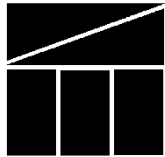


Adverse impact notification sent to Joint Commission on Administrative Rules, House Committee on Appropriations, and Senate Committee on Finance (COV § 2.2-4007.04.C): Yes Not Needed

If/when this economic impact analysis (EIA) is published in the *Virginia Register of Regulations*, notification will be sent to each member of the General Assembly (COV § 2.2-4007.04.B).



Virginia Department of Planning and Budget Economic Impact Analysis

12 VAC 5-230 State Medical Facilities Plan
Virginia Department of Health
Town Hall Action/Stage: 4245/7951
October 12, 2017

Summary of the Proposed Amendments to Regulation

The State Board of Health (Board) proposes to 1) make a distinction between simple and complex cardiac catheterization procedures, 2) no longer require hospitals to have open heart surgery services on premises as a condition to perform diagnostic and simple cardiac catheterization procedures, provided they follow certain guidelines, 3) assign greater value of diagnostic equivalent procedures for complex and pediatric cardiac catheterization procedures relative to simple ones, 4) lower the statistical threshold occupancy rates used in determining the need for additional nursing home beds, and 5) add and revise certain statistical threshold values to improve measurement accuracy.

Result of Analysis

The benefits likely exceed the costs for all proposed changes.

Estimated Economic Impact

Currently, all therapeutic cardiac catheterization procedures are considered the same in the regulation. The board proposes new definitions for simple (relieving coronary artery narrowing) and complex (correcting congenital or acquired structural valvular abnormalities) cardiac catheterization procedures to reflect current industry practices.

The board also proposes to no longer require, subject to a number of conditions, hospitals to have open heart surgery services on-site to perform simple procedures. Currently, only diagnostic and emergency therapeutic cardiac catheterization procedures can be performed without open heart surgery services back-up. According to the Virginia Department of Health (VDH), there are 29 hospitals with cardiac catheterization laboratories that do not have on-site open heart surgery services, but may start performing elective simple therapeutic procedures under the proposed regulation provided they adhere to certain guidelines. This change would benefit those affected hospitals in that they would be allowed to offer these procedures if they wish. This change will likely also improve access to these services as most of the hospitals without on-site heart surgery services tend to be in rural areas.

VDH believes that the risks of taking the time to transfer the patient with a simple cardiac issue to a hospital with an open heart surgery back-up outweigh the risks of getting the procedure done sooner at a hospital without one. Thus, outcomes are expected to be better if patients get simple therapeutic procedures without being transferred. In addition, elective simple procedures can be performed without open heart surgery back-up only if certain conditions are met. Those conditions are set by the American Heart Association/American Stroke Association's Percutaneous Coronary Intervention without Surgical Back-up Policy Guidance. This policy guidance includes ten requirements to improve the chances of a favorable outcome when simple elective procedures are performed without an open heart surgery back-up.

The Board further proposes to give greater relative value to complex and pediatric diagnostic equivalent procedures (DEP). DEP is a measure of the relative complexity of various cardiac catheterization procedures. Currently, a diagnostic procedure equals 1 DEP, a cardiac procedure (simple or complex) equals 2 DEPs, and a same session procedure (diagnostic and simple or complex procedure) equals 3 DEPs. Under the proposed regulation, diagnostic procedure will stay at 1 DEP, a simple therapeutic procedure will equal 2 DEPs, a same session diagnostic and simple therapeutic procedure will equal 3 DEPs, and a complex therapeutic procedure will equal 5 DEPs. If any of the procedures is for a pediatric patient, it will equal twice as many DEPs (i.e. a pediatric diagnostic procedure will equal 2 DEPs, a simple therapeutic pediatric procedure will equal 4 DEPs, a same session pediatric diagnostic and simple therapeutic procedure will equal 6 DEPs, and a pediatric complex therapeutic procedure will

equal 10 DEPs). According to VDH, pediatric procedures frequently require continuous anesthesia services and therefore tend to be complex.

The proposed greater DEP values for complex therapeutic and pediatric procedures will make it easier to demonstrate the need for expansion (12VAC5-230-390) or the need for new (12VAC5-230-400) cardiac catheterization services and the need for new (12VAC5-230-450) open heart surgery services because DEP thresholds for new or expansion of services are not changing. For example, if currently 500 diagnostics (500 DEPs), 200 simple (400 DEPs), and 100 complex (200 DEPs) procedures are performed on average per facility in a planning district, the average facility will have a total of 1,100 DEPs and no facility would qualify an expansion of services under 12VAC5-230-390 because on average there will be less than 1,200 cardiac catheterization DEPs per facility. However, under the proposed regulation, the same district will have an average of 1,400 DEPs (500 DEPs+400 DEPs+500 DEPs) per hospital and will satisfy that criteria for expansion. This proposed change will make it easier to demonstrate the need for additional cardiac catheterization and open heart surgery services. Ease of demonstration may reduce a barrier to entry into the catheterization and open heart surgery industry and promote competition. However, VDH notes that the expected impact may be limited because the majority of procedures are diagnostic and simple therapeutic.

Moreover, the Board proposes to lower the statistical threshold occupancy rate used in determining the need for additional Medicaid certified nursing home bed capacity. Currently, a health planning district must have at least 93% average annual occupancy rate to demonstrate the need for new or expansion of existing number of beds. The Board proposes to reduce the average annual occupancy rate to 90%. According to VDH, the Centers for Medicare and Medicaid Services now pay for Medicare short-stay rehabilitation patients in nursing facilities, which has caused facilities to reserve beds for those patients and served to help reduce the average length of stays and occupancy levels. The proposed change is expected to offset that reduction and provide a more accurate assessment of the need for additional nursing facility beds in each planning district. A lower statistical threshold to demonstrate the need for additional bed capacity than the current threshold should somewhat help ease a potential barrier to entry and promote competition in the nursing home industry.

Finally, the Board proposes to add and revise certain statistical threshold values to improve measurement accuracy. For example, the Board proposes to require in the case of determining the need for new beds, that the median annual occupancy rate in the district be at least 93% in addition to meeting the revised 90% average annual occupancy rate. Using median and average occupancy rates together is expected to better assess the need for new beds in the district given the statistical characteristics of this particular data set. Similarly, the Board proposes to include in the sample occupancy data from which the occupancy rates are calculated facilities that have been in operation at least one year as opposed to at least three years as currently required. VDH reports that a facility reaches its full capacity within a year and the current requirement does not allow useful data from the second and third years to be used in calculating bed need in the district.

Businesses and Entities Affected

The proposed changes apply to 105 hospitals that are either currently providing or may seek to provide cardiac catheterization services. Of these, there are 29 hospitals with cardiac catheterization laboratories that do not have on-site open heart surgery services but may start performing elective simple therapeutic procedures under the proposed regulation provided they adhere to certain guidelines.

Also, the proposed regulation applies to the 284 existing nursing homes in Virginia. The number of potential nursing home applicants for the development of nursing homes in Virginia is not known.

Localities Particularly Affected

The proposed changes do not affect a particular locality more than others.

Projected Impact on Employment

The proposed regulation would allow 29 hospitals that do not have on-site open heart surgery services to start performing elective simple therapeutic procedures. This change may shift some of the elective simple therapeutic procedures being performed at hospitals with open heart surgery back-up to hospitals without such a back-up, and accordingly shift demand for labor involved in performing such procedures among the hospitals.

The proposed greater DEP values for more complex and pediatric procedures would make it easier to demonstrate the need for such services and reduce a potential barrier to entry

into cardiac catheterization and open heart surgery services. Similarly, a lower statistical threshold to demonstrate the need for additional bed capacity should somewhat help ease a potential barrier to entry. A reduction in barriers to entry may lead to additional employment in those areas.

Effects on the Use and Value of Private Property

The shift of elective simple therapeutic procedures from hospitals that have open heart surgery back-up to hospitals without may affect their asset values accordingly.

Real Estate Development Costs

No impact on real estate development costs is expected.

Small Businesses:

Definition

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.”

Costs and Other Effects

Only one nursing home is considered a small business. The costs and other effects on that nursing home are the same as those discussed above.

Alternative Method that Minimizes Adverse Impact

No direct adverse impact on small businesses is expected.

Adverse Impacts:

Businesses:

The indirect adverse impact on hospitals that have open heart back-up services are the same as those discussed above.

Localities:

The proposed amendments will not adversely affect localities.

Other Entities:

The proposed amendments will not adversely affect other entities.

Legal Mandates

General: The Department of Planning and Budget 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 Number 17 (2014). Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the report 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.

Adverse impacts: Pursuant to Code § 2.2-4007.04(C): 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 within the 45-day period.

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.