

## OHCA Guideline

<b>Medical Procedure Class:</b>	Positive Airway Pressure (PAP) Device for the Treatment of Sleep Apnea
Initial Implementation Date:	January 1, 2012
Last Review Date:	November 1, 2019
Effective Date:	November 1, 2019
Next Review/Revision Date:	November 2022
* This document is not a contract, and these guidelines do not reflect or represent every conceivable situation. Although all items contained in these guidelines may be met, this does not reflect, or imply, any responsibility of this agency or department to change the plan provision to include the stated service as an eligible benefit.	
<input type="checkbox"/> New Criteria <span style="float: right;"><input checked="" type="checkbox"/> Revision of Existing Criteria</span>	
<b>Summary</b>	
<b>Purpose:</b>	To provide guidelines to assure medical necessity and consistency in the prior authorization process.
<b>Definitions</b>	
<p><b>Adenotonsillectomy:</b> An operation to remove both the adenoids and tonsils.</p> <p><b>Apnea:</b> The cessation of airflow for at least 10 seconds in adults. Because of children's different physiology and higher baseline respiratory rate, clinically relevant apneas may not last this long. Apneas of three to four seconds duration can be accompanied by oxygen desaturations.</p> <p><b>Apnea-hypopnea index (AHI):</b> In adults, the number of episodes of apnea and hypopnea per hour of sleep without the use of a positive airway pressure device. If the AHI or RDI for an adult is calculated based on less than 2 hours of sleep or recording time, the total number of recorded events used to calculate the AHI or RDI (respectively) must be at least the number of events that would have been required in a 2 hour period (i.e., must reach <math>\geq 30</math> events without symptoms or <math>\geq 10</math> events with symptoms).</p> <p><b>Capped Rental:</b> Monthly payments are made for the use of Durable Medical Equipment (DME) for a limited period of time not to exceed 13 months. Items are considered purchased after 13 months of continuous rental.</p> <p><b>Hypopnea:</b> An abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline and with at least a 4% decrease in oxygen saturation.</p> <p><b>Hypoventilation Syndrome:</b> Also known as Pickwickian syndrome, is a condition in which severely overweight people fail to breathe rapidly enough or deeply enough, resulting in low blood oxygen levels and high blood carbon dioxide (CO<sub>2</sub>) levels.</p> <p><b>Interpreting physician:</b> A physician who provides professional interpretation of data generated by sleep diagnostic tests. An interpreting physician shall be board-certified in sleep medicine by the American Board of Sleep Medicine (ABSM) or the American Board of Medical Specialties or must have completed a one-year sleep medicine fellowship accredited by the Accreditation Council for Graduate Medical Education (ACGME) or received a Certification of Special Qualifications (CSQ) or a Certification of Added Qualifications (CAQ) in Sleep Medicine issued by the American Osteopathic Association; An interpreting physician shall interpret the data generated by all sleep diagnostic tests conducted at a sleep diagnostic testing facility.</p>	

**Medical Necessity:** Services provided within the scope of the Oklahoma Medicaid Program shall meet medical necessity criteria. Requests by medical services providers for services in and of itself shall not constitute medical necessity. The Oklahoma Health Care Authority shall serve as the final authority pertaining to all determination of medical necessity. Medical necessity is established through consideration of the following standards

- 1) Services must be medical in nature and must be consistent with accepted health care practice standards and guidelines for the prevention, diagnosis or treatment of symptoms of illness, disease or disability;
- 2) Documentation submitted in order to request services or substantiate previously provided services must demonstrate through adequate objective medical records, evidence sufficient to justify the client's need for the service;
- 3) Treatment of the client's condition, disease or injury must be based on reasonable and predictable health outcomes;
- 4) Services must be necessary to alleviate a medical condition and must be required for reasons other than convenience for the client, family, or medical provider;
- 5) Services must be delivered in the most cost-effective manner and most appropriate setting; and
- 6) Services must be appropriate for the client's age and health status and developed for the client to achieve, maintain or promote functional capacity. OAC 317: 30-3-1-1 (f) (2)

**Obstructive Sleep Apnea Syndrome (OSA)** – Along with upper airway resistance syndrome (UARS), is an increase in respiratory effort due to breathing against relative or absolute airway obstruction resulting in more negative intrathoracic pressure and decreased or absent air flow.

**Positive airway pressure device (PAP):** In this guideline, the term PAP will refer to both a single level continuous positive airway pressure device, or CPAP, (E0601) and a bi-level respiratory assist device or BiPAP, without back-up rate (E0470) when it is used in the treatment of obstructive sleep apnea.

**Polysomnography (Polysomnogram) (PSG):** The process of using a polygraph to make a continuous record during sleep of multiple physiological variables, such as breathing, heart rate, and muscle activity. Polysomnography is distinguished from sleep studies by the inclusion of sleep staging.

**Polysomnogram type I sleep test:** The continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep with physician review, interpretation, and report. It is facility-based and must include sleep staging, which is defined to include a 1-4 lead electroencephalogram (EEG), electro-oculogram (EOG), submental electromyogram (EMG) and electrocardiogram (ECG). It must also include at least the following additional parameters of sleep: airflow, respiratory effort, and oxygen saturation by oximetry. It may be performed as either a whole night study for diagnosis only or as a split night study to diagnose and initially evaluate treatment. Only sleep studies performed in a Sleep Diagnostic Testing Facility may be reimbursable.

**Respiratory disturbance index (RDI):** In adults, the number of apneas plus hypopneas per hour of recording without the use of a positive airway pressure device. If the AHI or RDI for an adult is calculated based on less than 2 hours of sleep or recording time, the total number of recorded events used to calculate the AHI or RDI (respectively) must be at least the number of events that would have been required in a 2 hour period (i.e., must reach  $\geq 30$  events without symptoms or  $\geq 10$  events with symptoms).

**Restrictive Thoracic Disorders:** A group of thoracic deformities that result in inefficient coupling between the respiratory muscles and the thoracic cage, usually characterized by a restrictive defect and share the potential to cause long term hypercapnic respiratory failure.

**Ventilator:** An automatic machine designed to mechanically move breathable air into and out of the lungs, to provide respiration for a patient who is physically unable to breathe, or breathing insufficiently. Backup ventilators are not covered as per policy (317:30-5-211.10).

### Description

Positive airway pressure (PAP) is a method of respiratory ventilation used primarily in the treatment of sleep apnea. The continuous positive airway pressure (CPAP) machine blows air at a prescribed pressure (also called the titrated pressure). The titrated pressure is the pressure of air at which most (if not all) apneas and hypopneas have been prevented, and it is usually measured in centimeters of water (cm H<sub>2</sub>O). A Respiratory Assist Device (RAD) without backup rate delivers adjustable, variable levels of positive air pressure by way of tubing and a nasal or oral facial mask to assist in the spontaneous respiratory efforts of the patient.

### CPT Codes Covered Requiring Prior Authorization (PA)

E0470 - Respiratory Assist Device (RAD), bi-level capability, without backup rate feature, used with noninvasive interface, e.g. nasal or facial mask  
E0471 - Respiratory Assist Device (RAD), bi-level capability, with backup rate feature, used with noninvasive interface, e.g. nasal or facial mask  
E0601 - Continuous positive airway pressure (CPAP) device

### Approval Criteria

#### I. GENERAL

Documentation submitted in order to request services or substantiate previously provided services must demonstrate through adequate objective medical records, evidence sufficient to justify the clients need for the service in accordance with OAC 317: 30-3-1-1 (f) (2).

#### II. INDICATIONS

##### A. Initial coverage criteria for OBSTRUCTIVE SLEEP APNEA

In this guideline, the term PAP (positive airway pressure) device will refer to both a single level continuous positive airway pressure device (E0601) and a bi-level respiratory assist device without back-up rate (E0470) when it is used in the treatment of obstructive sleep apnea.

If the AHI or RDI for an adult is calculated based on less than 2 hours of sleep or recording time, the total number of recorded events used to calculate the AHI or RDI (respectively) must be at least the number of events that would have been required in a 2 hour period (i.e., must reach > 30 events without symptoms or > 10 events with symptoms).

1. For members 13 years of age and older, an **E0601** device is covered for the treatment of obstructive sleep apnea (OSA) if *all* criteria a - c are met:
  - a. The patient has a face-to-face clinical evaluation by the treating qualified medical professional within 6 months prior to the sleep test to assess the patient for obstructive sleep apnea.
  - b. The patient has a qualifying Polysomnogram, performed in a Sleep Diagnostic Testing Facility, dated within one year of the prior authorization request that meets **either** of the following criteria:
    1. The AHI or RDI is greater than or equal to 15 events per hour with a minimum of 30 events; or

2. The AHI or RDI is greater than or equal to 5 and less than 15 events per hour with a minimum of 10 events and documentation of **either**
    - i. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or
    - ii. Hypertension, ischemic heart disease, or history of stroke.
  - c. The patient and/or their caregiver have received instruction from the supplier of the device in the proper use and care of the equipment.
2. For members 12 year of age and younger, an **E0601** device is covered for the treatment of obstructive sleep apnea (OSA) if *all* criteria a – c are met:
    - a. The patient has a face-to-face clinical evaluation by the treating qualified medical professional within 6 months prior to the sleep test to assess the patient for obstructive sleep apnea.
    - b. A polysomnography that demonstrates an apnea index (AI) or apnea-hypopnea index (AHI)  $\geq 1$  and **one** of the following:
      1. Adenotonsillectomy has been unsuccessful in relieving OSA; or
      2. Adenotonsillar tissue is minimal; or
      3. Adenotonsillectomy is inappropriate based on OSA being attributable to another underlying cause (such as craniofacial anomaly); or
      4. Adenotonsillectomy is contraindicated.
    - c. The patient and/or their caregiver have received instruction from the supplier of the device in the proper use and care of the equipment.
  3. An **E0470** device is covered for those members with OSA who meet all criteria a – c above, in addition to the following criteria:
    - a. An E0601 has been tried and proven ineffective based on a therapeutic trial conducted in either a facility or in a home setting.
    - b. Ineffective is defined as documented failure to meet therapeutic goals using an E0601 during the titration portion of a facility-based study or during the home trial despite optimal therapy (i.e. proper mask selection, fitting, and appropriate pressure settings).
    - c. If an E0601 device is tried and found ineffective during the 3 month home trial, substitution of an E0470 does not require a new initial face-to-face clinical evaluation or a new sleep test. Substitution of an E0470 does not change the length of the trial unless there is less than 30 days remaining in the trial period.

A new authorization is required to switch devices. If more than 30 days remain in the trial period, the clinical re-evaluation would still occur between the 31st and 90th day following the initiation of an E0601 and objective documentation of adherence on the E0470 would need to occur prior to the 90th day following initiation of the E0601. Thirty (30) day retro authorization rules apply.

**B. Members who fail the INITIAL TRIAL FOR OBSTRUCTIVE SLEEP APNEA**

1. Members who fail the initial 3 month trial are eligible to re-qualify for a PAP device but must have a face-to-face clinical re-evaluation by the treating qualified medical professional to determine the etiology of the failure to respond to PAP therapy.
2. Even though it is not required, the qualified medical professional, at their discretion,

may choose to require a repeat sleep study in a facility based setting (Type 1) to determine the optimal CPAP settings for the member to support the need for the PAP device.

3. If the Qualified Medical Professional (QMP) recommends an additional trial based on their assessment during the face-to-face clinical re-evaluation; the provider may request an additional 3 month trial with documentation provided by the QMP even though the member did not meet the qualifying adherence to therapy schedule during the first 3 months.
4. If the member meets the adherence guidelines during the 2<sup>nd</sup> trial period; the PAP device will be eligible for continued rental to the 13 month capped rental period.
5. If the member does not meet the adherence guidelines during the 2<sup>nd</sup> trial period; it will be determined that the member is not in compliance with the PAP device and no additional months of rental will be authorized.
6. If there is discontinuation of usage of a PAP device at any time, the supplier is expected to ascertain this and stop billing for the equipment and related accessories and supplies.

#### C. PAP qualifications for RESTRICTIVE THORACIC DISORDERS

An E0470 or E0471 device is covered when criteria 1, 2, & 3 are met.

1. There is documentation in the member's medical record of a neuromuscular disease (e.g. amyotrophic lateral sclerosis) or a severe thoracic cage abnormality (e.g. post-thoracoplasty for TB).
2. One of the following:
  - a. An arterial blood gas PaCO<sub>2</sub>, done while awake and breathing the member's prescribed FIO<sub>2</sub> is greater than or equal to 45 mm Hg, or
  - b. Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing the member's prescribed recommended FIO<sub>2</sub>, or
  - c. or a neuromuscular disease (only) with either i or ii,
    - i. Maximal inspiratory pressure is less than 60 cm H<sub>2</sub>O, or
    - ii. Forced vital capacity is less than 50% predicted
3. Chronic obstructive pulmonary disease does not contribute significantly to the member's pulmonary limitation.

If *all* of the above criteria are met, either an E0470 or an E0471 device (based upon the judgment of the treating physician) will be covered for the first three months of therapy.

See section III. CONTINUED COVERAGE CRITERIA FOR E0470 AND E0471 DEVICES BEYOND THE FIRST THREE MONTHS for information on more than three months use.

#### D. PAP qualifications for SEVERE COPD

An E0470 device is covered if criteria 1, 2, & 3 are met.

1. An arterial blood gas PaCO<sub>2</sub>, done while awake and breathing the member's prescribed FIO<sub>2</sub>, is greater than or equal to 52 mm Hg.
2. Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater than or equal to a cumulative 5 minutes of nocturnal recording time (minimum

recording time of 2 hours), done while breathing oxygen at 2 LPM or the member's prescribed FIO<sub>2</sub> (whichever is higher).

3. Prior to initiating therapy, sleep apnea and treatment with a continuous positive airway pressure device (CPAP) has been considered and ruled out. Formal sleep testing is not required if there is sufficient information in the medical record to demonstrate that the beneficiary does not suffer from some form of sleep apnea (OSA, CSA and/or Comp SA) as the predominant cause of awake hypercapnia or nocturnal arterial oxygen desaturation).

If *all* of the above criteria for patients with COPD are met, an E0470 device will be covered for the first three months of therapy.

Examples:

An **E0471** device will be covered for a beneficiary with COPD in either of the two situations below, depending on the testing performed to demonstrate the need.

*Situation 1. For patients with COPD who qualified for an E0470 device, an E0471 started any time after a period of initial use of an E0470 device is covered if both criteria A and B are met:*

- A. *An arterial blood gas PaCO<sub>2</sub>, done while awake and breathing the member's prescribed FIO<sub>2</sub>, shows that the member's PaCO<sub>2</sub> worsens greater than or equal to 7 mm HG compared to the original result from criterion A, (above), AND,*
- B. *A facility-based PSG demonstrates oxygen saturation less than or equal to 88% for greater than or equal to a cumulative 5 minutes of nocturnal recording time (minimum recording time of 2 hours) while using an E0470 device that is not caused by obstructive upper airway events (i.e. AHI less than 5). Refer to the Positive Airway Pressure Devices LCD for information about E0470 coverage for obstructive sleep apnea.*

*Situation 2. For patients with COPD who qualified for an E0470 device, an E0471 device will be covered if, at a time no sooner than 61 days after initial issue of the E0470 device, both of the following criteria A and B are met:*

- A. *An arterial blood gas PaCO<sub>2</sub> is done while awake and breathing the member's prescribed FIO<sub>2</sub>, still remains greater than or equal to 52 mm Hg., AND,*
- B. *Sleep oximetry while breathing with the E0470 device, demonstrates oxygen saturation less than or equal to 88% for greater than or equal to a cumulative 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing oxygen at 2 LPM or the member's prescribed FIO<sub>2</sub>, whichever is higher.*

E. PAP qualifications for CENTRAL SLEEP APNEA or COMPLEX SLEEP APNEA

1. Central Sleep Apnea (CSA) diagnosis is defined by *all* of the following criteria:
  - a. An Apnea-Hypopnea Index (AHI) greater than or equal to 5; AND
  - b. The sum total of central apneas plus central hypopneas is greater than 50% of total apneas and hypopneas; AND
  - c. A central apnea-hypopnea index (CAHI) is greater than or equal to 5 per hour; AND
  - d. The presence of at least one of the following:
    - i. Sleepiness
    - ii. Difficulty initiating or maintaining sleep, frequent awakenings, or nonrestorative sleep
    - iii. Awakening short of breath
    - iv. Snoring
    - v. Witnessed apneas; AND
  - e. There is no evidence of daytime or nocturnal hypoventilation.

2. Complex Sleep Apnea (CompSA) is a form of sleep apnea specifically defined by *all* of the following criteria:
  - a. With use of a positive airway pressure device without a backup rate (E0601 or E0470), the Polysomnogram (PSG) shows a pattern of apneas and hypopneas that demonstrates the persistence or emergence of central apneas or central hypopneas upon exposure to CPAP (E0601) or a bi-level device without backup rate (E0470) device when titrated to the point where obstructive events have been effectively treated (obstructive AHI less than 5 per hour), AND
  - b. After resolution of the obstructive events, the sum total of central apneas plus central hypopneas is greater than 50% of the total apneas and hypopneas; AND
  - c. After resolution of the obstructive events, a central apnea-central hypopnea index (CAHI) greater than or equal to 5 per hour.
  
3. An E0470 or E0471 device is covered when, prior to initiating therapy, a complete facility-based, attended PSG is performed documenting the following (a and b):
  - a. The diagnosis of central sleep apnea (CSA) or complex sleep apnea (CompSA); AND
  - b. Significant improvement of the sleep-associated hypoventilation with the use of an E0470 or E0471 device on the settings that will be prescribed for initial use at home, while breathing the member's prescribed FIO2.

If *all* of the above criteria are met, either an E0470 or an E0471 device (based upon the judgment of the treating physician) will be covered for beneficiaries with documented CSA or CompSA for the first three months of therapy.

#### F. PAP qualifications for HYPOVENTILATION SYNDROME

1. An **E0470** device is covered if *both* criteria a and b and either criterion c *or* d are met:
  - a. An initial arterial blood gas PaCO<sub>2</sub>, done while awake and breathing the member's prescribed FIO<sub>2</sub>, is greater than or equal to 45 mm Hg.
  - b. Spirometry shows an FEV<sub>1</sub>/FVC greater than or equal to 70%. (Refer to SEVERE COPD (above) for information about device coverage for beneficiaries with FEV<sub>1</sub>/FVC less than 70%.)
  - c. An arterial blood gas PaCO<sub>2</sub>, done during sleep or immediately upon awakening, and breathing the member's prescribed FIO<sub>2</sub>, shows the member's PaCO<sub>2</sub> worsened greater than or equal to 7 mm HG compared to the original result in criterion A (above).
  - d. A facility-based PSG demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events (i.e., AHI less than 5.)

Refer to the Positive Airway Pressure Devices LCD for information about E0470 coverage for obstructive sleep apnea.

2. An **E0471** device is covered for a beneficiary with hypoventilation syndrome if *both* criteria a and b and either criterion c *or* d are met:
  - a. A covered E0470 device is being used, AND.
  - b. Spirometry shows an FEV<sub>1</sub>/FVC greater than or equal to 70%. (Refer to SEVERE COPD (above) for information about device coverage for beneficiaries with FEV<sub>1</sub>/FVC less than 70%), AND
  - c. An arterial blood gas PaCO<sub>2</sub>, done while awake, and breathing the member's prescribed FIO<sub>2</sub>, shows that the member's PaCO<sub>2</sub> worsens greater than or equal to 7 mm HG compared to the ABG result performed to

- qualify the beneficiary for the E0470 device (criterion A under E0470), OR
- d. A facility-based PSG demonstrates oxygen saturation less than or equal 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events (i.e., AHI less than 5 while using an E0470 device).

Refer to the Positive Airway Pressure Devices LCD for information about E0470 coverage for obstructive sleep apnea.

### **III. CONTINUED MEDICAL NECESSITY**

#### **CONTINUED COVERAGE CRITERIA FOR E0470 AND E0471 DEVICES BEYOND THE FIRST THREE MONTHS OF THERAPY**

1. Beneficiaries covered for the first three months of an E0470 or an E0471 device must be re-evaluated to establish the medical necessity of continued coverage beyond the first three months. While the beneficiary may certainly need to be evaluated at earlier intervals after this therapy is initiated, the re-evaluation will base a decision to continue coverage beyond this time must occur no sooner than 61 days after initiating therapy by the treating physician. Coverage will not continue for the fourth and succeeding months of therapy until this re-evaluation has been completed.
2. There must be documentation in the member's medical record about the progress of relevant symptoms and beneficiary usage of the device up to that time. Failure of the beneficiary to be consistently using the E0470 or E0471 device for an average of 4 hours per 24 hour period by the time of the re-evaluation (on or after 61 days after initiation of therapy) would represent non-compliant utilization for the intended purposes and expectations of benefit of this therapy. This would constitute reason to deny continued coverage as not reasonable and necessary.
3. A signed and dated statement completed by the treating physician no sooner than 61 days after initiating use of the device, declaring that the beneficiary is compliantly using the device (an average of 4 hours per 24 hour period) and that the beneficiary is benefiting from its use must be obtained by the supplier of the device for continued coverage beyond three months.
4. If the above criteria are not met, continued coverage of an E0470 or an E0471 device and related accessories will be denied as not reasonable and necessary.
5. In the event that criteria for continued coverage are not met, the device in question, being the property of the State of Oklahoma, must be recovered by the DME provider and provided to the ReUse program.

Note: Additional information may be requested.

#### **Discontinuation Criteria**

Continued coverage of a PAP device beyond the first three months of therapy requires the treating qualified medical professional conduct a clinical re-evaluation and document that the member is benefiting from PAP therapy.

All other indications for PAP not otherwise noted above as covered or non-covered, remain at discretion of Oklahoma Health Care Authority.

## Additional Information

### **I. SUPPLIES / ACCESSORIES**

Accessories used with a PAP device are covered when the criteria for the device are met. Either a non-heated or heated humidifier is covered when ordered by the treating qualified medical professional for use with a covered PAP device.

Suppliers should stay attuned to atypical utilization patterns of their clients. A member or their caregiver must specifically request refills of PAP accessories before they are dispensed. The supplier must not automatically dispense a quantity of supplies on a predetermined regular basis, even if the member has "authorized" this in advance.

Refer to the OHCA website for current codes.

### **II. REPLACEMENT**

If capped rental equipment has been in continuous use by the member for the equipment's useful life or if the item is irreparably damaged, lost, or stolen, a prior authorization must be submitted to obtain new equipment. The reasonable useful life for capped rental equipment cannot be less than five years. Useful life is determined by the delivery of the equipment to the member, not the age of the equipment.

If a PAP device is replaced during or following the 5 year reasonable useful lifetime because of loss, theft, or irreparable damage due to a specific incident, there must be a face-to-face evaluation by their treating qualified medical professional that documents the beneficiary continues to use and benefit from the PAP device. There is no requirement for a new sleep test or trial period.

## References

1. Food and Drug Administration (FDA) Current definitions for Sleep Disordered Breathing in Adults. SDB workshop 2018. Author: Patil, S. MD, PhD, Johns Hopkins University. Retrieved from <https://www.fda.gov/media/112603/download>
2. Local Coverage Determination (L33800): Respiratory Assist Devices. Nordin Medicare updated January 1, 2019. Retrieved from <https://med.nordinmedicare.com/documents/2230703/7218263/Respiratory+Assist+Devices+LCD+and+PA/25c966f2-e3e6-4d6d-8d74-d1a3491d257f>
3. National Coverage Determination, CMS January 2018. MLN Matters: Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA). Retrieved from <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM6048.pdf>
4. New England Journal of Medicine, April 11, 2019. Obstructive Sleep Apnea in Adults. Veasey, S. MD, Rosen, I. MD. 380:1442-9. DOI: 10.1056/NEJMc1816152
5. Oklahoma Health Care Authority, Policies & Rules, OAC 317:30-3-1-1.
6. Oklahoma Sleep Diagnostic Testing Regulation Act Title 63. Public Health and Safety. Chapter 84 – OK Sleep Diagnostic Testing Regulation Act. O.S. § 7200.1 - 72.00.5 (OSCN 2019)
7. UpToDate.com peer review, March 2019. Initiation of positive airway pressure therapy for obstructive sleep apnea in adults. Authors: Brown, L. MD, Lee, B. MD. Editors: Collop, N. MD, Finaly, G. MD. Retrieved from [https://www.uptodate.com/contents/initiation-of-positive-airway-pressure-therapy-for-obstructive-sleep-apnea-in-adults/print?search=positive%20airway%20pressure&source=search\\_result&selectedTitle=1~150&usage\\_type=default&display\\_rank=1](https://www.uptodate.com/contents/initiation-of-positive-airway-pressure-therapy-for-obstructive-sleep-apnea-in-adults/print?search=positive%20airway%20pressure&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1)
8. UpToDate.com peer review, October 2019. Noninvasive positive airway pressure therapy for the obesity hypoventilation syndrome. Author: Martin, T., MD. Editors: Badr, M. MD, Finlay G. MD. Retrieved from [https://www.uptodate.com/contents/noninvasive-positive-airway-pressure-therapy-for-the-obesity-hypoventilation-syndrome/print?search=positive%20airway%20pressure&source=search\\_result&selectedTitle=4~150&usage\\_type=default&display\\_rank=4](https://www.uptodate.com/contents/noninvasive-positive-airway-pressure-therapy-for-the-obesity-hypoventilation-syndrome/print?search=positive%20airway%20pressure&source=search_result&selectedTitle=4~150&usage_type=default&display_rank=4)
9. Washington State Medicaid, WAC 182-552-0400, Respiratory Care-Continuous positive airway pressure (CPAP) device and supplies, effective 8/1/2012.
10. WellCare, Pediatric Continuous Positive Airway Pressure (CPAP) for the treatment of Obstructive Sleep Apnea (<18 Years), HS-099, 6/7/2012.

## Appendix A:

### Oklahoma Sleep Diagnostic Testing Regulation Act

#### §63-7200.1. Short title.

This act shall be known and may be cited as the “Oklahoma Sleep Diagnostic Testing Regulation Act”.

Added by Laws 2009, c. 360, § 1.

#### §63-7200.2. Legislative findings.

The Oklahoma Legislature hereby finds that:

1. There is a growing need for sleep diagnostic testing in the diagnosis and treatment of sleep disorders;
2. Sleep diagnostic testing is being performed in Oklahoma; and
3. Oklahoma law does not provide sufficient regulation of sleep diagnostic testing to assure the protection of the public.

Therefore, there is a need to provide legislation to enable the appropriate entities to regulate persons performing sleep diagnostic testing on the citizens of this state.

Added by Laws 2009, c. 360, § 2.

#### §63-7200.3. Definitions.

As used in the Oklahoma Sleep Diagnostic Testing Regulation Act:

1. “Advanced practice nurse” means a person licensed to practice as an advanced practice nurse by the Oklahoma Board of Nursing pursuant to the Oklahoma Nursing Practice Act;
2. “Interpreting physician” means a physician who provides professional interpretation of data generated by sleep diagnostic tests. An interpreting physician shall be board-certified in sleep medicine by the American Board of Sleep Medicine (ABSM) or the American Board of Medical Specialties or must have completed a one-year sleep medicine fellowship accredited by the Accreditation Council for Graduate Medical Education (ACGME) or received a Certification of Special Qualifications (CSQ) or a Certification of Added Qualifications (CAQ) in Sleep Medicine issued by the American Osteopathic Association;
3. “Physician” means a person licensed to practice:
  - a. allopathic medicine and surgery by the State Board of Medical Licensure and Supervision pursuant to the Oklahoma Allopathic Medical and Surgical Licensure and Supervision Act, or
  - b. osteopathic medicine by the State Board of Osteopathic Examiners pursuant to the Oklahoma Osteopathic Medicine Act;
4. “Physician assistant” means a person licensed to practice as a physician assistant by the State Board of Medical Licensure and Supervision pursuant to the Physician Assistant Act;
5. “Sleep diagnostic test” means any technological recording procedure used for the diagnosis of sleep-related breathing disorders or other disorders of sleep;
6. “Sleep diagnostic testing facility” means a building or place situated in a fixed location or a mobile entity that is used to conduct sleep diagnostic tests and includes sleep disorder centers and laboratories

for sleep-related breathing disorders, but does not include a hospital that conducts sleep diagnostic tests for its patients, including sleep diagnostic tests performed under arrangements made by a hospital for its patients whereby the hospital exercises professional responsibility over the arranged services; and

7. "Supervising physician" means a physician responsible for the supervision of the sleep diagnostic testing performed, including, but not limited to, the quality of the testing performed, the proper operation and calibration of the equipment used to perform sleep diagnostic tests and the actions of nonphysician personnel engaged in the performance of the sleep diagnostic testing. A supervising physician shall be board-certified in sleep medicine by the American Board of Sleep Medicine (ABSM) or the American Board of Medical Specialties or shall have completed a one-year sleep medicine fellowship accredited by the Accreditation Council for Graduate Medical Education (ACGME), or received a Certification of Special Qualifications (CSQ) or a Certification of Added Qualifications (CAQ) in Sleep Medicine issued by the American Osteopathic Association.

Added by Laws 2009, c. 360, § 3. Amended by Laws 2010, c. 200, § 1, eff. Nov. 1, 2010.

§63-7200.4. Ordering and furnishing sleep diagnostic tests - Facility standards.

- A. Sleep diagnostic tests shall be ordered by a physician, physician assistant or advance practice nurse.
- B. Sleep diagnostic tests shall be furnished:
  - 1. By a sleep diagnostic testing facility;
  - 2. By, or under arrangements made by, a hospital for its patients whereby the hospital exercises professional responsibility over the arranged services; or
  - 3. In the patient's home.
- C. Sleep diagnostic testing facilities shall meet the following standards:
  - 1. Sleep diagnostic testing facilities shall be supervised by a supervising physician as defined by this act;
  - 2. On and after January 1, 2010, sleep diagnostic testing facilities shall be fully or provisionally certified or accredited by the American Academy of Sleep Medicine (AASM), the Joint Commission or the Accreditation Commission for Healthcare (ACHC), except that the full or provisional certification or accreditation by AASM, the Joint Commission, or ACHC shall not be required until June 30, 2010, for any sleep diagnostic testing facility that has submitted a complete application for certification or accreditation to AASM, the Joint Commission and/or ACHC on or before December 31, 2009;
  - 3. An interpreting physician shall interpret the data generated by all sleep diagnostic tests conducted at a sleep diagnostic testing facility; and
  - 4. Nonphysician personnel conducting sleep diagnostic tests shall perform their duties under the direction and supervision of the supervising physician.
- D. Sleep diagnostic tests performed in the patient's home shall be conducted under the supervision of a supervising physician and interpreted by an interpreting physician.

Added by Laws 2009, c. 360, § 4.

§63-7200.5. Violations - Enforcement - Promulgation of rules.

- A. It shall be unlawful for any facility or person to perform sleep diagnostic tests without having first complied with this act or as may otherwise be allowed by applicable law.
- B. The State Department of Health is authorized to enforce the provisions of this act.
- C. The State Board of Health shall promulgate rules and enforcement measures as necessary to implement the provisions of the Oklahoma Sleep Diagnostic Testing Regulation Act.

Added by Laws 2009, c. 360, § 5. Amended by Laws 2010, c. 200, § 2, eff. Nov. 1, 2010.