

RULE ADOPTIONS
VOLUME 43, ISSUE 16
ISSUE DATE: AUGUST 15, 2011
LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF RESPIRATORY CARE

Adopted Amendments: N.J.A.C. 13:44F-10.2 and 10.3

Adopted New Rule: N.J.A.C. 13:44F-10.2A

Delegation by a Respiratory Care Practitioner to Unlicensed Persons; Approval of Continuing Education Programs, Courses, Seminars and Articles; Determination of Credits; Performance-Based Competency Assessment; Approval; Determination of Credits; Licensee Certification of Compliance; Recordkeeping; Audit

Proposed: July 6, 2010 at 42 N.J.R. 1331(a).

Adopted: February 10, 2011 by the State Board of Respiratory Care, Kenneth Capek, Chairman.

Filed: July 6, 2011 as R.2011 d.211, **with a substantive change** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3), **with amendments to N.J.A.C. 13:44F-3.3 not adopted.**

Authority: N.J.S.A. 45:1-15.1 and 45:14E-7.

Effective Date: August 15, 2011.

Expiration Date: April 4, 2015.

Summary of Public Comments and Agency Responses:

The Board received comments on the notice of proposal from the following:

1. Wendy Russalesi, Executive Director, Jersey Association of Medical Equipment Services;
2. Jeffrey Reses;
3. Daryl Rogers;
4. Ronald Manno, President, Core Care Technologies, Inc.;
5. Robert Miller;
6. Michael Eddy, RRT;
7. Vikram Patel;
8. Erick Cooper, RRT, President, New Jersey Society for Respiratory Care;
9. Joseph Goss, RRT; and
10. John W. Indyk, Director of Governmental Affairs, Health Care Association of New Jersey.

[page=2189] 1. COMMENT: Several commenters objected to the proposed amendments to N.J.A.C. 13:44F-3.3(d)3 that would disallow the demonstration of respiratory equipment by unlicensed persons. The commenters believe that removing this task from the list of permissible actions that may be performed by an unlicensed person will delay the delivery of home oxygen equipment to patients, potentially compromising patient health and well being. The commenters believe that the current standard articulated in the rule, which requires a licensed respiratory care practitioner to visit the patient within 24 hours of equipment delivery in order to document and assess patients' needs, adequately ensures patient safety.

The commenters noted that in order to provide timely access to medically necessary equipment and services, home medical equipment providers initiate order processing immediately upon receipt from patients' prescribing physicians. Very often, home medical equipment providers receive orders for home oxygen services for a patient who is scheduled to be discharged from an inpatient setting. In such situations, it is common for the home medical equipment provider to deliver a portable oxygen system to the patient at the inpatient setting in order to facilitate the patient's discharge. Under such circumstances, it is unlikely that a licensed respiratory care practitioner employed by an inpatient facility

would assume responsibility for demonstrating this equipment to the patient and/or the patient's caregiver. The commenters noted that it is not practical, nor is it an efficient use of resources, to require a licensed respiratory care practitioner to visit the hospital to demonstrate this equipment for the patient and then to travel to the patient's home for the required follow-up visit.

Two commenters expressed concern that the proposed amendment could negatively impact home medical equipment provider hospice contracts and could have a negative effect in other healthcare settings. Other commenters noted that the proposed amendments will result in undue hardship for home medical equipment companies, noting that it will not be economically feasible for home medical equipment providers to employ the multiple respiratory therapists that would be needed to satisfy the new requirements. The commenters believe that most home medical equipment providers in the State will be forced out of business, leading to delayed patient care and increased admissions to hospitals and nursing facilities. Other commenters noted that the recent passage of the Affordable Care Act, combined with the added responsibility placed on licensees as a result of the proposed amendments will place a significant strain on licensed respiratory care practitioners' ability to practice in New Jersey.

Several commenters noted that the proposed amendments unreasonably require patients to wait for a respiratory care practitioner to demonstrate equipment, when technicians are appropriately trained to ensure that patients arriving home may continue their therapy without undue delay. The commenters also noted that technicians are re-evaluated on an annual basis in order to ensure their continued competency.

Several commenters requested that the Board define the terms "demonstration," "instruction" and "direct patient care," noting that the demonstration of oxygen concentrators does not constitute direct patient care.

RESPONSE: In light of the various issues that the commenters have raised, the Board believes that reconsideration of the proposed amendments to N.J.A.C. 13:44F-3.3 is necessary. Specifically, the Board believes that additional amendments to N.J.A.C. 13:44F-3.3(d) may be necessary in order to ensure that patients in an out-patient setting may continue to receive oxygen therapy in a timely and efficient manner and with as little disruption in care as possible. The Board, therefore, is not adopting the proposed amendments to N.J.A.C. 13:44F-3.3 at this time, and will undertake a thorough review of the commenters' suggestions and concerns. The Board intends to repropose amendments to N.J.A.C. 13:44F-3.3 in order to clarify the tasks that may be delegated to unlicensed persons, but mindful of the practical differences in in-patient and out-patients treatment settings.

2. COMMENT: Several commenters expressed support for the proposed amendments to N.J.A.C. 13:44F-3.3(d), noting that the amendments will help protect patients by ensuring that the care they receive is from a licensed respiratory care professional. One commenter noted that having an unlicensed driver or technician demonstrate equipment can be risky for the patient. Two commenters noted that the proposed amendments will result in greater oversight of unlicensed assistants, leading to enhanced patient safety and better quality of care. One commenter believes that the proposed amendments will result in increased employment opportunities for licensed respiratory care practitioners in New Jersey. One commenter noted that the elimination of the phrase "demonstration of basic respiratory care equipment" in N.J.A.C. 13:44F-3.3(d) will help eliminate confusion.

RESPONSE: Although the Board thanks the commenters for their support of the proposed amendments, as noted in the Response to Comment 1, the Board believes that reconsideration of the proposed amendments is warranted in light of the significant issues and concerns that have been raised by various commenters to the notice of proposal.

3. COMMENT: Several commenters inquired as to how the proposed amendments would be applied to the provision of oxygen to airline customers, to the sale and rental of oxygen delivery systems to New Jersey residents through the Internet and to the provision of standard nebulizers, which are commercially available from various sources without instruction.

RESPONSE: In light of the Board's decision to not adopt the proposed amendments to N.J.A.C. 13:44F-3.3, questions about the proposed amendments' application are moot.

4. COMMENT: Two commenters expressed support for the restriction in N.J.A.C. 13:44F-3.3(d) that prohibits unlicensed assistants from setting up and demonstrating complex respiratory equipment, such as PAP devices and ventilators. The commenters recommended that this prohibition remain in effect.

RESPONSE: The current restrictions in N.J.A.C. 13:44F-3.3(d) will remain in effect as the Board is not adopting the proposed amendments to N.J.A.C. 13:44F-3.3 at this time.

5. COMMENT: One commenter noted that the Board's existing rule on patient documentation requires records to be maintained for seven years, except in the case of a minor patient, where records must be maintained for an additional two years beyond the age of 18. Two commenters requested clarification that the records that are to be maintained for three years under the proposed amendments to N.J.A.C. 13:44F-3.3(e), are equipment related records, and not patient records.

RESPONSE: The Board is not adopting the proposed amendments to N.J.A.C. 13:44F-3.3. The commenter correctly notes that patient documentation must be retained consistent with the requirements of existing Board rule N.J.A.C. 13:44F-8.2.

6. COMMENT: One commenter noted that other health care providers, such as nurses and pharmacists must be allowed to provide oxygen if that is within the health care professional's scope of practice.

RESPONSE: The Board notes that although it is not adopting the proposed amendments to N.J.A.C. 13:44F-3.3, the Board does not disagree with the commenter's assertion, and notes that the proposed amendments to the rule did not curtail the ability of other licensed healthcare providers to provide oxygen therapy to patients within the provider's scope of practice.

7. COMMENT: Several commenters expressed support for the proposed amendments to the Board's continuing education requirements, noting that the amendments are both reasonable and necessary. One commenter expressed support for the increased flexibility that the proposed amendments to N.J.A.C. 13:44F-10.2(a) and (b) will provide to respiratory care practitioners in the State.

RESPONSE: The Board thanks the commenters for their support of the proposed amendments to the continuing education requirements.

8. COMMENT: One commenter suggested that the Board consider amending its continuing education rules in the future to permit licensees to obtain credits in courses or programs approved by the International Association for Continuing Education and Training (IACET).

RESPONSE: The Board thanks the commenter for the suggestion. The Board notes that N.J.A.C. 13:44F-10.2, as amended, provides licensees with varied courses and programs from which to choose in order to satisfy their continuing education obligations. However, if the Board determines in the future that additional sources of continuing education are necessary to permit licensees to satisfy their continuing education obligation, the Board will undertake a review of IACET-approved courses or programs to determine whether inclusion of such courses or [page=2190] programs under N.J.A.C. 13:44F-10.2 would be reasonable and appropriate.

9. COMMENT: One commenter believes that the proposed amendments to N.J.A.C. 13:44F-10.2(a)1, which provide that courses or programs within the scope of respiratory care offered or approved by the American Medical Association (AMA) or the American Nursing Association (ANA) are acceptable sources of continuing education for Board licensee, may not provide licensees with adequate guidance as to acceptable programs. The commenter also expressed concern regarding the equivalency of credits awarded by the AMA and the ANA to Board-awarded credits.

RESPONSE: The Board disagrees with the commenter's suggestion that the proposed amendments to N.J.A.C. 13:44F-10.2(a)1 lack clarity as to acceptable courses or programs. N.J.A.C. 13:44F-10.2(a) provides that courses or programs offered by the providers referenced in the rule will be deemed acceptable sources of continuing education for Board licensees provided the subject matter falls within the content areas set forth in N.J.A.C. 13:44F-10.1(c). Courses or programs offered by the AMA or the ANA (as approved providers under N.J.A.C. 13:44F-10.2(a)1) would qualify for continuing education credit, as long as the courses or programs provide instruction in the content areas articulated in N.J.A.C. 13:44F-10.1(c). The Board also notes that the proposed amendments clearly articulate the number of credits that licensees may claim for the successful completion of AMA or ANA courses. N.J.A.C. 13:44F-10.2(a)1 provides that one continuing education credit will be awarded for each course credit awarded by the provider.

10. COMMENT: Two commenters noted that although the National Board for Respiratory Care (NBRC) administers the advanced credentialing examination that the Board has proposed be eligible for continuing education credit under N.J.A.C. 13:44F-10.2(a)2, it is the American Association for Respiratory Care that grants continuing education credit for its completion. The commenters recommend that the reference to NBRC-approved continuing education in the proposed amendments be eliminated.

RESPONSE: The Board thanks the commenters for pointing out that the NBRC does not grant continuing education credit for the completion of advanced credentialing examinations. In order to eliminate any confusion that the reference to NBRC in N.J.A.C. 13:44F-10.2(a)2 may generate, the Board has changed the paragraph on adoption to delete the reference. As changed on adoption, N.J.A.C. 13:44F-10.2(a)2 refers to successful completion of an advanced credentialing examination approved for continuing education credit by the American Association for Respiratory Care.

11. COMMENT: Two commenters objected to the proposed amendments to N.J.A.C. 13:44F-10.2(a)6 that would increase the number of credits permitted for videotaped, Internet or other distance learning from 15 to 20. The commenters expressed concern about the monitoring of individuals and the level of actual knowledge imparted in such non-traditional sources of continuing education. The commenters do not believe that permitting licensees to obtain more than half of their continuing education credits from these non-traditional sources is reasonable.

RESPONSE: The Board believes that videotaped, Internet and other distance learning courses provide licensees with

valuable resources to meet their continuing education obligations, and disagrees with the commenters' suggestion that such courses do not impart actual knowledge. The Board also notes that increasing the number of credits a licensee may obtain in such courses to 20 could result in cost savings for licensees. Such courses permit licensees to forgo the expense, both time and money, of traveling to the more traditional continuing education courses or programs offered throughout the State. Although the Board has increased the number of credits that licensees may claim for completion of such courses from 15 credits to 20 credits, the Board notes that licensees are still required to obtain 10 credits through more traditional sources of continuing education, for a total of 30 credits per biennial period. The Board believes that its continuing education requirements, as proposed for amendment in N.J.A.C. 13:44F-10.2, will help to ensure that licensees receive continuing education that is well-rounded and reasonable.

12. COMMENT: Two commenters objected to the proposed amendments to N.J.A.C. 13:44F-10.2(b), which would permit licensees to earn one-half credit hour of continuing education for every 25 minutes of instruction or participation after the first credit hour has been earned, believing that this limitation is unreasonable. The commenters believe that all partial credit should be permitted without limitation.

RESPONSE: N.J.S.A. 45:14E-16 of the Respiratory Care Practitioner Licensing Act provides that each hour of instruction at a continuing education course or program, defined in N.J.A.C. 13:44F-10.2(b) as 50 minutes of content within a 60-minute clock hour, shall be equivalent to one continuing education credit. Consistent with this statutory mandate, existing Board rule N.J.A.C. 13:44F-10.2(b) provides that licensees will not be granted credit for courses that are less than one instructional hour in length. The proposed amendment, however, allows licensees to claim one-half credit hour for 25 minutes of instruction or participation after completing the first full credit hour in a course or program. The Board believes that the proposed amendment is consistent with its statutory mandate and will benefit licensees. The proposed amendment may permit licensees to take fewer courses in order to satisfy the 30-credit-hour requirement. The Board believes that the commenters' suggestion that would permit "partial credit" to be granted without limitation would be inconsistent with the express requirements of the Act.

13. COMMENT: One commenter objected to proposed new rule N.J.A.C. 13:44F-10.2A, which will permit a licensee to obtain continuing education credit for completing a Board-approved performance-based competency assessment (PBCA). The commenter does not believe that PBCAs are continuing education because he does not believe that such assessments will enhance a practitioner's skill. The commenter does not believe that PBCAs will benefit therapists or patients, and recommends that the Board not adopt the new rule.

RESPONSE: The Board disagrees with the commenter's suggestion that PBCAs will not enhance licensee skills. The Board believes that PBCAs will provide licensees with an invaluable resource through which to obtain or enhance their practice skills through the PBCAs focus on clinical respiratory procedures. Such focus, the Board believes, will positively impact patient care. The Board, therefore, declines to accept the commenter's suggestion to not adopt proposed new rule N.J.A.C. 13:44F-10.2A.

14. COMMENT: One commenter objected to proposed new rule N.J.A.C. 13:44F-10.2A, noting that the rule appears to contradict current law, which requires the Board to approve only those continuing education programs that are reasonably available to all respiratory care practitioners in the State on a reasonable, nondiscriminatory basis. The commenter believes that when a PBCA is offered at a healthcare facility, practitioners at other facilities would be discriminated against because they would not be permitted to participate in that particular facility's PBCA. The commenter also believes that the proposed new rule discriminates against education institutions and private entities that seek to provide continuing education to practitioners. The commenter notes that there are five respiratory care programs in the State capable of meeting the new rule's requirements to offer PBCAs but that such entities are precluded from participating because private entities cannot establish or contract with health care facilities to offer PBCAs under the new rule.

RESPONSE: The Board disagrees with the commenter's suggestion that proposed new rule N.J.A.C. 13:44F-10.2A is inconsistent with the statutory requirements for continuing education imposed under the Respiratory Care Practitioner Licensing Act. The Board does not believe that permitting a licensed healthcare facility to offer continuing education to its employees is discriminatory. Any licensed healthcare facility in the State may apply to the Board for approval to offer a PBCA under the rule. In addition, the new rule permits healthcare entities that provide respiratory care services, but which are not licensed healthcare facilities, to offer PBCAs to their employees. Under N.J.A.C. 13:44F-10.2A(b), such entities may apply to the Board for approval to offer PBCAs to their employees.

Federal Standards Statement

A Federal standards analysis is not required because the adopted amendments and new rule are governed by N.J.S.A. 45:14E-1 et seq., and are not subject to any Federal standards or requirements.

[page=2191] **Full text** of the adoption follows (additions to the proposal indicated in boldface with asterisks ***thus***; deletions from proposal indicated in brackets with asterisks ***[thus]***):

SUBCHAPTER 3. AUTHORIZED PRACTICE

13:44F-3.3 Delegation by a respiratory care practitioner to unlicensed persons

(a)-(c) (No change.)

(d) Activities that a licensed respiratory care practitioner may delegate to assistants are limited to the following routine tasks:

1. ***[Disassembling,]* **Processing**,* cleaning*[, disinfecting,]* **and*** sterilizing*[, assembling and delivery of]* **basic*** respiratory equipment; ***[and]*****

2. Maintaining and safe handling of oxygen and specialty gas cylinders and oxygen concentrators*[, including the performance of oxygen checks and charges.]***;** **and***

***3. Setting up, testing, exchanging and demonstrating equipment relating to basic respiratory delivery systems.**

i. An assistant shall not be permitted to set up, test, exchange or demonstrate mechanical ventilators or positive pressure equipment, such as continuous positive airway pressure and bi-level positive airway pressure devices, with or without artificial airways, in use continuously or intermittently. For purposes of this section, the term "exchange" does not mean delivery, and this section shall not preclude an unlicensed assistant from delivering such equipment to a patient's home.*

(e) A licensed respiratory care practitioner shall be responsible for any activities ***[that]* **which***** an assistant performs pursuant to (d) above*. ***[and shall assess and document proper assembly and operation of all respiratory equipment prior to use on a patient. Such documentation shall be retained for a period of three years.]***

(f) (No change.)

SUBCHAPTER 10. CONTINUING EDUCATION

13:44F-10.2 Approval of continuing education programs, courses, seminars and articles; determination of credits

(a) The following are acceptable sources of continuing education, provided the subject matter falls within the content areas set forth in N.J.A.C. 13:44F-10.1(c):

1. Successful completion of programs, courses or seminars offered or approved by the New Jersey Society for Respiratory Care, the American Association for Respiratory Care, the American Medical Association or the American Nursing Association: one continuing education credit for each course credit awarded;

2. Successful completion of an advanced credentialing examination approved for continuing education credit by the ***[National Board for Respiratory Care or the]*** American Association for Respiratory Care: one continuing education credit for each examination credit awarded;

Recodify existing 2.-4. as 3.-5. (No change in text.)

6. Successful completion of videotaped, Internet and other distance learning courses, approved by one of the organizations listed in (a)1 above, with verification by the course provider that the course was monitored and successfully completed by the licensee: one continuing education credit for each course credit awarded with a maximum of 20 credits per biennial licensure period.

(b) A licensee shall receive one continuing education credit for each hour of attendance at programs, courses and seminars approved by one of the organizations listed in (a)1 above. Credit shall not be granted for courses that are less than one instructional hour long. For purposes of this subchapter, an "instructional hour" represents a 60-minute clock hour with no less than 50 minutes of content within the hour. Programs may include one 10-minute break for each instructional hour. One-half credit hour of continuing education may be earned for 25 minutes of instruction or participation after the first credit hour increment has been earned.

13:44F-10.2A Performance-based competency assessment; approval; determination of credits

(a) A licensee may obtain continuing education credit for successful completion of a Board-approved performance-based competency assessment (PBCA) administered in a licensed healthcare facility, consistent with the following requirements:

1. The PBCA shall include the presentation of materials and objectives, procedure(s) demonstration by licensee attendees and a written examination certified by the healthcare facility's director of respiratory care. For purposes of this section, a "director of respiratory care" means a respiratory care practitioner licensed in the State of New Jersey who is responsible for the activities of all respiratory care practitioners employed by the healthcare facility, including oversight for the policies and procedures that guide respiratory care practice in the healthcare facility;
2. The PBCA shall include only clinical respiratory procedures within the scope of practice of the healthcare facility's department of respiratory care;
3. The director of respiratory care shall submit an application for Board approval of the PBCA at least 60 days prior to the administration of the PBCA. The application shall include: the name of the healthcare facility, the name of the director of respiratory care, the name and qualifications of the PBCA presenter, a description of the competency covered and the objectives to be achieved by the PBCA, a copy of the written examination and a copy of the PBCA attendee evaluation form or its equivalent;
4. The director of respiratory care shall provide licensee attendees of the PBCA with a certificate of completion, which shall include the title of the PBCA, the date the PBCA was completed and the number of continuing education credits awarded for completion of the PBCA; and
5. The PBCA shall be at least one instructional hour in length. For purposes of this section, an "instructional hour" means no less than 50 minutes of material presentation, procedure(s) demonstration and examination. One continuing education credit shall be awarded for each Board-approved PBCA to a maximum of six credits per biennial registration period;
 - i. The Board shall not approve a PBCA that is less than one instructional hour in length, except that when the presentation of materials and objectives, procedure(s) demonstration and written examination for a single topic is less than one instructional hour, two topics may be combined in one PBCA for Board approval. A Board-approved PBCA shall include no more than two topics.

(b) A PBCA may be administered by a healthcare entity, other than a licensed healthcare facility, that provides respiratory care services, provided the PBCA is certified by the healthcare entity's director of respiratory care. If the healthcare entity does not have a director of respiratory care, the entity's medical director shall certify the PBCA. The entity's director of respiratory care or medical director shall ensure compliance with all requirements of this section.

(c) The director of respiratory care or the medical director and all licensee attendees of the PBCA shall maintain documentation of successful completion of the PBCA for four years from the date of completion consistent with the requirements of N.J.A.C. 13:44F-10.3(a).

13:44F-10.3 Licensee certification of compliance; recordkeeping; audit

(a)-(b) (No change.)

(c) Failure to complete continuing education requirements may result in the imposition of penalties and/or license suspension pursuant to N.J.S.A. 45:1-21.