Virginia Regulatory Town Hall

townhall.virginia.gov

# Notice of Intended Regulatory Action (NOIRA) 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** | 2/17/11 |

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.*

## Purpose

*Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended 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.

## 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., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.*

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.*

## Need

*Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.*

---

At its February 2, 2008 meeting, the Advisory Board on Respiratory Care of the Board of Medicine recommended that the Board of Medicine request the Board of Health Professions to review polysomnography to determine if the activities of sleep technicians fall under the purview of respiratory care and to conduct a study into the need for regulation of sleep technicians or polysomnographers. Pursuant to that request, the Regulatory Research Committee of the Board of Health Professions undertook the review resulting in a report recommending licensure for the profession. House Bill 725 was passed by the 2010 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 detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.*

Regulations for licensure of polysomnographic technologists have not been developed or adopted but the structure and content of the Chapter will follow the pattern of regulations for other allied health professions.

**Part I. General Provisions.**
Definitions. Sets out the meaning of words and terms used in this chapter
Requirement for current name and address of record.
Applicability of public participation guidelines.
Fees for initial licensure, renewal administration of the profession.

**Part II. Requirements for Licensure.**
Application requirements.
Qualifications or credentials required for approval of application.
Requirements and schedule for renewal of licensure, including continuing education and/or current certification.
Requirements for reactivation of an inactive license or reinstatement of a lapsed license.

**Part III. Requirements for Practice as a Polysomnographic Technologist.**
Supervision and direction of a physician.
Supervisory responsibility of a polysomnographic technologist for unlicensed person or trainee.
Scope of practice of polysomnographic technologist.

**Part IV. Standards of Professional Conduct.**
Requirements for confidentiality and patient records.
Standards for practitioner-patient communication.
Practitioner responsibilities.
Sexual contact.

For the qualifications or credentials required for licensure, the statute generally requires the Board of Medicine to enact into regulation "the criteria for licensure as a polysomnographic tehnologist and the standards of professional conduct for holders of polysomnographic licenses." The Board will utilize information contained in the 2010 study of the Board of Health Professions on the Need to Regulate Polysomnographers in Virginia which set out the credentials, education and training available for minimal competency. The Board of Registered Polysomnographic Technologists (BRPT) is the currently the only organization that specifically certifies polysomnographers independent of other credentials or licensure. Other credentials are intended to designate a specialization in the field of respiratory care, but the Virginia law provides that no other health care provider licensed by the Board, specifically respiratory care practitioner, can be required to obtain a license as a polysomnographer. The American

Academy of Sleep Medicine may be developing its own credential and examination, so the Board will consider that credential, if and when it becomes available.

For the scope of practice of a polysomnographic technologist, the law is fairly specific about the procedures that are considered the practice of the profession. Those procedures are listed in § 54.1-2957.15 but the practice is not limited to only those procedures, so regulations may additionally specify the supervisory responsibilities of a licensed practitioners for performance of procedures by persons receiving training for certification by BRPT.

## Alternatives

*Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.*

In the development of proposed regulations, the Board will utilize the 2010 study of the Board of Health Professions on the Need to Regulate Polysomnographers in Virginia. Its conclusion was that the unlicensed practice of polysomnography poses a risk of harm to patients and that the Board of Medicine should establish a license for the profession based on appropriate specialized training and education. In its study, the Board of Health Professions investigated credentials held by persons who do sleep studies and identified those that are currently reimbursable by Medicare, those that are intended as an advanced certification for persons already licensed as respiratory care practitioners, and the certification that is available to persons who are polysomnographers independent of other credentials or licensure.

Additionally, the Board will mirror the format and, where applicable, the regulations for other allied health professions under its regulatory and statutory umbrella.

## Public participation

*Please indicate whether the agency is seeking comments on the intended regulatory action, including ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments on this notice.*

The agency is seeking comments on the intended regulatory action, including but not limited to 1) ideas to assist in the development of a proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency is also 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 comments may do so via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail, email, or fax to Elaine Yeatts at **elaine.yeatts@dhp.virginia.gov** or at 9960 Mayland Drive, Henrico, VA 23233 or by fax at (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 day of the public comment period.

A public hearing will be held after publication of proposed regulations and notice of the hearing may be found on the Virginia Regulatory Town Hall website (**www.townhall.virginia.gov**) and can be found in the Calendar of Events section of the Virginia Register of Regulations. Both oral and written comments may be submitted at that time.

## Participatory approach

*Please indicate, to the extent known, if advisers (e.g., ad hoc advisory committees, regulatory advisory panels) will be involved in the development of the proposed regulation. Indicate that 1) the agency is not using the participatory approach in the development of the proposal because the agency has authorized proceeding without using the participatory approach; 2) the agency is using the participatory approach in the development of the proposal; or 3) the agency is inviting comment on whether to use the participatory approach to assist the agency in the development of a proposal.*

The Board of Medicine will use the Advisory Board on Polysomnographic Technology in the development of the proposed regulations. The Advisory Board is composed of five members appointed by the Governor for four-year terms. Three members are polysomnographic technologists who have practiced for not less than three years, one member is a physician who specializes in the practice of sleep medicine and is licensed to practice medicine in the Commonwealth, and one member is a member of the public. Additionally, the Advisory Board will be assisted by representatives of the Virginia Academy of Sleep Medicine and other interested parties, who will be present and participating in its meetings.

Depending on the publication of the NOIRA, the Advisory Board will hold one or more meetings called for the purpose of developing regulatory language for the Board's consideration and approval. The Advisory Board has regularly scheduled meetings in February, June, and October.

## Family impact

*Assess the potential 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 institution of the family and family stability.