continually focused on growing markets that can build and sustain diverse services to meet the evolving needs of our rural communities. Virginia's Certificate of Public Need (COPN) program is critical to keeping rural hospitals open and preserving access to essential service lines and in-patient care.

For reasons stated in the public comment letter submitted by the Virginia Hospital & Healthcare Association, Clinch Valley Health and Lifepoint Health are strongly opposed to the recommendation approved by the Task Force at the August 23, 2024, meeting to include all imaging services project types in Expedited Review. We respectfully request that the Task Force remove this motion from its recommendations. Imaging services projects are typically highly contested and involve significant health planning impacts such that they should remain in full COPN review.

As the sole healthcare provider for many Virginians, weakening or removing COPN puts access to quality care at risk in rural communities. When COPN is reformed, rural communities and patients pay the price. Clinch Valley Health works to maintain delivery of critical in-patient service lines. Our community hospitals rely on revenues from diagnostic imaging services to subsidize many services provided to the community at a loss. Allowing imaging service projects to utilize the Expedited Review process will potentially lead to redundant imaging centers within hospital catchment areas and will negatively impact other vital service lines within hospitals that already have narrow operating margins.

Clinch Valley Health

For these reasons, we again respectfully ask the Task Force to retract its motion on imaging services and remove from Expedited Review these imaging services project types that are not generally non contested and do not present limited health planning impacts. Regarding all other recommendations of the Task Force on project types that should be considered for Expedited Review and the process for Expedited Review, we associate our organization with the previous public comments submitted by the Virginia Hospital & Healthcare Association and support its recommendations on these matters. Thank you for your consideration of this public comment and for the ongoing work of the Task Force.

Sincerely,

Peter Mulkey
Chief Executive Officer
Clinch Valley Health

August 30, 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, September 6, 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 upcoming September 6, 2024, meeting regarding recommendations approved at the August 23, 2024, meeting.

Wythe County Community Hospital offers comprehensive quality care where people need it most – close to home. We are part of Lifepoint Health, a national network of hospitals, with six community hospitals right here in Virginia. We are known for our expertise and leadership in hospital operations and are continually focused on growing markets that can build and sustain diverse services to meet the evolving needs of our rural communities. Virginia's Certificate of Public Need (COPN) program is critical to keeping rural hospitals open and preserving access to essential service lines and in-patient care.

For reasons stated in the public comment letter submitted by the Virginia Hospital & Healthcare Association, Wythe County Community Hospital and Lifepoint Health are strongly opposed to the recommendation approved by the Task Force at the August 23, 2024, meeting to include all imaging services project types in Expedited Review. We respectfully request that the Task Force remove this motion from its recommendations. Imaging services projects are typically highly contested and involve significant health planning impacts such that they should remain in full COPN review.

As the sole healthcare provider for many Virginians, weakening or removing COPN puts access to quality care at risk in rural communities. When COPN is reformed, rural communities and patients pay the price. Wythe County Community Hospital works to maintain delivery of critical in-patient service lines. Our community hospitals rely on revenues from diagnostic imaging services to subsidize many services provided to the community at a loss. Allowing imaging service projects to utilize the Expedited Review process will potentially lead to redundant imaging centers within hospital catchment areas and will negatively impact other vital service lines within hospitals that already have narrow operating margins.

For these reasons, we again respectfully ask the Task Force to retract its motion on imaging services and remove from Expedited Review these imaging services project types that are not generally non contested and do not present limited health planning impacts. Regarding all other recommendations of the Task Force on project types that should be considered for Expedited Review and the process for Expedited Review, we associate our organization with the previous public comments submitted by the Virginia Hospital & Healthcare Association and support its recommendations on these matters. Thank you for your consideration of this public comment and for the ongoing work of the Task Force.

Sincerely,

Vicki Parks
Chief Executive Officer
Wythe County Community Hospital

FAUQUIER HEALTH

August 30, 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, September 6, 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 upcoming September 6, 2024, meeting regarding recommendations approved at the August 23, 2024, meeting.

Fauquier Health offers comprehensive quality care where people need it most – close to home. We are part of Lifepoint Health, a national network of hospitals, with six community hospitals right here in Virginia. We are known for our expertise and leadership in hospital operations and are continually focused on growing markets that can build and sustain diverse services to meet the evolving needs of our rural communities. Virginia's Certificate of Public Need (COPN) program is critical to keeping rural hospitals open and preserving access to essential service lines and in-patient care.

For reasons stated in the public comment letter submitted by the Virginia Hospital & Healthcare Association, Fauquier Health and Lifepoint Health are strongly opposed to the recommendation approved by the Task Force at the August 23, 2024, meeting to include all imaging services project types in Expedited Review. We respectfully request that the Task Force remove this motion from its recommendations. Imaging services projects are typically highly contested and involve significant health planning impacts such that they should remain in full COPN review.

As the sole healthcare provider for many Virginians, weakening or removing COPN puts access to quality care at risk in rural communities. When COPN is reformed, rural communities and patients pay the price. Fauquier Health works to maintain delivery of critical in-patient service lines. Our community hospitals rely on revenues from diagnostic imaging services to subsidize many services provided to the community at a loss. Allowing imaging service projects to utilize the Expedited Review process will potentially lead to redundant imaging centers within hospital catchment areas and will negatively impact other vital service lines within hospitals that already have narrow operating margins.

FAUQUIER HEALTH

For these reasons, we again respectfully ask the Task Force to retract its motion on imaging services and remove from Expedited Review these imaging services project types that are not generally non contested and do not present limited health planning impacts. Regarding all other recommendations of the Task Force on project types that should be considered for Expedited Review and the process for Expedited Review, we associate our organization with the previous public comments submitted by the Virginia Hospital & Healthcare Association and support its recommendations on these matters. Thank you for your consideration of this public comment and for the ongoing work of the Task Force.

Sincerely,

Rebecca Segal
Chief Executive Officer
Fauquier Health

CHESAPEAKE REGIONAL HEALTHCARE

Reese Jackson
President and Chief Executive Officer

SUBMITTED ELECTRONICALLY AT: regulatorycomment@vdh.virginia.gov
karen.shelton@vdh.virginia.gov; Allyson.Flinn@vdh.virginia.gov

August 30, 2024

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

Re: COPN Expedited Review

Dear Commissioner Shelton and SHSP Task Force members:

Chesapeake Regional Healthcare ("CRH") submits this public comment to the State Health Services Plan (SHSP) Task Force in advance of its September 6, 2024, meeting, addressing SHSP Task Force recommendations approved at the August 23, 2024 meeting. CRH believes that the use of expedited review using the current COPN regulations should be limited to uncontested projects that present few health planning concerns. The wholesale use of expedited review for one entire category of projects (CT, MRI and PET imaging services), regardless of project scope, is inconsistent with comparative review requirements and the purpose of expedited review.

For the reasons set forth in this letter and in the Virginia Hospital and Healthcare Association public comment letter, CRH is opposed to the recommendation to include all imaging service project types under expedited review. The Task Force should revisit the issue before the SHSP Task Force releases its recommendations to the General Assembly.

Imaging projects are among the most competitive COPN reviews, resulting in more comparative reviews than any other project classification. There were 19 competitive reviews on imaging projects reflected on the DCOPN website over the last 5 years, more than the 13 competitive reviews on all other project classifications combined.[1]

CRH was involved in multiple competitive reviews on imaging projects over that timeframe. There was nothing uncontested about those projects, which involved relocations of CTs and MRIs across PD 20 and the approval of new project sites. Several of the projects received negative staff recommendations and went through the informal fact-finding process before the Commissioner's decision. One applicant claimed that it was bringing COPN authorized projects back to life after an operating hiatus and sought COPN approval to relocate several services dozens of miles across the planning district. The expedited review of all imaging projects in a 45-90 day timeframe would not provide sufficient safeguards for public comment in these cases.

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[1] See Staff Reports - Licensure And Certification (virginia.gov).

Expedited review was never designed for the consideration of an entire classification of reviewable services. Prior studies of the COPN process identified strict limitations on the use of expedited review. The 2015 HHR Secretary's COPN Work Group report[2] included a recommendation for potential approaches to greater use of expedited review. Recommendation 3e stated:

> VDH should: i) assess projects that may be appropriate for a 45-day expedited review process, which may include projects that are generally non-contested and/or raise comparatively few health planning concerns; ii) develop a process for reviewing such applications in a 45-day review period and identify the conditions under which such applications would require transition to a standard review cycle, and; iii) establish requirements for COPNs issued pursuant to a 45-day expedited review process, including conditions for indigent care and quality assurance.

CRH representatives have attended and have observed the care which the SHSP Task Force has taken in its efforts to develop a sound expedited review process. CRH remains concerned that the use of expedited review should be limited to projects identified by DCOPN which fit the uncontested profile, e.g., additional on-site iterations of COPN reviewable services based on institutional need. COPN decisions on where to place new COPN reviewable projects, including off-site expansions of COPN reviewable services within a planning district, should remain subject to the full administrative review process.

In addition to the practical aspects of considering the health planning effects of all imaging projects in a 45-90 day period, there are the legal considerations requiring comparative review by administrative agencies of applications for the same or similar service.[3] As the Richmond Circuit Court found in the *Charter Hospital of Charlottesville, Inc. v. Kenley* matter,[4] there are legal principles requiring comparative review of similar applications filed in the same time period. However, it is up to the agency to decide how to compare.

The requirement for comparative review led prior Virginia Department of Health commissioners and their staff to establish batching cycles for standard review applications and to limit changes to the letter of intent.[5] And, where standard review applications were being reviewed at the same time as applications under expedited review, the Department elected to review and make decisions on both types of applications at the same time, noting that "the Ashbacker doctrine appears to require such" and that "the fact that regulations for the administrative review process provide for expedited review of certain qualified projects cannot supersede the principle that comparative review be

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[2] The full report from this 2015 Secretary's COPN Work Group (the ("COPN Work Group") is available online at PDF (virginia.gov).

[3] See *Ashbaker Radio Corp. v. FCC*, 326 U.S. 327 (1945).

[4] In chancery, case no. N-2275-2 (August 1985).

[5] *See, e.g., Lewis-Gale Hosp. v. Stroube*, 31 Va. Cir. 263, 270 (July 1993) (noting that the "primary purpose of 'batching' related health care projects is to allow the health care planning agency to consider applications for identical (or even nearly identical) projects serving identical regions with an eye toward which project most effectively and efficiently serves the public health interest"); see also March 16, 1999 letter from Paul Parker, DCOPN Director, to Thomas W. McCandlish re: letter of intent by Cataract Center, LLC (limiting changes to letters of intent); April 17, 2001 letter from Erik Bodin, DCOPN Director, to Paul Boynton, EVHSA Director, re: Change in Applicant triggering new application (same).

made of opposing applications filed in a contemporaneous period of time for a similar limited service."[6]

The use of expedited review in COPN decisions involving allocation of resources to meet public needs should be limited to situations where the location and type of service is uncontested and does not adversely affect the allocation of needed resources across a planning district. The wholesale review of one group of COPN reviewable services in an expedited review process does not accomplish that goal and should be reconsidered. CRH also supports the previous public comments submitted by the Virginia Hospital & Healthcare Association, and we generally support its recommendations on other expedited review matters.

Sincerely,

Reese Jackson, President/CEO

[6] February 14, 1985 letter from James B. Kenley, State Health Commissioner, to Greg Luce, Esq. re: nursing home applications in PD 20 (requiring comparative review of expedited and standard review applications).

SUBMITTED ELECTRONICALLY AT: regulatorycomment@vdh.virginia.gov
karen.shelton@vdh.virginia.gov; Allyson.Flinn@vdh.virginia.gov

September 3, 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, September 6, 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 upcoming September 6, 2024, meeting regarding recommendations approved at the August 23, 2024 meeting.

Inova is Northern Virginia's leading non-profit health system, with more than two million annual patient encounters at inpatient and ambulatory care sites across Northern Virginia. As our region's leading safety net provider, Inova maintains Virginia's most generous charity care policy, our region's most robust network of care sites with particular attention to serving under-resourced communities, and Northern Virginia's only Level One trauma center. Virginia's Certificate of Public Need program is essential to ensuring an appropriate and effective distribution of high-quality healthcare services in our region, as well as ensuring every provider is held accountable to serving all patients regardless of their payer or ability to pay.

For the reasons stated in the public comment letter submitted by the Virginia Hospital & Healthcare Association, Inova is strongly opposed to the recommendation approved by the Task Force at the August 23, 2024, meeting to include all imaging services project types in Expedited Review. We respectfully request that the Task Force remove this motion from its recommendations. Imaging services project types are typically highly contested and involve significant health planning impacts such that they should remain in the well-established full COPN review.

Eliminating full COPN review of imaging services will result in a markedly negative outcome for appropriate distribution of health services in Northern Virginia, especially for patients who are uninsured or underinsured who rely on equitable access. Given Northern Virginia's high percentage of commercially insured residents, opening the door to unfettered expansion of imaging services would invite profit-seeking entities, increasingly from out of state, to stand up imaging centers in high-income, well-served zip codes with the goal of capturing commercially insured market share. The eventual outcome of unchecked imaging expansion is a higher regional health spend, not less, as providers order clinically unnecessary or duplicative imaging to justify their significant capital investment.

Moreover, as Virginia COPN does not specifically regulate freestanding emergency services, a lower standard of imaging review risks inviting proliferation of high cost, high margin freestanding emergency

departments that risk confusing patients and are not associated with community need or adequate health planning metrics. While this has not been reality in Virginia due in part to appropriate health planning and COPN oversight, this specific concern has been top of mind for Virginia legislators evidenced in recent years by numerous bills that sought to more strictly regulate off-site emergency departments in response to the same kind of proliferation that has occurred in other states with lesser standards of COPN review.

For these reasons, we again respectfully ask the Task Force to retract its motion on imaging services and remove from Expedited Review these imaging services project types that are not generally non contested and do not present limited health planning impacts. Regarding all other recommendations of the Task Force on project types that should be considered for Expedited Review and the process for Expedited Review, we associate our organization with the previous public comments submitted by the Virginia Hospital & Healthcare Association and support its recommendations on these matters. Thank you for your consideration of this public comment and for the ongoing work of the Task Force.

Sincerely,

Michael Forehand
Vice President, Government Relations and Public Affairs
Inova Health System

Mary Washington Healthcare
Executive Office

SUBMITTED ELECTRONICALLY AT: regulatorycomment@vdh.virginia.gov
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September 3, 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, September 6, 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 upcoming September 6, 2024, meeting regarding recommendations approved at the August 23, 2024, meeting.

Mary Washington Healthcare began in 1899 as an eight-room hospital in Fredericksburg, Virginia. Today, it has evolved into a non-profit regional system of two hospitals (571 beds), four emergency departments, and over 80 healthcare facilities and wellness services. Our Board of Trustees is made up of community leaders who serve in a volunteer capacity to guide our direction.

Our mission to our community is clear. Mary Washington Healthcare exists to improve the health of the people in the communities we serve. As a non-profit corporation, we invest our profits back into the organization through such activities as upgrading our technology, developing new services, and hiring new staff. The result is continuous improvement in the scope and quality of care we are able to provide to the community. Our ability to sustain our mission and meet the needs of our growing community is dependent on the governance and resilience of the COPN process.

For reasons stated in the public comment letter submitted by the Virginia Hospital & Healthcare Association, Mary Washington Healthcare is strongly opposed to the recommendation approved by the Task Force at the August 23, 2024, meeting to include all imaging services project types in Expedited Review. We respectfully request that the Task Force remove this motion from its recommendations. Imaging services project types are typically highly contested and involve significant health planning impacts such that they should remain in full COPN review.

Planning District 16 is one of the fastest-growing population hubs in the State of Virginia, as such, we depend on the COPN process to constrain the development of excess capacity and underutilization of medical facilities, encourage cost-effectiveness and quality, and promote geographic and economic accessibility to healthcare services. The proliferation of imaging and lack of full COPN review and

sound health planning would be detrimental to our system's ability to continue to maintain access to essential health services in the community.

In the past 20 years, healthcare providers practicing in Planning District 16 have submitted 25 letters of intent for COPN review of imaging services. Of that count, fifteen were approved by COPN while the remaining 10 were either withdrawn or denied. In many cases, these applications were either fully contested with a competing application, some requiring IFFC review (e.g. COPN VA-8269 vs. COPN VA-8267 and COPN VA-8452 vs. COPN VA-8474 and COPN VA-8475) or were formally opposed by other healthcare providers in the region (e.g. COPN VA-8594 and COPN VA-8762).

We respectfully ask the Task Force to retract its motion on imaging services and remove from Expedited Review these imaging services project types that are not generally non contested and do not present limited health planning impacts. Regarding all other recommendations of the Task Force on project types that should be considered for Expedited Review and the process for Expedited Review, we associate our organization with the previous public comments submitted by the Virginia Hospital & Healthcare Association and support its recommendations on these matters.

Thank you for your consideration of this public comment and for the ongoing work of the Task Force.

Sincerely,

Michael McDermott, MD, MBA
President
Chief Executive Officer

New Information on COPN for next SHSP Task Force Sept 6, 2024

Keith Berger <keberger2@verizon.net>
Mon 9/2/2024 2:01 PM
To:Flinn, Allyson (VDH) <Allyson.Flinn@vdh.virginia.gov>
Cc:THOMAS EPPES, JR. <famlymd@aol.com>

1 attachments (981 KB)
2024 Virginia_con_law-a_comparison_with_other_states_20180419.pdf;

Hello Allyson and all SHSP Task Force Members:

I wanted to let everyone know that they may be interested in hearing about some recent data on the impact of Florida's 2019 repeal of their CON laws on in-patient psychiatric beds. Portions of this email will also serve as part of my official comments to the commissioner requested by September 6th.

PS. unfortunately, due to a schedule conflict, I am unable to attend the Richmond Sept 6 meeting. I've asked Dr. Eppes to facilitate any discussion regarding these issues. KEB

So here are the new findings:

***Florida experienced a significant increase in adult inpatient psychiatric beds after CON repeal as follows* (Florida reports the number of inpatient adult psych beds annually. The Florida legislature repealed CON for adult psych beds (and other things) effective 2019):**

In 2019, the reported number of beds was 4,475. By 2023, the reported number was 6,777!

From 2014–2019, with CON laws in place, the number of adult psych beds only increased by 507 (around 100 beds/year). After CON repeal, the number of beds increased by 2,302 (about 575 beds/year).

These numbers are available here and are provided by the Florida Department of Health.

"…this tells us a lot about the rapid increase in access that follows CON reform!"

I would also like to make the following points:

1. Arguments that COPN laws improve access, cost and quality of healthcare have long been disproven by over (120) peer reviewed studies. In fact, the

data consistently show a significant negative impact on access and cost with no change to underserved populations. Florida appears to be no exception. I have previously circulated to the task force the April 2024 summary published by economist Matthew Mitchell reviewing the ENTIRE literature on CON studies throughout the US, repeatedly confirming these findings (everyone on the Task Force should have previously received a copy of his paper).

2. With regard specifically to the state of Virginia, Virginia as compared to neighboring non-CON states has FAR FEWER hospital, rural, and ASC beds per capita than the comparison states. To see this graphically take a look at the attached brief summary of testimony Mr. Mitchell gave here in committee in Richmond in 2018. See the (4) graphs comparing Virginia to non-CON states in pages 6-9 in his article. The graphs speak for themselves.
3. Attached: testimony by Matt Mathews*, Virginia's Certificate-of-Public-Need Law: A Comparison with Other States from April8, 2018.*Excellent assessment on Virginia's situation.

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,

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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.

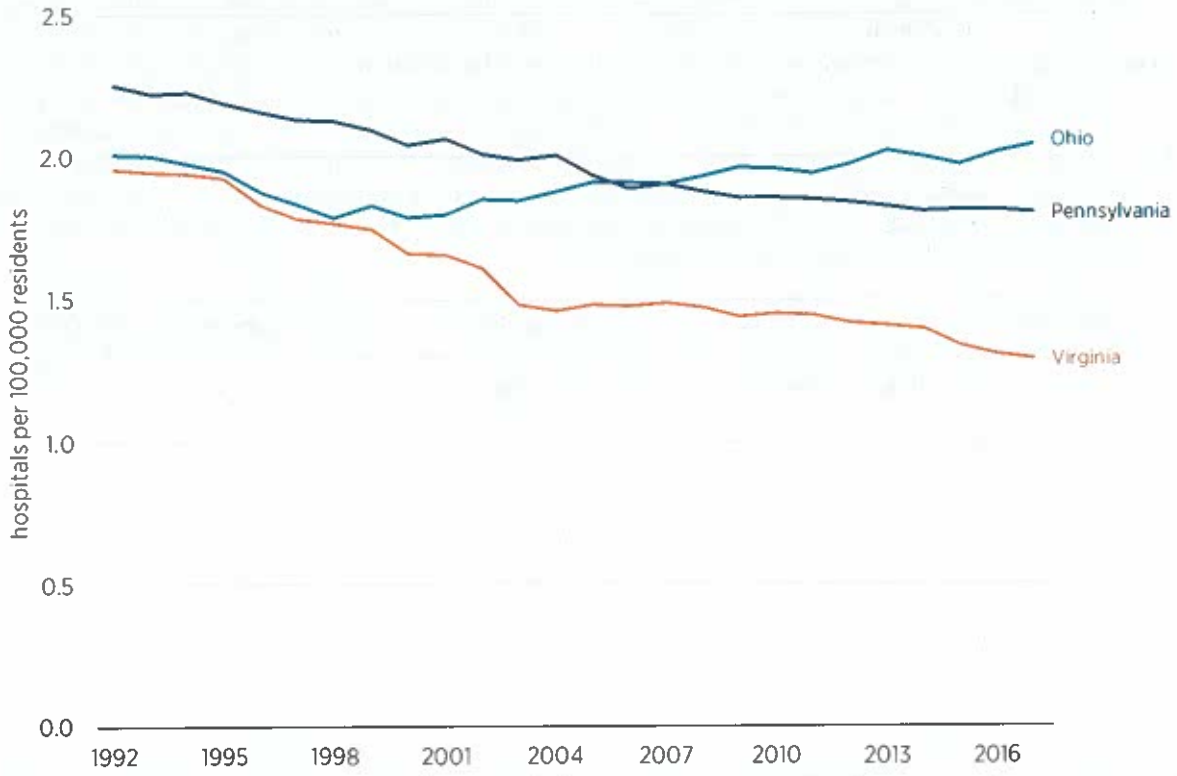
All of the evidence reviewed in table 1 was derived from point estimates in regression analyses. Though a regression is one of the best ways to assess the effect of a policy while controlling for other factors, it is not an intuitive concept for many. So to better illustrate the data behind these results, 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.

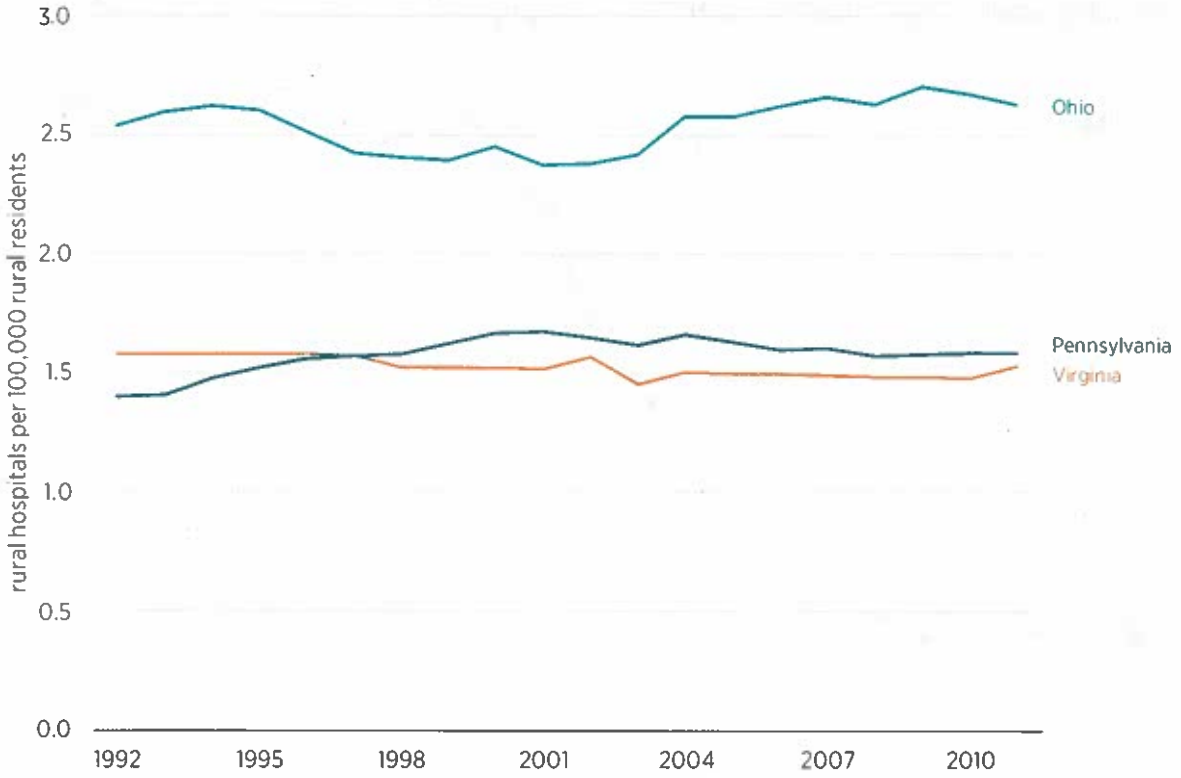
FIGURE 1. HOSPITALS PER 100,000 RESIDENTS



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.

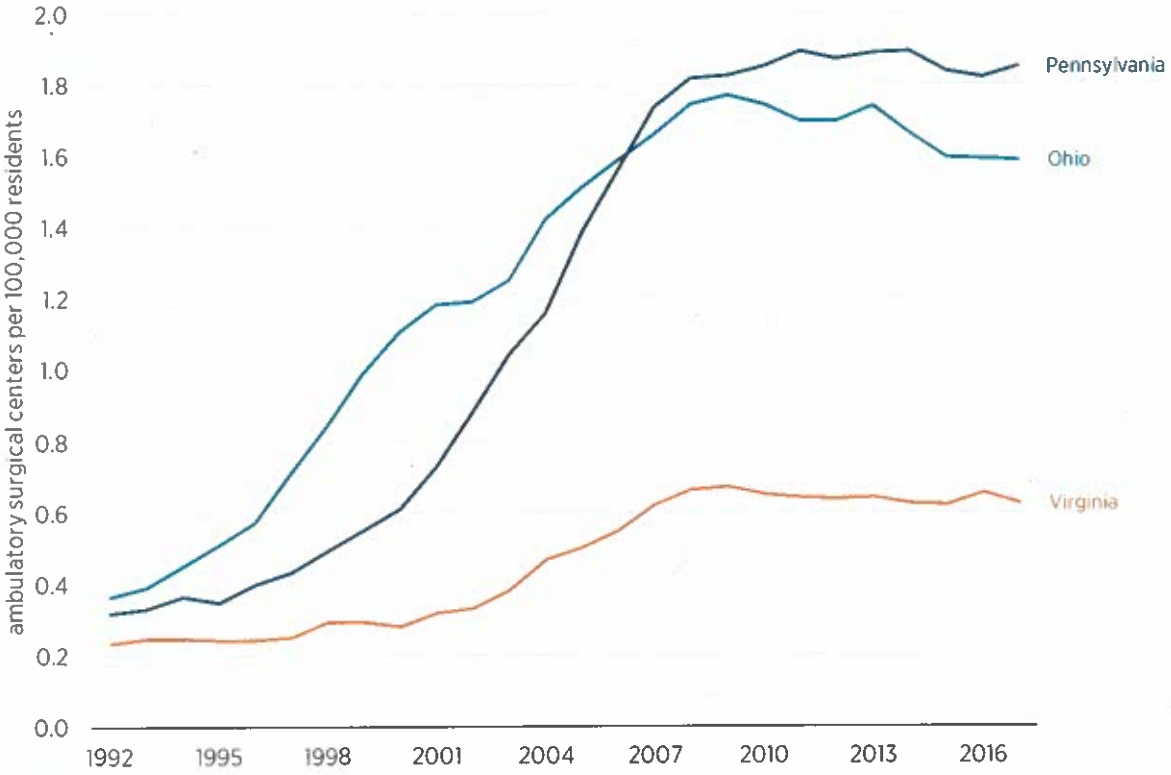
FIGURE 2. RURAL HOSPITALS PER 100,000 RURAL RESIDENTS



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.

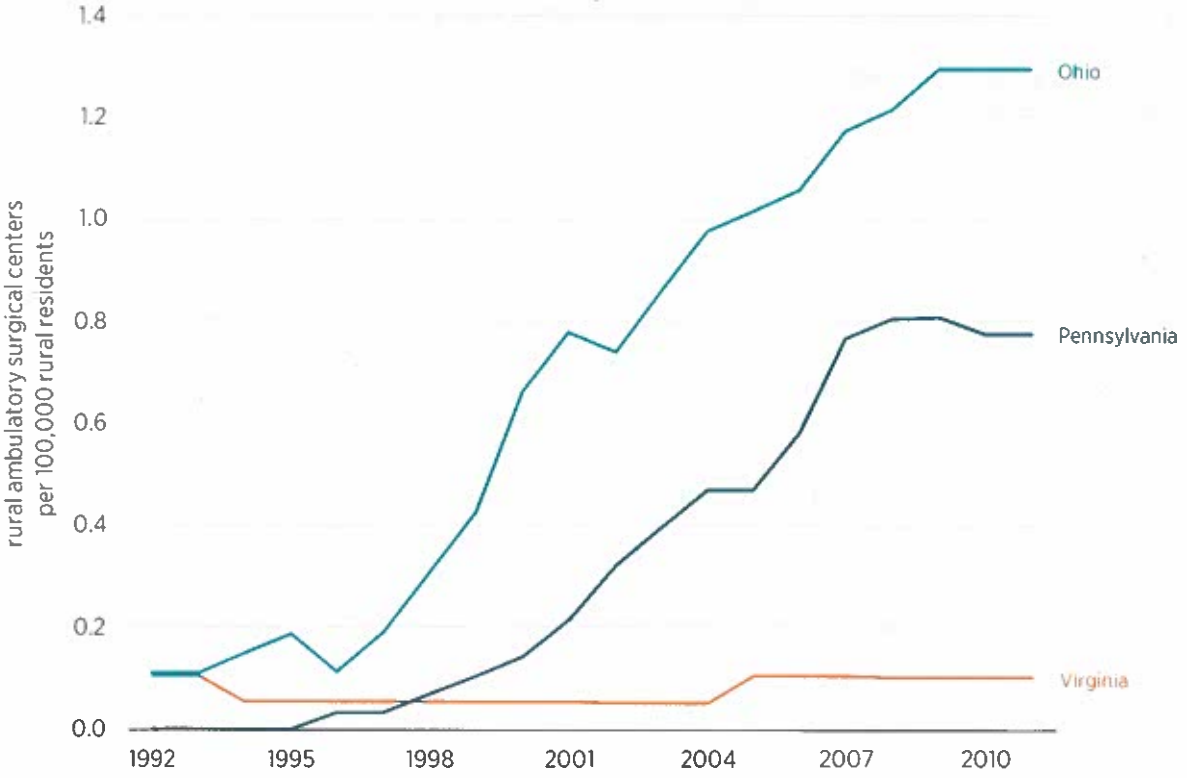
FIGURE 3. AMBULATORY SURGICAL CENTERS PER 100,000 RESIDENTS



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

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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

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Do Certificate-of-Need Laws Limit Spending?

Matthew D. Mitchell

Economic Theory and the Original Rationale for Certificate of Need

Thirty-five states and the District of Columbia currently impose certificate-of-need (CON) restrictions on the provision of health care.[1] These rules require those hoping to open or expand specific types of healthcare facilities to first prove to a state regulator that their community "needs" the particular service. For example, Virginia providers wishing to open a neonatal intensive care unit, start a rehabilitation center, or even purchase a new CT scanner for an existing practice must first prove to the state health commissioner that their community needs the service in question.[2] Providers wait years and spend tens or even hundreds of thousands of dollars convincing CON authorities to approve their projects.[3] In the process, incumbent providers are often invited to testify against their would-be competitors. It was originally hoped that the CON process would reduce healthcare price inflation, though over the years, the rationale in favor of CON has shifted a number of times.

In 1964, New York implemented the first CON program.[4] A decade later, Congress enacted the National Health Planning and Resources Development Act, thereby withholding

[1] In some states, such as Virginia, these restrictions are known as a Certificate of Public Convenience and Necessity. In July 2016, New Hampshire eliminated its CON program. For more details about the history of CON programs in the states, see Matthew Mitchell and Christopher Koopman, "40 Years of Certificate-of-Need Laws across America," Mercatus Center at George Mason University, Arlington, VA, October 14, 2014.
[2] "CON—Certificate of Need State Laws" (Washington, DC: National Conference of State Legislatures, August 2016), http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx.
[3] Virginia's Dr. Mark Monteferrante spent five years and $175,000 seeking permission to add a second MRI machine to his practice. Kent Hoover, "Doctors Challenge Virginia's Certificate-of-Need Requirement," *Washington Bureau, Business Journals*, June 5, 2012.
[4] Mitchell and Koopman, "40 Years of Certificate-of-Need Laws across America."

federal healthcare dollars from any state that failed to implement its own CON program.[5] By 1979, every state except Louisiana had responded to this incentive and implemented a CON program.[6] The federal incentive was repealed in 1987 following a change in Medicare reimbursement practices, and more than a dozen states have since repealed their CON programs. But in 35 states and the District of Columbia, CON laws still restrict the supply of some healthcare services.

The rationale behind the 1974 federal legislation was clear. Under a section titled "Findings and Purpose," Congress declared,

> The massive infusion of Federal funds into the existing health care system has contributed to inflationary increases in the *cost* of health care and failed to produce an adequate supply or distribution of health resources, and consequently has not made possible equal access for everyone to such resources.[7]

Note the emphasis on cost. From the beginning, a primary goal of CON programs was to rein in the excessive growth of healthcare costs.[8] Then, as now, healthcare price inflation was a perennial concern. Note also that the authors of this legislation believed healthcare price inflation to be a result of other federal policies. In what way might a law restricting supply reduce cost? I begin with a simple economic model of supply and demand and then consider three slightly more elaborate models.

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[5] National Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641 (1975).
[6] Mitchell and Koopman, "40 Years of Certificate-of-Need Laws across America."
[7] Pub. L. No. 93-641, emphasis added.
[8] For research testing CON's ability to meet the other goals of the National Health Planning and Resources Development Act, see Thomas Stratmann and Jacob Russ, "Do Certificate-of-Need Laws Increase Indigent Care?," Mercatus Working Paper No. 14-20, Mercatus Center at George Mason University, Arlington, VA, July 2014; Thomas Stratmann and Matthew C. Baker, "Are Certificate-of-Need Laws Barriers to Entry? How They Affect Access to MRI, CT, and PET Scans," Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, January 2016; 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.

The Simple Model of Supply and Demand

In everyday language, we speak of cost in *per unit* terms: How much does one slice of pizza cost? What is the going rate for a gallon of unleaded gasoline? Simple economic theory offers a straightforward answer to the question of how a supply restriction might reduce this sort of cost: it can't. In a supply-and-demand model, there is no way that a supply restriction can reduce per unit cost. It *might* reduce overall healthcare expenditures—the total amount that people spend on health care in a given time period. But although reducing per unit cost is a worthy goal, it is far from obvious that reducing overall expenditures is desirable. Figure 1 explains why.

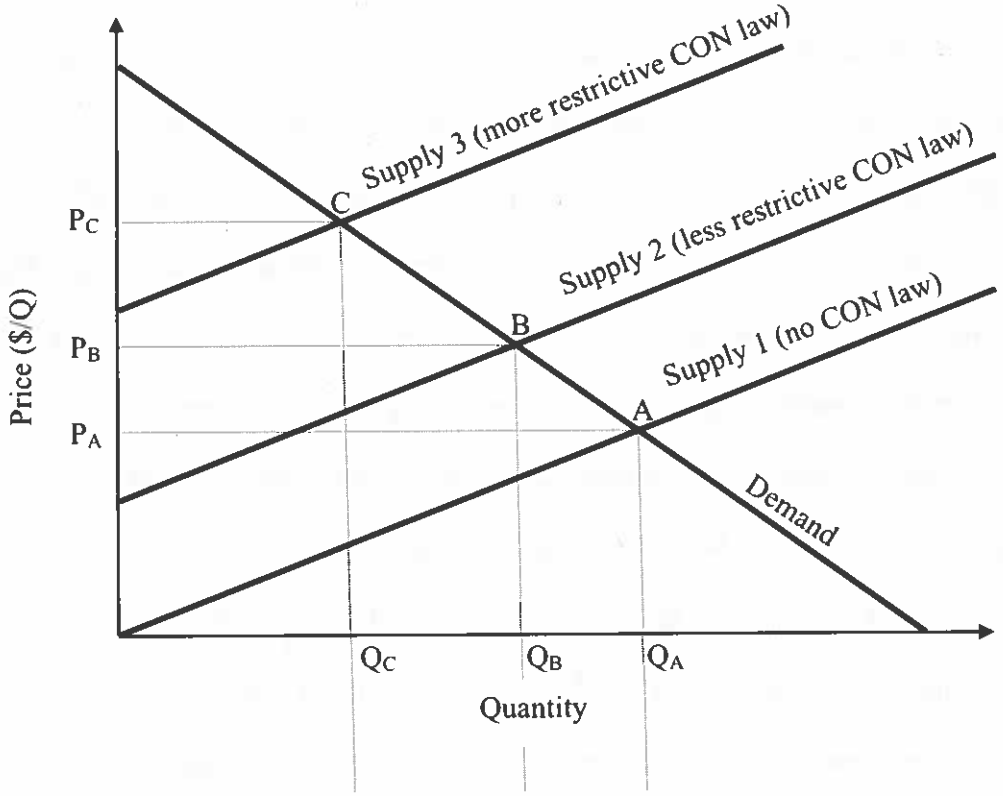
Panel A of figure 1 shows a demand curve intersected by three different supply curves. The market supply of health care without a CON law is indicated by Supply 1. The restricted supply of health care with a CON law is indicated by *either* Supply 2 or Supply 3, with the difference depending on how restrictive the CON process is. Consistent with standard practice, the supply restriction is modeled as a leftward shift in the supply curve; by limiting entry, CON laws ensure that a smaller quantity of services is available at any given price.

Note that as supply is restricted, the per unit price unambiguously rises, and the quantity consumed unambiguously falls. Because the supply restriction causes consumers to pay more and consume less, it unambiguously reduces what economists call "consumer surplus," which is the value that consumers derive from a product in excess of its price.[9]

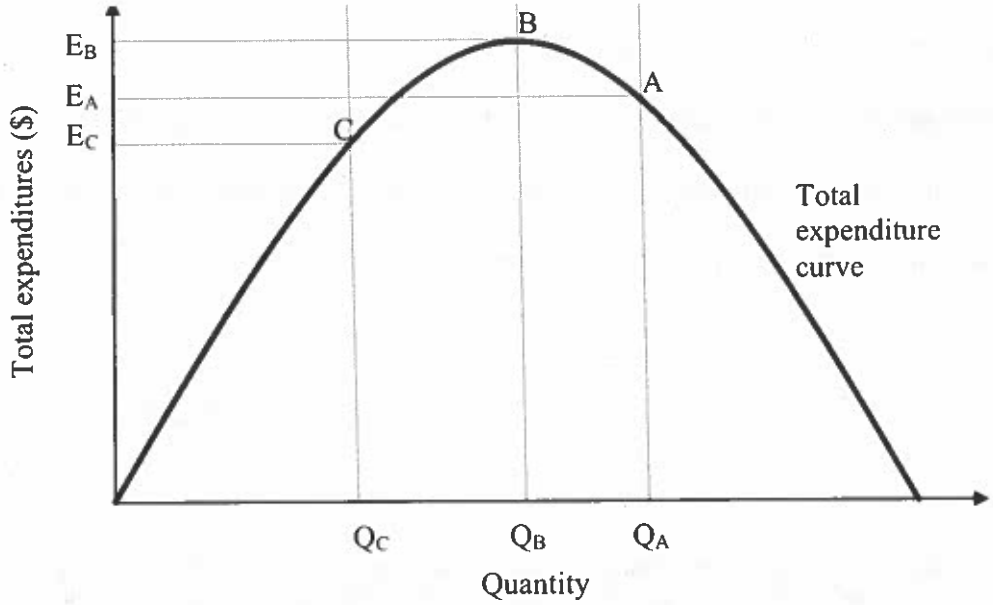
[9] Consumer surplus is measured by the area above the price line and below the demand curve. It gets smaller as supply decreases (shifts leftward). Total producer surplus, measured by the area below the price line and above the supply curve, is also reduced. However, a supply restriction may make a few firms better off by allowing them to capture a larger *portion* of the producer surplus at the expense of other producers. This artificially large portion of producer surplus is known as rent.

Figure 1. A Supply Restriction

Panel A. The Effect of a Supply Restriction on Price



Panel B. The Effect of a Supply Restriction on Total Expenditures



However, because of the third-party-payer problem in health care, patients may not directly pay the higher prices. They and others will indirectly pay higher prices through higher insurance premiums, higher taxes, or both. Patients will, of course, be directly affected by the diminished quantity of healthcare services available to them. That is, they will experience a reduction in welfare resulting from the leftward shift in the quantity of services.

Note, however, that the supply restriction has an *ambiguous* effect on total expenditures. This is because total expenditures—depicted in panel B of figure 1—are equal to the price per unit multiplied by the number of units sold. Because the supply restriction raises the price per unit but lowers the number of units sold, it has an ambiguous effect on total expenditure.

As shown in panel B, total expenditures might rise to E_B or fall to E_C, depending on whether the price increase or the quantity decrease dominates.[10] Note also that if consumers are less price sensitive and the demand curve is steeper (less elastic), the price-increasing effect is likely to dominate, and the supply restriction is likely to increase total expenditures.

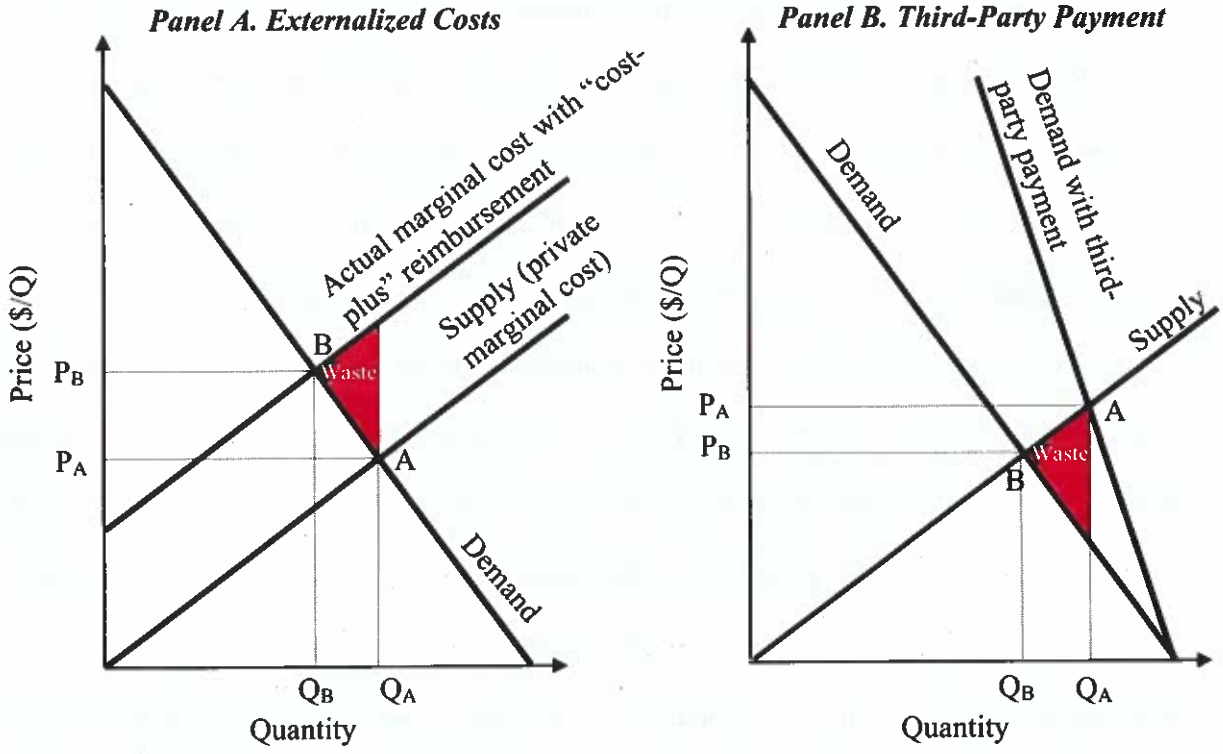
Despite the stated objective of the federal legislation promoting CON, this simple model suggests that CON laws cannot reduce cost in the per unit sense in which most people think of it. Instead, CON laws are expected to increase the per unit cost of healthcare services, although they *might* reduce total expenditures if they restrict consumption enough to outweigh the higher per unit cost. It is important to note, however, that if CON laws do succeed in reducing overall expenditures, they do so only by restricting the availability of services, limiting consumer choice, and reducing consumer welfare.

[10] The answer depends on whether the original, nonrestricted supply curve intersects the demand curve in the elastic portion, above and to the left of B, or in the inelastic portion, below and to the right of B.

Externalities

A more complex model might account for the fact that other public policies have distorted the healthcare market so that market participants are divorced from the true marginal costs of their decisions. In this case, a CON regulation might counteract the harm of such policies, but as we will see, it is hardly the most efficient means of doing so. Figure 2 depicts two ways that public policies might distort the healthcare market by creating an externality. I will consider each in turn.

Figure 2. Externalities



Cost-plus reimbursement. In panel A of figure 2, the equilibrium is at point A, where supply and demand intersect. If providers internalized all their costs, this equilibrium would be efficient because marginal cost would equal marginal benefit. But at the time that many states adopted

CON, Medicare reimbursed hospitals for their costs on a "retrospective" basis. Healthcare researchers Stuart Guterman and Allen Dobson described this reimbursement practice in 1986: "Under this system, hospitals were paid whatever they spent; there was little incentive to control costs, because higher costs brought about higher levels of reimbursement."[11]

This reimbursement method was often referred to as a "cost-plus" system because it encouraged hospitals to overinvest in certain inputs. In other words, hospitals were able to externalize some of their costs of care and to pass them on to taxpayers. As a result, *actual* marginal costs were higher than the private marginal costs of hospitals.

These actual marginal costs are indicated by the marginal cost curve that sits above the supply curve in the left panel of figure 2. With this sort of reimbursement system, the efficient production point would be at point B, where true marginal cost equals marginal benefit. But because firms fail to internalize all costs, the actual equilibrium is at point A, resulting in what economists call a "deadweight loss." This deadweight loss is depicted by the red triangle and is labeled "Waste." It indicates that for the quantity of units of health care between Q_B and Q_A, marginal cost exceeds marginal benefit.

Under this type of reimbursement system, CON laws—by restricting supply—might be one way to move the market toward the more efficient outcome (Q_B). A more straightforward solution, however, would be to change the way Medicare reimburses hospitals. Indeed, Congress pursued this straightforward solution more than 30 years ago with the adoption of Public Law 98-21.[12]

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[11] Stuart Guterman and Allen Dobson, "Impact of the Medicare Prospective Payment System for Hospitals," *Health Care Financing Review* 7, no. 3 (Spring 1986): 97–114.
[12] Social Security Amendments of 1983, Pub. L. No. 98-21, 97 Stat. 65 (1983).

That legislation phased in Medicare's Prospective Payment System, thus ending retrospective, cost-plus reimbursement. Therefore, the externalized-costs rationale for CON has not been relevant for decades. As Mark Botti, an official in the Antitrust Division of the Department of Justice, noted in 2007 testimony before the Georgia State Assembly,

> We [antitrust officials at the Department of Justice and the Federal Trade Commission] made that recommendation [that states rethink their CON laws] in part because the original reason for the adoption of CON laws is no longer valid. Many CON programs trace their origins to a repealed federal mandate, the National Health Planning and Resources Development Act of 1974, which offered incentives for states to implement CON programs. At the time, the federal government and private insurance reimbursed healthcare expenses predominantly on a "cost-plus basis." This is a very important point. The original reason for CON laws was not, as some have argued, that competition inherently does not work in healthcare or that market forces promote over-investment. Instead, CON laws were desired because the reimbursement mechanism, i.e., cost-plus reimbursement, incentivized over-investment. The hope was that CON laws would compensate for that skewed incentive. . . . CON laws appear not to have served well even their intended purpose of containing costs. Several studies examined the effectiveness of CONs in controlling costs. The empirical evidence on the economic effects of CON programs demonstrated near-universal agreement among health economists that CON laws were unsuccessful in containing healthcare costs.
>
> In addition to the fact that CON laws have been ineffective in serving their original purpose, CON laws should be reexamined because the reimbursement methodologies that may in theory have justified them initially have changed significantly since the 1970s. The federal government no longer reimburses on a cost-plus basis.[13]

Indeed, it is instructive to note that Congress eliminated the incentive for states to implement CON regulations in 1987, one year after Medicare's new reimbursement practice was fully phased in.

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[13] Mark J. Botti, "Competition in Healthcare and Certificates of Need" (Testimony 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, US Department of Justice Antitrust Division, Washington, DC, February 23, 2007). In support of his claim that economists were in "near-universal agreement" that CON laws failed to contain healthcare costs, Botti cites David S. Salkever, "Regulation of Prices and Investment in Hospitals in the United States," in *Handbook of Health Economics*, ed. A. J. Culyer and J. P. Newhouse, vol. 1B (New York: Elsevier, 2000), 1489–1535.

The third-party-payer problem. Although policymakers long ago addressed the problem of externalized costs by abandoning cost-plus reimbursement, market participants might be divorced from true marginal cost in another way. Third parties such as governments and insurance companies cover some or all of the costs of decisions made by patients and their providers, and because patients fail to pay the full costs of their decisions, their demand for healthcare services is greater and less price sensitive than it otherwise would be.

Governments currently pay about 64 cents out of every healthcare dollar spent in the United States.[14] But even when taxpayers don't pick up the bill, public policy encourages third-party payment through private insurance. During World War II, wage and price controls prevented employers from paying their employees the prevailing market wage. To attract talented workers, some employers offered fringe benefits such as health insurance because those benefits were not limited by the wage controls. After the controls were lifted, Congress found it difficult to remove the favorable tax treatment of health insurance, and it has remained untaxed ever since.[15]

This favorable tax treatment of health insurance encourages employers to compensate their employees with more (untaxed) benefits and less (taxed) cash. And this arrangement has long been blamed for introducing various distortions to the healthcare market.[16] Among other things, this policy has exacerbated the third-party-payer problem by changing the nature of health insurance. Traditionally, insurance covers low-probability, high-cost events such as death,

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[14] David U. Himmelstein and Steffie Woolhandler, "The Current and Projected Taxpayer Shares of US Health Costs," *American Journal of Public Health* 106, no. 3 (March 1, 2016): 449–52.

[15] Rexford E. Santerre and Stephen P. Neun, *Health Economics: Theory, Insights, and Industry Studies*, 5th ed. (Mason, OH: South-Western Publishing, 2010), 316; Milton Friedman, "Pricing Health Care: The Folly of Buying Health Care at the Company Store," *Wall Street Journal*, February 3, 1993.

[16] Martin Feldstein and Bernard Friedman, "Tax Subsidies, the Rational Demand for Insurance and the Health Care Crisis," *Journal of Public Economics* 7, no. 2 (April 1, 1977): 155–78; Jonathan Gruber, "The Tax Exclusion for Employer-Sponsored Health Insurance," *National Tax Journal* 64, no. 2 (2011): 511–30; Jeremy Horpedahl and Harrison Searles, "The Tax Exemption of Employer-Provided Health Insurance," Mercatus on Policy, Mercatus Center at George Mason University, Arlington, VA, September 2013.

accidents, or disease. But in the case of health insurance, favorable tax treatment and various regulatory mandates have caused health insurers to cover entirely predictable expenses such as checkups, screenings, immunizations, diet counseling, breastfeeding consultation, nutritional supplements, and much more.[17]

As a result, patients are able to purchase routine and entirely foreseeable health services while pushing some portion of the cost off onto others who pay insurance premiums. This arrangement has caused the effective demand for healthcare services to be greater and less price sensitive than it otherwise would be, thereby pivoting the demand curve out to the right.[18] This situation is depicted in panel B of figure 2. Here, the equilibrium is at point A, where the "Supply" curve intersects the "Demand with Third-Party Payment" curve. As in the case of externalized costs, the equilibrium is inefficient because marginal cost exceeds the marginal benefit, as indicated by the demand curve.

As in the case of externalized costs, policymakers *might* be able to correct this problem by restricting supply through CON programs, thus raising the price and getting consumers to internalize more of the cost. Note, however, that if this is the goal of CON regulation, it contradicts the *named* goal of reducing cost. Moreover, to do this properly, policymakers would need to estimate how much of the cost is externalized, as well as the degree to which private arrangements such as cost-sharing already correct for this problem.[19] Then they would need to shift the supply curve up by the exact amount of the externalized cost; if the shift were too little or too great, wasteful inefficiencies would remain.

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[17] Maureen Buff and Timothy Terrell, "The Role of Third-Party Payers in Medical Cost Increases," *Journal of American Physicians and Surgeons* 19, no. 2 (Summer 2014): 75–79.
[18] Santerre and Neun, *Health Economics: Theory, Insights, and Industry Studies*, 115–35.
[19] John V. C. Nye, "The Pigou Problem: It Is Difficult to Calculate the Right Tax in a World of Imperfect Coasian Bargains," *Regulation* 31, no. 2 (Summer 2008).

It is not clear that policymakers have the knowledge or the expertise to make this assessment—especially because their decisions are unguided by market signals.[20] Nor is it clear that CON is a precise enough tool to allow them to shift the supply curve the proper amount.

Those considerations aside, CON is hardly the most efficient or equitable way to address the third-party-payer problem. A far more direct approach would be to address the policies that encourage third-party payment in the first place, just as Congress once addressed the externalized cost problem by changing Medicare reimbursement practices.

If, for example, policymakers are concerned that patients are spending too much on health care, a straightforward approach would be to eliminate the tax privilege for employer-provided health insurance and to repeal the insurance mandates that require insurers to cover routine and foreseeable procedures. Doing so would cause the effective demand for health care to more closely resemble patients' actual marginal benefits.

In contrast, CON regulations restrict the ability of everybody to access medical services such as psychiatric care (regulated by CON procedures in 26 states), neonatal intensive care (regulated by 23 states), and MRI scans (regulated by 16 states).[21] This restriction means that all patients—even those who pay out of pocket and don't push costs onto third parties—have less access to valuable medical services.

Before I move on to the third theoretical model, one more point is worth emphasizing. Recall that in the previous section, I noted that a supply restriction would be more likely to increase total expenditures when demand was less elastic. Because the third-party-payer problem

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[20] F. A. Hayek, "The Use of Knowledge in Society," *American Economic Review* 35, no. 4 (September 1, 1945): 519–30; F. A. Hayek, "Competition as a Discovery Procedure," trans. Marcellus Snow, *Quarterly Journal of Austrian Economics* 5, no. 3 (Fall 2002): 9–23.

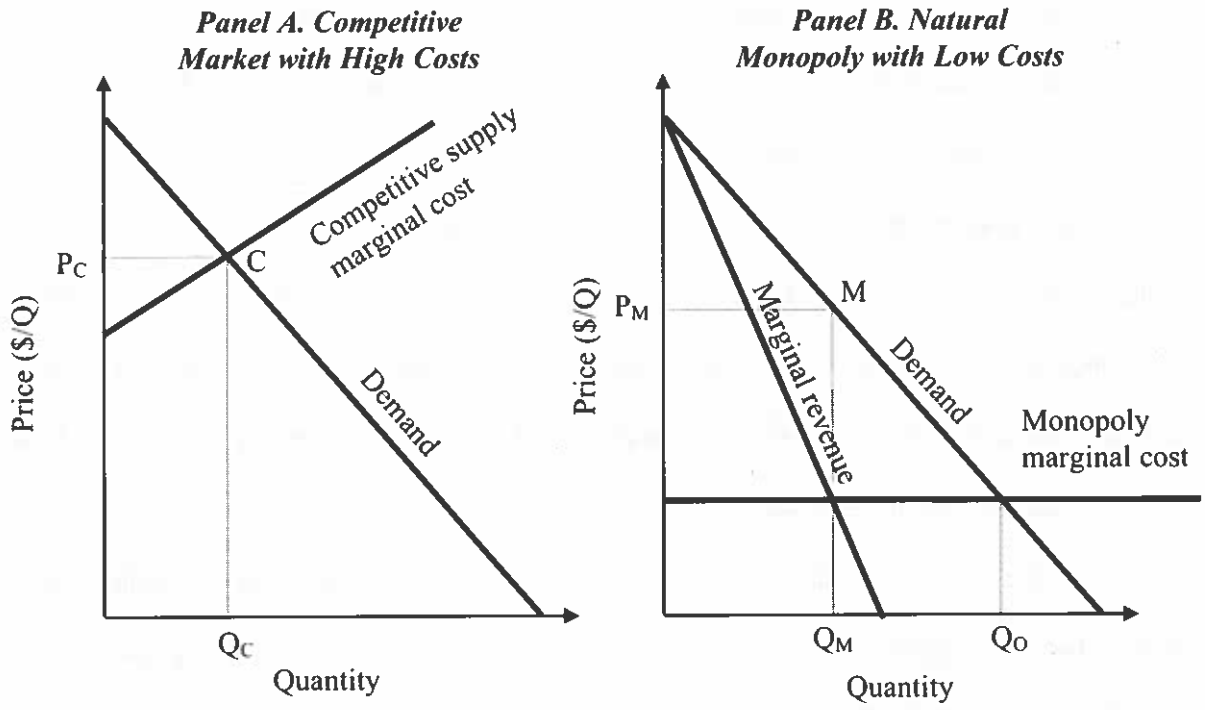
[21] For state CON regulations, see "CON—Certificate of Need State Laws."

tends to cause the effective demand curve to be less elastic than it otherwise would be, this model suggests that CON is likely to increase rather than decrease total expenditures.

Economies of Scale

Another slightly more complex model might posit that there are economies of scale in the provision of medical services and that a few hospitals or even one large hospital might be able to deliver care with a lower cost than can many smaller ones. This situation is depicted in figure 3.

Figure 3. Competition vs. Natural Monopoly



Panel A shows a competitive industry with comparatively high production costs. Because the industry is competitive, firms are unable to mark up the price. Therefore, they set the price at marginal cost P_C.

Panel B shows a monopolist with comparatively low production costs. The monopolist uses its pricing power to set price above marginal cost, at P_M, but even this marked-up price is lower than that charged by the competitive firms, because the monopolist enjoys economies of scale in production.

It is possible that policymakers have this sort of model in mind. Perhaps by channeling more patients to a few hospitals, regulators may allow these individual hospitals to achieve some economies of scale. Relatedly, some policymakers have recently begun to argue that CON might allow these hospitals to increase the quality of their care by becoming more proficient in certain procedures.[22]

As health economists Robert Ohsfeldt and John Schneider observe, however, CON "is an unacceptably blunt instrument for quality enhancement in a sector as innovative and dynamic as health care," especially when there are more direct and effective ways to achieve the same end.[23] In any case, the most recent evidence suggests that, if anything, CON is associated with lower, not higher, quality.[24]

This natural monopoly theory has problems. For one thing, the model is most appropriate in industries such as power production that require large fixed-cost investments in plant but have low marginal costs of operation. This model is only somewhat descriptive of the healthcare

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[22] Mary S. Vaughan-Sarrazin et al., "Mortality in Medicare Beneficiaries Following Coronary Artery Bypass Graft Surgery in States with and without Certificate of Need Regulation," *Journal of the American Medical Association* 288, no. 15 (October 16, 2002): 1859–66.

[23] Robert L. Ohsfeldt and John E. Schneider, *The Business of Health: The Role of Competition, Markets, and Regulation* (Washington, DC: AEI Press, 2006), 39.

[24] More recent work, using better data and methods, fails to find a link between CON and quality. See Iona Popescu, Mary S. Vaughan-Sarrazin, and Gary E. Rosenthal, "Certificate of Need Regulations and Use of Coronary Revascularization after Acute Myocardial Infarction," *Journal of the American Medical Association* 295, no. 18 (May 10, 2006): 2141–47. For an overview, see Vivian Ho, Meei-Hsiang Ku-Goto, and James G. Jollis, "Certificate of Need (CON) for Cardiac Care: Controversy over the Contributions of CON," *Health Services Research* 44, no. 2, pt. 1 (April 2009): 483–500. Finally, for one of the best attempts to get at causation, see 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. They find that CON is associated with lower-quality care.

industry, where the marginal cost of healthcare providers' salaries is significant. Additionally, there is reason to believe that when firms are protected from competition, they will have higher, not lower, production costs because administrators will tend to be less disciplined about cost minimization.[25] These factors explain why hospital prices in monopoly markets are more than 15 percent higher than those in markets with four or more competitors.[26]

Most important, however, even if the natural monopoly model did describe the healthcare market, artificial restrictions on entry would be unlikely to improve conditions. The economist David Henderson explains why:

> Economists tend to oppose regulating entry. The reason is as follows: If the industry really is a natural monopoly, then preventing new competitors from entering is unnecessary because no competitor would want to enter anyway. If, on the other hand, the industry is not a natural monopoly, then preventing competition is undesirable. Either way, preventing entry does not make sense.[27]

In other words, as the name implies, a natural monopoly occurs naturally. If the market will bear only one firm, then policymakers need not artificially restrict entry.

The Interest-Group Model for CON

The preceding models have all been normative: they've focused on whether or not CON laws are desirable in the sense that they increase consumer welfare and efficiency. But perhaps the most informative models of CON are positive in the sense that they explain why CON programs exist irrespective of their desirability.

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[25] This finding is known as x-inefficiency. For more details, see Harvey Leibenstein, "Allocative Efficiency vs. 'X-Efficiency,'" *American Economic Review* 56, no. 3 (June 1, 1966): 392–415.
[26] Zack Cooper, Stuart V. Craig, Martin Gaynor, and John Van Reenen, "The Price Ain't Right? Hospital Prices and Health Spending on the Privately Insured," NBER working paper, National Bureau of Economic Research, Cambridge, MA, December 2015.
[27] David R. Henderson, "Natural Monopoly," ed. David R. Henderson, *The Concise Encyclopedia of Economics* (Indianapolis, IN: Liberty Fund Inc., 2008).

Positive models stress that a CON law is a special privilege afforded to a particular interest group, namely the incumbent provider who benefits from a lack of competition. A large body of literature suggests that interest groups seeking special privileges through the political process have an advantage over the consumers and taxpayers who bear the costs of those privileges.

First, it takes time, money, and effort to get politically engaged. But, being few in number, the members of a special interest group typically find it easier than large, diffuse interests to organize for political action.[28]

Second, such groups tend to be well informed about their industry. Often, they are able to capitalize on voter ignorance and irrationality[29] or to use their superior knowledge of the industry to dominate the regulatory process, or both.[30]

Third, concentrated interest groups are often able to control the agenda, thus allowing them to steer committee outcomes to their benefit.[31]

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[28] Mancur Olson, *The Logic of Collective Action: Public Goods and the Theory of Groups*, Second Printing with New Preface and Appendix, Revised (Cambridge, MA: Harvard University Press, 1965); Jonathan Rauch, *Government's End: Why Washington Stopped Working* (New York: PublicAffairs, 1999).

[29] On voter ignorance, see Anthony Downs, *An Economic Theory of Democracy* (New York: Harper & Row, 1957); Geoffrey Brennan and Loren E. Lomasky, *Democracy and Decision: The Pure Theory of Electoral Preference* (Cambridge, UK: Cambridge University Press, 1997). On voter irrationality, see Bryan Caplan, *The Myth of the Rational Voter: Why Democracies Choose Bad Policies* (Princeton, NJ: Princeton University Press, 2008).

[30] George J. Stigler, "The Theory of Economic Regulation," *Bell Journal of Economics and Management Science* 2, no. 1 (April 1, 1971): 3–21; Richard A. Posner, "Theories of Economic Regulation," *Bell Journal of Economics and Management Science* 5, no. 2 (October 1, 1974): 335–58; Sam Peltzman, "Toward a More General Theory of Regulation," *Journal of Law and Economics* 19, no. 2 (August 1, 1976): 211–40; Ernesto Dal Bó, "Regulatory Capture: A Review," *Oxford Review of Economic Policy* 22, no. 2 (June 20, 2006): 203–25; Patrick A. McLaughlin, Matthew Mitchell, and Ethan Roberts, "When Regulation Becomes Privilege," Mercatus Center at George Mason University, Arlington, VA, forthcoming.

[31] On using control of the agenda to determine the outcome, see Duncan Black, "On the Rationale of Group Decision-Making," *Journal of Political Economy* 56, no. 1 (February 1, 1948): 23–34; Kenneth Joseph Arrow, *Social Choice and Individual Values* (New Haven: Yale University Press, 1951); Richard D McKelvey, "Intransitivities in Multidimensional Voting Models and Some Implications for Agenda Control," *Journal of Economic Theory* 12, no. 3 (June 1976): 472–82. On keeping certain items off the agenda, see Peter Bachrach and Morton S. Baratz, "Two Faces of Power," *American Political Science Review* 56, no. 4 (December 1, 1962): 947–52.

Fourth and finally, firms tend to get better at political activity the more they engage in it, giving incumbents a marked advantage over new entrants.[32]

All these factors explain why the CON process seems to favor incumbent firms through features such as steep application fees, long wait periods, and a notice-and-comment process that allows incumbents to argue against competition. They also explain why hospital lobbies typically support CON laws while federal antitrust authorities at the Justice Department and the Federal Trade Commission have long opposed them.[33]

If, as the interest group models imply, CON laws exist to serve special interests rather than the general interest, then those laws are especially costly. Figure 4 demonstrates why. The model assumes, for simplicity, that marginal costs are identical under competitive and monopolistic conditions. (This assumption is made for ease of explanation; it does not drive the analysis.)

Without CON, the market equilibrium would be at A, where marginal cost equals marginal benefit. If an incumbent provider is able to obtain a monopoly privilege through CON, however, then the provider will limit the quantity supplied and will charge a higher price. Standard economic theory predicts that the monopolist will charge price P_B because at that price, marginal revenue is equal to marginal cost, thus maximizing profit. This pricing results in a traditional monopoly deadweight loss, indicated by the red triangle.[34]

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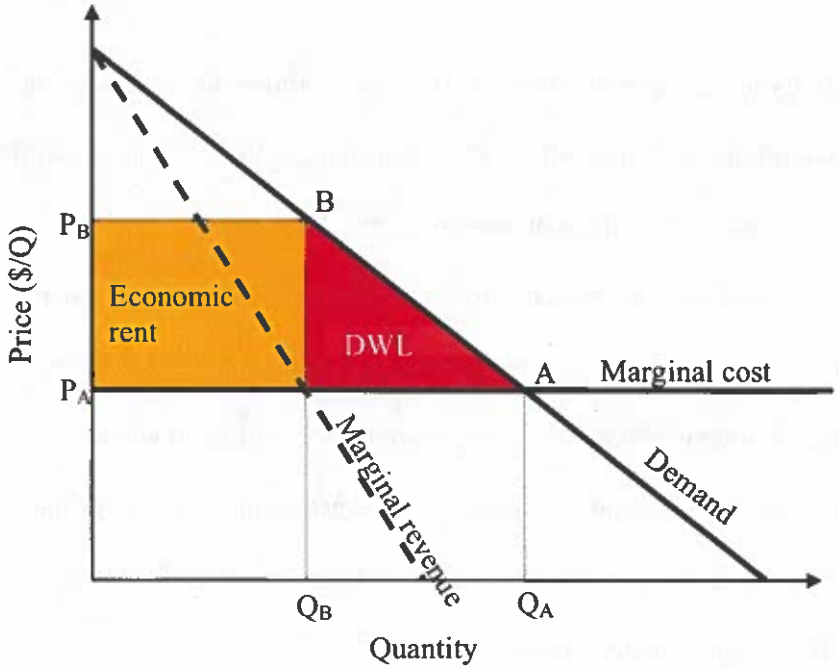
[32] Lee Drutman, *The Business of America Is Lobbying: How Corporations Became Politicized and Politics Became More Corporate* (New York: Oxford University Press, 2015).

[33] For one recent example, see 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, https://www.ftc.gov/policy/policy-actions/advocacy-filings/2016/01/joint-statement-federal-trade-commission-antitrust.

[34] Economists consider this an economic loss because consumers and would-be competitors lose more than the monopolist gains. For more details, see James R. Hines, "Three Sides of Harberger Triangles," NBER Working Paper 6852, National Bureau of Economic Research, Cambridge, MA, December 1998.

Figure 4. CON as a Special Interest



But there is a potential for further social losses. The monopolist's profit—which comes at the expense of consumers and would-be competitors—is indicated by the yellow rectangle and is known as "economic rent." Because this rent can represent a substantial economic profit, firms will be willing to invest scarce resources seeking it.[35] They will lobby, donate to political action committees, and alter their business models to satisfy political preferences. Not all those activities are legal. For example, according to federal prosecutors, former HealthSouth CEO Richard Scrushy paid former Alabama Governor Don Siegelman more than $500,000 for a seat

[35] Gordon Tullock, "The Welfare Costs of Tariffs, Monopolies, and Theft," *Western Economic Journal [Economic Inquiry]* 5, no. 3 (June 1, 1967): 224–32; Anne O. Krueger, "The Political Economy of the Rent-Seeking Society," *American Economic Review* 64, no. 3 (1974): 291–303.

on the state's certificate-of-need board. Both men were convicted of bribery (among other crimes) in June 2006.[36]

Illegal or not, this activity has an opportunity cost. This cost is known as "rent-seeking," and it can be enormously wasteful. Indeed, under the right circumstances, firms might be willing to invest more resources in rent-seeking than the rent is even worth.[37]

But this is only one of several costs of special-interest privilege.[38] For example, when firms can obtain anticompetitive privileges, entrepreneurial talents will be directed at seeking those privileges rather than developing new ways to please customers, resulting in what economists call "unproductive entrepreneurship."[39] This practice is especially costly over the long run because it robs an industry of the sort of entrepreneurial dynamism that characterizes healthy growth and because it locks in outdated business models.[40]

For these reasons, the special-interest theory of CON regulation suggests that CON laws will result in higher costs, lower quality, and less innovation.

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[36] Kyle Whitmire, "Ex-Governor and Executive Convicted of Bribery," *New York Times*, June 30, 2006.

[37] Known as "overdissipation," this outcome is possible when there are many rent-seekers and when there are increasing returns to political activity. Gordon Tullock, "Efficient Rent Seeking," in *Toward a Theory of the Rent-Seeking Society*, ed. James M. Buchanan, Robert D. Tollison, and Gordon Tullock (College Station: Texas A&M University Press, 1980), 97–112; Dennis C. Mueller, *Public Choice III*, 3rd ed. (Cambridge, UK: Cambridge University Press, 2003), 331–37. For evidence that there are increasing returns to political activity, see Drutman, *The Business of America Is Lobbying*; Matthew Mitchell, "Of Rent-Seekers and Rent-Givers," review of *The Business of America Is Lobbying*, by Lee Drutman, Library of Law and Liberty, December 14, 2015.

[38] Matthew Mitchell, *The Pathology of Privilege: The Economic Consequences of Government Favoritism* (Arlington, VA: Mercatus Center at George Mason University, 2012).

[39] William J. Baumol, "Entrepreneurship: Productive, Unproductive, and Destructive," *Journal of Political Economy* 98, no. 5 (October 1, 1990): 893–921.

[40] Kevin M. Murphy, Andrei Shleifer, and Robert W. Vishny, "The Allocation of Talent: Implications for Growth," *Quarterly Journal of Economics* 106, no. 2 (May 1, 1991): 503–30; Kevin Murphy, Andrei Shleifer, and Robert Vishny, "Why Is Rent-Seeking So Costly to Growth?," *American Economic Review Papers and Proceedings* 83, no. 2 (1993): 409–14; Stephen L. Parente and Edward C. Prescott, *Barriers to Riches*, repr. ed. (Cambridge, MA: MIT Press, 2002); Adam Thierer, *Permissionless Innovation: The Continuing Case for Comprehensive Technological Freedom* (Arlington, VA: Mercatus Center at George Mason University, 2014).

Summary of the Economic Theory

In this section, I have reviewed several economic models of a supply restriction such as CON. None of those theories suggest that a CON regulation will decrease healthcare prices. Instead, theory predicts that a CON regulation will raise per unit cost, limit the supply of healthcare services, reduce consumer welfare, and lead to the misallocation of resources in rent-seeking activity.

Theory suggests that CON laws might reduce healthcare expenditures if the effects of the quantity reduction outweigh the effects of the price increases. But this theory would only hold if the demand for health care were relatively elastic, which is unlikely given the third-party-payer problem. CON regulations might mitigate a policy-induced externality, but they are hardly the most efficient or equitable means of doing so.

In the next section, I turn to the data and examine 40 years of empirical studies on the effects of CON on spending.

What Do the Data Show?

Table 1 reports the empirical literature assessing the effect of CON on various spending outcomes. For ease of reference, the studies are divided into four categories: (1) the effect of CON on cost per procedure, price, or charge; (2) the effect of CON on total expenditures; (3) the effect of CON on efficiency; and (4) the effect of CON on investment. Studies that assess CON along multiple spending outcomes appear more than once in the table. The scope of the analysis is limited to only published, peer-reviewed papers, and it encompasses 20 studies spanning the course of 40 years.[41]

[41] Being focused on published, peer-reviewed papers, the table omits some high-quality government reports that were prepared by academics. Those reports are consistent with the findings reported in the table. See, for example, Daniel Sherman, "The Effect of State Certificate-of-Need Laws on Hospital Costs: An Economic Policy Analysis," Staff Report of the Bureau of Economics, Federal Trade Commission, Washington, DC, January 1988; Christopher J. Conover and Frank A. Sloan, "Evaluation of Certificate of Need in Michigan," Report to the Michigan Department of Community Health (Durham, NC: Duke University Center for Health Policy, Law, and Management, May 2003), http://ushealthpolicygateway.com/wp-content/uploads/2009/07/mi-con-intro-iii.pdf.

Table 1. Empirical Studies of CON and Spending

Author(s)	Year	Title	Publication	Effect of CON on cost/price/investment/efficiency	Quotes
Effect of CON on per unit costs, prices, or charges					
Noether	1988	"Competition among Hospitals"	*Journal of Health Economics*	CON increases the average price for specific disease categories such as congestive heart failure and pneumonia.	"CON's strongest effect is that it creates cost-raising inefficiencies which are passed on in higher prices."
Grabowski, Ohsfeldt, and Morrisey	2003	"The Effects of CON Repeal on Medicaid Nursing Home and Long-Term Care Expenditures"	*Inquiry: The Journal of Medical Care Organization, Provision, and Financing*	CON repeal has no statistically significant effect on per diem Medicaid nursing home charges or per diem Medicaid long-term-care charges.	"The results . . . show that regulatory change did not have a statistically significant effect on either Medicaid payment rates or overall days."
Ho and Ku-Goto	2013	"State Deregulation and Medicare Costs for Acute Cardiac Care"	*Medical Care Research and Review*	Removing CON decreases the cost of some procedures.	"We found that states that dropped CON experienced lower costs per patient for coronary artery bypass grafts (CABG) but not for percutaneous coronary intervention (PCI)."
Bailey	2016	"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	Removing CON reduces hospital charges by 5.5% five years after repeal.	"CON repeal . . . is associated with . . . a statistically significant 1.1% reduction in average hospital charges per year (a 5.5% reduction for a mature CON repeal)."
Effect of CON on expenditures					
Sloan and Steinwald	1980	"Effects of Regulation on Hospital Costs and Input Use"	*Journal of Law and Economics*	Comprehensive CON programs have no effect on hospital expenditures per patient day, while noncomprehensive programs increase hospital expenditures per patient day.	"The short-run effect of a mature, noncomprehensive program is to raise total expense per adjusted patient day by nearly 5 percent; the long-run effect is over twice this."
Sloan	1981	"Regulation and the Rising Cost of Hospital Care"	*Review of Economics and Statistics*	CON has no effect on hospital expenditures per admission, per patient day, or per adjusted patient day.	"The certificate-of-need coefficients imply CON has had no impact on costs."
Lanning, Morrisey, and Ohsfeldt	1991	"Endogenous Hospital Regulation and Its Effects on Hospital and Non-Hospital Expenditures"	*Journal of Regulatory Economics*	CON increases per capita hospital, nonhospital, and total health expenditures.	". . . the coefficient of CON is positive and statistically significant in all three expenditure equations. The most pronounced effect is on hospital expenditures, where CON appears to add 20.6 percent to per capita hospital expenditures in the long run. This is consistent with the view that CON programs act to protect inefficient hospitals from competition."

Antel, Ohsfeldt, and Becker	1995	"State Regulation and Hospital Costs"	*Review of Economics and Statistics*	CON increases per-day and per-admission hospital expenditures but has no relationship to per capita hospital expenditures.	"CON investment controls imply higher per day and per admission costs, but have no statistically significant effect on per capita cost."
Conover and Sloan	1998	"Does Removing Certificate-of-Need Regulations Lead to a Surge in Health Care Spending?"	*Journal of Health Politics, Policy, and Law*	CON has no effect on total per capita health expenditures; there is no evidence of a surge in spending after repeal.	"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."
Miller, Harrington, and Goldstein	2002	"Access to Community-Based Long-Term Care: Medicaid's Role"	*Journal of Aging and Health*	CON increases per capita Medicaid community-based care expenditures.	"Use of a nursing home CON or combined CON/moratorium was associated with increased community-based care expenditures."
Grabowski, Ohsfeldt, and Morrisey	2003	"The Effects of CON Repeal on Medicaid Nursing Home and Long-Term Care Expenditures"	*Inquiry: The Journal of Medical Care Organization, Provision, and Financing*	CON repeal has no statistically significant effect on either aggregate Medicaid nursing-home or aggregate Medicaid long-term-care expenditures.	"Using aggregate state-level data from 1981 through 1998, this study found that states that repealed their CON and moratorium laws had no significant growth in either nursing home or long-term care Medicaid expenditures"
Rivers, Fottler, and Younis	2007	"Does Certificate of Need Really Contain Hospital Costs in the United States?"	*Health Education Journal*	CON laws increase hospital expenditures per adjusted admission.	"The results indicate that CON laws had a positive, statistically significant relationship to hospital costs per adjusted admission. . . .These findings suggest not only that CON do not really contain hospital costs, but may actually increase them by reducing competition."
Hellinger	2009	"The Effect of Certificate-of-Need Laws on Hospital Beds and Healthcare Expenditures: An Empirical Analysis"	*American Journal of Managed Care*	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.	"Certificate-of-need programs did not have a direct effect on healthcare expenditures. . . . 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."
Rivers, Fottler, and Frimpong	2010	"The Effects of Certificate of Need Regulation on Hospital Costs"	*Journal of Health Care Finance*	Stringent CON programs increase hospital expenditures per admission.	"Implications from these results include the inability of CNR [CON] to contain HC [hospital costs] as assumed or expected, and the possibility that CNR [CON] may actually increase HC [hospital costs], while reducing competition."
Rahman et al.	2016	"The Impact of Certificate-of-Need Laws on Nursing Home and Home Health Care Expenditures"	*Medical Care Research and Review: MCRR*	CON increases the growth in Medicare and Medicaid expenditures on nursing home care but decreases growth in home healthcare expenditures.	"Compared with states without CON laws, Medicare and Medicaid spending in states with CON laws grew faster for nursing home care and more slowly for home health care."

Bailey	2016	"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	CON is associated with higher overall per capita healthcare expenditures and with higher per capita Medicare expenditures.	"CON increases total health spending [per capita] by a statistically significant 3.1%. Increases are especially high for spending on physician care—a statistically significant 5.0%. . . . CON is estimated to increase overall Medicare spending [per capita] by a statistically significant 6.9%."
Effect of CON on Hospital Efficiency					
Eakin	1991	"Allocative Inefficiency in the Production of Hospital Services"	*Southern Economic Journal*	CON hospitals are less efficient than non-CON hospitals.	". . . hospitals subject to CON regulations have a greater measure of allocative inefficiency by .88 to 1.03 percentage points."
Bates, Mukherjee, and Santerre	2006	"Market Structure and Technical Efficiency in the Hospital Services Industry: A DEA Approach"	*Medical Care Research and Review*	CON hospitals are not any less efficient than non-CON hospitals.	"Evidence also implies that the presence of a state certificate-of-need law was not associated with a greater degree of inefficiency in the typical metropolitan hospital services industry."
Ferrier, Leleu, and Valdmanis	2010	"The Impact of CON Regulation on Hospital Efficiency"	*Health Care Management Science*	CON hospitals are more efficient than non-CON hospitals.	"In general, we found that the hospital sector in states with active CON regulations performed better in terms of aggregate technical and mix efficiency, irrespective of the stringency or laxness of this oversight."
Rosko and Mutter	2014	"The Association of Hospital Cost-Inefficiency with Certificate-of-Need Regulation"	*Medical Care Research and Review*	CON hospitals are more efficient than non-CON hospitals.	"Average estimated cost-inefficiency was less in CON states (8.10%) than in non-CON states (12.46%)."
Effect of CON on Investment					
Salkever and Bice	1976	"The Impact of Certificate of Need Controls on Hospital Investment"	*Milbank Memorial Fund Quarterly: Health and Society*	CON does not decrease investment but does change its composition.	"CON did not reduce the total dollar volume of investment but altered its composition, retarding expansion in bed supplies but increasing investment in new services and equipment."
Hellinger	1976	"The Effect of Certificate-of-Need Legislation on Hospital Investment"	*Inquiry: The Journal of Medical Care Organization, Provision, and Financing*	CON legislation induced hospitals to increase investments.	"The empirical results support the hypotheses that [CON] legislation has not significantly lowered hospital investment and that hospitals anticipated the effect of [CON] legislation by increasing investment in the period preceding the enactment of the legislation."

Per Unit Costs, Prices, and Charges

The first four studies summarized in table 1 address the idea of cost as it is commonly used in everyday language.[42] Those studies assess the effect of CON on *per unit* costs, prices, or charges (a charge is the initial amount that the payer is billed, whereas a price is the amount that the payer actually pays after negotiation).[43]

As noted in the previous section, economic theory suggests that a supply restriction is likely to increase per unit costs and prices. And, indeed, the empirical evidence is consistent with this prediction. Three of these four studies found CON to be associated with higher per unit prices, costs, or charges, while the fourth—which focused only on per diem Medicaid charges for nursing-home and long-term care—found that repeal of CON had no statistically significant effect on those charges.[44]

One study found that "CON's strongest effect is that it creates cost-raising inefficiencies which are passed on in higher prices."[45] Another found that removing CON decreased the per unit cost of coronary artery bypass grafts, though not the cost of percutaneous coronary intervention.[46] The most recent study found that average hospital charges fell 1.1 percent per

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[42] Monica Noether, "Competition among Hospitals," *Journal of Health Economics* 7, no. 3 (September 1988): 259–84; David C. Grabowski, Robert L. Ohsfeldt, and Michael A. Morrisey, "The Effects of CON Repeal on Medicaid Nursing Home and Long-Term Care Expenditures," *Inquiry: The Journal of Medical Care Organization, Provision, and Financing* 40, no. 2 (2003): 146–57; Vivian Ho and Meei-Hsiang Ku-Goto, "State Deregulation and Medicare Costs for Acute Cardiac Care," *Medical Care Research and Review* 70, no. 2 (April 2013): 185–205; 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, July 2016.

[43] Although prices are more important, economically, charges are easier to observe. For more details, see Bailey, "Can Health Spending Be Reined In through Supply Constraints?"

[44] The three studies that found CON increases prices, charges, or per unit costs were Noether, "Competition among Hospitals"; Ho and Ku-Goto, "State Deregulation and Medicare Costs for Acute Cardiac Care"; and Bailey, "Can Health Spending Be Reined In through Supply Constraints?" The study that failed to find any statistically significant effect was Grabowski, Ohsfeldt, and Morrisey, "The Effects of CON Repeal on Medicaid Nursing Home and Long-Term Care Expenditures."

[45] Noether, "Competition among Hospitals."

[46] Ho and Ku-Goto, "State Deregulation and Medicare Costs for Acute Cardiac Care."

year for each of the five years following repeal of CON; in other words, five years following repeal, the charges were 5.5 percent lower than they would otherwise have been.[47]

Expenditures

The next 12 studies in table 1 assess the effect of CON on healthcare expenditures or on the growth of those expenditures, usually measured on a per capita basis.[48] In other words, the studies assess the effect of CON on the total amount that is spent on a patient or state resident, rather than on the price per unit of service. In this sense, those studies are comparable to the effect described in panel B of figure 1.[49] As noted previously, that theoretical framework shows that a supply restriction such as CON might lead to either more spending or less spending, depending on whether the price-raising effect or quantity-reducing effect of the supply restriction dominates.

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[47] Bailey, "Can Health Spending Be Reined In through Supply Constraints?"

[48] Frank A. Sloan and Bruce Steinwald, "Effects of Regulation on Hospital Costs and Input Use," *Journal of Law and Economics* 23, no. 1 (1980): 81–109; Frank A. Sloan, "Regulation and the Rising Cost of Hospital Care," *Review of Economics and Statistics* 63, no. 4 (1981): 479–87; Joyce A. Lanning, Michael A. Morrisey, and Robert L. Ohsfeldt, "Endogenous Hospital Regulation and Its Effects on Hospital and Non-Hospital Expenditures," *Journal of Regulatory Economics* 3, no. 2 (June 1991): 137–54; John J. Antel, Robert L. Ohsfeldt, and Edmund R. Becker, "State Regulation and Hospital Costs," *Review of Economics and Statistics* 77, no. 3 (1995): 416–22; Christopher J. Conover and Frank A. Sloan, "Does Removing Certificate-of-Need Regulations Lead to a Surge in Health Care Spending?," *Journal of Health Politics, Policy, and Law* 23, no. 3 (June 1, 1998): 455–81; Nancy A. Miller, Charlene Harrington, and Elizabeth Goldstein, "Access to Community-Based Long-Term Care: Medicaid's Role," *Journal of Aging and Health* 14, no. 1 (February 2002): 138–59; Grabowski, Ohsfeldt, and Morrisey, "The Effects of CON Repeal on Medicaid Nursing Home and Long-Term Care Expenditures"; Patrick A. Rivers, Myron D. Fottler, and Mustafa Zeedan Younis, "Does Certificate of Need Really Contain Hospital Costs in the United States?," *Health Education Journal* 66, no. 3 (September 1, 2007): 229–44; Fred J. Hellinger, "The Effect of Certificate-of-Need Laws on Hospital Beds and Healthcare Expenditures: An Empirical Analysis," *American Journal of Managed Care* 15, no. 10 (October 2009): 737–44; Patrick A. Rivers, Myron D. Fottler, and Jemima A. Frimpong, "The Effects of Certificate of Need Regulation on Hospital Costs," *Journal of Health Care Finance* 36, no. 4 (2010): 1–16; Momotazur Rahman et al., "The Impact of Certificate-of-Need Laws on Nursing Home and Home Health Care Expenditures," *Medical Care Research and Review: MCRR* 73, no. 1 (February 2016): 85–105; Bailey, "Can Health Spending Be Reined In through Supply Constraints?"

[49] It is not uncommon for such papers to use the term *cost*, but their focus is on expenditure in the sense that they are looking at total spending and not at the cost per service.

Of those 12 studies, only one suggests that CON is associated with reduced expenditures.[50] And even in that case, the connection was tenuous. The author found CON to be associated with fewer hospital beds, and he found that fewer hospital beds were associated with slightly slower growth in aggregate healthcare expenditures per capita. Importantly, however, he found that "certificate-of-need programs did not have a direct effect on healthcare expenditures."[51]

Of the remaining 11 studies that assess the effect of CON on expenditures, 7 found evidence that CON increases expenditures,[52] 2 found no statistically significant effect,[53] and 2 found that CON increased some expenditures while reducing others.[54]

Hospital Efficiency

The next four studies in table 1 assess the effect of CON on hospital efficiency.[55] Essentially, those studies examine how cost-effectively hospitals transform inputs into outputs.[56] Economic theory offers no clear prediction for how CON might affect an individual hospital's efficiency.

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[50] Hellinger, "The Effect of Certificate-of-Need Laws on Hospital Beds and Healthcare Expenditures."
[51] Ibid., 737.
[52] Sloan and Steinwald, "Effects of Regulation on Hospital Costs and Input Use"; Lanning, Morrisey, and Ohsfeldt, "Endogenous Hospital Regulation and Its Effects on Hospital and Non-Hospital Expenditures"; Antel, Ohsfeldt, and Becker, "State Regulation and Hospital Costs"; Miller, Harrington, and Goldstein, "Access to Community-Based Long-Term Care"; Rivers, Fottler, and Younis, "Does Certificate of Need Really Contain Hospital Costs in the United States?"; Rivers, Fottler, and Frimpong, "The Effects of Certificate of Need Regulation on Hospital Costs"; Bailey, "Can Health Spending Be Reined In through Supply Constraints?"
[53] Sloan, "Regulation and the Rising Cost of Hospital Care"; Grabowski, Ohsfeldt, and Morrisey, "The Effects of CON Repeal on Medicaid Nursing Home and Long-Term Care Expenditures."
[54] Conover and Sloan, "Does Removing Certificate-of-Need Regulations Lead to a Surge in Health Care Spending?"; Rahman et al., "The Impact of Certificate-of-Need Laws on Nursing Home and Home Health Care Expenditures."
[55] B. Kelly Eakin, "Allocative Inefficiency in the Production of Hospital Services," *Southern Economic Journal* 58, no. 1 (1991): 240–48; Laurie J. Bates, Kankana Mukherjee, and Rexford E. Santerre, "Market Structure and Technical Efficiency in the Hospital Services Industry: A DEA Approach," *Medical Care Research and Review* 63, no. 4 (August 2006): 499–524; Gary D. Ferrier, Hervé Leleu, and Vivian Valdmanis, "The Impact of CON Regulation on Hospital Efficiency," *Health Care Management Science* 13, no. 1 (March 2010): 84–100; Michael D. Rosko and Ryan L. Mutter, "The Association of Hospital Cost-Inefficiency with Certificate-of-Need Regulation," *Medical Care Research and Review* 71, no. 3 (January 22, 2014): 280–298.
[56] For more details see Bates, Mukherjee, and Santerre, "Market Structure and Technical Efficiency in the Hospital Services Industry."

Although most of the theoretical models reviewed in the previous section suggest that CON will increase per unit prices and reduce the quantity of healthcare services, it is possible that by forcing more services to take place in a few large hospitals, CON might allow those hospitals to achieve economies of scale, even if this reduction comes at the price of reduced services elsewhere. Indeed, the empirical literature is mixed on CON and particular hospital efficiency. Two studies find that CON increases some measures of hospital efficiency,[57] one study finds no effect,[58] and one study finds that CON reduces hospital efficiency.[59]

Hospital Investment

Two early studies assessed the effect of CON on investment. Those studies reflect the goal of reducing unnecessary capital expenditures. One of the studies found that CON failed to reduce investment, though it did change the composition of the investment.[60] The other study found that CON backfired, causing hospitals to increase investment immediately before CON was implemented in anticipation that it would make future investments more difficult.[61]

Conclusion

In most industries, the economic viability of a new product or service is determined by the market signals of prices, profit, and loss. These signals are governed by the values of consumers and producers. If market participants do not deem a product or service to be worth

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[57] Ferrier, Leleu, and Valdmanis, "The Impact of CON Regulation on Hospital Efficiency"; Rosko and Mutter, "The Association of Hospital Cost-Inefficiency with Certificate-of-Need Regulation."
[58] Bates, Mukherjee, and Santerre, "Market Structure and Technical Efficiency in the Hospital Services Industry."
[59] Eakin, "Allocative Inefficiency in the Production of Hospital Services."
[60] David S. Salkever and Thomas W. Bice, "The Impact of Certificate-of-Need Controls on Hospital Investment," *Milbank Memorial Fund Quarterly: Health and Society* 54, no. 2 (1976): 185–214.
[61] Fred J. Hellinger, "The Effect of Certificate-of-Need Legislation on Hospital Investment," *Inquiry: The Journal of Medical Care Organization, Provision, and Financing* 13, no. 2 (1976): 187–93.

the opportunity cost of producing it, the product or service will not be economically viable and will soon disappear.

In the healthcare markets of 35 states and the District of Columbia, however, many of the decisions are not left to market participants. Instead, they are governed by regulators empowered to permit—or refuse to permit—new and expanded services. Those laws are called certificate-of-need laws because regulators are supposed to determine whether or not consumers need the services in question.

Providers seeking permission to operate can spend years and tens or even thousands of dollars attempting to obtain permission. During this process, incumbent providers are often invited to offer their own opinion about the desirability of competition.

Although CON regulations were once promoted by the federal government as a way to limit healthcare costs, economic theory offers little reason to suppose they work as intended. Instead, economic theory predicts that a supply restriction such as CON will increase per unit costs and decrease the quantity of services. Furthermore, it predicts that CON laws may lead to either increases or decreases in total healthcare spending, depending on whether the price-increasing or the quantity-reducing effects of CON dominate.

Although CON laws may help internalize externalities created by other public policies such as insurance mandates and public funding, a more efficient and equitable way to address these externalities would be to reform the policies that cause them. Even though CON laws might allow individual hospitals to increase efficiency by channeling more patients to one location, thus achieving economies of scale, these laws might alternatively decrease hospital efficiency by making administrators less cost conscious. Finally, economic theory predicts that

CON laws will allow small but concentrated special interests to profit at the expense of consumers and other providers.

A review of 20 peer-reviewed academic studies finds that CON laws have worked largely as economic theory predicts and that they have failed to achieve their stated goal of cost reduction. The overwhelming weight of evidence suggests that CON laws are associated with both higher per unit costs and higher total expenditures. The evidence is mixed on whether CON laws have increased the efficiency of particular hospitals by channeling more patients through fewer facilities, and there is no evidence that CON decreased overall investment as its proponents had hoped. The weight of evidence suggests that CON regulations persist because they protect politically potent special interests from competition.