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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 set seq.
Regulation title(s)	Regulations Governing the Practice of Audiology & Speech-Language Pathology
Action title	Practice of FEES by SLP's
Date this document prepared	2/12/15

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 of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

Proposed regulations set forth the educational qualifications, the supervised experience and the certification necessary for performance of an endoscopic evaluation of swallowing by speech-language pathologists. Additional requirements include referral from a qualified physician, performance in a health care facility with protocols for emergency medical backup, and reports to the referring physician.

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.

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ASHA = American Speech-Language-Hearing Association

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 12, 2015, the Board of Audiology and Speech-Language Pathology adopted final amendments for 18VAC30-20-10 et seq., 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. ...

In addition, the Board has general authority to promulgate regulations specifying additional training as necessary.

§ 54.1-103. Additional training of regulated persons; reciprocity; endorsement.

A. The regulatory boards within the Department of Professional and Occupational Regulation and the Department of Health Professions may promulgate regulations specifying additional training or conditions for individuals seeking certification or licensure, or for the renewal of certificates or licenses.

Purpose

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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.

The purpose of the planned action is to establish rules for the training, supervision and practice of SLP's in the performance of fiberoptic endoscopic evaluation of swallowing (FEES). There is a need for regulation because the Board's policy statement (guidance document) states that an SLP who performs FEES must be "specially trained" and work under the supervision of a physician provided there are protocols in place for emergency response.

While the Board's guidance document is helpful to the practitioner community, it is not enforceable and does not set forth regulations delineating the meaning of "specially trained." Therefore, SLP's do not have a clear standard for their training and practice, and the Board would have difficulty sanctioning an SLP for inadequate training and supervision. There is concern that patient safety and appropriate treatment could be compromised if SLP's perform FEES improperly and without necessary physician supervision and guidance. Proposed regulations will establish specific regulations to address those concerns.

Substance

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

Proposed regulations set forth the educational qualifications, the supervised experience and the certification necessary for performance of an endoscopic evaluation of swallowing by speech-language pathologists. Additional requirements include referral from a qualified physician, performance in a health care facility with protocols for emergency medical backup, and reports to the referring physician.

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) The primary advantage to the public is access to qualified health care practitioners to perform an evaluative procedure for patients with the protection of appropriate training, supervision and protocols for emergencies. Patients who have difficulty with transportation or positioning issues may be evaluated in a setting where there is a physician readily available. There are no disadvantages because the requirements are consistent with requirements in other states and with professional standards for FEES.

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- 2) There are no advantages or disadvantages to the agency or the Commonwealth.
- 3) There are no other pertinent matters; language was developed with input from and participation by all interested parties.

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 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.

There were no changes made to the text of the proposed regulation.

Public comment

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Please <u>summarize</u> 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
Renee Bricker, UVA Medical Center	Supports; regulations would help facilities ensure adequate training of their SLP's in FEES; will help decrease adverse effects from the procedure and be more financially efficient	Board acknowledges the support
Gary Pillow	Supports; allowing qualified SLP's to perform FEES will be a giant leap forward in patient care, especially in rural settings	Board acknowledges the support
Scott Rankin	Supports, the regulation would protect the public and the practitioner	Board acknowledges the support

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

Proposed new section number, if applicable	Current requirement	Proposed change, rationale, and consequences
141	N/A	Since there are other endoscopic procedures that may not be within the scope of practice for an SLP, for the purposes of this section, an endoscopic procedure is defined as "a flexible endoscopic evaluation of swallowing limited to the use of flexible endoscopes to observe, collect data, and measure the parameters of swallowing for the purposes of functional assessment and therapy planning." Subsection B sets out the qualifications necessary for an SLP to include: 1. Completion of a course or courses or an educational program offered by a provider approved in 18VAC30-20-300 that includes at least 12 hours on endoscopic procedures; 2. Successful performance of at least 25 flexible endoscopic procedures

under the immediate and direct supervision of a board-certified otolaryngologist or another speech-language pathologist who has successfully performed at least 50 flexible endoscopic procedures beyond the 25 required for initial qualification and has been approved in writing by a board-certified otolaryngologist to provide that supervision; and

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- 3. Current certification in Basic Life Support (BLS).
- Section 300 references approved providers of continuing education, which may include all related professional organizations/associations, health care organizations accredited by the Joint Commission on Accreditation of Healthcare Organizations, colleges and universities, and providers of Category 1 continuing medical education. Consequently, there are numerous resources available for an SLP who is not already qualified to perform endoscopic procedures to become qualified if it is necessary for his/her practice.
- To ensure that an SLP has the skills and training to perform the procedure, the qualifications include performance of at least 25 under supervision. An otolaryngologist may supervise the practical experience requirement. If an SLP has performed at least 50 procedures over and above the 25 required for initial qualification and been approved in writing by a board-certified otolaryngologist, the SLP may supervise training in FEES.
- The requirement for Basic Life Support is essential to ensure the SLP has emergency care skills necessary to handle an adverse reaction or problem that might develop.

Subsection C requires that the SLP who qualifies to perform an endoscopic procedure must "maintain documentation of course completion and written verification from the supervising otolaryngologist or speech-language pathologist of successful completion of flexible endoscopic procedures."

• Since the Board will not certify SLP's in an endoscopic procedure, it is necessary for the licensee to maintain documentation of meeting the education and training requirement, so if there is ever a complaint filed, there will be evidence of compliance.

Subsection D provides that an endoscopic procedure shall "only be performed by a speech-language pathologist on referral from an otolaryngologist or other qualified physician."

• The SLP is performing an evaluative test, but the need for that evaluation and the medical diagnosis resulting from the evaluation can only be determined by a qualified physician, usually an otolaryngologist.

Subsection E states that a speech-language pathologist shall "only perform an endoscopic procedure in a facility that has protocols in place for emergency medical backup." Specifically, a flexible endoscopic evaluation of swallowing shall only be performed by a speech-language pathologist in either:

1. A licensed hospital or nursing home under the general supervision of a physician who is readily available in the event of an emergency, including physical presence in the facility or available by telephone; or

2. A physician's office at which the physician is on premises and available to provide on-site supervision.

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• While serious complications or adverse reactions are relatively low for FEES examinations, it is necessary to have medical backup available in case a problem develops. The only appropriate settings for an SLP to do an endoscopic evaluation would be a licensed hospital or nursing home (where the physician would be readily available in person or by phone and where there would be other licensed health care practitioners available) or in a physician office at which the physician is on site and available to the patient.

Subsection F requires that "the speech-language pathologist shall promptly report any observed abnormality or adverse reaction to the referring physician and/or an appropriate medical specialist. The speech-language pathologist shall provide a report of an endoscopic procedure to the referring physician in a timely manner and, if requested, shall ensure access to a visual recording for viewing."

• The purpose of a FEES procedure is solely to address the swallowing function, not to make a medical diagnosis. Therefore, if there are clinical indications for further evaluation, the physician needs to be promptly notified. A visual recording of the FEES procedure is not always necessary for the physician's report but should be available in case there is a need to see for himself what the SLP observed.

Subsection G clarifies that a speech-language pathologist is not authorized to possess or administer prescription drugs except as provided in § 54.1-3408 B of the Code of Virginia.

§ 54.1-3408 B allows a prescriber to administer drugs and devices, or to "cause drugs and devices to be administered to patients in state-owned or state-operated hospitals or facilities licensed as hospitals by the Board of Health or psychiatric hospitals licensed by the Department of Behavioral Health and Developmental Services by other persons who have been trained properly to administer drugs and who administer drugs only under the control and supervision of the prescriber."

Subsection H provides that if a speech-language pathologist has been performing flexible endoscopic evaluations of swallowing prior to the effective date of regulation, he or she may continue to perform such evaluations provided he or she has written verification from a board-certified otolaryngologist that he has the appropriate training, knowledge and skills to safely perform such evaluations.