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Proposed 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	7/8/15

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 (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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. Proposed 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).

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

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. A more detailed discussion is provided in the "Detail of changes" section below.

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 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.

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.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is 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) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail to Elaine Yeatts at Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, VA 23233 or **elaine.yeatts@dhp.virginia.gov** or by fax to (804) 527-4434**.** Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last date of the public comment period.

A public hearing will be held after this regulatory stage is published in the *Virginia Register of Regulations* 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.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including: **a) fund source / fund detail; and** **b) a delineation of one-time versus on-going expenditures**	There are no costs for implementation and enforcement specific to this regulatory action. Audiologists are not required to submit evidence of education and training. If the Department investigates a complaint involving cerumen management, the audiologist may be required to show evidence of appropriate training.
Projected cost of the new regulations or changes to existing regulations on localities.	There are no costs to localities.

Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	Audiologists who want to include cerumen management in their practice would be affected.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	There is no estimate because the Board does not know how many audiologists currently perform cerumen management or how many will choose to do so in accordance with regulation.
All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: **a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and** **b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.**	Audiologists with an AuD. degree may qualify if their program included such training. Otherwise, they will qualify by completion of a course or workshop in cerumen management by an approved provider.
Beneficial impact the regulation is designed to produce.	The beneficial impact is greater assurance of advanced training in cerumen management and greater protection in setting out contraindications for such treatment by audiologists.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

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. Subsequently, comments on the Notice of Intended Regulatory Action indicated a need to revise some of the provisions of the emergency regulations. To address the comments and recommend revisions, the Ad Hoc Committee was re-convened with Leah Ball, Au.D. replacing Marty Lenhardt as the representative for SHAV.

After discussion of the comments and issues relating to public safety, the Committee recommended changes to the emergency regulations that were subsequently adopted by the Board as replacement emergency regulations and proposed regulations to replace the emergency regulations.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

There are no alternative regulatory methods consistent with health and safety of patients. The Board adopted proposed regulations that are less restrictive than the emergency regulations, which became effective on December 29, 2014, to accommodate concerns by some audiologists that the contraindications for treatment were too restrictive and limiting.

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

Commenter	Comment	Agency response
Jamie Clark, AuD	Appreciates board work in outlining responsibilities. Requests certain changes: 1. Allow cerumen removal for person with hearing in one ear if audiologist has a certain amount of experience. 2. Add patient on blood thinners or aspirin as a pre-existing condition or contraindication. 3. Consider modification to prohibition on cerumen removal for foreign body in the ear.	1. Board eliminated hearing in one ear as a contraindication for treatment. 2. Regulation does include bleeding disorders but Board did not choose to add blood thinners as a contraindication. 3. The contraindication of actual or suspected foreign body in the ear was retained but amended to allow cerumen removal if there are hearing aid components located in the lateral one-third portion of the ear canal.
Julie Verhoff, Au.D., Ph.D.	Restriction on cerumen removal for patients 12 years or younger is too	Regulation was amended accordingly with age restriction eliminated.

	limited and would impact practice.	
Cheryl Wray	Qualification of Au.D. degree in program that includes cerumen management too limiting; should allow master's degree audiologist to do cerumen without further training.	The Board did not amend the requirement for an Au.D. with education/training in the program or additional courses or workshops in cerumen management. The educator on the Ad Hoc Committee related that cerumen management was not taught until recent years in audiology programs, all of which are Au.D. programs, and not taught in all such programs today. Therefore, the additional coursework or workshops should be required and is not burdensome.
Rita Chaiken, Au.D. Atlanta Audiology Services	Has taught audiologists cerumen management workshops since 1995; generally supportive of the training/education requirement. Recommended changes in contraindications: 1. Eliminate hearing in only one ear. 2. Allow some limited treatment for perforated tympanic membrane. 3. Amend current tympanostomy tubes to allow instrumentation. 4. Amend history of ear surgery. 5. Diabetes, HIV infection or bleeding disorders; with care, patients could be treated. 6. Eliminate actual or suspected foreign body in ear. 7. Stenosis or bony exostosis of the ear canal should be left up to comfort of audiologist. 8. Cerumen impaction that occludes the ear canal should not be prohibited. 9. Inability to see at least 25% of tympanic membrane should be eliminated.	1. Eliminated contraindication of hearing in one ear. 2. Retained prohibition for perforated tympanic membrane. 3. Eliminated contraindication for current tympanostomy tubes. 4. Retained contraindication of ear surgery but added the qualifier "that results in distortion of the external ear canal." 5. Eliminated contraindication of diabetes but retained HIV and bleeding disorders. 6. Retained contraindication of actual or suspected foreign body, but excluded hearing aid components located in the lateral one-third portion of the ear canal. 7. Retained the contraindication of stenosis or bony exostosis. 8. Retained cerumen impaction that occludes but amended to specify occlusion of "visualization of the tympanic membrane." 9. Eliminated contraindication of inability to see at least 25% of the tympanic membrane.
Lorraine Gardner, Au.D.	Comments similar to Dr. Chaiken seen above. Objects to limitations on cerumen management in general	The Code of Virginia was amended in 2014 to specify that limited cerumen management was included in the scope of practice of an audiologist. Therefore, it is clear that the intent of the legislation was to allow cerumen management with certain limitations established in regulation.
Kim Cavitt, Au.D. Vice-Chair of Illinois Board of Speech Pathology and Audiology	Virginia has protections in place in regulatory provisions for unprofessional practice; restrictions or limitations on cerumen management are unnecessary. Suggested removing all contraindications.	Same response as above.
David Taylor	Requests amendment to allow MA degree audiologists to do cerumen	The Board did not amend the requirement for an Au.D. with education/training in the

	management without further training. Says he had such a course at San Diego State University.	program or courses or workshops specifically in cerumen management. The educator on the Ad Hoc Committee related that cerumen management was not taught until recent years in audiology programs, all of which are Au.D. programs, and not taught in all such programs today. Therefore, the additional coursework or workshops should be required and is not burdensome. If an audiologist has had a course in a program approved by ASHA or AAA, he should qualify under subsection A (2) of Section 241.

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.

Detail of changes

*Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please list separately: (1) all differences between the **pre**-emergency regulation and this proposed regulation; and 2) only changes made since the publication of the emergency regulation.*

Differences between the emergency regulations that became effective on 12/29/14 are **bolded and/or bracketed. The proposed regulations are identical to the revised emergency regulations submitted for executive branch review and approval.**

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.*

			There were no changes from the emergency regulation in effect.
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.* ***The Board added "or other accrediting body recognized by the board" in A (1) to allow for additional recognition if an equivalent accrediting body develops in the proposed and re-submitted emergency regulations.*** 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 on contraindications was substantially amended form the original emergency regulations effective 12/29/14. The proposed regulation is identical to the re-submitted emergency regulation.*** ***The prohibition on performance of cerumen management by an audiologist on a patient who is younger than 12 years of age was eliminated; and the following changes from the 12/14 emergency regulations were also adopted**:* 1. ~~Hearing in only one ear;~~ ~~2.~~ A perforated tympanic membrane; [~~3.~~2.] Inflammation, tenderness, [drainage,] 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.~~3.] History of ear surgery [~~, excluding past tympanostomy tubes or simple tympanoplasty~~ that results in distortion of the external ear canal] ; [~~7.~~4. ~~Diabetes mellitus.~~] HIV infection [~~,~~] or bleeding disorders; [~~8.~~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] ; [~~9.~~6.] Stenosis or bony exostosis of the ear canal; [or ~~10.~~7.] Cerumen impaction that totally occludes the [~~ear canal~~ visualization of the tympanic membrane~~; or~~ ~~11. Inability to see at least 25% of the tympanic membrane~~] ***After hearing from other audiologists, the otolaryngologist and the audiologist, who served on the Regulatory Advisory Panel and who are trained in cerumen management, agreed that certain contraindications could be eliminated but advised that others should be retained because improper technique could do permanent damage and jeopardize hearing**.* 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.* ***There were no changes recommended in subsection D.***