



Virginia Department of Planning and Budget **Economic Impact Analysis**

12 VAC 5-410 Regulations for the Licensure of Hospitals in Virginia
Virginia Department of Health
Town Hall Action/Stage: 6159/9887
July 18, 2023

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Code of Virginia (Code) and Executive Order 19. The analysis presented below represents DPB's best estimate of the potential economic impacts as of the date of this analysis.¹

Summary of the Proposed Amendments to Regulation

The State Board of Health (Board) proposes to amend the regulation for the licensure of hospitals to implement changes resulting from a periodic review, conform to the Code of Virginia (Code), and implement multiple recent legislative mandates. The proposed changes would also group related requirements, remove outdated language, make certain terminology more consistent throughout the regulation, and update the text to reflect current practice.

Background

The proposed changes are intended to implement the results of a 2020 periodic review, which include incorporating legislative mandates that were inadvertently omitted, addressing current clinical and industry practices, and updating licensing processes and procedures.² This action would also implement more recent legislative mandates, which the Virginia Department

¹ Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the analysis should include but not be limited to: (1) the projected number of businesses or other entities to whom the proposed regulatory action would apply, (2) the identity of any localities and types of businesses or other entities particularly affected, (3) the projected number of persons and employment positions to be affected, (4) the projected costs to affected businesses or entities to implement or comply with the regulation, and (5) the impact on the use and value of private property.

² See <https://townhall.virginia.gov/L/ViewPReview.cfm?PRid=1960>. Some changes recommended to the Board by commenters were deemed inappropriate for a Fast-track action and will be implemented separately.

of Health (VDH) reports have largely been previously implemented in practice because statutory requirements apply even if a regulation has not yet been updated to reflect a particular mandate.

The relevant legislative mandates are as follows:

- Chapter 72 of the 2021 *Acts of Assembly, Special Session I*, which prohibits discriminating against health insurance enrollees on the basis of the enrollee being a litigant or potential litigant due to a motor vehicle accident.³ This mandate is already in effect.
- Chapters 1080 and 1081 of the 2020 *Acts of Assembly*, which prohibited balance billing by out-of-network providers.⁴ This mandate is already in effect.
- Chapter 1088 of the 2020 *Acts of Assembly*, which requires hospitals to provide quarterly reports pertaining to the employment of certified sexual assault nurse examiners.⁵ This reporting requirement would be implemented through the proposed changes to sections 380 and 1190 for general and outpatient surgical hospitals, respectively.
- Chapter 220 of the 2021 *Acts of Assembly*, which requires medical care facilities to allow individuals with disabilities who require assistance as a result of a disability to be accompanied by a designed support person during admission to a medical care facility.⁶ This mandate is already in effect.
- Chapters 80 and 81 of the 2022 *Acts of Assembly*, which were identical, require that hospitals and emergency medical services agencies that voluntarily install newborn safety devices for the reception of children must ensure that the devices meet specified safety and security standards.⁷ This mandate is already in effect.
- Chapter 218 of the 2022 *Acts of Assembly* requires hospitals and health care providers that choose to make health care records available through a secure website must also make a minor's records available to the patient's parent unless the hospital/health care provider cannot make the record available in a way that prevents information disclosure.⁸ This

³ See <https://townhall.virginia.gov/l/viewmandate.cfm?mandateid=1341>.

⁴ See <https://townhall.virginia.gov/l/viewmandate.cfm?mandateid=1349>.

⁵ See <https://lis.virginia.gov/cgi-bin/legp604.exe?ses=201&typ=bil&val=ch1088>.

⁶ See <https://townhall.virginia.gov/L/viewmandate.cfm?mandateid=1180>.

⁷ See <https://townhall.virginia.gov/L/viewmandate.cfm?mandateid=1255>.

⁸ See <https://townhall.virginia.gov/L/viewmandate.cfm?mandateid=1249>.

mandate would be implemented through the proposed changes to sections 370 and 1260 for general and outpatient surgical hospitals, respectively.

- Chapters 678 and 679 of the 2022 *Acts of Assembly*, which were identical, require hospitals to make reasonable efforts to screen uninsured patients to determine whether the patient is eligible for medical assistance from the Department of Medical Assistance Services or for financial assistance under the hospital's financial assistance policy.⁹ This mandate would be implemented through the proposed changes to sections 215 and 1178 for general and outpatient surgical hospitals, respectively.
- Chapters 177 and 222 of the 2005 Acts of Assembly, which directed the Board to add minimum design and construction guidelines for hospitals and nursing facilities in the regulations for licensure.¹⁰ The proposed changes in this action would replace references to the Facility Guidelines Institute's (FGI) 2018 *Guidelines for Design and Construction of Hospitals (FGI Guidelines)* with the 2022 edition and update the documents incorporated by reference. This change will only be binding for facility plans that are dated after this regulatory action is effective.

Accordingly, the Board proposes to make a number of changes to the regulation. The most substantive changes are summarized below. The fifteen sections indicated with an asterisk include changes that would implement a legislative mandate.

- Section 130 Return of license. This section would be renamed to "Surrender of license; mid-term change of license." This section specifies that a hospital must notify the director of VDH's Office of Licensure and Certification (OLC) in writing 30 calendar days before changing (i) the hospital's location (including the location of any emergency department not located on the hospital's campus), ownership, operator, or name of the nursing facility; (ii) bed capacity, except as provided in section 110 with respect to disasters and public health emergencies; or (iii) the services provided, regardless of whether licensure is required for that service; and closure of the hospital. The proposed changes to the regulation would add that OLC shall determine if any of the changes listed above affect either the terms of the license

⁹ See <https://townhall.virginia.gov/L/viewmandate.cfm?mandateid=1257>.

¹⁰ See <https://townhall.virginia.gov/l/viewmandate.cfm?mandateid=1359>. This mandate was first implemented in 2005 to add the 2006 *Guidelines for Design and Construction of Hospital and Health Care Facilities* issued by the American Institute of Architects as minimum design standards. These standards are updated every four years and the regulation has been updated accordingly via exempt actions. See also <https://fgiguideines.org/guidelines/editions/>.

or the continuing eligibility for a license, and that an inspector may inspect the hospital during the process of evaluating a proposed change.

The proposed changes would also add stipulations that licenses cannot be transferred or assigned, and that a change in the operator of the hospital requires that a new license be issued. Further, if the hospital facility is closing, it shall notify patients, legal representatives, and the OLC at least seven calendar days prior to closing where all clinical records are to be located following closure or cessation of operations.

- Section 140 Inspection procedure. The proposed changes include adding language about frequency of inspections, which matches the OLC's current practice. The Board also proposes to add more details regarding the inspection process so that facilities know what to expect during an inspection and to create a rebuttable compliance presumption for outpatient surgical hospitals.¹¹
- Section 150 Plan of correction. The proposed changes specify the minimum elements of a plan of correction, and also add a 15-day timeline for the submission of a plan of correction upon receiving an inspection report and a 45-day timeline for submission and completion of a plan of correction. The Board's intent is to standardize the plan of correction process and make it more similar to the federal plan of correction process, so that the same requirements for the documentation and completion of remedial actions are consistently applies across all hospitals.¹²
- Section 160 Revocation of License.* This section would be renamed "Disciplinary action" and expanded to provide a more specific and detailed list of the grounds upon which the VDH commissioner may take disciplinary action against a hospital, the options available to the commissioner for disciplinary action, and how a hospital may obtain a license after suspension or revocation. The proposed changes would also implement the legislative mandates relating to prohibitions on balance billing and discriminating against health insurance enrollees on the basis of the enrollee being a litigant or potential litigant due to a motor vehicle accident.

¹¹ Agency Background Document (ABD), page 24. See https://townhall.virginia.gov/l/GetFile.cfm?File=58\6159\9887\AgencyStatement_VDH_9887_v2.pdf.

¹² ABD, p. 26.

- Section 215 Financial assistance in general hospitals and Section 1178 Financial assistance in outpatient surgical hospitals.* These new sections would describe the minimum requirements for information disclosure about financial assistance, for payment plans, and for renegotiation of payment plans.¹³ Adding these sections would implement Chapters 678 and 679 of the 2022 *Acts of Assembly*.
- Section 225 Newborn safety devices.* This new section would add the safety standards for those hospitals that voluntarily install newborn safety devices, as specified in Chapters 80 and 81 of the 2022 *Acts of Assembly*. The requirements include that the device be located inside the hospital in an area that is conspicuous and visible to employees or personnel, be staffed 24 hours a day by a healthcare provider, is climate controlled and serves as a safe sleep environment for an infant, and identifiable by appropriate signage. However, hospitals are not required to install such a device.¹⁴
- Section 235 Persons with a disability; designated support person in general hospitals and Section 1171 Persons with a disability; designated support persons in outpatient surgical hospitals.* These new sections would add minimum requirements for access to a designated support person at the time of admission to each type of facility respectively. The intention is to clarify what requirements apply outside of a Governor-declared public health emergency due to COVID-19. These changes would implement Chapter 220 of the 2021 *Acts of Assembly*.¹⁵
- Section 370 Medical records and Section 1260 Medical records.* Both sections would be amended to conform with Chapter 218 of the 2022 *Acts of Assembly*, which requires hospitals that choose to make health care records available through a secure website to also make a minor's records available to the patient's parent or guardian through that website.¹⁶
- Section 380 Nursing service and 1190 Nursing staff.* The proposed changes would specify that hospitals' quarterly reports about nursing services are due no later than 30 calendar days after January 1st, April 1st, July 1st, and October 1st, and that the reports include the total number of certified sexual assault nurse examiners employed by the hospital and that the

¹³ ABD, p. 33.

¹⁴ ABD, p. 34 and <https://lis.virginia.gov/cgi-bin/legp604.exe?ses=221&typ=bil&val=ch80>.

¹⁵ ABD, p. 42.

¹⁶ ABD, p. 46.

locations and contact information for each location these services are provided. These changes would implement Chapter 1088 of the 2020 *Acts of Assembly*.

- Section 444. Newborn service medical direction; etc. Update the breast milk storage times to match current Centers for Disease Control and Prevention (CDC) recommendations.¹⁷ The current language requires milk stored under refrigeration to be consumed or disposed of within 24-48 hours of collection. The new language would increase the threshold to within 96 hours of collection.
- Section 465 Long-term care nursing services. This new section would repeat certain requirements found in 12 VAC 5-390 *Regulation for the Licensure of Nursing Facilities*. The intention is to easily ensure that hospitals are aware that these requirements also apply to long-term care service units, which are certified nursing facilities that operate under a general hospital license.¹⁸
- Section 442 Obstetric service design and equipment criteria, Section 445 Newborn service design and equipment criteria, Section 650 General building and physical plant information, Section 760 Long-term care nursing units, and 1350 Local and state codes and standards.* These five sections currently contain references to applicable sections of the 2018 *Guidelines*; the proposed changes would update these references and update the list of documents incorporated by reference to the 2022 *FGI Guidelines*, thereby maintaining compliance with the 2005 legislative mandate described above.

Estimated Benefits and Costs

The primary benefit of the proposed changes would be to improve clarity for hospitals surrounding the requirements to maintain their license, what to expect in an inspection, how to submit and undertake a plan of correction (if necessary), other current requirements, and the provisions of the CDC guidelines. Entities wishing to build new facilities would know to use the updated 2022 *FGI Guidelines* for construction plans. To the extent that these changes improve the quality of service, transparency of hospital policies (especially regarding financial assistance), and patient outcomes, both patients and their families would also benefit from the proposed changes.

¹⁷ See https://www.cdc.gov/breastfeeding/recommendations/handling_breastmilk.htm.

¹⁸ ABD, p. 56-57. These changes were a result of the periodic review.

Hospitals are expected to face some costs to comply with some of the proposed changes. VDH reports that the new reporting requirements for specific nurse staffing would lead to new ongoing recordkeeping costs for all hospitals; however, VDH estimates that these costs are not expected to exceed \$5,000 per year.¹⁹ Hospitals that use secure websites to share health records with patients may incur some costs to provide access to minor patients' parents and guardians; however, these costs are expected to be minimal. The requirements for certified nursing facilities operated under a hospital's license may result in some costs for hospitals that operate such long-term nursing care units if they were not previously aware of those requirements.

Hospitals are also expected to face one-time costs from updating their internal policies and procedures related to designated support persons, certified nursing facilities, parent or guardian electronic access to minor patient's records, discharge planning, financial assistance, and infection control and prevention. VDH estimates that it would cost \$1,250 one-time to amend an existing policy on each topic to conform to the regulatory minimums. If hospitals do not already have policies and procedures on these topics, VDH estimates that hospitals would incur a one-time cost of \$5,000 per topic to develop these policies and procedures. Some hospitals may not incur any costs if the policies and procedures meet or exceed the proposed regulatory minimums.

Other new costs may optionally arise if a hospital meets one of the newly added criteria for reporting a mid-term change of license, or if the facility is closing and must comply with new requirements with respect to informing patients and legal representatives about where medical records will be located.

VDH also reports that as a result of the mandate to comply with the 2022 *FGI Guidelines*, there may be a quantifiable indirect cost equal to a 1.4 percent increase in construction costs for a 160-bed general hospital, a 2.7 percent increase in construction costs for a 12-bed general hospital that is certified as a critical access hospital, and a 0.7 percent to 1.3 percent increase in construction costs for a multi-specialty outpatient surgical hospital.²⁰

¹⁹ ABD, p. 11.

²⁰ See ORM Economic Review Form, page 4:

https://townhall.virginia.gov/l/GetFile.cfm?File=58\6159\9887\ORM_EconomicImpact_VDH_9887_v1.pdf.

Businesses and Other Entities Affected

VDH reports that there are 106 licensed general hospitals and 67 outpatient surgical hospitals, that will all be required to comply with the regulatory changes.²¹ These include public bodies – the VCU Health Systems Authority, Lee County Hospital Authority, and Chesapeake Hospital Authority – which all run licensed hospitals. The remaining facilities are privately owned and operated, often with a single entity operating multiple facilities in multiple locations.

The Code of Virginia requires DPB to assess whether an adverse impact may result from the proposed regulation.²² An adverse impact is indicated if there is any increase in net cost or reduction in net revenue for any entity, even if the benefits exceed the costs for all entities combined. As noted above, the proposed changes would create new costs for licensed general hospitals and outpatient surgical hospitals, even if some of those changes are required by federal and state law and have already been borne by nursing facilities. Thus, an adverse impact is indicated.

Small Businesses²³ Affected:²⁴

The proposed amendments appear to adversely affect some small businesses.

²¹ On a call with DPB, VDH noted that The University of Virginia Hospital, hospitals administered by Veterans Affairs, and psychiatric hospitals licensed by the Department of Behavioral Health and Developmental Services were all exempt from licensure by VDH. Accordingly, the requirements of this regulation would not apply to them.

²² Pursuant to Code § 2.2-4007.04(D): In the event this economic impact analysis reveals that the proposed regulation would have an adverse economic impact on businesses or would impose a significant adverse economic impact on a locality, business, or entity particularly affected, the Department of Planning and Budget shall advise the Joint Commission on Administrative Rules, the House Committee on Appropriations, and the Senate Committee on Finance. Statute does not define “adverse impact,” state whether only Virginia entities should be considered, nor indicate whether an adverse impact results from regulatory requirements mandated by legislation.

²³ Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as “a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.”

²⁴ If the proposed regulatory action may have an adverse effect on small businesses, Code § 2.2-4007.04 requires that such economic impact analyses include: (1) an identification and estimate of the number of small businesses subject to the proposed regulation, (2) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the proposed regulation, including the type of professional skills necessary for preparing required reports and other documents, (3) a statement of the probable effect of the proposed regulation on affected small businesses, and (4) a description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation. Additionally, pursuant to Code § 2.2-4007.1, if there is a finding that a proposed regulation may have an adverse impact on small business, the Joint Commission on Administrative Rules shall be notified.

Types and Estimated Number of Small Businesses Affected

VDH estimates that three of the outpatient surgical hospitals may meet the definition of “small business.”²⁵

Costs and Other Effects

Small businesses would face the same costs described above. Specifically, they would incur costs arising from the new recordkeeping and reporting requirements for certain nursing staff. They may also incur costs associated with updating existing policies or developing new policies as needed. Thus, an adverse impact is indicated for small businesses.

Alternative Method that Minimizes Adverse Impact

Because the proposed changes reflect statutory requirements, there are no clear alternative methods that both reduce adverse impact and meet the intended policy goals.

Localities²⁶ Affected²⁷

The proposed amendments do not introduce direct costs for local governments. Lee County Hospital Authority and Chesapeake Hospital Authority operate hospitals. Consequently, to the extent that local funding is provided for these Authorities, an adverse economic impact is indicated for Lee County and the City of Chesapeake.

Projected Impact on Employment

The proposed amendments are unlikely to impact the number of general hospitals and outpatient surgical facilities that obtain and remain licensed and the staffing in those facilities. Thus, the proposed amendments are not projected to significantly impact employment.

Effects on the Use and Value of Private Property

The proposed amendments raise costs for general hospitals and outpatient surgical facilities, which would reduce their value. The proposed amendments do not affect real estate development costs in general but would result in a small increase in construction costs for new facilities based on changes contained in the updated 2022 *FGI Guidelines*.

²⁵ ABD, p.10.

²⁶ “Locality” can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulatory change are most likely to occur.

²⁷ § 2.2-4007.04 defines “particularly affected” as bearing disproportionate material impact.