

**NORTH CAROLINA RESPIRATORY CARE BOARD  
RALEIGH, NORTH CAROLINA**

**IN RE: REQUEST FOR DECLARATORY )  
RULING REGARDING SERVICES PROVIDED BY )     **DECLARATORY RULING**  
BREATH OF LIFE TREATMENT CENTER, INC. )**

I, Joseph Coyle, as Chair of the North Carolina Respiratory Care Board (the "Board"), and based on a resolution by the Board of this date, duly adopted pursuant to N.C. Gen. Stat. § 150B-4, do hereby issue this declaratory ruling. This declaratory ruling will interpret N.C. Gen. Stat. § 90-648 (10) and § 90-664 (1) in regard to the activities of Breath of Life Treatment Center, Inc. of Cary, North Carolina, which is hereafter designated as "Breath of Life Treatment Center" in this Declaratory Ruling.

Ms. Colleen Leonard, the owner of Breath of Life Treatment Center, and Mr. Stuart Kurlander, an attorney in the Latham & Watkins law firm who represents Breath of Life Treatment Center have provided the facts on which this ruling is based. This ruling is binding upon the Board so long as the facts that the Board deems to be material are accurately stated, but the ruling only pertains to the operation of the Breath of Life Treatment Center in Cary operated by Ms. Leonard and is based on the specific information that has been provided to the Board. The Board also reserves the right, prospectively, to change the conclusions which are contained in this ruling.

**FACTUAL BASIS FOR THE RULING**

Mr. Kurlander provided detailed information about the Breath of Life Treatment program in correspondence sent to the Board after an initial meeting that was attended by Ms. Leonard, Mr. Kurlander and a colleague, and other individuals familiar with the Breath of Life Treatment Protocol and the technology it uses. After the meeting, Mr. Kurlander furnished the following additional materials:

- Correspondence and notices from the United States Food and Drug Administration about Hyperbaric Therapy, issued to Hyperbaric Technologies, Inc. (August 2, 2000) and to Pan-America Hyperbarics, Inc. (May 20, 2002);
- A one-page synopsis of the training course offered by the International Hyperbarics Association, which Ms. Leonard attended;
- A copy of the Policy and Procedures Manual used by the Breath of Life Treatment Center;
- A document summarizing the credentials of the health professionals who serve on the Advisory Board for the Breath of Life Treatment Center; and
- A copy of the most recent fire inspection of the Breath of Life Treatment Center that was conducted by the Fire Department of the Town of Cary.

In addition, the Board has considered, and hereby takes official notice of the following:

- Information about the curriculum for respiratory care practitioners, pertaining to the training that students receive in the administration of oxygen:
  - Oxygen therapy is first covered in course RCP 110 as designated in North Carolina Community College System course catalog. The course includes 45 hours of class room instruction and 45 hours of lab instruction.
  - Oxygen therapy is covered in each clinical course as designated in the North Carolina Community College System common course catalog and it is documented by clinical psychomotor evaluation forms. Clinical Courses include RCP 132, RCP 210, RCP 156 and RCP 238 which include a minimum of 1080 hours of clinical instruction.
  - The oxygen therapy is covered extensively on the National Board for Respiratory Care (NBRC) Certified Respiratory Therapist (CRT) exam which is used to qualify for licensing.
  - Each skill is also defined in the American Association for Respiratory Care (AARC) clinical practice guidelines as to the application requirements of oxygen therapy in the adult, pediatric and infant populations.

## ANALYSIS

### *Summary of Analysis*

Based on the analysis set forth below, the Board concludes that the operation of the hyperbaric chamber by the Breath of Life Treatment Center in Cary as described below does not constitute the Practice of Respiratory Care under N.C. Gen. Stat. § 90-648(10), and so no license from this Board is required in order to operate the hyperbaric chamber under the circumstances described to the Board. However, the use of an oxygen concentrator does constitute the practice of respiratory care, and therefore, if Breath of Life continues to employ an oxygen concentrator in the treatment protocol, then it may only do so lawfully by having a Respiratory Care Practitioner, or another appropriately licensed health care professional acting within the recognized scope of practice to apply or supervise the application of the oxygen therapy.

### *Background Information Provided*

Based on information submitted by Mr. Kurlander and Ms. Leonard, Breath of Life Treatment Center, Inc. provides the following services under orders of a physician licensed pursuant to Article 90 of the North Carolina General Statutes :

- Hyperbaric Air Therapy for treatment of certain diseases and conditions ; and
- Oxygen Therapy by means of an oxygen concentrator, in combination with the Hyperbaric Air Therapy.

The services provided at Breath of Life Treatment Center, Inc. are provided by individuals who were trained on the job to perform the treatments. They include Nursing Assistants, Medical Technician Assistants and/or Emergency Medical Technicians. These individuals provide the therapy based on

prescriptions written by physicians and other appropriately licensed health care professionals. These individuals function under the general medical supervision of a physician who is licensed pursuant to Article 90 of the North Carolina General Statutes.

The Hyperbaric Air Therapy is being provided at the Breath of Life Treatment Center, Inc. by means of a portable inflatable mild hyperbaric chamber that has been approved by the Food and Drug Administration to treat acute mountain sickness and other conditions, under various FDA communications that were provided to the Board, including the FDA Letter of August 1, 2000.

The materials provided by Mr. Kurlander also included the Policies and Procedures that have been used by the Breath of Life Treatment Center in Cary. These Policies and Procedures address how to pressurize and depressurize the chamber, how to check the status of a client undergoing treatment during the course of the treatment, and some emergency procedures. The Policies and Procedures reference the use of an oxygen concentrator. Mr. Kurlander's letter, as well as other information furnished to the Board, have stressed the differences in the pressures used in the Breath of Life Treatment Program, which are described as "Mild Hyperbarics," and the pressures used in other Hyperbaric Treatments such as those used in treating deep sea divers. The pressures used in the Breath of Life Treatment program are indicated to range no higher than 1.3 Atmospheres, while other Hyperbaric Treatments, such as those used to treat decompression illness typically range up to 3 atmospheres.

Breath of Life Treatment Center, Inc. is utilizing the mild hyperbaric chamber off-label and advertising the Hyperbaric Air Therapy to treat the following conditions:

- |                             |  |
|-----------------------------|--|
| 1. Autism                   | 9. Inflammation Conditions             |
| 2. ADD/ADHD                 | 10. Infections                         |
| 3. Brain Injury             | 11. Migraines                          |
| 4. Cerebral Palsy           | 12. Reflex Sympathetic Dystrophy (RSD) |
| 5. Chronic Fatigue Syndrome | 13. Stroke                             |
| 6. Crohn's Disease          | 14. Sports Injuries                    |
| 7. Diabetes                 | 15. Post Surgery                       |
| 8. Fibromyalgia             |  |

### *Analysis of the Use of the Hyperbaric Chamber*

The information provided by Breath of Life to the Board addresses other agencies' recognition of the use of the hyperbaric chambers. Based on the FDA's recognition of the use of hyperbaric chambers with the low pressures (1.3 atmospheres or less) described in the information presented to the Board by Breath of Life, the Board concludes that the use of the hyperbaric chamber in the manner described by Breath of Life is not within the scope of practice of Respiratory Care as defined in N.C. Gen. Stat. § 90-648(10). The FDA has determined that the pressure used in these "mild hyperbaric chambers" is safe in non-institutional settings. Based on this FDA finding, the Board concludes that the operation of the mild hyperbaric chamber whose use is described by Breath of Life does not constitute "Hyperbaric oxygen therapy," as defined in N.C. Gen. Stat. § 90-648(10)(e). Accordingly, and although any off-label use of the hyperbaric chamber entails an application of the device which has not been studied, Breath of Life may continue to use the hyperbaric chamber as described in the materials submitted to the Board without having a licensed RCP directly involved in the treatments, or physically present.

### *Analysis of the Use of the Oxygen Concentrator*

The Board has reached a different conclusion with regard to use of an oxygen concentrator as part of the Breath of Life Treatment protocol. The application of any oxygen device, including an oxygen concentrator, is clearly within the scope of Practice of Respiratory Care because this involves the therapeutic application of a medical gas, namely oxygen, and so this does constitute the Practice of Respiratory Care under N.C. Gen. Stat. § 90-648(10)(a). The fact that use of oxygen therapy is recognized as part of the hyperbaric chamber as described in the FDA correspondence does not alter or affect this conclusion, which is made based on the express and explicit language of the statute.

Having determined that the use of the oxygen concentrator does bring the activities of Breath of Life within the scope of practice regulated by the Board, it is necessary to determine whether any of the statutory exemptions from licensure that are recognized by the Respiratory Care Practice Act apply to Breath of Life. The provisions of N.C. Gen. Stat. § 90-664 (1) exempt individuals who meet specified criteria from the requirement of being licensed under the Respiratory Care Practice Act. In order to come within the exemption granted under this provision, a person must meet each of several different criteria:

- The person must be “registered, certified, credentialed, or licensed to engage in another profession or occupation in this State, or must be working under the supervision of such a person”;
- The person must be performing work incidental to or within the practice of that profession or occupation; and
- The person may not represent himself or herself as a respiratory care practitioner.

The Board has reviewed and analyzed each of these requirements as they pertain to the administration of Oxygen Therapy by Breath of Life in conjunction with Hyperbaric Air Therapy. The Board has made the following determinations with regard to these exemption provisions:

The only information provided to date which addressed the training or credentialing of any of the individuals involved in the Breath of Life program is a one-page synopsis of a training course sponsored by the International Hyperbarics Association (“IHA”). We note that the information provided indicates that the only person involved in the Breath of Life program in Cary who has attended this training course is Ms. Leonard herself. Therefore, no information has been provided about the training of any other person which might qualify any other individual for an exemption from the Act.

Analysis of the one-day training course whose curriculum was described in the materials submitted to the Board, and which Ms. Leonard attended, does not establish that Ms Leonard has been “registered, certified, credentialed, or licensed to engage in another profession or occupation,” in the language of N.C. Gen. Stat. § 90-664 (1). The one-page synopsis that was provided does not provide any details of the amount of time devoted to each segment of the curriculum, and no information has been provided about the scope of any examination that attendees must pass to demonstrate their competence in the knowledge and skills presented during the course.

Based on the information provided, a significant part of the curriculum of the IHA course is devoted to presentations by physicians that address the applications of hyperbaric oxygen therapy for treatment of various conditions, and it appears that these segments of the course address the possible clinical indications of the therapy rather than addressing the procedures for using the components of

the therapy, including oxygen concentrators. The Board also noted that this course is approved for continuing medical education credits, meaning that the course is designed to supplement or refresh knowledge or skills already acquired as a result of other training, rather than providing training that would lead to acquiring new skills or competencies in a new discipline.

The remaining parts of the one-day training course are devoted to what is described as hands-on training, composed of three components:

- Physician demonstrations of how to put patients into the chambers;
- How to operate the chambers; and
- How to use oxygen concentrators.

No information has been provided about the particular issues or areas that pertain to the use of the oxygen concentrator which are addressed during the IHA Course, or the amount of time that is devoted to the training. In addition, as already noted, no information has been provided about the detail of any examination questions on this or any other item. Thus, it is impossible to determine that any particular knowledge or skill in the use of an oxygen concentrator is conveyed during the course. However, it is clear that this is just one of a number of different topics covered during a one-day course.

By contrast, the Board is aware of the knowledge and skills in the administration of oxygen that are acquired by persons who train to become Respiratory Care Practitioners. Students who are training to become Respiratory Care Practitioners attend literally hundreds of hours of classroom and practical training in the therapeutic application of medical gases. In addition, students typically receive at least a full half-day of classroom training specifically relating to the use of oxygen concentrators, typically supplemented by 20-40 hours of direct practical experience during the course of their study in the use of oxygen concentrators. At the conclusion of their training, RCP students must demonstrate competency in a variety of areas by taking examinations to demonstrate their competency in the Practice of Respiratory Care. While the Board does not mean to imply that the training received by an RCP student is the only ground for competency in the therapeutic use of oxygen, it is apparent, after comparing the information available to the Board about RCP training with the information presented by Breath of Life, that the training of RCP students in the application and use of oxygen concentrators is much more detailed and extensive than the training offered in the IHA course.

## **CONCLUSION**

As detailed in the above analysis, the Board has reviewed the information provided by Breath of Life, along with other information available to the Board based on its supervision of Respiratory Care training programs, and the Board concludes that the administration of Hyperbaric Air Therapy using a mild hyperbaric chamber at pressures of 1.3 atmospheres or less under medical supervision and upon the orders of a physician licensed pursuant to Article 90 of the North Carolina General Statutes, does not constitute the Practice of Respiratory Care as defined in N.C. Gen. Stat. § 90-648 (10)(e) and therefore does not require a licensed respiratory care practitioner to be involved in the application.

After reviewing the information provided, the Board concludes that the administration of oxygen in combination with a mild hyperbaric chamber does constitute the Practice of Respiratory Care as defined in N.C. Gen. Stat. § 90-648 (10)(e) and therefore requires that a licensed respiratory care practitioner or other appropriately licensed individual must be involved in these treatments as

described below. Based solely on the information provided, and reserving the opportunity to revise this ruling upon receipt of additional information, the Board concludes that in order for the Breath of Life Treatment Center to continue to use an oxygen concentrator, it must give a respiratory care practitioner or other appropriately licensed individual, authority and responsibility to, ensure the safe and effective use of the oxygen concentrator in the following ways:

- By having a respiratory care practitioner or other appropriately licensed individual review and approve protocols, policies and procedures for safe and effective use of any oxygen concentrator at each location where the oxygen therapy is administered;
- By ensuring that a respiratory care practitioner or other appropriately licensed individual is available to supervise the individuals providing the oxygen therapy; and
- By ensuring that a respiratory care practitioner or other appropriately licensed individual documents the training, skills evaluations and reviews for each individual providing the oxygen therapy, and also documents the maintenance and safe functioning of any oxygen concentrator located at each site.

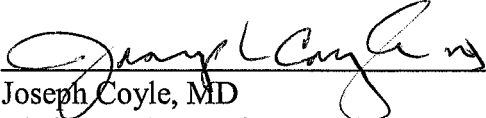
For purposes of this ruling, “supervision” or “supervise” shall mean that the supervising respiratory care practitioner or other appropriately licensed individual is available for supervision and consultation to the Breath of Life Treatment Center. The supervision may be in telephone or in person. If required, the supervisor must be readily available by telephone and able to respond on-site.

The Board notes that in issuing this ruling, it is only approving the use of an oxygen concentrator under the conditions enumerated above, not any other oxygen therapy device.

For purposes of this ruling appropriately licensed individuals shall include a registered nurse, licensed by the North Carolina Board of Nursing, or a physician, licensed by the North Carolina Medical Board.

The Board further concludes that individuals who have attended the one-day IHA course described in this Declaratory Ruling are not exempt from the requirements of the North Carolina Respiratory Care Practice Act pursuant to N.C. Gen. Stat. § 90-664 (1), based solely on their attendance at the IHA course.

This the 12th day of July 2007.

  
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Joseph Coyle, MD  
Chair, North Carolina Respiratory Care Board


## CERTIFICATE OF SERVICE

I certify that I have served a copy of the foregoing Declaratory Ruling on the following persons by depositing the copy by certified mail, return receipt requested in an official depository under the exclusive care and custody of the United States Postal Service in the properly addressed postage-paid wrapper.

Coleen Leonard  
Breath of Life Treatment Center, Inc.  
103 A Brady Court  
Cary, NC 27510

Stuart Kurlander  
Attorney & Counselor at Law  
Latham & Watkins, LLP  
555 Eleventh Street N.W. Suite 1000  
Washington, DC 20004-1304

This 12<sup>th</sup> day of July, 2007.

  
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Floyd E. Boyer, RRT, RCP  
Executive Director  
North Carolina Respiratory Care Board