

Review of Unlicensed Personnel in The Practice of Polysomnography

April 2005

ISSUE

The health, safety, and welfare of California consumers is being jeopardized as a result of the rapid growth of sleep medicine, its lack of regulatory oversight and relaxed guidelines for reimbursement of polysomnography services, which has paved the way for a growing number of unlicensed personnel who, under the supervision of other unlicensed personnel, are providing an array of sleep-related diagnostic and therapeutic services, many of which are governed by the Respiratory Care Practice Act.

BACKGROUND

Interest in sleep theories has been around for centuries, though sleep studies and disorders as they relate to medicine is a relatively new field. Literature indicates sleep studies were introduced into the medical community in the mid-1970s. One of the first well recognized sleep associations was founded in the 1970s and several associations followed thereafter. National certification for sleep technicians was available as early as 1979 (though accreditation of this certification program, by the National Organization for Competency Assurance was obtained in 2002). Sleep medicine began to expand rapidly in the late 1980s and in 1996, the American Medical Association recognized sleep medicine as a specialty.

Some 80 sleep disorders have been identified, though currently only a small percentage of these disorders are *commonly* diagnosed (and in some instances treated) through polysomnography. Polysomnography is the collective process of monitoring and recording physiologic data during sleep to diagnose and in some instances, treat sleep disorders. Some of the physiologic variables include, but are not limited to, neural electroencephalographic activity, eye movements, rhythm electrocardiogram, respiratory effort, nasal airflow, oxygen saturation, body position, limb movements, esophageal pH, and penile tumescence (swelling as a result of blood/fluid in tissues).

Pamela K. Minkley, CPFT, RRT, RPSGT, described the technology used in polysomnography in an article titled "Respiratory Care Practitioners and Sleep Medicine: Opportunities and Challenges," published in the May 1998 issue of *Respiratory Care*. She wrote:

"Polysomnography borrows and adapts technology from electroneurodiagnostics, pulmonary diagnostics, respiratory care, biomedical science, and other fields. It requires adaptation of clinical aspects of neurology, pulmonary, and sleep medicine with aspects of gastrointestinal medicine, ear, nose, and throat medicine, urology, psychiatry, psychology, and social work. It is an amalgamation of skills that is a specialty unto itself - sleep medicine and technology... Respiratory care and electroneurodiagnostics contribute many of the educational competencies that provide a base upon which to build."

In California, a significant number of providers contributing to the practice of polysomnography are *licensed* respiratory care practitioners and *unlicensed*, educated electroneurodiagnostic technicians. There are also other unlicensed individuals who lack the education and training to competently perform polysomnography from all aspects. Currently, there is one organization that offers a sleep technician credential, that requires as little as 18 months of on-the-job training, under the supervision of non-licensed personnel, to qualify for the examination. However, this credential is not held by all nor required to be held by those practicing polysomnography.

The respiratory-related monitoring involved in polysomnography and the treatment for respiratory-related sleep disorders fall within the Respiratory Care Practice Act (**RCPA**). The rising number of new sleep programs and demand for sleep services has contributed to the growing number of unlicensed personnel practicing respiratory care as it relates to polysomnography. Because this is a relatively new field and encompasses knowledge and technology from other fields of medicine, in addition to respiratory and pulmonary care, the Board opted to delay enforcement action for the unlicensed practice of respiratory care pending further exploration of this emerging field to determine the best method to serve and protect California consumers.

ASSOCIATIONS

There are several private organizations or associations that hold an interest in sleep medicine. Following are those organizations that have a direct interest in the Board's review of polysomnography services and potential regulatory initiatives or amendments and/or in sleep medicine in general.

American Academy of

Sleep Medicine (AASM) [www.aasmnet.org]

Sleep Disorder Programs Accrediting Body

The AASM was initially named the American Sleep Disorders Association and was founded in 1987. The name change to the American Academy of Sleep Medicine (AASM) occurred in 1999. According to their website, the AASM "is leading the effort to make sleep medicine an independent medical specialty." The AASM advocates for insurance reimbursement and promotes a public health message of good sleep. The AASM offers education courses and provides research in the field for its members. The AASM is also establishing fellowship training programs for physicians. The AASM is most notably recognized for its accreditation of sleep disorder programs.

AASM representatives have been very active both in California and nation-wide regarding issues of regulating polysomnography.

The Association of Polysomnographic Technologists (APT) [<http://www.aptweb.org>] **Profession Advocate**

The APT was established in or about in 1978. The APT describes itself as an international society of professionals dedicated to improving the quality of sleep and wakefulness in all people.

The APT has issued the following position papers, available on its website, titled:

Position Paper on Exemption from Existing Respiratory Care Practice Acts-Adopted 5/6/03

Limited Licensure of Polysomnographic Professionals Under Respiratory Care - Adopted 5/7/03

Polysomnographic Technology a Distinct Profession - Adopted 6/3/03

Model State Exemption Language and Definitions - Adopted 6/16/03

The position papers convey that the practice of polysomnography is a distinct profession requiring its own education curriculum and that states with respiratory care practice acts should not regulate the field, in any manner. The APT has publicly advocated, not for separate state regulation and oversight, but for legislative exemption from state regulation and oversight.

Sleep Research Society (SRS) [<http://www.sleepresearchsociety.org/site/>]

Sleep/Medical Research

The SRS's goal is to advance research and training in the sleep technology field. The SRS has over 900 members; 2/3 are full memberships, meaning these members hold doctoral degrees and either have published sleep-related research or have documentation of research; the remaining 1/3 is largely made up of students. In addition, 30% of their total membership includes members outside the U.S..

The Board of Registered Polysomnographic Technologists (BRPT) [www.brpt.org] **Credentialing Body**

Established in 1978, the BRPT is an independent, non-profit certification board that seeks to cultivate the highest professional and ethical standards for polysomnographic technologists by providing an internationally recognized credential. The BRPT provides the "Registered Polysomnographic Technologist" examination and obtained accreditation by the National Organization for Competency Assurance (NOCA) in 2002 [NOCA was established in 1977 and is the leader in setting standards for credentialing organizations].

The BRPT's vision is to promote national and international recognition and acceptance of the RPSGT credential as the professional standard for polysomnographic technologists. The BRPT is also currently assisting the Committee on the Accreditation of Allied Health Education Programs' (CAAHEPs) effort in establishing standards for stand-alone polysomnography programs.

American Society of Electroneurodiagnostic

Technologists (ASET) [www.aset.org]

Research & Profession Advocate

ASET is a volunteer, not-for-profit entity organized under section 501(c) 6 of the IRS code. It is incorporated in the state of Alabama and maintains headquarters in Kansas City, MO, with a paid professional staff of 6.

ASET is a related field that works in cooperation with polysomnographic associations. Founded in 1959, the ASET is the largest national association for professionals who investigate the electrical activity of the brain and the nervous system. ASET members include physicians (neurologists, radiologists, etc.), technologists, lab managers, institutions involved in electroencephalographic technology (EEG) and students (there are no requirements to become a member). These technologists record electrical activity arising from the brain, spinal cord, peripheral nerves, somatosensory or motor nerve systems as it relates to sleep & sleep disorders, reactions to outside stimuli, and the effects of head trauma or infectious diseases.

American Association for Respiratory Care (AARC) [www.aarc.org] *Research & Profession Advocate*

The AARC was established in 1947 and is committed to enhancing professionalism of respiratory care practitioners, improving performance on the job, and helping RCPs broaden their scope of knowledge essential to their success. With more than 35,000 members nationwide, the AARC is the only professional society for respiratory therapists. The AARC has chapter affiliates in 44 states.

The AARC provides that polysomnography is a subspecialty of respiratory care and that 50 - 60% of the graduates from respiratory accredited education programs are capable of entering the polysomnography work force upon graduation. In addition, the AARC assisted the Committee on the Accreditation of Allied Health Education Programs' (CAAHEPs) effort in establishing standards for 1 year polysomnography "add-on" programs to existing respiratory care educational programs in 2003.

In June 2004, the AARC's Board of Medical Advisors (BOMA) unanimously supported a motion

"to support the future goal of state regulation of the occupation of polysomnography and those who provide said polysomnography services and related sleep studies."

The AARC's BOMA is comprised of physicians representing various medical organizations including the:

- American Thoracic Society (ATS);
- American College of Chest Physicians (ACCP);
- American Society of Anesthesiologists (ASA);
- American Academy of Pediatrics (AAP);
- American College of Allergy, Asthma and Immunology (ACAAI);
- Society of Critical Care Medicine (SCCM), and
- the National Association for Medical Direction of Respiratory Care (NAMDR).

National Board for Respiratory Care (NBRC) [www.nbrc.org] *Credentialing Body*

The National Board for Respiratory Care, Inc. (NBRC) is a voluntary health certifying board, created in 1960 to evaluate the professional competence of respiratory therapists. The NBRC is a member of the National Organization for Competency Assurance (NOCA), and its examination programs are accredited by the National Commission for Certifying Agencies (NCCA). Accreditation by the NCCA signifies unconditional compliance with stringent testing and measurement standards among national health testing organizations. Since its inception, the NBRC has issued over 250,000 professional credentials to more than 150,000 individuals, and currently tests nearly 15,000 candidates annually.

The NBRC provides five nationally recognized exams for credentialing: the Certified Respiratory Therapist (CRT) (This entry-level respiratory examination is used by 48 states, including California, as a prerequisite for licensure); the Registered Respiratory Therapist (RRT); the Certified Pulmonary Function Technologist (CPFT); the Registered Pulmonary Function Technologist (RPFT), and the Neonatal/Pediatric Respiratory Care Specialist.

The NBRC is moving toward the development of a specialty certification in polysomnography for credentialed respiratory therapists.

California Thoracic Society [<http://www.thoracic.org/chapters/california/about.asp>]

The California Thoracic Society (CTS) is the professional society committed in its mission to improve California lung health and advance the science and practice of pulmonary and critical care medicine. It is the largest chapter of the American Thoracic Society and the medical section of the American Lung Associations throughout the state.

In addition, CTS is a specialty society officially recognized by the California Medical Association (CMA). CTS activities focus on clinical pulmonary, sleep and critical care practice issues, education, government, and payer policies for access to care issues.

The Society has 700 members, including pulmonary physicians, critical care specialists, internists, pediatric pulmonologists, allergists, thoracic surgeons, PhDs, RCPs, and advanced practice nurses.

The CTS has been very active in the Board's review of polysomnography and potential regulatory amendments or initiatives that may result.

SLEEP DISORDERS

The International Classification of Sleep Disorders identifies over 80+ sleep disorders in the following classifications:

1. Dyssomnias (Disorders of Sleep or Wakefulness)

- a. Intrinsic Sleep Disorders (i.e. Narcolepsy, Sleep Apnea, Restless Legs Syndrome)
- b. Extrinsic Sleep Disorders (i.e. Altitude Insomnia)
- c. Circadian Rhythm Sleep Disorders (i.e. Jet Lag Syndrome)
2. Parasomnias (Disruptive Physical Act while Sleeping)
 - a. Arousal Disorders (i.e. Sleepwalking, Sleep Sex [rape-like behavior])
 - b. Sleep-Wake Transition Disorders (i.e. Sleep Talking, Nocturnal Leg Cramps)
 - c. Parasomnia Associated with REM Sleep (i.e. Sleep Paralysis, REM Sleep-Related Sinus Arrest)
 - d. Other Parasomnia (i.e. Sleep Bruxism [teeth grinding], Sleep-Related Abnormal Swallowing Syndrome, Infant Sleep Apnea, Sudden Infant Death Syndrome)
3. Sleep Disorders Associated with Mental, Neurologic or Other Medical Disorder
 - a. Associated with Mental Disorders (i.e. Psychoses, Mood Disorders, Anxiety Disorders)
 - b. Associated with Neurologic Disorders (i.e. Cerebral Degenerative Disorders, Parkinsonism, Sleep-Related Epilepsy, Sleep-Related Headaches)
 - c. Associated with Other Medical Disorders (i.e. Nocturnal Cardiac Ischemia, Chronic Obstructive Pulmonary Disease, Sleep-Related Asthma, Sleep-Related Gastroesophageal Reflux)
4. Proposed Sleep Disorders (i.e. Pregnancy-Related Sleep Disorders, Sleep Choking Syndrome)

The most common sleep disorders currently diagnosed and/or treated via polysomnography testing is sleep apnea. Other more commonly tested disorders include: restless legs syndrome, narcolepsy, and insomnia.

Sleep Apnea¹

Sleep apnea is a serious, potentially life-threatening condition that is far more common than generally understood. There are two types of sleep apnea: central and obstructive. Central sleep apnea, which is less common, occurs when the brain fails to send the appropriate signals to the breathing muscles to initiate respirations. Obstructive sleep apnea is far more common and occurs when air cannot flow into or out of the person's nose or mouth although efforts to breathe continue.

It has been estimated that as many as 18 million Americans have sleep apnea. In a given night, the number of involuntary breathing pauses or "apneic events" may be as high as 20 to 30 or more per hour. Early recognition and treatment of sleep apnea is important because it may be associated with irregular heartbeat, high blood pressure, heart attack, and stroke.

In addition to the primary care physician, pulmonologists, neurologists, or other physicians with specialty training in sleep disorders may be involved in making a definitive diagnosis and initiating treatment. Several tests are available for evaluating a person for sleep apnea. Polysomnography is a test that records a variety of body functions during sleep, such as the electrical activity of the brain, eye movement, muscle activity, heart rate, respiratory effort, air flow, and blood oxygen levels. The Multiple Sleep Latency Test (MSLT) measures the speed of falling asleep. The MSLT may be useful to measure the degree of excessive daytime sleepiness and to rule out other types of sleep disorders. These tests are used both to diagnose sleep apnea and to determine its severity.

The specific therapy for sleep apnea is tailored to the individual patient based on medical history, physical examination, and the results of polysomnography. Medications are generally not effective in the treatment of sleep apnea. Oxygen administration may safely benefit certain patients but does not eliminate sleep apnea or prevent daytime sleepiness. Thus, the role of oxygen in the treatment of sleep apnea is controversial, and it is difficult to predict which patients will respond well. It is important that the effectiveness of the selected treatment be verified; this is usually accomplished by polysomnography.

Restless Legs Syndrome²

Restless legs syndrome (RLS) is a sleep disorder in which a person experiences unpleasant sensations in the legs described as creeping, crawling, tingling, pulling, or painful. These sensations usually occur in the calf area but may be felt anywhere from the thigh to the ankle. One or both legs may be affected; for some people, the sensations are also felt in the arms. RLS symptoms worsen during periods of relaxation and decreased activity. The severity of symptoms varies from night to night and over the years as well.

¹National Institutes of Health National Heart, Lung, and Blood Institute *Facts About Sleep Apnea*
<http://www.nhlbi.nih.gov/health/public/sleep/sleepapn.htm> NIH Publication No. 95-3798, September 1995

²National Institutes of Health National Heart, Lung, and Blood Institute *Facts About Restless Leg Syndrome (RLS)*
<http://www.nhlbi.nih.gov/health/public/sleep/sleepapn.htm> NIH Publication No. 96-3645, October 1996

Narcolepsy³

Narcolepsy is a chronic sleep disorder with no known cause. The main characteristic of narcolepsy is excessive and overwhelming daytime sleepiness, even after adequate nighttime sleep. A person with narcolepsy is likely to become drowsy or to fall asleep, often at inappropriate times and places. Daytime sleep attacks may occur with or without warning and may be irresistible. These attacks can occur repeatedly in a single day. Drowsiness may persist for prolonged periods of time. In addition, nighttime sleep may be fragmented with frequent awakenings. It is estimated that narcolepsy afflicts as many as 200,000 Americans.

Insomnia⁴

Insomnia is the perception or complaint of inadequate or poor-quality sleep because of one or more of the following: difficulty falling asleep; waking up frequently during the night with difficulty returning to sleep; waking up too early in the morning, and/or unrefreshing sleep. Insomnia is not defined by the number of hours of sleep a person gets or how long it takes to fall asleep. Insomnia can be classified as transient (short term), intermittent (on and off), and chronic (constant).

STANDARDS

Standards for polysomnography were first published by the American Thoracic Society in 1988 specifically for cardiopulmonary sleep studies. Other organizations have since published guidelines that vary in scope and in the level of detail.

American Thoracic Society Standards

Standards for Cardiopulmonary Sleep Studies (1988) [<http://www.thoracic.org/adobe/statements/sleepstudy1-11.pdf>]

These guidelines adopted in 1988, provide, that since 1978, "respiratory physicians have become increasingly aware of the need to consider an evaluation of ventilation and gas exchange during sleep in patients with a variety of established or suspected cardiorespiratory disorders including the sleep apnea syndromes, chronic obstructive pulmonary disease, asthma, cystic fibrosis, interstitial lung disease, pulmonary hypertension, structural chest wall abnormalities, respiratory neuromuscular disorders and central hypoventilation syndromes." These standards provide indications for cardiopulmonary sleep studies, timing and number of sleep studies, measurement techniques, scoring and interpretation of data, and screening and ambulatory monitoring techniques.

Indications and Standards for Use of Nasal Continuous Positive Airway Pressure (CPAP) in Sleep Apnea Syndromes (1994) [<http://www.thoracic.org/adobe/statements/cpap1-8.pdf>]

These standards discuss the indications, complications and treatment criteria for the adult and pediatric population. The consensus statement for adult treatment of obstructive sleep apnea with CPAP provides that it "should be based on the usual clinical evaluation and objective *assessment* of sleep and breathing" as described. These standards also note that the etiology (cause or origin of disease), clinical manifestations, and treatment of obstructive sleep apnea in the pediatric population are different from those in adults.

American Academy of Sleep Medicine (AASM) [<http://www.aasmnet.org/practiceparameters.asp>]

The AASM began publishing "Clinical Practice Parameters" in 1992 and has compiled guidelines for 33 various practice parameters. The purpose of these practice parameters is to provide guidance and aid to physicians in the diagnosis and treatment of sleep disorders.

American Association for Respiratory Care

Polysomnography Clinical Practice Guideline (1995) [http://www.rcjournal.com/online_resources/cpgs/polycpg.html]

These guidelines provide a description of polysomnography as well as indications, precautions, limitations/validation of results, resources, and infection control guidelines. Personnel qualifications are also provided with the understanding that all personnel should work under the direction of a physician specifically trained in the diagnosis and treatment of sleep disorders. Level II personnel should be credentialed or licensed as a Registered Polysomnographic Technician, a Registered Electroencephalographic Technologist, Respiratory Care Practitioner or Registered Nurse.

California Thoracic Society [http://www.thoracic.org/chapters/california_adobe/physiology.pdf]

Pulmonary Physiology Laboratory Personnel Qualifications-Position Paper (2002)

The CTS's position paper revised in January 2002, categorizes pulmonary function personnel into three levels. At the top of this hierarchy is the "Senior/Supervising Pulmonary Technologist" in which the CTS recommends

³National Institutes of Health National Heart, Lung, and Blood Institute *Facts About Narcolepsy*
<http://www.nhlbi.nih.gov/health/public/sleep/sleepapn.htm> NIH Publication No. 96-3649, October 1996

⁴National Institutes of Health National Heart, Lung, and Blood Institute *Facts About Insomnia*
<http://www.nhlbi.nih.gov/health/public/sleep/sleepapn.htm> NIH Publication No. 95-3801, October 1995

advanced credentials (i.e. Registered Pulmonary Function Technologist) to perform sleep studies.

SLEEP FACILITIES/PROGRAMS

Polysomnography is being conducted in acute-care hospitals and independent facilities as well as in *hotel rooms, and patients' homes*. Currently there is no regulatory oversight of sleep laboratories or unlicensed sleep personnel. Presumably California licensed physicians are directly overseeing the operations of sleep laboratories, though there is no way to assure this. The quality and standard of care of each sleep program can not be determined except for the small percentage of sleep programs who hold recognized accreditation. However, accreditation is not required by the State nor by most, if any, insurance carriers for reimbursement. Sleep laboratories and the locations for sleep laboratories continue to expand with no regulatory oversight and few programs holding voluntary accreditation.

It is believed that sleep labs are opening regularly because there are no requirements for the set-up or operation of facilities, there is a demand for sleep testing, and there is significant income to be gained. Results to a survey issued by the Board in 2004 (discussed later) indicate that over half of respondents agreed that the demand for polysomnography services is greater than California facilities can currently provide (ref: question 2). In an article titled "Conundrums in Sleep Medicine," published in a 1999 issue of *CHEST Magazine*, Nancy A. Collop, MD, FCCP writes:

"Sleep laboratories are opening regularly in this country. What is required to set up a sleep laboratory? Money and a building! Anyone can open a sleep laboratory, and it seems that just about everyone is. In the small city of Charleston where I reside, there are at least seven sleep laboratories run by a variety of specialists, including ear, nose, and throat; pulmonologists; and neurologists. Many of these physicians do not have any specific training in sleep medicine. There is also a lack of quality control in sleep laboratories. In some labs, technicians "score" the sleep study, and the physician never actually reviews the study, but only develops an interpretation based on the scores. Portable sleep studies are also being performed with even less quality control. What is the reason for the popularity of sleep laboratories? Patients and income. The significance to the pulmonologist is many of these labs are being run by us or are in direct competition with us.

Should there be better controls? I say yes. The American Sleep Disorders Association (ASDA) [currently named the AASM] was established to promote and improve the practice of sleep medicine. The ASDA has an accreditation process for sleep laboratories. This accreditation, however, is currently **not** required by most states, or more importantly, by most insurance carriers for reimbursements."

There is an Internet site [www.corfnet.net] which touts their ability to help investors in lucrative business opportunities by opening various health centers including sleep laboratories. They even provide that physician and polysomnographer services can be "purchased." The South Florida Medical Management advertises to "assist healthcare providers and investors in broadening their scope of services and maximizing the use of their existing facilities by developing sleep labs/centers as a compliment to their practice location or as an adjacent structure." The internet site provides that the cost of these programs vary depending upon many factors including "whether or not the owners have a resident physician & polysomnographer or will need to purchase these services."

Sleep studies performed in hotel rooms is being promoted for new and continuing sleep programs and is up for debate as to whether this practice is professional or unscrupulous. A company named Sleepwell Diagnostic Center provides investor updates through an internet site [www.sleepstest.com] where it is reporting numerous sleep centers opening nation-wide in hotels. A 2004 article in the Salt Lake Tribune written by Carey Hamilton provides "David Kay, the founder of **California**-based Sleepwell, came up with the idea of putting a sleep center in a hotel after his doctor sent him to a California sleep center in an office building in a 'terrible location.'" Sleep testing in hotel rooms has also been reported to the Board in a less favorable light citing "unlicensed technicians with 3 days training in polysomnography are administering CPAP and/or BiPAP to many sleep study patients."

Home sleep studies is also a popular choice by sleep disorder programs citing familiar surroundings are conducive to obtaining accurate sleep measures. Home sleep studies may be attended or non attended. There remains a division among the sleep community as to whether home sleep studies are as effective as studies performed in a laboratory, with strong arguments on both sides.

The AASM and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) have an accreditation processes for sleep programs/laboratories. However, the AASM is more widely recognized as the accrediting body for sleep programs. The AASM offers voluntary accreditation for sleep disorder programs and has designed standards for accreditation for laboratories evaluating only sleep-related breathing disorders as well

as full-service programs. Some sleep programs also provide polysomnographic evaluations of infant apnea and other pediatric sleep disorders, and REM-related nocturnal penile tumescence studies, although these are not required for accreditation. [reference: <http://www.aasmnet.org/centervslab.asp>]. The AASM reports (as of 10/04) it has accredited a total of 604 sleep programs in the United States, to which California represents 7.1% of this figure:

Alabama	33	Kentucky	27	North Dakota	1
Alaska	1	Louisiana	15	Ohio	45
Arizona	8	Maine	2	Oklahoma	3
Arkansas	5	Maryland	9	Oregon	12
California	43	Massachusetts	9	Pennsylvania	31
Colorado	5	Michigan	20	Rhode Island	3
Connecticut	15	Minnesota	11	South Carolina	5
Delaware	4	Mississippi	14	South Dakota	2
D.C.	2	Missouri	10	Tennessee	18
Florida	24	Montana	5	Texas	15
Georgia	19	Nebraska	4	Utah	2
Hawaii	3	Nevada	6	Vermont	1
Idaho	5	New Hampshire	2	Virginia	8
Illinois	24	New Jersey	16	Washington	17
Indiana	19	New Mexico	2	West Virginia	7
Iowa	6	New York	25	Wisconsin	16
Kansas	9	North Carolina	16	Wyoming	0

As of October 2004, there are 43 sleep programs located in California accredited by the AASM and 11 by the JCAHO. Based on the number of these accredited facilities and internet listings, it is estimated that there are a **minimum of 175 sleep labs or companies** providing polysomnography services in California (54 of which hold accreditation).

An article titled "Respiratory Care Practitioners and Sleep Medicine: Opportunities and Challenges," published in the May 1998 issue of *Respiratory Care* and written by Pamela K. Minkley, CPFT, RRT, RPSGT, provides,

"Accredited sleep centers have grown from 3 in 1977 to 337 in 1996. Accredited and nonaccredited centers may number as many as 3,000 today [1998]."

Using actual figures today and the figures provided in this article, the projected growth would be a total of 5,370 sleep facilities, both accredited and non accredited, in the U.S. with **381 located in California** [604 labs/337 labs=1.79 / 1.79 x 3000 = 5,370 / 5,370 x .071=381] .

In addition to testing performed at sleep facilities, it is also being conducted in physician offices. As of October 2004, there are 193 physicians accredited in sleep medicine by the American Board of Sleep Medicine. Yet it is believed that this figure only represents half (or even less) of the physicians actually practicing sleep medicine for a total estimate of 386 practicing physicians . **It is believed that 10% or 39 of these physicians are not associated with a lab and are performing testing in their office.**

ESTIMATED NUMBER OF SLEEP TESTING SITES: 317

$$[(175 + 381)/2 = 278 + 39 = 317]$$

Results to a survey issued by the Board in 2004 (discussed later) indicate that this total (317) would be broken down into the following types of sleep programs (ref: question 7):

Facility Type	% of Lab/Facilities (taken from Survey question no. 7)	No. of Lab/Facilities (based on Board estimate of total facilities)
Stand-alone	40%	127
Acute care setting	36%	114
Physician office	12%	38
Home care	5%	16
Hotel room	2%	6

Other	5%	16
Total		317

REIMBURSEMENT

Health insurers are providing reimbursement for polysomnography, with the only requirement as it relates to personnel or facilities, is that services are performed by properly trained personnel in a facility-based sleep study laboratory, not in the home or in a mobile facility. "Properly trained personnel" is not defined. However, the Centers for Medicare & Medicaid Services is currently reviewing its national coverage decision regarding the diagnosis of patients with Obstructive Sleep Apnea (OSA) requiring CPAP therapy [\[http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=110\]](http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=110). "Current national coverage guidelines specify that only a polysomnography done in a facility-based sleep study laboratory be used to identify patients with OSA requiring CPAP (CIM 60-17). CMS has received a request from Dr. Terence M. Davidson, MD, of the University of California San Diego, School of Medicine to modify this decision to include the use of portable multi-channel home sleep testing devices as an alternative to facility-based polysomnography in the evaluation of OSA." This review is expected to be complete in 2005.

Results to a survey issued by the Board in 2004 (discussed later) indicate that the most often billed polysomnography tests are reimbursed by Medicare for approximately \$550. It was noted that Medi-Cal's reimbursement is as low as half this amount, from \$250 to \$350 (ref: question 5). Many respondents cited that reimbursement in general is too low (ref: question 3) and that they believe many patients are not seeking or are not able to obtain these services as a result (ref: question 4).

The Centers for Medicare & Medicaid Services issued the following "fraud" alerts as they relate to reimbursement:

Medicare Fraud Alert (January 1997)

Sleep studies (95807) were billed but not furnished. In addition to sleep studies, most claims reported the same battery of pulmonary tests. Medical records did not document the tests. Pulmonary tests included:

- 94060 - Bronchospasm Evaluation,
- 94375 - Respiratory Flow volume Loop,
- 94200 - Maximum Breathing Capacity,
- 94664 - Aerosol or Vapor Inhalations,
- 94762 - Pulse Oximetry, overnight Monitoring, and
- 94620 - Pulmonary Stress Testing.

Medicare Fraud Alert (1996)

Suppliers have been billing DMERC Region C for therapeutic ventilators (E0453). One of these suppliers was justifying the use of therapeutic ventilators by falsely listing a diagnosis of respiratory failure for patients who are suffering from sleep apnea.

Four referring physicians submitted documentation for CPAP (continuous positive airway pressure) or BiPAP (bi-level positive airway pressure, inspirational and expirational) equipment used for sleep apnea, however, in each case the supplier filed a number of claims showing a diagnosis of respiratory failure.

JOB DESCRIPTIONS

The APT, AASM, BRPT and the ASET established a joint committee to provide recommendations that specifically address the minimum skills and competencies required for Polysomnographic Technologists. As a result, in 2002, the committee developed job descriptions identifying duties, qualifications and education for three levels of polysomnography personnel (i.e. trainee, technician, technologist) **[Attachment 1 - also available at: <http://www.aptweb.org/pdf/JobDescriptions.pdf>]**. Briefly, each level performs the same functions but with varied levels of complexity and supervision.

Polysomnographic Trainee

A Polysomnographic Trainee develops competency in and performs the basics of polysomnographic testing and associated interventions under direct supervision of a Polysomnographic Technician or a Polysomnographic Technologist.

Education and/or Experience

High school diploma or GED plus 6 months of direct patient care experience or 1 year of postsecondary education. **OR** Current enrollment in an accredited educational program leading to an associate degree with an emphasis in polysomnography.

Polysomnographic Technician

A Polysomnographic Technician performs comprehensive polysomnographic testing and analysis, and associated interventions under the general oversight of a Polysomnographic Technologist (RPSGT) and/or the clinical director (MD, PhD, DO) or designee. A Polysomnographic Technician can provide supervision of a Polysomnographic Trainee.

Education and/or Experience

Successful completion of a polysomnography program, of no less than one year duration, associated with a state licensed and/or a nationally accredited educational facility. **OR** A minimum of 6 months of experience as a Polysomnographic Trainee with documented proficiency in all required competencies.

Polysomnographic Technologist

A Polysomnographic Technologist works under the general supervision of the clinical director (M.D., D.O., or PhD) or designee to provide comprehensive evaluation and treatment of sleep disorders. This may involve polysomnography, diagnostic and therapeutic services or patient care and education. A Polysomnographic Technologist can perform the duties defined for a Polysomnographic Technician and may provide oversight of other staff.

Education and/or Experience

Successful completion of an accredited educational program leading to an associate degree with an emphasis in polysomnography. **OR** Successful completion of a polysomnography program of no less than one than one year duration associated with a state licensed and/or a nationally accredited educational facility or equivalent experience and documented proficiency at all competencies required of a Polysomnographic Technician. **AND** Certification by the Board of Registered Polysomnographic Technologists as a Registered Polysomnographic Technologist or equivalent.

Job Descriptions as They Relate to the Respiratory Care Practice Act

According to job descriptions mentioned above, a large portion of the duties of credentialed polysomnographic personnel, fall within the California Respiratory Care Practice Act's scope of practice:

- * Calibrating [respiratory care] equipment
- * Performing physiologic calibrations [related to respiratory care procedures]
- * Performing routine positive airway pressure (PAP) mask fitting
- * Maintaining PAP and oxygen titration, etc...
- * Establishing baseline oxyhemoglobin saturation
- * Documenting routine observation and clinical respiratory events
- * Implementing appropriate interventions, including actions necessary for patient safety and therapeutic intervention such as continuous and bi-level positive airway pressure, oxygen administration, etc.
- * Verifying integrity of data [as it relates to respiratory care] (repeats the physiological and instrument calibrations)
- * Demonstrating the knowledge and skills necessary to recognize and provide age specific care in the treatment, assessment, and education of neonatal, pediatric, adolescent, adult, and geriatric patients [as it relates to respiratory care].

The APT also provides four core competencies, all of which fall under the Respiratory Care Practice Act's scope of practice:

- * Capnography in Polysomnographic Technology
- * Supplemental Low Flow Oxygen Titration in Polysomnographic Technology
- * PAP Titration in Polysomnographic Technology
- * Monitoring Pulse Oximetry in Polysomnographic Technology

EDUCATION/BRPT CREDENTIAL

Polysomnography educational programs are limited to a few unaccredited programs designed specifically to polysomnography and accredited respiratory care and electroneurodiagnostic programs with a "polysomnography endorsement." Graduates from all of these programs are considered viable candidates to fill sleep technician vacancies among those employers who value the knowledge and experience of educated employees. However, in qualifying for the private credentialing examination, more value is given to those graduates of accredited electroneurodiagnostic programs. Polysomnography education as a whole, is in its infancy as demonstrated by the limited number of educational programs, the recent development of accreditation standards, and the need for balanced recognition of all qualified educational programs.

In April 2003, the Commission on Accreditation of Allied Health Education Programs (CAAHEP) finalized accreditation standards for a one-year add-on polysomnography certificate complimenting existing respiratory care programs. Thereafter, also in 2003, the BRPT was accepted as a sponsoring member of the newly-formed Committee on Accreditation for Polysomnography (CoAPSG) within the CAAHEP to which they are currently

developing standards for stand-alone polysomnography programs.

There are approximately 15 polysomnography education programs in the United States, including those that are specifically designed as polysomnography programs and those respiratory care and electroneurodiagnostic programs with a polysomnography "endorsement." There are also a handful of polysomnography training courses ranging in length from two days to two weeks.

The BRPT provides the "Registered Polysomnographic Technologist (RPSGT)" examination and obtained accreditation by the National Organization for Competency Assurance (NOCA) in 2002 [NOCA was established in 1977 and is the leader in setting standards for credentialing organizations]. The BRPT has 36 testing sites, 30 of which are located in the U.S. and 4 of these 30 located in California. Eligibility requirements to sit for the exam include anywhere from 6 to 18 months of paid work experience and possession of a current certification for basic cardiac life support (**Attachment 2**). The months of experience is weighted on any other professional accreditations (not licensure) and/or education obtained from any one of the 7 accredited electroneurodiagnostic programs with a polysomnography endorsement, located in the U.S..

In California, there is one institution, Orange Coast College, who provides a formal education in polysomnography. Orange Coast College offers a 2-year polysomnography program as well as a 1 year add-on certificate to the respiratory care or electroneurodiagnostic technology two-year programs (**Attachment 3** compares course requirements for each certificate/degree). However, the only education recognized by the BRPT in qualifying to sit for the RPSGT credentialing examination is the 1 year add-on certificate for the electroneurodiagnostic program; the 2-year polysomnography program and the 1 year add-on certificate to respiratory care are **not** recognized.

An applicant completing one of the "BRPT approved" electroneurodiagnostic education programs must only obtain an additional 6 months of paid experience to qualify to sit for the RPSGT examination. Whereas a graduate of a respiratory care program who earned a private respiratory care credential, must obtain an additional 12 months of experience, even if he/she completed a 1 year polysomnography add-on certificate. If that same respiratory care graduate did not apply for the private respiratory care credential (even if he/she is a licensed RCP), he/she would be considered the same as a candidate with no education who is required to obtain 18 months of paid work experience to qualify for the exam.

Since 2003, when the CAAHEP approved standards for the one-year add-on polysomnography certificate to existing accredited respiratory care programs, the NBRC has been moving towards establishing an additional polysomnography credentialing examination for respiratory therapists. The NBRC is recognized by NOCA and provides the respiratory therapy exam recognized by 48 states for RCP licensure. The NBRC provides daily computerized testing at 7 sites located throughout California. This new credentialing examination may be available as early as 2006.

WORKFORCE

In April 2003, Applied Measurement Professional, Inc., published "Salary, Demographic, and Educational Needs Survey Report" which was conducted for the Association of Polysomnographic Technologists (APT). The survey process began in 2002 and was concluded in 2003. Surveys were sent to 4,578 technologists, centers, and laboratories in 2002 [2,608 to APT members and 1,970 laboratories served by a sleep equipment manufacturer]. The study sample returned 894 usable surveys.

The executive summary provides, "Typical respondents spent most of their time in hospital-based sleep disorders centers organized under a respiratory care department (43%) or a separate sleep disorders department (42%)....Labs in which respondents worked typically performed 22 sleep studies per week...Approximately 97% of respondents indicated they performed sleep studies on geriatric patients and 99% performed studies on adults. About 62% of respondents indicated they performed sleep studies on adolescents. About 40% conducted studies on pediatric patients and about 8% of respondents conducted studies on neonates. Only 6% of respondents reported their center performed in-home studies and 9% reported performing remote studies."

"Almost three-fourths of respondents held the RPSGT credential...The next largest group of respondents held a respiratory therapy credential. Cross-tabulating these two groups found 306 (34.2%) respondents held both the RPSGT and one of the respiratory therapy credentials." Because respondents could mark more than one credential, the RPSGT did account for the largest group, even though 1/2 of the respondents held the RCP credential. In fact, if taking the "cross-tabulating" into consideration and reducing the RPSGT credential by 306 RCPs, you would find that the largest group would be RCPs (50%) followed by RPSGTs (38.5%). The survey indicated the nursing credential was the least held with only 4.5% of respondents indicating this type of credential. This was also the only other credential mentioned where these individuals could likely also hold a "license" as a nurse.

The BRPT indicates there are 261 RPSGTs in California. Of these, 44 or 17% are licensed RCPs (a much lower percentage than the 34.2% found in the survey). To determine the California workforce based on the survey results above, this would indicate that 217 RPSGTs (not RCPs) make up 38.5% of California workforce. This would indicate that **the total number of sleep personnel would be near 563**, with: 217 RPSGTs, who are not also RCPs (38.5%); 281 RCPs (50%), and the remaining 65 personnel with neither of these credentials (11.5%). However, it should be taken into consideration that 1) respondents in the above survey were either APT members or laboratories serviced by one sleep equipment manufacturer whose client-base is unknown and 2) the actual number of licensed RCPs compared to the actual number of credentialed RPSGTs in California differ greatly from those results received in the survey.

Previously, under "SLEEP FACILITIES/PROGRAMS," it was estimated that there are approximately 317 sleep facilities/programs in California. Results from the Board's survey issued in 2004 (discussed later), indicates the types of facilities and the number of sleep technicians employed at each facility are as follows:

Facility Type	% of Lab/Facilities (taken from Survey question no. 7)	No. of Lab/Facilities (based on Board estimate of total facilities)	No. of Sleep Technicians Employed at Each Type of Facility (Survey question 10)	TOTAL NO OF SLEEP TECHNICIANS
Stand-alone	40%	127	3	381
Acute care setting	36%	114	3	342
Physician office	12%	38	1	38
Home care	5%	16	1	16
Hotel room	2%	6	1	6
Other	5%	16	2	32
TOTAL	100%	317		815

Averaging these two broad figures for sleep technicians, it is estimated there are approximately

689 SLEEP TECHNICIANS (LICENSED AND UNLICENSED) IN CALIFORNIA. (563 + 815 /2=689)

ESTIMATED NO. OF LICENSED RCPS PRACTICING AS SLEEP TECHNICIANS: 207 (30%)

ESTIMATED NO. OF "OTHER" LICENSED PROFESSIONALS PRACTICING AS SLEEP TECHS: 34 (5%)

ESTIMATED NO. OF UNLICENSED PERSONNEL PRACTICING AS SLEEP TECHS: 448 (65%)

It is believed that over 1/2 of the sleep personnel in California are unlicensed based on the APT's survey results compared to the actual figures of credentialed and licensed RCPs in the California workforce and the rapidly

growing trend to establish new sleep facilities/programs. An article titled *Respiratory Therapists' Role in Sleep Medicine* in the Oct/Nov 2000 issue of RT, The Journal for Respiratory Care Practitioners, reports that,

“because there are no regulatory requirements, many sleep labs use college students who are trained on the job and perform the studies as a way to make some money while in school. Some use nurses and electroencephalography technologists, and/or other use respiratory therapists. A sleep technologist could be-and often is-a person with no prior medical background.”

Further, there are several "help wanted" advertisements for sleep technician positions (nation-wide) where only a high school education is required.

Unlicensed personnel have no regulatory oversight. There are no requirements for minimum education, training, experience, continuing education, or competency testing. Unlicensed personnel are not fingerprinted by a central agency to identify criminal history which may be relevant to the practice or the location of the practice. Nor is there a mechanism to rescind practice privileges in the event a person is found to be a threat to patients (i.e. incompetency, negligence, etc...).

RCP SHORTAGE

Currently, the demand for respiratory therapists is greater than the supply. The National Bureau for Labor Statistics reports in its 2004-05 Occupation Outlook Handbook, that "Employment of respiratory therapists is expected to increase faster than the average for all occupations through the year 2012, because of substantial growth in numbers of the middle-aged and elderly population—a development that will heighten the incidence of cardiopulmonary disease." Yet, the supply of respiratory therapists has been reported to be insufficient.

In the late 90s, employers and educational programs noted a sharp decline in the number of respiratory care practitioners and students entering respiratory care programs. While in 2003 education programs have seen improvements in enrollment, employers continue to report difficulty in finding respiratory therapists to fill jobs. Some employers have reported that after failed attempts to find respiratory therapists, they have turned to other licensed and unlicensed personnel to fill positions.

PATIENT HARM: CLINICAL HAZARDS/COMPLICATIONS

As with respiratory therapy, knowledge of normal cardiorespiratory, neurological and sleep physiology is required and provides the basis for monitoring polysomnograms and recognizing pathologic processes.

Risks are increased when unqualified personnel are charged with overseeing polysomnographic studies because they lack the knowledge foundation, education, training, and experience to make accurate assessments and evaluations as it relates to: 1) equipment operation or calibration; 2) patient responses, and 3) contraindications. Unqualified personnel also lack the ability to assess the need for and apply intervention methods and cannot be relied upon to produce valid test results. Education, training and experience are all crucial components in determining one's competency.

Inability to recognize hazards and be aware of and properly use intervention methods could lead to permanent injury to the patient, even death. Inaccurate test results can lead to the improper diagnosis and treatment jeopardizing patient safety and resulting in unnecessary expenditures.

Results to a survey issued by the Board in 2004 (discussed later) indicate significant competence and patient harm issues:

- ' Nearly half of respondents stated they were aware of patients being retested as a result of personnel failing to perform an initial test or treatment correctly or failing to ensure equipment was calibrated properly (ref: question 29). Many respondents cited poorly skilled technicians as the cause.
- ' While most respondents indicated that they were unaware of patient harm resulting from improper testing or equipment calibration (ref: question 30), the majority of respondents indicated that if polysomnography was performed by inexperienced (uneducated and untrained) personnel it could result in serious patient harm or even patient death (ref: question 31).

- ' Respondents indicated that there was between "some" and "absolute" possibility that a patient's personal rights would be violated or well being jeopardized if a polysomnographic technician had a criminal history of any one of the following: 1) fraud/theft; 2) alcohol abuse; 3) drug abuse; 4) battery, and 5) sexual misconduct. A criminal history of "sexual misconduct" rated the highest possibility for patient harm (ref: question 37).
- ' A small percentage of respondents indicated they were aware of cases where a patient alleged or was the victim of fraud/theft; battery, and sexual misconduct (ref: question 38).
- ' A small percentage of respondents were also aware of cases where it was suspected or found that diagnostic testing or treatment by the technician was impaired due to the technician being under the influence of alcohol and/or drugs (ref: question 39).

AARC Clinical Guidelines [http://www.rcjournal.com/online_resources/cpgs/cpg_index.asp]

Polysomnography (1995)

This Guideline was developed jointly by the AARC Cardiopulmonary Diagnostics CPG Focus Group and representatives of the Association of Polysomnography Technologists (APT). Both groups have approved its content.

Precautions/Complications:

- & Skin irritation may occur as a result of the adhesive used to attach electrodes to the patient.
- & At the conclusion of the study, adhesive remover is used to dissolve adhesive on the patient's skin. Adhesive removers (e.g., acetone) should only be used in well-ventilated areas.
- & The integrity of polysomnographic equipment's electrical isolation must be certified by engineering or biomedical personnel qualified to make such assessment.
- & The adhesive used to attach EEG electrodes, (eg, collodion) should not be used to attach electrodes near the patient's eyes and should always be used in well-ventilated areas.
- & Due to the high flammability of collodion and acetone, they should be used with caution, especially in those patients who require supplemental oxygen.
- & Collodion should be used with caution in those patients with reactive airways disease and in small infants.
- & Patients with parasomnias or seizures may be at risk for injury related to movements during sleep. Institution-specific policies and guidelines describing personnel responsibilities and appropriate responses should be developed.

Application of Continuous Positive Airway Pressure to Neonates via Nasal Prongs, Nasopharyngeal Tube, or Nasal Mask (2004 Revision & Update)

Hazards and complications associated with equipment include the following:

- & Obstruction of nasal prongs from mucus plugging or kinking of nasopharyngeal tube may interfere with delivery of CPAP and result in a decrease in FIO₂ through entrainment of room air via opposite naris or mouth.
- & Inactivation of airway pressure alarms
 - Increased resistance created by turbulent flow through the small orifices of nasal prongs and nasopharyngeal tubes can maintain pressure in the CPAP system even when decannulation has occurred. This can result in failure of low airway pressure/disconnect alarms to respond.
 - Complete obstruction of nasal prongs and nasopharyngeal tubes results in continued pressurization of the CPAP system without activation of low or high airway pressure alarms.
- & Activation of a manual breath (commonly available on infant ventilators) may cause gastric insufflation and patient discomfort particularly if the peak pressure is set inappropriately high.
- & Insufficient gas flow to meet inspiratory demand resulting in a fluctuating baseline pressure and an increase in the work of breathing.
- & Excessive flow results in overdistension from increased work of breathing due to incomplete exhalation and inadvertent PEEP levels
- & Decannulation or malpositioning of prongs or nasopharyngeal tubes causing fluctuating or reduced CPAP levels
- & Aspiration or accidental swallowing of small pieces of the detachable circuit or nasal device assembly
- & Nasal excoriation, scarring, pressure necrosis, and septal distortion
- & Skin irritation of the head and neck from improperly secured bonnets or CPAP head harnesses

Hazards and complications associated with the patient's clinical condition include:

- & Lung overdistension leading to
 - Air leak syndromes
 - Ventilation-perfusion mismatch
 - CO₂ retention and increased work of breathing
 - Impedance of pulmonary blood flow with a subsequent increase in pulmonary vascular resistance and decrease in cardiac output
- & Gastric insufflation and abdominal distention potentially leading to aspiration
- & Nasal mucosal damage due to inadequate humidification

Pulse Oximetry (1991)

Hazards/Complications:

- & Pulse oximetry is considered a safe procedure, but because of device limitations, false-negative results for hypoxemia (below normal oxygen content in arterial blood) and/or false-positive results for normoxemia or hyperoxemia may lead to inappropriate treatment of the patient. In addition, tissue injury may occur at the measuring site as a result of probe misuse (i.e. pressure sores, electrical shock and burns).

Management of airway emergencies (possibly caused by apnea event) (1995)

Precautions/Hazards and/or Complications:

- & Translaryngeal intubation or cricothyrotomy is usually the route of choice. It may be necessary occasionally to use a surgical airway. Controversy exists as to whether intubation is hazardous in the presence of an unstable injury to the cervical spine. In one series the incidence of serious cervical spine injury in a severely injured population of blunt trauma patients was relatively low, and commonly used methods of precautionary airway management rarely led to neurologic deterioration.
 - Failure to establish a patent airway
 - Failure to intubate the trachea
 - Failure to recognize intubation of esophagus
 - Upper airway trauma, laryngeal, and esophageal damage
 - Aspiration
 - Cervical spine trauma
 - Unrecognized bronchial intubation
 - Eye injury
 - Vocal cord paralysis
 - Problems with ETT tubes
 - Cuff perforation; Cuff herniation; Pilot-tube-valve incompetence; Tube kinking during biting; Inadvertent extubation; Tube occlusion
 - Bronchospasm
 - Laryngospasm
 - Dental accidents
 - Dysrhythmias
 - Hypotension and bradycardia due to vagal stimulation
 - Hypertension and tachycardia
 - Inappropriate tube size
 - Bleeding
 - Mouth ulceration
 - Nasal-intubation specific
 - Nasal damage including epistaxis; Tube kinking in pharynx; Sinusitis and otitis media
 - Tongue ulceration
 - Tracheal damage including tracheoesophageal fistula, tracheal innominate fistula, tracheal stenosis, and tracheomalacia
 - Pneumonia
 - Laryngeal damage with consequent laryngeal stenosis, laryngeal ulcer, granuloma, polyps, synechia
 - Surgical cricothyrotomy or tracheostomy specific
 - Stomal stenosis; Innominate erosion
 - Needle cricothyrotomy specific
 - Bleeding at insertion site with hematoma formation; Subcutaneous and mediastinal emphysema; Esophageal perforation
- & Emergency ventilation
 - Inadequate oxygen delivery

- Hypo- or hyperventilation
- Gastric insufflation and/or rupture
- Barotrauma
- Hypotension due to reduced venous return secondary to high mean intrathoracic pressure
- Vomiting and aspiration
- Prolonged interruption of ventilation for intubation
- Failure to establish adequate functional residual capacity in the newborn
- Movement of unstable cervical spine (more than by any commonly used method of endotracheal intubation)
- Failure to exhale due to upper airway obstruction during percutaneous transtracheal ventilation

APT Core Competencies

Capnography in Polysomnographic Technology (2003)

Precautions

- & There is a potential for localized erythema or skin burns from the TcCO₂ electrode at high heater temperatures.

Supplemental Low Flow Oxygen Titration in Polysomnographic Technology (2003)

Precautions and/or Possible Complications

- & In patients with chronic obstructive pulmonary disease, adding supplemental oxygen may lead to an increase in PaCO₂ and a decrease in the drive to breath which impairs the hypoxic drive. Fire hazard is increased with the use of oxygen in the sleep disorders facility. Power outage can lead to inability to use the oxygen concentrator and adequate back up should be in place.

Continuous Positive Airway Pressure (CPAP)

Continuous Positive Airway Pressure is delivered through an apparatus generally covering the nose and mouth and provides constant positive airway pressure throughout both inspiration and expiration. It is the most common treatment used in patients diagnosed with sleep apnea, the most common sleep disorder diagnosed and treated through polysomnography.

Hazards and Complications ⁵

Most hazards and complications associated with CPAP are caused by either the increased pressure or the apparatus. The increased work of breathing caused by the apparatus can lead to hypoventilation and hypercapnia. In addition, because CPAP does not augment spontaneous ventilation, patients with an accompanying ventilatory insufficiency may hypoventilate during application. Barotrauma is a potential hazard of CPAP and is more likely to occur in the patient with emphysema and blebs. Gastric distention may occur especially if CPAP pressures above H₂O are needed. This may lead to vomiting and aspiration in the patient with an inadequate gag reflex.

Monitoring and Trouble Shooting ⁶

CPAP poses a real danger of hypoventilation. Experience with long-term CPAP clearly demonstrates that patients must be able to maintain adequate excretion of carbon dioxide on their own if the therapy is to be successful.

For these reasons, patients receiving CPAP must be closely and continuously monitored for untoward effects. In addition, it is vital that the CPAP device be equipped with means to monitor the pressure delivered to the airways and alarms to indicate the loss of pressure due to system disconnect or mechanical failure. These are essential components of any CPAP device.

The most common problem with positive airway pressure therapies is system leaks. When using a mask, a tight seal must be maintained in order to keep pressure levels above atmospheric. Any significant leaks in the system will result in the loss of positive airway pressure. Because a tight seal requires a tight fitting mask, pain and irritation may occur in some patients, especially if the therapy is prolonged.

⁵ Scanlan, Craig L., Wilkins, Robert L., Stoller, James K.. 1999. *Egan's Fundamentals of Respiratory Care*, Seventh Edition. pgs. 783-786. Mosby

⁶ Scanlan, Craig L., Wilkins, Robert L., Stoller, James K.. 1999. *Egan's Fundamentals of Respiratory Care*, Seventh Edition. pgs. 783-786. Mosby

The development of the new nasal CPAP units has addressed some of the comfort issues as well as correction of leakage associated with CPAP, however its use intermittently for this purpose has not been well documented.

A more serious problem associated with CPAP is the possibility of gastric insufflation and aspiration of stomach contents. As with IPPB by mask, this potential hazard can be eliminated by use of nasogastric tube.

The RCP must also ensure that the flow is adequate to meet the patient's needs with the use of CPAP systems. Generally the flow is initially set to 2 to 3 times the patient's minute ventilation. Thereafter, flow adjustments are made by carefully observing the airway pressure. Flow is adequate when the system pressure drops no more than 1 to 2 cm H₂O during inspiration.

U.S. Food and Drug Administration MAUDE Database

The U.S. Food and Drug Administration compiles reports of events associated with medical equipment into their MAUDE database. Examining a few reports associated with polysomnography equipment provides some insight to events taking place.

Patient Suffers Abdomen Burns

This report provides "a patient suffered burns on his abdomen during a sleep study procedure. Strain gauge leads were plugged into the battery test receptacle instead of the abdominal outlets of a dc converter box, which caused the strain gauge to heat up. The patient's surgery had to be postponed due to the burn. The incident was the result of user error on the part of the technician."

Patient Sent to Emergency Room-Respiratory Distress

This report provides a sleep study patient experienced a rise in PACO₂, which the sleep facility alleged resulted from use of a specific piece of equipment. Patient had Chronic Obstructive Pulmonary Disease (COPD) and known high baseline CO₂. Patient was sent to the emergency room, placed on bi-level positive pressure (BIPAP) therapy and CO₂ levels dropped.

The device was returned and found to meet all operating specifications. "Further conversation with the sleep facility has led to the conclusion that the patient condition, along with titration and use of oxygen in the sleep lab, contributed to a reduction in the patient's respiratory drive to a level that required hospitalization. There was no malfunction of the device. "

Patient Sent to Emergency Room - Mask Burn/Pressure Necrosis

This report provides that a "patient had cracked and peeling skin on both sides of the nose and staining on the area around the lips and nose where a gold seal mask [CPAP mask] came in contact with the skin. The patient could smell a chemical and had a burning/stinging sensation. Patient was sent to the emergency room where they diagnosed pressure necrosis [the localized death of living cells as from infection or the interruption of blood supply] because of the coloring on the face....This facility is using cidex opa solution to disinfect cpap (sleep lab) masks.

The bottle label for cidex opa includes in the warning section a note to 'avoid contact with eyes, skin or clothing. Direct contact with skin may cause temporary staining.'...Proper rinsing of instruments after disinfecting with cidex opa should eliminate the potential for patient contact. Rinsing is detailed in the...directions for use section and is very specific regarding volumes of water, duration of rinsing and recommends repeated rinsing."

Patient Sustains 1st Degree Chemical Burn

This report provides that a patient undergoing a sleep study sustained a 1st degree chemical burn to their face from a CPAP mask disinfected with Cidex OPA. It was determined through discussions between the manufacturer of Cidex OPA and the risk management department at the sleep facility that the cleaning and disinfection instruction for Cidex OPA solution were not followed by the facility.

Anesthesia Complications Related to Obstructive Sleep Apnea

Patients with sleep apnea require special precautions and measures to ensure safe anesthetic care which may include awake intubation, postoperative intubation and mechanical ventilation, tracheostomy (if other attempts to manage the airway are unsuccessful), and vigil monitoring for apnea events post surgery. Anesthesiologists have noted patients have been misdiagnosed as not having obstructive sleep apnea, despite precautionary sleep studies, leading to complications during surgery.

PATIENT HARM: NATURE OF PRACTICE INVITES CRIMINAL ACTIVITY

Polysomnographs are generally performed during an "overnight stay" or throughout a significant period of the day and are often in hotel-room like settings or even in actual hotel rooms or patients' homes. The mere fact that one is "sleeping" places the patient in a vulnerable position. Sleep technicians most often place electrodes and other monitoring equipment on a patient's head, chest, waist, and/or legs and make readjustments as necessary. "Bed restraints" are also used on occasion. While rare, there are also sleeping disorders that cause paralysis or disorientation upon waking, and a "sleep sex" disorder which studies cite activities from disruptive moaning to

rape-like behavior toward bed partners, without any memory of the events the next morning. Complaints of sexual misconduct upon the part of the technologists have been made, though no evidence can be found that the complaints were founded. Lack of regulation places patients at risk not only of incompetent practice but criminal acts. The Board's experience has been that the less education a group of individuals possesses, the more likely there is criminal behavior. Criminal background checks would reveal convictions for sexual or physical abuse, theft, fraud, alcohol/drug, lewd conduct, etc...

Based on the number of estimated sleep labs/facilities (reported previously), and responses to a survey issued by the Board in 2004 (discussed later) 57% of facilities/labs do **not** perform criminal background checks. Eliminating the "acute care setting" from the equation, over 75% (or an estimated 157) of the stand-alone, physician office, home care, hotel room and other type of labs do not perform criminal background checks.

Previously in the report, the Board estimated there are 317 facility/labs that provide polysomnography services. Responses to survey questions estimating the percentage of each type of facility (ref: survey question 7) and the percentage of each type of facility that performs background checks (ref: survey question 40) breaks down as follows:

Facility Type Conducting Background Checks

Facility Type	Labs/Facilities		Perform Background Check		Do NOT Perform Background Check	
	%	No.	%	No.	%	No.
Stand-alone	40%	127	28%	36	72%	91
Acute care setting	36%	114	78%	89	22%	25
Physician office	12%	38	17%	6	83%	32
Home care	5%	16	26%	4	74%	12
Hotel room	2%	6	3%	0	97%	6
Other	5%	16	0%	0	100%	16
Totals		317		135		182

In an article titled "Protecting Yourself, How to keep the police away from your sleep lab (and what to say to them if they do show up on the doorstep)" published in the July 15, 2003 issue of *Advance Newsmagazines*, Pam Ryan, RPSGT, writes:

"Imagine this scenario: As you're tending to the sleep lab's business as usual, a police detective shows up, hands you his card, and says he needs to question you as part of an ongoing investigation he's conducting. He explains that a female patient is claiming she was sexually molested during her stay. He looks you in the eye and asks, "What measures do you personally take to prevent this kind of occurrence?"

"If you don't believe this scenario ever could really happen, think again. In fact, this situation occurred recently at a Midwest sleep lab. The police questioned two technologists at the police station, toured the facility, reviewed the patient file and polysomnography recording, and questioned the lab manager, lab director and hospital security director on site."

"The police eventually dismissed the case and cleared the lab and its techs of any wrongdoing, but this scenario reminds us that sleep labs may be more vulnerable to claims of sexual misconduct than other types of health care facilities. What other medical tests are so lengthy, occur in bedrooms, and often are conducted in isolated situations?"

***Vermont v. Nicholas Tonzola* [159 Vt. 491, 497, 621 A.2d 243, 246 (1993)]**

This case affirmed the original conviction of Tonzola, an "unlicensed" EEG technician, for three counts of lewd and lascivious conduct and two counts of perjury. "One patient testified that during the course of the EEG, defendant fondled her breast, touched her pubic area, and wet her lips with his fingers. The court found defendant guilty of L&L. A second patient testified that during her EEG, defendant touched her breast and pubic area, and told her to 'suck on' his penis. Defendant told her not to tell anyone. Defendant was found guilty of L&L. The third patient testified that defendant wet her lips with his fingers, and then put his fingers in her mouth. When she tried to remove his fingers by using her tongue, defendant asked her if she'd 'like to have something else to suck on.' Although she said no, defendant exposed his penis. She turned her head away and asked him to call a nurse. Defendant was found guilty of L&L.

Newsclips Unlicensed Personnel

A number of newsclips can be found alleging sexual misconduct against unlicensed professionals employed as: lab technicians, emergency medical technicians, ultrasound technicians, x-ray technicians, radiology technicians, and developmental disabilities technicians. In fact, in September 2004, in California, a lab technician, Dante Arnaud, 37, of Santa Ana was arrested for sexual battery and sexual penetration by a foreign object. Arnaud allegedly came into at least 7 woman's rooms in the maternity ward at Garden Grove Hospital and Medical Center, on the pretense of drawing blood samples and conducting breast and vaginal examinations.

***Enright v. Inspector General* [1991.06.19 DAB CR138 Dillard P. Enright vs The Inspector General]**

In this case, the Court found that determination of Enright's trustworthiness to work with patients is the same whether he functions as a laboratory technician or a nurse.

Enright was a practicing licensed nurse (regulated by the State of South Dakota) and a certified laboratory technician (through a private credentialing agency). Enright was terminated from employment for unprofessional conduct, as a result of two incidents of inappropriately touching male patients in the genital area while employed as a nurse. The first patient claimed Enright sexually molested him in the early morning hours and had been "somewhat affected" by the incident. The second patient claimed that he had awakened while he was a patient, Enright (on the night shift) was standing next to his bed. Enright had his hand in the patient's genital area. When the patient woke up, Enright quickly removed his hands and grabbed the patient's arm. Enright asked how the patient's arm was, and indicated to the patient that he was "checking the I.V."

Subsequently, the nursing board immediately suspended Enright's nursing license and ultimately accepted Enright's license surrender in response to charges stemming from these incidents.

Shortly after Enright surrendered his license, the Inspector General excluded him from participating in the Medicare program and directed that he be excluded from participation in the Medicaid program, until such time as he received a license to provide health care.

In this case, Enright sought to provide services to the Medicare and Medicaid programs as a "lab technician," a profession, he claimed, which is different than that of a licensed nurse.

In this decision, the Court writes, "When Petitioner fondled those two patients, he broke a high duty of care and trust. In a hospital, a patient may be completely helpless and totally dependent on the professional care of the hospital staff. Patients need to believe that when hospital personnel touch their bodies, it is for professional reasons, not to gratify the sexual desires of the hospital staff. There is testimony that one of the patients Petitioner fondled needed therapy to deal with the consequences of Petitioner's conduct. Petitioner's breach of those patients' trust and the duty he owed them is serious and extensive." The hospital administrator, "realized this, and this concern was a factor in his determination to terminate Petitioner. Penticoff stated: '[t]he patients in the hospital basically give us their life and soul and put a lot of trust in us, and that trust had been violated, so I then terminated Mr. Enright.'"

The Court found that while nursing would likely involve a greater amount of patient contact, Petitioner might also have a considerable amount of patient contact as a laboratory technician. Witnesses testified that, like nursing, the profession of laboratory technician involves patient contact and trust. Laboratory technicians act as phlebotomists, which means that they directly draw blood from the patients for testing, in open and closed door situations, in the patient's room or in the emergency room. The Court found that the two professions are not so different that the same standards of trustworthiness would not be applicable to both. In Enright's case, a determination of his trustworthiness to work with patients is the same whether he functions as a laboratory technician or a nurse.

The court concluded that the Inspector General's determination to exclude Enright from participation in the Medicare and Medicaid programs until he obtains a valid nursing license is reasonable and appropriate.

SURVEY RESPONSES

In the Summer of 2004, the Board developed three surveys related to the practices of polysomnography, pulmonary function testing and hyperbaric oxygen therapy. At the latter part of August 2004, the Board issued notices to some 1,545 organizations and persons holding in interest in one or more of these professions, encouraging input into these practices via surveys available on its website. Hard copies were also mailed to 200 of these various organizations/persons.

Approximately 491 of these organizations/persons are directly associated with the practice of polysomnography and include: accredited sleep centers; RPSGTs (credentialed technicians); sleep centers found on the Internet; sleep associations, and sleep disorder patient advocacy groups. Hard copies of the survey were sent to 67 organizations/persons affiliated with polysomnography. 29 surveys were returned to the Board. **Attachment 4** is a tabulation of all of the received responses.

Respondents indicated overall that:

- % there is a significant demand for polysomnographic services
- % reimbursement for services is inadequate
- % 59% of locations where polysomnography services are provided are in independent facilities/labs, physician offices, home care, and hotel rooms (36% performed in acute-care settings; 5 % "other")
- % Polysomnography is performed on all age groups (from less than 3 mos. old to 80 yrs. or older), with the majority of services provided to the 40-59 yrs. of age group
- % the potential for patient harm is significant should a technician have a criminal background
- % 43% of the workforce is comprised of unlicensed personnel - over half of unlicensed personnel have no or no related college education
- % polysomnography performed by untrained and uneducated personnel could result in serious patient harm or death
- % Between 1 and 2 years of education and between 100 and 300 hours of clinical experience is necessary to practice with minimum competency at the entry level
- % 2 years of education and over 300 hours of clinical experience is necessary to practice with minimum competency at the advance level of practice

Most believe regulation of sleep technicians would bring about more confidence in these services and would provide physicians more viable resources. An overwhelming majority believe that regulation of sleep technicians would increase the number of educational/training programs. In response to the final survey question which asks, "Which of the following components of regulation (if employed to certify 'polysomnographic technicians') do you believe would protect a patient's rights and prevent patient harm (check all that apply)?" 25 total respondents to this question marked:

Regulatory Component	Number of Respondents Marking Each Category (they believe would protect a patient's rights and prevent patient harm)
Competency Testing	18
Criminal Background Check	22
Formal Education	15
Formal Training	19
Continuing Education/Training	20
None	1

OTHER STATES

Following are how some states have addressed the issue of polysomnography crossing over each State's Respiratory Care Practice Act (as of November 2004):

Alabama - Exemption

In May 2004, Alabama enacted its own Respiratory Care Practice Act. Included is an exemption from the Act that provides, "Any individual employed as a polysomnographic [sic] technologist working in a sleep center or diagnostic sleep clinic."

Idaho - Licensed RCP or Permitted Polysomnography Personnel under Respiratory Care Act

Idaho's respiratory scope of practice provides, "Only persons who are licensed as respiratory care practitioners...or who hold a permit issued by the board as registered polysomnographic technologists, polysomnographic technicians or polysomnographic trainees may provide polysomnography related respiratory care services."

Louisiana - Proposed Legislation Providing Exemption Failed

A bill (HB 309) was introduced in 2003 that would have provided an exemption for polysomnography personnel from the Respiratory Care Act. This bill died in the Senate Committee on Health and Welfare. As of November 2004, no new legislation has been introduced.

Maryland - Proposed Legislation Creating New License Category

In 2004, legislation (HB 1181) was introduced to require licensure as a polysomnographic technologist, technician or trainee in order to practice polysomnography. A provision was added to clarify that the practice of polysomnography is within a licensed respiratory care practitioner's scope of practice. Status unclear.

Nebraska - Exemption

Effective July 2004, the following exemption applies: "The performance of oxygen therapy or the initiation of noninvasive positive pressure ventilation by a registered polysomnographic technologist relating to the study of sleep disorders if such procedures are performed or initiated under the supervision of a licensed physician at a facility accredited by the American Academy of Sleep Medicine."

New Jersey - Requires RCP Licensure - Unsuccessful Legislative Attempts to Provide Exemption

In 2002, the State Respiratory Board had prepared (but not published) a finding that would have provided that any person performing respiratory care as part of polysomnography must be a licensed RCP within 3 years. However, since then legislation has been introduced to provide an exemption. In 2003, legislation (S2749) was introduced to provide "The practice of polysomnography is NOT the practice of respiratory care." This bill died in the Senate Health, Human Services and Senior Citizens Committee. In May 2004, new legislation was introduced (A 2661) to provide a similar exemption and has not been set for committee (as of November 2004). Other reports indicate licensure as a RCP will be required to perform polysomnography by 3/31/06.

New Hampshire - Legal Exemption

Legislative amendments made in 2003, provided an exemption as follows, "Respiratory care performed as part of a limited scope of practice, as defined by the board, by certified pulmonary function technicians (CPFT), registered pulmonary function technologists (RPFT) or registered polysomnographic technologists (RPSGT) in a diagnostic laboratory or research setting."

New York - RCP Licensure Required

A declaratory ruling by the New York Education Department (which regulates RCPs) requires licensure as a RCP to perform polysomnography.

North Carolina - Declaratory Rulings Providing Exemption

The Respiratory Act includes "sleep related testing" as the practice of respiratory care. However, North Carolina has issued two "Declaratory Rulings" exempting the practice of polysomnography in these two instances from requiring licensure as a RCP.

Ohio - Legal Exemption

Ohio's law provides specific exemptions in its Respiratory Act for the practice of polysomnography by credentialed technologists.

South Carolina - Legal Exemption for Accredited Sleep Labs

Practice Act provides an exemption to, "an individual or other health care professional who is licensed by the State or who has proven competency in one or more of the functions included in the definition of the practice of

respiratory care as long as the person does not represent himself as a respiratory care practitioner. As it relates to respiratory care, individuals exempt pursuant to this section must provide proof of formal training for these functions which includes an evaluation of competence through a mechanism that is determined by the board and the committee to be both valid and reliable. The clinical assessment of artificial pressure adjuncts to the respiratory system may not be performed by any other person without proof of formal training and exemption by the board."

Regulations provide, "Registered Polysomnographic Technologists (RPSGT's) practicing in an accredited sleep medicine facility are exempt from this regulation so long as they are practicing under physician direction and do not hold themselves out as respiratory care practitioners or practice respiratory care."

Washington - RCP License Required for Diagnostic Monitoring and Therapeutic Interventions

Washington's respiratory care scope of practices includes, "Diagnostic monitoring of and therapeutic interventions for desaturation, ventilatory patterns, and related sleep abnormalities to aide the physician in diagnosis." However an exemption provides that this does not prohibit "any person from performing *sleep monitoring tasks* as set forth in this subsection under the supervision or direction of a licensed health care provider."

West Virginia - To Require Licensure

Efforts underway to require some form of licensure to practice polysomnography.

Wyoming - Respiratory Act includes Polysomnography And Provides Exemption

Legislation enacted in 2003 created a "Respiratory Care Board." The respiratory care scope of practice includes "sleep diagnostics procedures," and "neurodiagnostics." The Act provides the following exemption: "An individual who, by passing an examination which includes content in one (1) or more of the functions included in this act, offered by a testing body certified by the national commission for health certifying agencies or its equivalent, shall not be prohibited from performing procedures for which they were tested."

OTHER COUNTRIES

Canada - Switzerland - United Kingdom

These countries are moving towards requiring some form of licensure in order to practice polysomnography.

(continued)

ASSOCIATION POSITIONS

Regulation Support

The AARC finds polysomnography to be a "sub-specialty" of respiratory care and recognizes that by virtue of their license, RTs are performing sleep studies today and have been involved in this field since its inception. In April 2003, the CAAHEP unanimously approved the CoARC's Standards and Guidelines for the Respiratory Care Profession which allows respiratory care programs to seek accreditation of a polysomnography certificate of completion option as an "add-on" to their existing program.

An article in the American College of Chest Physicians, Chest magazine (circa 1999), titled *Conundrums in Sleep Medicine*, indicates some form of regulatory control for sleep labs and personnel should be in place.

The majority of respondents to the Board's 2004 survey indicate support for some form of regulation and an overwhelming majority believe that educational programs would evolve if the profession was regulated.

Regulation Opposition

The AASM has attended various meetings regarding this subject and has voiced its opposition to regulation of the field at this time. To date, no written opposition has been made.

The APT has established four position papers opposing regulation in connection with respiratory care licensure and has publicly advocated for exemption from respiratory care practice acts. Their argument is that the diagnostic utility of polysomnography depends on the ability to correlate specific changes or abnormalities of one physiological parameter rather than independent measurements of each variable, such as respiratory function, within the parameter. Though, respiratory function is noted as being the most common disturbance and treatment available to be tested via sleep evaluation. While the APT recognizes many functions are considered respiratory care, it believes respiratory care boards who bar the limited practice of respiratory care by polysomnographic technologists, are limiting the "availability, safety and quality of PSG monitoring, diagnostic and therapeutic services to patients." The APT also states that the mere association with respiratory care licensure boards, threatens the autonomy of the practice of polysomnography. At this time, no written opposition has been made.

The CTS has expressed opposition to regulating, in any manner, the practice of polysomnography. The CTS has conveyed that the supervising physician or medical director should have direct responsibility of personnel. **Attachment 5** is a position paper the CTS provided the Board on November 24, 2004. While the Board agrees with this position, there is no mechanism or recourse to ensure all physicians are providing oversight, testing competency, and requiring criminal histories and/or applying standards to these measures.

(continued)

ALTERNATIVE RESOLUTIONS

Following are alternatives considered prior to making a final recommendation

Alternative 1: Enforce existing law

This alternative would require all personnel performing any "polysomnography related respiratory care services" to be licensed as a RCP. Because respiratory care is intertwined in polysomnography, this alternative would virtually require a RCP license to practice polysomnography.

Alternative 2: Provide exemption from the RCPA to allow sleep credentialed personnel to perform polysomnography, including "polysomnography related respiratory care services."

This alternative would allow approximately 1/3 of the current estimated workforce to continue performing polysomnography. This alternative would virtually eliminate personnel from gaining work experience needed to qualify for the credentialing examination.

Alternative 3: Provide exemption from the RCPA to allow the performance of polysomnography by any person under the direct supervision of a licensed physician.

This alternative would provide that the licensed physician providing oversight would be held responsible for unlicensed personnel performing polysomnography. This alternative would result in different standards for competency and cannot ensure direct supervision is actually provided. This alternative would for the most part, not change any existing practices including the lack of criminal background checks performed on unlicensed personnel as well as the inability to discipline or "revoke" privileges to practice polysomnography when incompetence or criminal behavior is found. Rather, an unlicensed person can move onto a new sleep disorder program without mentioning his/her incompetence or criminal behavior, and will likely not be recognized or questioned because of the demand for polysomnography personnel.

Alternative 4: Establish a New Licensure Category for Polysomnographic Technologist

This alternative would create one new licensure category within the following framework:

I. Definitions, Legislative Amendments/Additions

- A. "Polysomnography" means an order by a California physician or by written procedures and protocols approved by the medical director of a sleep disorder program and in accordance with federal and state laws and regulations, the process of analysis, attended monitoring and recording of physiologic data during sleep and wakefulness to assist in the 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.
- B. "Polysomnography related respiratory care services" means the limited practice of respiratory care in the provision of polysomnography services which includes the diagnostic and therapeutic use of oxygen, noninvasive ventilatory assistance of spontaneously breathing patients and cardiopulmonary resuscitation, establishment of baseline oxyhemoglobin saturation, routine fitting of positive airway pressure mask or cannula, maintenance of nasal and oral airways that do not extend into the trachea, continuous observation, analysis and recording of carbon dioxide concentrations in respiratory gases, and other respiratory events, validation of respiratory-related data integrity, calibration of respiratory care devices, implementing appropriate interventions, including actions necessary for patient safety, and applying the knowledge and skills necessary to recognize and provide age specific respiratory care in the treatment, assessment, and education of neonatal, pediatric, adolescent, adult, and geriatric patients.
- C. "Sleep disorder program" means any sleep disorder center, laboratory, facility, home or any other area where polysomnography is conducted and such program is under the supervision of a California licensed physician or medical director who is responsible for patient care provided in such center or laboratory.
- D. Define "Medical Director" as it relates to polysomnography services as follows:
"Medical director" means a physician and surgeon who is a member of a health care facility's active medical staff, who specializes in sleep medicine, is knowledgeable in respiratory care, and is licensed to practice medicine pursuant to California Business and Professions Code Chapter 5."

II. RCPs and Polysomnographic Technologist [PSGT] DESIGNATION - OPTIONAL

RCPs would have the option of adding the PSGT designation to their current RCP license. However this designation would not be required to perform polysomnography. The PSGT designation would entitle the RCP to also use the title and initials of the PSGT.

The status of the PSGT designation would be solely dependant upon the status of the RCP license (i.e. cancelled, delinquent, current). All renewal and licensing requirements are tied only to the RCP license - no new additional requirements would be imposed. If the RCP license cancels and the individual wanted to obtain an independent PSGT license, he/she would need to apply for licensure and meet those requirements.

The RCP could voluntarily remove the designation at any time. The Board could remove the designation in a rare case after formal discipline where the RCP violated polysomnography services that were not respiratory related and would have no bearing on the RCP license. This would be very rare as most discipline taken would be primarily against the RCP license.

A. Requirements for Initial Designation

1. Current Licensure as a RCP **AND** successful completion of the NBRC or BRPT examinations.

III. Create New License Category - Polysomnographic Technologist [PSGT]

A. Supervision

1. The PSGT works under the [general] supervision of a medical director.

B. Scope of Practice

Those services defined as "polysomnography" and "polysomnography related respiratory care services."

C. Requirements

1. Current licensure as a California RCP **OR**
2. Graduation from an accredited respiratory care program **OR**
3. Graduation from an accredited electroneurodiagnostics program **OR**
4. Graduation from a polysomnography educational program approved by the board **OR**
5. 18 months (3000 hours) of full-time paid work experience as a "polysomnographic technologist applicant" including 1000 hours in "polysomnography related respiratory care services" **AND**
6. Successful completion of the BRPT or NBRC polysomnography examinations **AND**
7. High School Graduate or its equivalent **AND**
8. 18 years or older **AND**
9. Current CPR certificate **AND**
10. Criminal Background Clearance **AND**
11. any other educational courses, clinical practice or work experience identified by the Board through regulation.

D. License Renewal

1. Every two years
2. Require 15 hours of CE
3. Include conviction statement
4. Include statement to verify CPR current

IV. Work Permit as a Polysomnographic Technologist Applicant [PSGA]

Individuals who apply for the PSGT license who meet all the requirements with the exception of the education or work experience, may also request a work permit to gain paid work experience. Experience earned toward qualifying for the PSGT license must be paid and must be while the applicant maintains a current work permit. [However, grandfather provisions will need to apply here].

A. Supervision

1. The PSGA works under the direct supervision of a California licensed physician, a California licensed respiratory care practitioner, or a California Respiratory Polysomnographic Technologist.
2. Direct supervision as used in this section means the supervising person shall be assigned to the trainee, shall be on the premises where such polysomnographic services are provided and shall be

immediately available in the patient area.

B. Scope

1. The PSGA may perform those diagnostic and therapeutic procedures defined as "polysomnography" and "polysomnography respiratory care related services," with the exception that the PSGA is not authorized to make assessments.

C. Requirements

1. Meet all requirements for the PSGT license
2. Provide employer information
3. Provide names/credentials for "direct supervision"
4. Employer and "direct supervision" acknowledgment

D. Work Permits

1. Initial work permit issued for a period of 6 months
2. Extended work permit
 - a. issued in 1-year increments not to exceed 3 ½ years from the start date of the initial work permit
 - b. Extended work permits require a written request which includes:
 - i. Conviction statement
 - ii. Verification of current CPR
 - iii. Employer information
 - iv. Names/credentials for "direct supervision"
 - v. Employer and "direct supervision" acknowledgment

V. Fees

- A. Application Fee: \$200
- B. PSGA Initial Work Permit: \$0
- C. PSGA Extended Work Permit: \$125 for each extended work permit issued
- D. Initial License Fee: \$48 - \$136 [\$8 for each month of initial licensure]
- E. License Renewal: \$230 every 2 years
- F. Add PSGT Designation to RCP License: \$100
- G. Renewal of PSGT Designation to RCP License: \$0

Fees may change. Once an implementation plan is developed and costs are calculated, fees may be adjusted to ensure a self-funded licensing group.

VI. Continue Existing Exemptions

The existing exemptions in the RCPA would stay in tact. These include other licensed professions practicing within their scope, self practice, students, etc...

VII. Miscellaneous Provisions

1. Must maintain current certification in CPR
2. Clarify that a PSGT or PSGA applicant may not provide respiratory care beyond "polysomnography related respiratory care services" as defined above.
3. Clarify that a PSGT or PSGA applicant may only provide services within his/her scope of practice in conjunction with a "sleep disorders program" as defined above.
2. All provisions of the RCPA would apply equally to PSGTs and PSGAs.
3. Replace RCP appointed by the Senate Rules Committee with a PSGT or RCP with a PSGT designation (either while vacant or upon the appointment expiration date of a filled position).

RECOMMENDATION

The Professional Licensing Committee recommends Alternative 4. This alternative provides the greatest protection to consumers by ensuring competency or documented direct oversight, criminal background checks, and a mechanism in which to discipline or “revoke” privileges to practice polysomnography.

ATTACHMENTS

1. APT, AASM, BRPT and ASET Job Descriptions
2. BRPT Eligibility Requirements
3. Orange Coast College Education Comparison: Neurodiagnostic Degree w/Polysomnography Certificate vs. Respiratory Care Degree w/Polysomnography Certificate
4. 2004 Board Survey Tabulated Responses
5. CTS Position Statement