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 5-412 Regulations for Licensure of Abortion Facilities
Department of Health
Town Hall Action/Stage: 4295/7333
January 13, 2016

Summary of the Proposed Amendments to Regulation

In this action, the State Board of Health (Board) proposes to: 1) exempt existing abortion facilities from meeting the Facilities Guidelines Institute (FGI) Guidelines requirements, unless they build an addition or have a major renovation, 2) require that new buildings, additions, and major renovations meet the 2014 FGI Guidelines requirements (rather than the 2010 FGI Guidelines requirements), 3) specify that abortion facilities that perform only medication induced abortions meet general building requirements (instead of the special building requirements for office-based procedures and operating rooms), 4) amend requirements for when villi or fetal parts cannot be identified with certainty in the tissue removed in the abortion, 5) no longer require that abortion facilities have a written agreement with a licensed general hospital regarding emergency treatment as this requirement is duplicative of federal law and unnecessary, 6) no longer require abortion facilities to develop, implement, and maintain policies and procedures for the screening of sexually transmitted diseases as this service is not a part of abortion procedures, and 7) amend other language to be consistent with the Code or to make the regulation more clear.

Estimated Economic Impact

Exempting Existing Facilities

The current regulation requires that abortion facilities, both existing and newly constructed, comply with state and local codes, zoning, and building ordinances, the Virginia Uniform Statewide Building Code, and specified sections of the 2010 *Guidelines for Design and Construction of Health Care Facilities* of the Facilities Guidelines Institute. In practice, 12 of the 16 abortion facilities operating in the Commonwealth have been licensed with variances from meeting the FGI *Guidelines* requirement. For the majority of facilities, complying with the requirement would have cost hundreds of thousands of dollars.

The Board proposes to amend the requirement to apply to "construction of new buildings and additions, or major renovations to existing buildings for occupancy as an abortion facility that perform only surgical abortions or a combination of surgical and medication induced abortions." The amended language would exempt existing facilities from the requirement, unless an addition or major renovation is built. Abortion facilities would no longer need to apply for variances with this change. According to the Department of Health, applying for a variance merely consists of asking for a variance in writing (can be one paragraph or one sentence) when applying for the yearly license renewal. So no longer needing to apply for a variance saves only a negligible amount of time and effort for facilities. On the other hand, the proposal to exempt existing facilities from the requirement will likely reduce uncertainty for these facilities since the possibility of having to meet the *Guidelines* requirement for their existing buildings (without an addition or major renovation) due to the possibility of their variance application disapproved will no longer apply.

2014 vs 2010 FGI Guidelines

The Board proposes to require that new buildings, additions, and major renovations meet the 2014 FGI *Guidelines*[1] requirements rather than the 2010 FGI *Guidelines* requirements. The Facility Guidelines Institute published a study[2] that estimates the change in costs of applying the 2014 *Guidelines* rather than the 2010 *Guidelines* for hospitals and outpatient facilities. The study

[1] The applicable 2014 edition is called *Guidelines for Design and Construction of Hospitals and Outpatient Facilities*.

[2] Gormley T, Garland J, Jones W. "Estimated Cost of Applying the 2014 vs. the 2010 FGI Guidelines for Design and Construction Requirements to Hospitals and Outpatient Facilities."

breaks up hospitals and outpatient facilities into five facility types, and lists the estimated percentage cost increases for each category, as well as other across-the-board changes that would reduce costs. Based upon the study's cost estimate for the category that best fits abortion facilities and other factors that likely reduce the estimated costs for abortion facilities,[3] the proposal to require that new buildings, additions, and major renovations meet the 2014 FGI Guidelines requirements rather than the 2010 FGI Guidelines requirements would on average increase net cost by less than two percent. The Board and the architects and engineers associated with the Facility Guidelines Institute believe that adopting the 2014 edition will increase patient and staff health and safety. Thus, the proposed amendment will likely produce a net benefit.

Surgical vs Medication Induced

The Board proposes to specify that abortion facilities that perform only medication induced abortions need not be designed and constructed or renovated with the full requirements for office-based procedures and operating rooms, but instead need only meet general building requirements. The Board also proposes to add the following definition: "'Medication induced abortion' means any abortion caused solely by the administration of any medication or medications given to a woman in the first trimester of pregnancy with the intent to produce abortion." There is one current facility that falls into this category. If this facility were to undertake a major renovation or build an addition, this proposed change would potentially save the owners hundreds of thousands of dollars in construction costs. The proposed amendment would also produce commensurate savings for the construction of new facilities that perform only medication induced abortions, but no surgical abortions.

When Villi or Fetal Parts Cannot Be Identified

Under both the current regulation and the proposed regulation, all tissues removed resulting from the abortion procedure must be examined to verify that villi or fetal parts are present. Under the current regulation, if villi or fetal parts cannot be identified with certainty, the tissue specimen must be sent for further pathologic examination and the patient alerted to the

[3] The facility type that best fits abortion facilities includes dialysis centers. One of the items listed as contributing to cost increases in this category is a new requirement for a soiled workroom in renal dialysis centers. Since this does not apply to abortion facilities, the listed estimate of a 2.68% cost increase for the category is likely too high for abortion facilities. Combined with the across-the-board changes and a Board proposal to exempt abortion facilities from a FGI *Guideline* procedure room size requirement, the likely average net cost change for abortion facilities is less than 2%.

possibility of an ectopic pregnancy. The Board proposes to instead require that when villi or fetal parts cannot be identified with certainty, the patient be notified that pregnancy tissue was not identified and the possibility of ectopic pregnancy be explained to the patient. In such cases, the patient is to be offered a pathologic examination of the tissue including a disclosure of the cost; and should the patient desire, the tissue specimen would be sent for further pathologic examination. In essence, the proposed language enables the patient to make an informed decision whether or not to order a pathologic examination of the tissue, and to incur its associated cost. The proposed amendment likely produces a net benefit since it allows the patient to make an informed decision, rather than requiring that a potentially unwanted test be conducted.

Emergency Services and Screening for Sexually Transmitted Diseases

The current regulation requires that "A written agreement shall be executed with a licensed general hospital to ensure that any patient of the abortion facility shall receive needed emergency treatment." The Board determined that a written agreement is not necessary to ensure that any patient of the abortion facility shall receive needed emergency treatment due to the federal Emergency Medical Treatment and Labor Act. According to the Department of Health, all facilities have thus far been able to obtain such written agreements. Thus this proposed amendment will not significantly affect existing abortion facilities. The proposed amendment would save the time involved for obtaining such agreements for any potential future facilities.

The current regulation requires that "The abortion facility shall develop, implement, and maintain policies and procedures for screening of sexually transmitted diseases consistent with current guidelines issued by the U.S. Centers for Disease Control and Prevention." Pursuant to the recommendation of the Board's physician's regulatory advisory panel, the Board proposes to eliminate this provision as it is unrelated to abortion procedures. The Department of Health has accepted a statement indicating that the facility does not have such procedures as fulfilling the requirement.[4] Thus to the extent that abortion facilities have been aware of this, the proposed amendment would not have a large impact.

[4] Source: Virginia Department of Health

Businesses and Entities Affected

The proposed amendments pertain to the 16 licensed abortion facilities within the Commonwealth, as well as any potential future abortion facilities. Six of the facilities qualify as small businesses.[5]

Localities Particularly Affected

The 16 abortion facilities operating in the Commonwealth are located in the following localities: Alexandria (2), Blacksburg (1), Charlottesville (2), Fairfax (1), Falls Church (1), Henrico (1), Newport News (1), Norfolk (1), Richmond (2), Roanoke (2), and Virginia Beach (2).[6]

Projected Impact on Employment

The proposed amendments will likely not significantly affect total employment.

Effects on the Use and Value of Private Property

Due to significant reduction in associated cost, the proposal to specify that abortion facilities that perform only medication induced abortions need not be designed and constructed or renovated with the full requirements for office-based procedures and operating rooms, may increase the likelihood that such facilities are renovated or constructed.

Real Estate Development Costs

The proposal to require that new buildings, additions, and major renovations meet the 2014 FGI *Guidelines* requirements rather than the 2010 FGI *Guidelines* requirements would on average increase net cost for the construction of new buildings, additions, and major renovations of surgical abortion facilities by less than two percent.

The proposal to specify that abortion facilities that perform only medication induced abortions need not be designed and constructed or renovated with the full requirements for office-based procedures and operating rooms would potentially save the owners hundreds of thousands of dollars in construction costs.

[5] Data source: Virginia Department of Health
[6] Ibid

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

The proposal to require that new buildings, additions, and major renovations meet the 2014 FGI *Guidelines* requirements rather than the 2010 FGI *Guidelines* requirements would on average moderately increase net costs for small surgical abortion facilities that undergo such construction projects.

The proposal to specify that abortion facilities that perform only medication induced abortions need not be designed and constructed or renovated with the full requirements for office-based procedures and operating rooms, but instead need only meet general building requirements, would reduce costs for small facilities that perform only medication induced abortions and undergo building construction.

The proposals to no longer require that abortion facilities: a) have a written agreement with a licensed general hospital to ensure that any patient of the abortion facility shall receive needed emergency treatment, and b) develop, implement, and maintain policies and procedures for screening of sexually transmitted diseases, will moderately reduce costs for small abortion facilities.

Alternative Method that Minimizes Adverse Impact

The proposal to require that new buildings, additions, and major renovations meet the 2014 FGI Guidelines requirements rather than the 2010 FGI Guidelines requirements will moderately increase costs in net for small abortion facilities that undergo such projects. Not amending the regulation to include the 2014 edition requirements would eliminate the moderate net cost increase, but would also eliminate the likely increase in potential patient and staff health and safety.

Adverse Impacts:

Businesses:

The proposal to require that new buildings, additions, and major renovations meet the 2014 FGI Guidelines requirements rather than the 2010 FGI Guidelines requirements would on average moderately increase net costs for surgical abortion facilities that undergo such construction projects.

Localities:

The proposed amendments are unlikely to adversely affect localities.

Other Entities:

The proposed amendments are unlikely to 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.

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