Virginia Regulatory Town Hall

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Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Board of Audiology & Speech-Language Pathology; Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC30-20-10 et seq.
Regulation title	Regulations Governing the Practice of Audiology & Speech-Language Pathology
Action title	Regulations pertaining to limited cerumen management by audiologists
Date this document prepared	9/25/14

This form is used when an agency wishes to promulgate an emergency regulation (to be effective for up to one year), as well as publish a Notice of Intended Regulatory Action (NOIRA) to begin the process of promulgating a permanent replacement regulation.

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Preamble

The APA (Code of Virginia § 2.2-4011) states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of subdivision A. 4. of § 2.2-4006.

1) Please explain why this is an emergency situation as described above.
2) Summarize the key provisions of the new regulation or substantive changes to an existing regulation.

Section 2.2-4011 of the Code of Virginia states that agencies may adopt emergency regulations in situations in which Virginia statutory law requires that a regulation be effective in 280 days or

less from its enactment. Chapter 327 of the 2014 Acts of the Assembly (HB500) included such an enactment; the bill was signed by the Governor on 3/27/14.

The key provisions of the amended regulations are: 1) a definition of "limited cerumen management;" 2) qualifications and specific training necessary for an audiologist to perform cerumen management; 3) contraindications for such a practice by an audiologist; and 4) requirements for informed consent, documentation, and referral.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

18VAC30-20-10 et seq. Regulations Governing the Practice of Audiology & Speech-Language Pathology are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400 (6) provides the Board of Audiology & Speech-Language Pathology the authority to promulgate regulations to administer the regulatory system:

> ***§ 54.1-2400 -General powers and duties of health regulatory boards***
> *The general powers and duties of health regulatory boards shall be:*
> *...*
> *6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title. ...*

Authority for the Board to adopt regulations for limited cerumen management in the practice of audiology is found in the amendment to § 54.1-2600 and the 2nd enactment in Chapter 327 of the 2014 Acts of the Assembly:

§ 54.1-2600. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Audiologist" means any person who engages in the practice of audiology.

"Board" means the Board of Audiology and Speech-Language Pathology.

"Practice of audiology" means the practice of conducting measurement, testing and evaluation relating to hearing and vestibular systems, including audiologic and electrophysiological measures, and conducting programs of identification, hearing conservation, habilitation, and rehabilitation for the purpose of identifying disorders of the hearing and vestibular systems and

modifying communicative disorders related to hearing loss, including but not limited to vestibular evaluation, *limited cerumen management,* electrophysiological audiometry and cochlear implants. Any person offering services to the public under any descriptive name or title which would indicate that audiology services are being offered shall be deemed to be practicing audiology.

"Practice of speech-language pathology" means the practice of facilitating development and maintenance of human communication through programs of screening, identifying, assessing and interpreting, diagnosing, habilitating and rehabilitating speech-language disorders, including but not limited to:

1. Providing alternative communication systems and instruction and training in the use thereof;

2. Providing aural habilitation, rehabilitation and counseling services to hearing-impaired individuals and their families;

3. Enhancing speech-language proficiency and communication effectiveness; and

4. Providing audiologic screening.

Any person offering services to the public under any descriptive name or title which would indicate that professional speech-language pathology services are being offered shall be deemed to be practicing speech-language pathology.

"Speech-language disorders" means disorders in fluency, speech articulation, voice, receptive and expressive language (syntax, morphology, semantics, pragmatics), swallowing disorders, and cognitive communication functioning.

"Speech-language pathologist" means any person who engages in the practice of speech-language pathology.

2. That the Board of Audiology and Speech-Language Pathology shall promulgate regulations governing cerumen management by audiologists, which shall include requirements related to training and qualifications of audiologists who perform cerumen management, to implement the provisions of this act to be effective within 280 days of its enactment.

Section 2.2-4011 of the Code of Virginia states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of subdivision A. 4. of § 2.2-4006.

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

Since cerumen management is a more advanced skill in the practice of audiology, requiring additional knowledge and training, regulations specify the education and specific training necessary to perform it on patients. Additionally, audiologists must know the contraindications for performance by an audiologist and the conditions which require referral to a medical doctor. The goal of the amended regulation is to provide a framework for safe practice in an advanced procedure that, before 2014, was not recognized in Virginia as being within the scope of practice of an audiologist. By the change in law and regulation, the practice is expanded to include limited cerumen management, but the qualifications for such practice and the limitations of practice by an audiologist are essential to protect patients.

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

If an audiologist does not have the clinical knowledge and skills or if he attempts to perform cerumen management on a patient beyond his scope of practice or in spite of contraindications, he can do serious damage to a patient's ear. If an audiologist is adequately trained and practices according to the standard of care and the Board's regulation, the public's health and safety should be protected.

Substance

Please detail any changes that will be proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, and likely impact of proposed requirements
10	n/a	Sets out definitions for words and terms used in the chapter	Adds a definition for: "Limited cerumen management" as the identification and removal of cerumen from the cartilaginous outer one-third portion of the external auditory canal in accordance with minimum standards and procedures set forth in this chapter. *Definition adopted is consistent with ASHA position and language in other states.*
n/a	241	n/a	Subsection A sets out the basic educational qualification for performance of cerumen management to include: 1) Be a graduate of a doctoral program in audiology accredited by the Council on Academic Accreditation of the American Speech-Language-Hearing Association

			which included didactic education and supervised clinical experience in cerumen management as specified in subsection B of this section; or 2) Complete a course or workshop in cerumen management which provides training as specified in subsection B of this section and which is approved by the American Speech-Language Hearing Association (ASHA) or the American Academy of Audiology (AAA). *Audiologists who were educated prior to the adoption of a doctoral (AuD or PhD) program in audiology would not have been taught the basic education and skills for performance of cerumen management. While those skills are currently included in some doctoral programs, other schools award a doctoral degree but do not include cerumen management in their curriculum. Therefore, graduates without specific course work can still qualify by completion of a course or workshop approved by ASHA or AAA if it covers the knowledge and competencies outlined in subsection B of this section.* Subsection B sets out the training an audiologist must satisfactorily complete to perform cerumen management and specifies that documentation of such training must be maintained. The elements of satisfactory training include: 1. Recognizing the presence of pre-existing contraindications that necessitate referral to a physician; 2. Recognizing patient distress and appropriate action to take if complications are encountered; 3. Use of infection control precautions; 4. Procedures for removal of cerumen, including cerumen loop, gentle water irrigation, suction and the use of material for softening; 5. Observation of each type of cerumen management procedure performed by a qualified audiologist or physician; and 6. Successful performance, under direct supervision by an audiologist qualified to perform cerumen management or a physician, of each type of cerumen management procedure. *Training and education required for safe practice was adopted from the ASHA position paper and other states, such as Maryland, New Jersey and Michigan, which have similar regulatory provisions.* Subsection C states a prohibition on performance of cerumen management by an audiologist on a patient who is younger than 12 years of age or on a patient who has any of the following pre-existing contraindications: 1. Hearing in only one ear; 2. A perforated tympanic membrane; 3. Inflammation, tenderness, or open wounds or traces of

			blood in the external ear canal; 4. Drainage from the external ear canal or middle ear; 5. Current tympanostomy tubes; 6. History of ear surgery, excluding past tympanostomy tubes or simple tympanoplasty; 7. Diabetes mellitus, HIV infection or bleeding disorders; 8. Actual or suspected foreign body in the ear; 9. Stenosis or bony exostosis of the ear canal; 10. Cerumen impaction that totally occludes the ear canal; or 11. Inability to see at least 25% of the tympanic membrane. *The contraindications were also taken from similar regulations in other states and from the professional position paper. Additionally, the otolaryngologist and the audiologist, who served on the Regulatory Advisory Panel and who are trained in cerumen management, were instrumental in understanding which patients with certain conditions should not be managed by an audiologist.* Subsection D provides that an audiologist performing cerumen management shall obtain informed written consent of the patient or legally responsible adult and maintain documentation of such consent and the procedure performed in the patient record. It also specifies that the audiologist shall refer patients to a physician if they exhibit contraindications or experience any complication, such as dizziness, during the procedure. *Requirements for written informed consent, documentation and referral are essential to protect patient health and safety. They also protect the audiologist if it is necessary to document that he worked within his scope of practice and secured appropriate consent for the procedure.*

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

In order to utilize the expertise needed to develop regulations for limited cerumen management, the President of the Board convened a Regulatory Advisory Panel or Ad Hoc Committee on cerumen management by audiologists. The Committee was chaired by A. Tucker Gleason, Ph.D., CCC-A, Board Member; other members included Lillian Beasley Beahm, Au.D., CCC-A, Board Member; Wayne Shaia, M.D., Virginia Society of Otolaryngology (VSO); Ayasakanta Rout,

Ph.D., James Madison University, and Marty Lenhardt, Au.D., representing the Speech-Language-Hearing Association of Virginia (SHAV). At its meeting on July 22, 2014, the Committee reviewed the legislative mandate (HB500), regulations from other states, recommendations from SHAV and the Position Statement on External Auditory Canal Examination and Cerumen Management from the American Speech-Language-Hearing Association (ASHA).

Regulations for education and training, contraindications for management by an audiologist and performance of the practice were unanimously recommended to the full Board for adoption at its meeting in September. Any comment on the subsequent Notice of Intended Regulatory Action will be considered when the Board adopts proposed amendments to replace the emergency regulations.

Public participation

Please indicate the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public meeting is to be held to receive comments on this notice.

Please also indicate, pursuant to your Public Participation Guidelines, whether a Regulatory Advisory Panel or a Negotiated Rulemaking Panel has been used in the development of the emergency regulation and whether it will also be used in the development of the permanent regulation.

The agency is seeking comments on the regulation that will permanently replace this emergency regulation, including but not limited to 1) ideas to be considered in the development of the permanent replacement regulation, 2) the costs and benefits of the alternatives stated in this background document or other alternatives, and 3) the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) the probable effect of the regulation on affected small businesses, and 3) the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**), or by mail, email, or fax to Elaine Yeatts, Agency Regulatory Coordinator, Department of Health Professions, 9960 Mayland Drive, Henrico, VA 23233; elaine.yeatts@dhp.virginia.gov; 804-527-4434. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (**http://www.townhall.virginia.gov**) and on the Commonwealth Calendar website

(http://www.virginia.gov/cmsportal3/cgi-bin/calendar.cgi). Both oral and written comments may be submitted at that time.

Family impact

Assess the potential impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

There is no impact on the family.