Virginia

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Final Regulation
Agency Background Document

Agency name	Board of Medicine, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC85-140
Regulation title	Regulations Governing the Practice of Polysomnographic Technologists
Action title	Initial regulations for licensure
Date this document prepared	12/27/13

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

Please provide a brief summary (no more than 2 short 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

The Advisory Board on Polysomnographic Technologists reviewed the statutory mandate for the Board of Medicine to establish the qualifications for licensure and renewal and the standards of practice for the profession as mandated by Chapter 838 of the 2010 Acts of the Assembly. Regulations necessary to ensure minimal competency for practice, continued competency for renewal of licensure, supervisory responsibilities, and standards of conduct for safe practice will adopted by the Board.

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 or board taking the action, and (3) the title of the regulation.

On December 6, 2013, the Board of Medicine adopted final regulations for 18VAC85-140-10 et seq., Regulations Governing the Practice of Polysomnographic Technologists.

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.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Medicine 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:*
>
> *1. To establish the qualifications for registration, certification or licensure in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.*
>
> *2. To examine or cause to be examined applicants for certification or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.*
>
> *3. To register, certify or license qualified applicants as practitioners of the particular profession or professions regulated by such board.*
>
> *...*
> *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. ...*

Specific authority for regulation of polysomnographic technologist practice is found in Chapter 29 of Title 54.1:

> ***§ 54.1-2957.14. Advisory Board on Polysomnographic Technology; appointment; terms; duties.***

A. The Advisory Board on Polysomnographic Technology shall assist the Board in carrying out the provisions of this chapter regarding the qualifications, examination, and regulation of licensed polysomnographic technologists.

The Advisory Board shall consist of five members appointed by the Governor for four-year terms. Three members shall be at the time of appointment polysomnographic technologists who have practiced for not less than three years, one member shall be a physician who specializes in the practice of sleep medicine and is licensed to practice medicine in the Commonwealth, and one member shall be appointed by the Governor from the Commonwealth at large.

Vacancies occurring other than by expiration of term shall be filled for the unexpired term. No person shall be eligible to serve on the Advisory Board for more than two consecutive terms.

B. The Advisory Board shall, under the authority of the Board, recommend to the Board for its enactment into regulation the criteria for licensure as a polysomnographic technologist and the standards of professional conduct for holders of polysomnographic licenses.

The Advisory Board shall also assist in such other matters dealing with polysomnographic technology as the Board may in its discretion direct.

§ 54.1-2957.15. Unlawful to practice as a polysomnographic technologist without a license.

A. It shall be unlawful for any person not holding a current and valid license from the Board of Medicine to practice as a polysomnographic technologist or to assume the title "licensed polysomnographic technologist," "polysomnographic technologist," or "licensed sleep tech."

B. Nothing in this section shall be construed to prohibit a health care provider licensed pursuant to this title from engaging in the full scope of practice for which he is licensed, including, but not limited to, respiratory care professionals.

C. For the purposes of this chapter, unless the context requires otherwise:

"Polysomnographic technology" means the process of analyzing, scoring, attended monitoring, and recording of physiologic data during sleep and wakefulness to assist in the clinical assessment and diagnosis of sleep/wake disorders and other disorders, syndromes, and dysfunctions that either are sleep related, manifest during sleep, or disrupt normal sleep/wake cycles and activities.

"Practice of polysomnographic technology" means the professional services practiced in any setting under the direction and supervision of a licensed physician involving the monitoring, testing, and treatment of individuals suffering from any sleep disorder. Other procedures include but are not limited to:

a. Application of electrodes and apparatus necessary to monitor and evaluate sleep disturbances, including application of devices that allow a physician to diagnose and treat sleep

disorders, which disorders include but shall not be limited to insomnia, sleep-related breathing disorders, movement disorders, disorders of excessive somnolence, and parasomnias;

b. Under the direction of a physician, institution and evaluation of the effectiveness of therapeutic modalities and procedures including the therapeutic use of oxygen and positive airway pressure (PAP) devices, such as continuous positive airway pressure (CPAP) and bi-level positive airway pressure of non-ventilated patients;

c. Initiation of cardiopulmonary resuscitation, maintenance of patient's airway (which does not include endotracheal intubation);

d. Transcription and implementation of physician orders pertaining to the practice of polysomnographic technology;

e. Initiation of treatment changes and testing techniques required for the implementation of polysomnographic protocols under the direction and supervision of a licensed physician; and

f. Education of patients and their families on the procedures and treatments used during polysomnographic technology or any equipment or procedure used for the treatment of any sleep disorder.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it 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 goal of this action is to comply with provisions of Chapter 838 of the 2010 Acts of the Assembly for licensure of polysomnographers. The Board of Health Professions undertook a review of the need to regulate the profession resulting in a report recommending licensure. House Bill 725 was passed by the General Assembly with a mandate for licensure.

Applying established criteria for studying the need to regulate a profession, the Board of Health Professions concluded the following in its 2010 report:

1. The field of sleep medicine is a rapidly emerging discipline within medicine.
In the past two decades, sleep medicine has grown from an obscure, multidisciplinary field pursued by neurologists, otolaryngologists, chest physicians, cardiothoracic physicians, psychiatrists and other specialists to a recognized subspecialty. The American Medical Association recognized sleep medicine as a self-designated practice specialty in 1995 and in 2006 the American Board of Medical Specialties began certifying Sleep Medicine subspecialists in Family Medicine, Internal Medicine, Pediatrics, Otolaryngology and Psychiatry and Neurology.

The field of polysomnography (sleep medicine technology) has grown alongside sleep medicine. The Registered Polysomnographic Technologist (RPSGT) certification provides a nationally

recognized credential for persons performing polysomnography. This credential is considered the gold-standard of credentials for sleep technicians by the American Academy of Sleep Medicine. The Board of Registered Polysomnographic Technologists (BRPT) registered eight polysomnographers in 1979. Today, there are over 13,000 registered polysomnographers.

2. Several professions perform polysomnography.

In keeping with the history of sleep medicine, personnel with diverse backgrounds developed expertise in sleep medicine technology (polysomnography) including electroneurodiagnosticians, pulmonary function technologists, respiratory therapists, registered nurses and polysomnographic technologists. Due to the variety of practitioners performing polysomnograms, it is difficult to estimate the number of persons performing polysomnography. Allowing for a great degree of uncertainty, staff roughly estimates that there may be up to 1,000 persons performing polysomnograms inVirginia. As of July 6, 2009, the BRPT website listed 293 RPSGT's with Virginia addresses.

3. Polysomnography is performed in diverse settings.

As sleep medicine has developed, its practice has expanded from research facilities, into hospitals and recently into independent diagnostic testing facilities. These facilities may be accredited by the American Academy of Sleep Medicine or the Joint Commission. Many advertised sleep clinics are not accredited. While performing a brief internet search, staff identified 132 advertised sleep centers with independent addresses. Only 58 of these were accredited or associated with accredited facilities. Polysomnograms are usually performed at night. The delegating physician is usually only available by telephone contact.

4. Polysomnography shares only a few modalities with respiratory therapy, however respiratory-related conditions account for the greater majority of diagnoses and treatment.

Polysomnograms measure a minimum of eleven parameters, but often include many more. Only a few of these may be related to respiration, including oximetry, airflow or capnography. Other measurements include eye movement, muscle movement and brainwave measurements. Over 80 sleep disorders have been identified. Only a few of these are related to respiration, including sleep-related apneas. Other disorders include narcolepsy, restless leg syndrome, REM sleep behavior disorder and insomnia.

One study, supported by anecdotal evidence, suggests that up to 95 percent of conditions diagnosed at sleep centers are respiratory sleep disorders, predominately sleep apnea. Polysomnographers treat these disorders using respiratory care-related modalities, specifically positive airway pressure and/or low flow supplemental oxygen. Polysomnographers often implement these interventions following a preliminary diagnoses made by the polysomnographer in prescribed split-night studies.

5. The unlicensed practice of polysomnography poses a risk of harm to patients.

Several factors contribute to the risk of harm:

- The Commonwealth of Virginia has previously determined that the unlicensed practice of respiratory care poses a risk of harm to consumers.
- Patients are often alone with polysomnographers. These patients are often asleep, and are vulnerable to incompetence, negligence or malfeasance on the part of polysomnographers.
- Physicians rely on proper diagnostic tests performed by polysomnographers to diagnose sleep disorders. Improper testing may lead to improper diagnoses, diminishing the health and well-being of patients and possibly leading to further injury or death due to fatigue-related accidents which may also pose a risk to others.
- In the form of prescribed split-night studies, physicians delegate the task of preliminary diagnoses and preliminary treatment of sleep apnea in high probability cases to polysomnographers.

In order to address the risk of harm to patients, regulations will prescribe qualifications for minimal competency and standards for appropriate oversight of professional practice to protect the health and safety of patients being treated by polysomnographers.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

Regulations specify qualifications for licensure, including completion of an educational program and certification examination, criteria for renewal and continued competency, requirements for supervision and professional practice and fees for obtaining and maintaining licensure.

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 an expansion of physician extenders through the licensure and practice of polysomnographic technologists. Licensure will offer assurance of consistent education, training and minimum competency and oversight by the Board of Medicine. There is no restriction on the current scope of practice of respiratory care practitioners, but there is an opportunity for a new profession with appropriate education and training. There are no disadvantages to the public.
2) There are no advantages or disadvantages to the agency or the Commonwealth. The number of licensees is expected to be relatively small, and the disciplinary caseload

expected to be minimal. Since these licesnees will be regulated under the Board of Medicine and the Advisory Board on Polysomnography and will be licensed and disciplined with existing staff, there are few additional administrative costs for licensure.

3) There are no other pertinent matters.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.

There were no changes made to the proposed regulations.

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.

The comment period for the proposed regulations was August 26, 2013 to October 25, 2013. A public hearing was conducted on October 18, 2013, at which Kathe Henke, representing the Virginia Academy of Sleep Medicine spoke in favor of the regulations as proposed.

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.

Section number	Proposed requirements	Intent and likely impact of proposed requirements
10	Sets out definitions of terms used in regulation by either referencing the applicable Code or by stating the meaning.	The only definition in regulation of any significance is that of the term "active practice" which is identical to the definition in regulations for a similar profession under Medicine – respiratory care practitioners. The term is used in requirements for evidence of competency for someone whose license has been lapsed or who has been inactive from practice. The intent is to provide specificity to the regulation in which the term is used; the impact is found in the use of the term in section 90.
20	Provides reference for this chapter to the chapter establishing public participation guidelines for the Board of Medicine	The intent and impact are consistency with all chapters of the Board.
30	Sets requirements for current name and address to be maintained with the Board;	The intent and impact are consistency in requirements for all chapters of the Board and

	the regulation is identical to other chapters.	all regulated entities.
40	Establishes the fees required for licensure and renewal. Fees are identical to all allied professions regulated by the Board.	The intent and impact are consistency in requirements for all chapters of the Board and all regulated entities. Fees are established in order to cover the administrative and disciplinary expenses associated with regulation of the profession.
50	Sets forth the application requirements, including a completed application, fee, professional credential, verification of practice and information about disciplinary actions taken or pending in other jurisdictions.	The intent and impact are consistency in requirements for all chapters of the Board and all regulated entities. While the credential required is specific to polysomnography, the application requirements are the same as those for all other professions under the Board of Medicine.
60	Establishes the licensure requirements, including documentation of current certification as a RPSGT, a NBRC-SDS, or other credential approved by the Board. An applicant is also required to provide documentation of current certification in BCLS.	The intent of the requirement is to include all nationally recognized credentials in polysomnography as qualification for licensure in Virginia. Licensed respiratory care practitioners are allowed by law to practice polysomnography without an additional license, but the advanced credential from NBRC is included in section 60 to qualify an RCP who might want the polysomnographic technologist license. The board has included authorization for any other professional credential or certification, provided the credentialing body is a member of the National Organization for Competency Assurance (NOCA) to ensure legitimacy of the credential. If the American Academy of Sleep Medicine does develop a certification in polysomnography, the Board will be able to recognize that credential as well. The impact of the requirement for licensure is establishment of minimal competency in the profession. Training in basic life support is essential since polysoms are sometimes caring for people who may require resuscitation.
70	Establishes the requirements for renewal of licensure, including payment of the biennial fee, current certification in BCLS and an attestation to completion of continuing education. The provisions for late renewal are consistent with other professions under the Board.	The requirements are consistent with other professions under Medicine, all of which require continuing education or current professional certification as evidence of continuing competency, as required by § 54.1-2912.1. Respiratory care requires evidence of active practice to renew, but the Board did not establish that as a requirement for renewal of a polysomnographic technologist. Given the fact that a licensee is often alone with a patient

		during a sleep test, current BCLS was considered essential for continuing competency.
80	Establishes the provision for an inactive license in polysomnographic technology.	The intent and impact are consistency in requirements for all chapters of the Board and all regulated entities. (see 18VAC85-40-61)
90	Establishes the requirements for reinstatement or reactivation, including current BCLS and the provision of information about continued active practice (as defined in section 10) in other jurisdictions during that period, or attestation of at least 10 hours of CE for each year, or recertification of the examination for one of the credentials required for initial licensure. Fees for reactivation or reinstatement are the same for this profession as for other allied professions under the Board.	The intent and impact are consistency in requirements for all chapters of the Board and all regulated entities. (see 18VAC85-40-65) The option of active practice as evidence of continued competency requires a minimum of 160 hours of practice (broadly defined) in the 24-month period immediately preceding an application for reinstatement or reactivation.
100	Establishes the requirements of continuing education of 20 hours per biennium for renewal of an active license as a polysomnographic technologist. The listing of organizations or association that are authorized to approve CE for the profession in subsection A includes all professional groups recommended by the Advisory Board. The other provisions of section 100 are identical to CE requirements for the other allied health professions under the Board.	The intent and impact are consistency in requirements for a similar profession – respiratory care practitioners (see 18VAC85-40-66). A requirement of 10 hours per year (or 20 hours biennially) is minimal for consistency with the statutory requirement for evidence of continuing competency to renew a license under the Board of Medicine. By an inclusive listing of professional entities through which courses may be approved, there will be ample opportunities for the requirement to be met at minimal cost to licensees.
110	Sets the general responsibility of a licensee to practice the profession upon receipt of written or verbal orders from a qualified practitioner and under medical direction – as required by § 54.1-2957.15. The practice is broadly defined to include all aspects of the profession.	The intent of the requirement is consistency with the statutory definition of the practice and with other professions under Medicine (see definition of active practice in 18VAC85-40-10).
120	Sets out the supervisory responsibilities of a polysomnographic technologist, including responsibility for safe and appropriate delegation of tasks to unlicensed personnel.	Polysomnographic technologists work with assistants and trainees and are responsible for assignment of patient care tasks that are not discretionary and do not require professional judgment. Delegation should be patient-specific and should include a discussion of potential complications and expected results. The intent of the regulation on supervision is to clearly state the general parameters for delegation to unlicensed persons without being prescriptive about the tasks that may or may not be assigned.

		The type of supervision required is dependent on several factors, including complexity of patient needs, demonstrated competency and experience of the unlicensed person and the practice setting. Licensees are required to routinely meet with unlicensed personnel to review and evaluate patient care and treatment, and a licensee must review notes on patient care entered by the unlicensed person before reporting results to the supervising physician and must document the review in the patient record. The impact on current practice should be minimal, as practitioners report that the regulations are consistent with polysomnographic practices that are focused on safe and effective sleep studies. Regulations on supervision of occupational therapy personnel were used as the model for this section (18VAC85-80-100, 110, 111).
130	Sets out a standard for confidentiality between practitioner and patient.	The intent and impact are consistency in requirements for all chapters of the Board and all regulated entities. (see 18VAC85-40-85)
140	Sets out the standard for maintenance and disclosure of patient records, consistent with professions in which practitioners may be self-employed or may be employed by a health care entity that owns the records	The intent and impact are consistency in requirements for all chapters of the Board and all regulated entities. (see 18VAC85-40-86)
150	Sets out the standard for practitioner-patient communication and informed consent; set the standard for termination of a practitioner-patient relationship.	The intent and impact are consistency in requirements for all chapters of the Board and all regulated entities. (see 18VAC85-40-87)
160	Sets the standard for practitioner responsibility for performance of procedures, delegation to subordinates and exploitation of the relationship for personal gain.	The intent and impact are consistency in requirements for all chapters of the Board and all regulated entities. (see 18VAC85-40-88)
170	Sets the standard for a prohibition on solicitation or remuneration in exchange for referrals.	The intent and impact are consistency in requirements for all chapters of the Board and all regulated entities. (see 18VAC85-40-89)
180	Sets the standard for sexual contact with a patient, a former patient or a key third party in the relationship.	The intent and impact are consistency in requirements for all chapters of the Board and all regulated entities. (see 18VAC85-40-90)
190	Sets the standard for refusing to provide information as requested or required by the Board or its representative.	The intent and impact are consistency in requirements for all chapters of the Board and all regulated entities. (see 18VAC85-40-91)