

NORTH CAROLINA RESPIRATORY CARE BOARD
Position Statement
Continuous Positive Airway Pressure Devices

This Position Statement from the North Carolina Respiratory Care Board will interpret the relevant provisions of statutes and rules which relate to the provision of Continuous Positive Airway Pressure (CPAP) Devices for patients who use these devices in the home care environment. For purposes of this position statement, the term "CPAP" includes: CPAP, BiPAP[®] Resironics, BiLevel CPAP, Auto Titrate CPAP, VPAP[®] ResMed, and other continuous positive airway pressure units or devices.

Each of these devices function by delivering positive airway pressure. To be used safely and effectively, it is essential for an appropriately trained health care professional, usually a Respiratory Care Practitioner, to perform an assessment of each patient, to select and fit an appropriate device based on the assessment, to provide training for the individual on its use, and to follow-up with the individual to assure compliance with the therapeutic regimen. Without appropriate assessment, training, and follow-up, there is a substantial risk that the device will not be properly used. Improper use can create a direct risk of injury to the patient, but improper use also can harm the patient by diminishing or eliminating the therapeutic benefit of the device. Without suitable training and follow-up, a patient may not use the CPAP device appropriately, or may not feel comfortable in using it at all.

It has come to the attention of the Board that some Home Medical Equipment (HME) companies may be providing CPAP units or devices to patients without appropriate assessment and education. Information received directly from one company's employee, from the Carolina Sleep Society, and from a company brochure indicates that at least one HME company may have shipped CPAP units or devices to patients without providing or arranging for any face-to-face assessment and education with the patient or for appropriate follow-up with the patient.

The Board has concluded that face-to-face assessment and education of the patient, as well as appropriate follow-up, is essential in providing CPAP units or devices. Providing CPAP units or devices without assessment, education and follow-up presents a substantial risk of harm to the patient because it is likely to increase the incidence of patient noncompliance with the prescribed treatment regimen.

Several relevant portions of the Board's statute and rules directly relate to this requirement of assessment, education and follow up in the provision of CPAP units or devices:

- First, the practice of respiratory care, as defined in North Carolina General Statute 90-647 (10) includes "...the observing and monitoring of signs and symptoms, general behavior, and general physical response to respiratory care treatment and diagnostic testing...." and includes " the performance of diagnostic

testing and therapeutic application of mechanical or physiological ventilatory support". When a CPAP device or unit is first provided to a patient, it is crucial that an appropriate professional should have a face-to-face encounter. By the very nature of this activity, the provision of CPAP units and devices to patients will involve fitting the apparatus and ensuring its proper function. Therefore, providing CPAP units and devices involves both "the performance of diagnostic testing and therapeutic application of mechanical or physiological ventilatory support," as well as "the observing and monitoring of signs and symptoms, general behavior, and general physical response to respiratory care treatment." Accordingly, the Board has determined that the application of CPAP devices constitutes the practice of respiratory care and should not be undertaken without having a licensed RCP or other appropriately licensed professional involved to supervise the process. For purposes of this position statement the term "supervise" is defined as, "The authority and responsibility to direct the performance of activities as established by policies and procedures for safe and appropriate completion of services", as codified in NC General Statute 90-648 (3).

- In addition, failing to create and maintain respiratory care records documenting the assessment and treatment provided to each patient is a violation of Board Rule 21 NCAC 61 .0307 (15).
- The Board recognizes that there is an exemption in the Practice Act at GS 90-654(4) and defined in GS 90-648 (13), that permits "support activities" to be conducted by persons who are not licensed by the Board.

Procedures that do not require formal academic training, including the delivery, setup, and maintenance of the apparatus. The term also includes giving instructions on the use, fitting, and application of apparatus, but does not include therapeutic evaluation and assessment.

Accordingly, the Board has determined that the North Carolina Respiratory Care Act and the Board's administrative rules prohibit the therapeutic application of CPAP units or devices without appropriate face-to-face assessment and education initially, as well as appropriate follow up, all conducted by a Respiratory Care Practitioner licensed by the Board or by another appropriately licensed or certified professional who is providing these services within that other professional's recognized scope of practice. Providing CPAP units or devices without following these safeguards poses a substantial risk of harm to patients and is detrimental to public health, safety, and welfare.

Under no circumstances shall any type of CPAP units or devices be shipped to a patient in North Carolina without providing or arranging for face-to-face education and evaluation of the patient and appropriate follow-up.
