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Final Regulation
Agency Background Document

Agency name	Board of Audiology & Speech-Language Pathology; Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC30-20-10 et seq.
Regulation title(s)	Regulations Governing the Practice of Audiology & Speech-Language Pathology
Action title	Regulations pertaining to limited cerumen management by audiologists
Date this document prepared	2/24/16

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The key provisions of the proposed 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. Final regulations are intended to replace emergency regulations that became effective on December 29, 2014, pursuant to Chapter 327 of the 2014 Acts of the Assembly (HB500) and that expire of June 28, 2016.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

N/A

Statement of final agency action

Please provide a statement of the final action taken by the agency including:1) the date the action was taken;2) the name of the agency taking the action; and 3) the title of the regulation.

On February 18, 2016, the Board of Audiology and Speech-Language Pathology amended Regulations Governing the Practice of Audiology and Speech-Language Pathology.

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.

Enactment for Chapter 327 of the 2014 Acts of the Assembly:

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.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

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.

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 briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both.

Section 10 is amended to include 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.
Subsection A of section 241 sets out the basic educational qualification for performance of cerumen management to include: 1) Be a graduate of a doctoral program in audiology that is accredited by the Council on Academic Accreditation of the American Speech-Language-Hearing Association or other accrediting body recognized by the board and that 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). Subsection B of section 241 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.

Subsection C of section 241 sets out the contraindications for performance of cerumen management to include:

1. A perforated tympanic membrane;
2. Inflammation, tenderness, drainage, or open wounds or traces of blood in the external ear canal;
3. History of ear surgery that results in distortion of the external ear canal;
4. HIV infection or bleeding disorders;
5. Actual or suspected foreign body in the ear, excluding hearing aid components that are located in the lateral one-third portion of the ear canal;
6. Stenosis or bony exostosis of the ear canal; or
7. Cerumen impaction that totally occludes the visualization of the tympanic membrane.

Subsection D of section 241 provides that an audiologist performing cerumen management shall obtain informed 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.

Issues

Please identify the issues associated with the proposed regulatory action, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.

1) There are no disadvantages to the public. With the passage of the 2014 legislation, it is clear that cerumen management of a limited nature is within the scope of practice of audiologists who have been specially trained in the procedure. Proposed regulations protect patients by specifying the necessary training and the medical conditions and situations in which it is not appropriate for a patient to have cerumen removed by an audiologist.

2) There are no particular advantages or disadvantages to the agency or the Commonwealth.

3) There are no other pertinent matters of interest.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities particularly affected.

Family impact

Please assess the impact of this 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.

Changes made since the proposed stage

*Please list all changes that made to the text of the proposed regulation and the rationale for the changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. *Please put an asterisk next to any substantive changes.*

Section number	Requirement at proposed stage	What has changed	Rationale for change
241	Subsection D requires written informed consent for performance of cerumen management.	Eliminated the requirement that the informed consent be in writing but requires that consent be documented in the patient record.	The change is in response to comment. The Board determined that written consent is not necessary for the procedure, but the audiologist should document that he has discussed the need for cerumen management and documented consent in the record.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate. Please distinguish between comments received on Town Hall versus those made in a public hearing or submitted directly to the agency or board.

Commenter	Comment	Agency response
Lorraine Gardner, Au.D. Submitted on Townhall	• Objects to requirement for written consent; does seek verbal consent. • Questions the limitation on outer third portion of the ear canal. • Mandatory referral burdensome to patients. Objects to limitation on practice by audiologists.	• Subsection D was amended to eliminate requirement for written informed consent. • While the Board appreciates the skill of most audiologists in performing cerumen management, the Code of Virginia specifies that only "limited" cerumen management is within the scope of their practice.
Leah Ball, AuD. Submitted on Townhall	• Agrees with contraindications listed in the revised emergency regs. • Disagrees with requirement for *written* informed consent and the limitation of 1/3 of ear canal.	• Same response as above
12 people signed the identical letter Submitted directly to the agency	• Requested reducing or eliminating restrictions on audiologists in removing ear wax. Audiologists should be allowed to remove all ear wax and foreign bodies. Should be allowed to use judgment when referral is warranted; should be no limitations.	The Code of Virginia clearly specifies that "limited" cerumen management is within the scope of practice for audiologists. An amendment to the definition of the *practice of audiology* would be necessary to remove all limitations.
Cheris Frailey for American Speech-Language-Hearing Association Submitted at Public Hearing on Dec. 11, 2015	• Remove the term "limited"; audiologists are governed by their Code of Ethics and should be able to use professional judgment. • Contraindications should be eliminated; audiologists can manage with appropriate instrumentation. • Should include audiologists with master's degrees who were grandfathered in transition to doctoral degrees.	• Same response as above. The ASHA Code of Ethics may be followed by audiologists who belong to ASHA but the Code of Virginia prevails in the licensure and regulation of audiologists. • The Ad Hoc Committee of otolaryngologists and audiologists determined the listing of contraindications. • Information from educational programs in Virginia indicated that training in cerumen management was not included in the master's level programs

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes.

Describe new provisions and/or all changes to existing sections. Explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation

The amended final regulations are identical to the emergency regulations currently in effect and the proposed regulations as published with the exception of the change in subsection D noted above.

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 sets out the contraindications for cerumen management by an audiologist. It includes: 1. A perforated tympanic membrane; 2. Inflammation, tenderness, drainage, or open wounds or traces of blood in the external ear canal; 3. History of ear surgery that results in distortion of the external ear canal; 4. HIV infection or bleeding disorders; 5. Actual or suspected foreign body in the ear, excluding hearing aid components that are located in the lateral one-third portion of the ear canal; 6. Stenosis or bony exostosis of the ear canal; or 7. Cerumen impaction that totally occludes the visualization of the tympanic membrane. *Several contraindications that were originally included in the emergency regulations were deleted in proposed regulations in response to public comment, including patients with diabetes and children under the age of 12. Others were modified to make them less restrictive. Those that were retained were conditions that the Ad Hoc Committee and the Board agreed should be referred to an otolaryngologist.* 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 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.