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

18 VAC 30-20 Regulations of the Board of Audiology and Speech-Language Pathology
Department of Health Professions
Town Hall Action/Stage: 4257/7268
August 25, 2015

Summary of the Proposed Amendments to Regulation

The proposed regulation provides a regulatory framework for practice in cerumen management which was not recognized in Virginia as being within the scope of practice of an audiologist before 2014.

Result of Analysis

The benefits likely exceed the costs for all proposed changes.

Estimated Economic Impact

Prior to 2014, Virginia law and regulations did not address cerumen (commonly known as ear wax) management within the scope of practice of an audiologist though various forms of it were practiced by some audiologists to various extents. Cerumen management involves identification and removal of cerumen from the ear canal. According to the Board of Audiology and Speech-Language Pathology (Board), if an audiologist does not have the clinical knowledge and skills or if he attempts to perform cerumen management on a patient beyond his or her scope of practice or in spite of contraindications, he or she can do serious damage to a patient's ear.

In order to address potential health and safety concerns, Chapter 327 of the 2014 Acts of the Assembly (HB500) added "limited cerumen management" to the scope of audiology practice and directed the Board to establish criteria for its practice. Pursuant to the legislative mandate,

the Board promulgated emergency regulations which became effective on December 29, 2014. The proposed regulation will replace the emergency regulation permanently.

With this action, the Board proposes to define "limited cerumen management" as the identification and removal of cerumen from the cartilaginous outer one-third portion of the external auditory canal. The Board also proposes to allow the practice of limited cerumen management by only those audiologists i) who are a graduate of an accredited doctoral program in audiology that included didactic education and supervised clinical experience in cerumen management, or ii) who completed an approved course or workshop in cerumen management. Furthermore, the Board sets out the contraindications to identify cases when the procedure shall not be performed, but the patient be referred to a physician; requires audiologists to obtain written consent of the patient or legally responsible adult; and maintain documentation. The proposed rules do not require audiologists to submit evidence of training and education, or consent documents to the Board, but instead require the evidence be available when and if the Department of Health Professions investigates a complaint.

The proposed training and education could occur within a practice under direct supervision. Training courses are also being developed by the state and national professional associations specifically for cerumen management. Parts of the training may be done online, but certain parts of the training must be done in-person with an audiologist who is already qualified or with a physician. The cost of the training and education may vary. The Speech-Language Hearing Association of Virginia is currently offering a one-day training in September 2015 at a cost of $230 for members and $300 for non-members. However, since the proposed regulation applies only if an audiologist wishes to perform limited cerumen management and if an audiologist chooses to obtain education and training to perform it, we can reliably infer that the anticipated benefits likely exceed compliance costs to him or her in terms of time, travel, and training fees.

Other benefits of the proposed regulation include: explicitly allowing qualified audiologists to perform cerumen management on a limited basis and possibly avoiding an extra visit to a physician's office for limited cerumen management, establishing what the allowed scope of cerumen management by an audiologist is, establishing under what circumstances it

may or may not be performed, and consequently providing a greater degree of patient health and safety compared to its practice without any standards.

While the proposed regulation is expected to be beneficial, the magnitude of benefits may be relatively small. As mentioned above, prior to 2014, various forms of cerumen management had been performed by some audiologist to various extents. The Board is unaware of any complaints or investigations related to practice of cerumen management when there was no regulatory framework on cerumen management by audiologists.

Businesses and Entities Affected

The proposed rules affect audiologists who want to include limited cerumen management in their practice. Currently, there are 517 licensed audiologists in Virginia, but the Board does not know how many of them are currently practicing cerumen management and how many may choose to perform this procedure in the future.

Localities Particularly Affected

The proposed changes apply throughout the Commonwealth.

Projected Impact on Employment

The proposed amendments are unlikely to affect employment.

Effects on the Use and Value of Private Property

The proposed rules are not anticipated to affect the use and value of private property.

Real Estate Development Costs

The proposed amendments are unlikely to affect real estate development costs.

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 proposed rules introduce compliance costs to audiologists in terms of time, travel, and course fees to obtain training and education only if the audiologist does not

have the appropriate training and education and he or she chooses to perform limited cerumen management and he or she would have performed it without obtaining the appropriate training and education if there were no regulations. However, it is highly unlikely that an audiologist would have performed a procedure that he or she is not trained and educated in for liability reasons. Thus, the compliance costs are likely negligible.

Alternative Method that Minimizes Adverse Impact

The adverse impact on audiologists is likely negligible as discussed above.

Adverse Impacts:

Businesses:

The proposed regulation is not anticipated to adversely impact non-small businesses.

Localities:

The proposed amendments will not adversely affect localities.

Other Entities:

No other entities are anticipated to be adversely affected.

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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