



Proposed Regulation Agency Background Document

Agency name	Board of Audiology & Speech-Language Pathology; Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC30-20-10 set seq.
Regulation title	Regulations Governing the Practice of Audiology & Speech-Language Pathology
Action title	Practice of FEES by SLP's
Date this document prepared	6/16/11

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*.

Brief summary

In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.

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.

ASHA = American Speech-Language-Hearing Association

FEES = Fiberoptic endoscopic evaluation of swallowing

SHAV= Speech-Language-Hearing Association of Virginia

SLP=Speech-Language Pathologist

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

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

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, 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 new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the “Detail of changes” section.)

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 the regulatory action poses 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.
- 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 requirements of the proposal, which are more restrictive than applicable federal requirements. Include a rationale 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.

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 and notice of the public hearing may appear on the Virginia Regulatory Town Hall website (www.townhall.virginia.gov) and the Commonwealth Calendar. 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 requirements create the anticipated economic impact.

<p>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source, and (b) a delineation of one-time versus on-going expenditures.</p>	<p>As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners or entities for necessary functions of regulation. There would be a one-time expense of less than \$500 for promulgation of the amended rule. All notifications will be done electronically to minimize the cost. There are no on-going expenditures.</p>
<p>Projected cost of the new regulations or changes to existing regulations on localities.</p>	<p>None</p>
<p>Description of the individuals, businesses or other entities likely to be affected by the new regulations or changes to existing regulations.</p>	<p>Speech-language pathologists</p>
<p>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 (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.</p>	<p>There are 3737; the agency has no estimate of how many SLP’s are already performing FEES and how many might choose to become trained to do so. It would be a very small percentage of the total number because it is a specialized test performed for a relatively small number of SLP patients. SLP’s typically work in large school systems or hospital systems or as part of a physician practice.</p>
<p>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. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. 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.</p>	<p>For SLP’s who are not currently performing FEES procedures and want to become qualified would have to obtain 12 hours of coursework from a provider approved to offer CE. All of those hours can be counted towards fulfillment of the CE requirement for renewal of licensure, <u>so the costs incurred to qualify in FEES would not be over and above costs for CE currently required.</u></p> <p>Endoscopic courses available through ASHA appeared to be approximately \$75 for 2-3 hours; a 10-hour course from another provider was listed at \$380.</p>
<p>Beneficial impact the regulation is designed to produce.</p>	<p>Access to qualified practitioners who can assist in evaluation of swallowing disorders for patients.</p>

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.

Regulations were drafted by an Ad Hoc Committee that included the two associations of practitioners who practice FEES, the Speech-Language-Hearing Association of Virginia (SHAV) and the Virginia Society of Otolaryngology-Head and Neck Surgery (VSO). In discussion of whether it is within the scope of practice for a speech-language pathologist to use endoscopes, the VSO has suggested that the Tennessee law adopted in 2007 would be a model for regulations in Virginia. The Tennessee law provides:

(B) The practice of speech language pathology shall include the use of rigid and flexible endoscopes to observe the pharyngeal and laryngeal areas of the throat in order to observe, collect data, and measure the parameters of communication and swallowing for the purpose of functional assessment and rehabilitation planning. A speech language pathologist who uses an endoscope shall meet all of the following conditions:

(i) A speech language pathologist must obtain written verification from a board certified otolaryngologist that the speech language pathologist is competent in the proper and safe use of an endoscope. The otolaryngologist's determination of competency shall be based upon the speech language pathologist's training in the proper use of endoscopes, the successful completion of a university course or other educational program of at least fifteen (15) hours on endoscopy, and the successful performance of at least twenty-five (25) endoscopic procedures under the supervision of an otolaryngologist or another speech language pathologist who has successfully performed at least fifty (50) endoscopic procedures and has been approved in writing by a board-certified otolaryngologist to provide such supervision. The speech language pathologist shall maintain this written verification on file at all times at the primary practice location of the speech language pathologist.

(ii) A speech language pathologist shall not perform a procedure utilizing an endoscope unless the patient has been referred to the speech language pathologist by an otolaryngologist or other qualified physician for the performance of such procedure.

(iii) A speech language pathologist shall perform only non-operative procedures with an endoscope.

(iv) In every setting in which a speech language pathologist performs a procedure using an endoscope, there must be protocols in place for emergency medical backup. If the procedure is performed in a community setting such as a physician's office, a physician must be on the premises and provide on-site supervision. If the procedure is performed in an institutional setting such as a hospital or nursing home, a physician must provide general supervision and be readily available in the event of an emergency, including but not limited to physical presence at the institution or availability by telephone.

(v) In all cases the speech language pathologist shall send to the referring physician in a timely manner a report and visual recording of each endoscopic procedure performed upon referral of that physician. If the referring physician is not an otolaryngologist, the speech language pathologist shall also provide a visual recording of the endoscopic procedure to an otolaryngologist if directed to do so by the referring physician.

The Tennessee law, as well as laws and regulations from a number of other states and the policy statements on FEES from the American Speech-Language-Hearing Association (ASHA) were reviewed and considered in the development of regulations.

Regulatory flexibility analysis

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.

While the Board has adopted a guidance document on the performance of FEES by SLP’s, the guidance is not enforceable. Therefore, there are no alternative methods consistent with health, safety and welfare that will accomplish the objective.

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
32 commenters provided essentially the same comment	Supports adoption of practice regulations, including training, supervision and practice standards for SLP’s to perform FEES – a skill that requires advanced education and training necessary to ensure quality of patient care and safety. Regulations would allow an SLP to practice with specialty training and patients would benefit. Supports ASHA standards and Code of Ethics.	The agency concurs with the comment and was guided by ASHA guidelines and Code of Ethics.
Speech-Language-Hearing Association of Virginia	Supports the proposed regulation to establish criteria for training, supervision & practice of SLP’s in performance of fiberoptic endoscopic evaluation of swallowing. With appropriate regulations, patients will be protected and physicians will be involved in any medical diagnoses.	The agency concurs that regulations setting criteria for FEES will help SLP’s acquire the training and skills necessary to perform this specialized procedure and better protect patients.

Family impact

Please assess the 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.

Detail of changes

Proposed new section number, if applicable	Current requirement	Proposed change, rationale, and consequences
141	N/A	<p>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 <i>“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.”</i></p> <p>Subsection B sets out the qualifications necessary for an SLP to include:</p> <ol style="list-style-type: none"> 1. <i>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;</i> 2. <i>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</i> 3. <i>Current certification in Basic Life Support (BLS).</i> <ul style="list-style-type: none"> • 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

		<p>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.</p> <ul style="list-style-type: none"> • 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. <p>Subsection C requires that the SLP who qualifies to perform an endoscopic procedure must <i>“maintain documentation of course completion and written verification from the supervising otolaryngologist or speech-language pathologist of successful completion of flexible endoscopic procedures.”</i></p> <ul style="list-style-type: none"> • 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. <p>Subsection D provides that an endoscopic procedure shall <i>“only be performed by a speech-language pathologist on referral from an otolaryngologist or other qualified physician.”</i></p> <ul style="list-style-type: none"> • 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. <p>Subsection E states that a speech-language pathologist shall <i>“only perform an endoscopic procedure in a facility that has protocols in place for emergency medical backup.”</i> Specifically, a flexible endoscopic evaluation of swallowing shall only be performed by a speech-language pathologist in either:</p> <ol style="list-style-type: none"> 1. <i>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</i> 2. <i>A physician’s office at which the physician is on premises and available to provide on-site supervision.</i> <ul style="list-style-type: none"> • 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. <p>Subsection F requires that <i>“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</i></p>
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		<p><i>access to a visual recording for viewing.”</i></p> <ul style="list-style-type: none"> • 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. <p>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.</p> <p>§ 54.1-3408 B allows a prescriber to administer drugs and devices, or to <i>“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.”</i></p> <p>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.</p>
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