



Ohio Legislative Service Commission

Bill Analysis

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Sub. H.B. 165

130th General Assembly

(As Reported by S. Commerce and Labor)

Reps. Roegner, Thompson, Wachtmann, Beck, Hood, Huffman, Scherer, Schuring, Sears, Batchelder

BILL SUMMARY

- Exempts certified hyperbaric technologists who meet specified requirements from the laws governing the practice of respiratory care.
- Requires that exempted certified hyperbaric technologists administer hyperbaric oxygen therapy under the direct supervision of a physician, a physician assistant, or an advanced practice registered nurse.

CONTENT AND OPERATION

Overview

The bill exempts certified hyperbaric technologists (CHTs) who meet the bill's requirements from the laws governing the practice of respiratory care.¹ Under current law, only a respiratory care professional licensed by the Ohio Respiratory Care Board may administer hyperbaric oxygen therapy.² Because CHTs are not licensed by the Respiratory Care Board, they may not legally administer such therapy. The bill allows a CHT to provide hyperbaric oxygen therapy without a Board-issued license but requires that the CHT (1) be certified by the National Board of Diving & Hyperbaric Medical Technology, (2) have filed the person's current CHT certificate with the Board and paid the associated fee, and (3) administer hyperbaric oxygen therapy under the direct supervision of a physician, physician assistant, or advanced practice registered nurse.³

¹ R.C. 4761.11(A)(11).

² R.C. 4761.10, not in the bill.

³ R.C. 4761.01(G) and 4761.11(A)(11).

Hyperbaric oxygen therapy

Hyperbaric oxygen therapy involves breathing pure oxygen in a pressurized room or chamber in an effort to increase the amount of oxygen in blood. Under such conditions, the air pressure is raised to three times higher than normal air pressure, allowing a person's lungs to gather up to three times more oxygen. The blood then carries this oxygen throughout a person's body, stimulating the release of substances called growth factors and stem cells and promoting healing.⁴

Hyperbaric oxygen therapy is used to treat certain medical conditions, including air or gas embolism, bone infections, burns, carbon monoxide poisoning, crush injuries, decompression sickness, gangrene, radiation injuries, severe anemia, skin grafts, soft tissue infections, and wounds. A patient may receive hyperbaric oxygen therapy in either a single chamber or multi-person room. In a single chamber, the patient lies on a padded table inside a clear plastic tube approximately seven feet in length. In a multi-person room, the patient may sit or lie down. To deliver the oxygen, a lightweight, clear hood or mask may be placed over the patient's face.⁵

Therapy sessions typically last from one to two hours, with the patient monitored throughout the session. Potential complications associated with hyperbaric oxygen therapy include temporary nearsightedness, middle ear and inner ear injuries, organ damage, and seizures. In addition, because pure oxygen is flammable, there is a risk of fire. To minimize that risk, a patient cannot take any item into the chamber or room that could ignite a fire (such as an electronic device) and must remove hair and wound-care products that are petroleum-based.⁶

Current regulation of hyperbaric oxygen therapy

Because the federal Food and Drug Administration (FDA) classifies oxygen as a drug, it can only be administered on the order of a physician. Federal law authorizes the FDA to regulate the marketing of hyperbaric chambers as Class II medical devices, thereby requiring valid scientific evidence that the devices are safe and effective for their intended use. Intended use includes specific diseases and conditions the device

⁴ Mayo Clinic, *Hyperbaric oxygen therapy* (last visited March 27, 2014), <<http://www.mayoclinic.com/health/hyperbaric-oxygen-therapy/MY00829>>.

⁵ Mayo Clinic, *Hyperbaric oxygen therapy*. See also National Library of Medicine, *Hyperbaric oxygen therapy* (last visited March 27, 2014), available at <<http://www.nlm.nih.gov/medlineplus/ency/article/002375.htm>>.

⁶ Mayo Clinic, *Hyperbaric oxygen therapy*, and National Library of Medicine, *Hyperbaric oxygen therapy*.



treats. At present, the FDA relies on the Undersea and Hyperbaric Medical Society⁷ (UHMS) for guidance on the safety and effectiveness of hyperbaric oxygen therapy for specific diseases and conditions.⁸

The federal Centers for Medicare and Medicaid Services (CMS) and private health insurers also depend upon the advice of UHMS when determining which diseases and conditions are appropriate for reimbursement for hyperbaric oxygen therapy. To date, UHMS has recognized the following diseases and conditions for hyperbaric oxygen therapy: air or gas embolism, carbon monoxide poisoning, gas gangrene, crush injury, decompression sickness, central renal artery occlusion, severe anemia, intracranial abscess, soft tissue infections, osteomyelitis, radiation injury, skin grafts, burn injuries, and wounds.⁹ In general, CMS and private insurers will not reimburse the treatment of "off-label" diseases not yet recognized by UHMS.¹⁰ These include Alzheimer's disease, arthritis, autism, cerebral palsy, chronic fatigue syndrome, fibromyalgia, Lyme disease, migraines, multiple sclerosis, Parkinson's disease, stroke, tinnitus, and traumatic brain injury.¹¹

The FDA also requires that a hyperbaric chamber manufacturer demonstrate that its devices comply with standards relating to the construction and operation of hyperbaric chambers, as set by the American Society of Mechanical Engineers and the National Fire Prevention Association.¹²

⁷ UHMS is an international, nonprofit association serving 2,000 physicians, nurses, and scientists in the fields of hyperbaric and dive medicine. See generally <http://membership.uhms.org/?page=About_UHMS>.

⁸ Hyperbaric Link, *About Hyperbaric Oxygen Therapy, FDA Clearance and UHMS Approval* (last visited March 27, 2014), available at <<http://www.hyperbariclink.com/hyperbaric-oxygen-therapy/clearance-and-approval.aspx>>.

⁹ See generally <<http://membership.uhms.org/?page=Indications>>.

¹⁰ Centers for Medicare and Medicaid Services, *National Coverage Determination for Hyperbaric Oxygen Therapy* (last visited March 27, 2014), available at <<http://www.cms.gov/medicare-coverage-database/indexes/ncd-alphabetical-index.aspx>> at p. 7.

¹¹ Hyperbaric Link, *Diseases and Conditions Treated with Hyperbaric Oxygen Therapy* (last visited March 27, 2014), available at <<http://www.hyperbariclink.com/diseases-and-conditions/diseases-and-conditions.aspx>>.

¹² Hyperbaric Link, *About Hyperbaric Oxygen Therapy, FDA Clearance and UHMS Approval* (last visited March 27, 2014), available at <<http://www.hyperbariclink.com/hyperbaric-oxygen-therapy/clearance-and-approval.aspx>>.

Certified hyperbaric technologists

The National Board of Diving & Hyperbaric Medical Technology, certifies hyperbaric technologists.¹³ Typically, hyperbaric technologists administer hyperbaric oxygen therapy in medical settings. According to the National Board, an applicant to become a CHT must be a licensed health professional, such as respiratory therapist, physician assistant, paramedic or other emergency medical technician, registered nurse, nurse practitioner, physician, or nurse aide.

An individual seeking certification as a hyperbaric technologist must meet the following requirements: (1) be at least 18 years of age with a high school diploma or equivalent, (2) have completed a Board-approved hyperbaric medicine introductory training course along with a transcutaneous oxygen monitoring¹⁴ module, (3) have undergone a clinical internship of 480 hours, including 40 hours under the supervision of a clinical preceptor, and (4) have submitted a registration form that includes evidence of licensure or certification as a medical professional. Then, the individual is eligible to take the CHT certification exam. Once certified, a CHT must earn a minimum of 12 continuing education credits every two years.¹⁵

Exemption from the practice of respiratory care

The bill exempts certified hyperbaric technologists who meet the bill's requirements from the laws governing the practice of respiratory care.¹⁶ The Ohio Respiratory Care Board regulates the practice of respiratory care, which includes administering, monitoring, recording the results of, and instructing in the use of medical gases. Therefore, under current law, hyperbaric oxygen therapy must be administered by a licensed respiratory care professional or another licensed health care professional whose scope of practice includes respiratory care services.¹⁷ Because the Board does not license CHTs, they may not administer hyperbaric oxygen therapy in Ohio.

¹³ See generally <<http://www.nbdhmt.org>>.

¹⁴ A method of measuring oxygen in the blood by attaching electrodes to skin. See <http://medical-dictionary.thefreedictionary.com/transcutaneous+oxygen>.

¹⁵ National Board of Diving & Hyperbaric Medical Technology, *Certified Hyperbaric Technologist Resource Manual* (last visited March 27, 2014), available at <http://www.nbdhmt.org/forms/CHT_Resource_Manual.pdf>.

¹⁶ R.C. 4761.11.

¹⁷ R.C. 4761.10 and 4761.11.

The bill exempts CHTs from the practice of respiratory care and the Board's licensure requirements, thereby permitting them to provide hyperbaric oxygen therapy.¹⁸ To qualify for the bill's exemption, an individual must meet all of the following requirements:

(1) The individual must be certified by the National Board of Diving & Hyperbaric Medical Technology;

(2) The individual must be employed as a CHT;

(3) The individual must have filed with the Ohio Respiratory Care Board a copy of the person's current certification as a hyperbaric technologist and paid the fee associated with that filing;

(4) The individual must administer hyperbaric oxygen therapy under the direct supervision of a physician, a physician assistant, or an advanced practice registered nurse without representing that the individual is engaged in the practice of respiratory care.¹⁹ The bill defines "hyperbaric oxygen therapy" as the administration of pure oxygen in a pressurized room or chamber, and specifies that it does not include ventilator management.²⁰

Because the bill exempts CHTs entirely from the practice of respiratory care, CHTs will not be subject to the authority of, or discipline by, the Ohio Respiratory Care Board.

Filing a CHT certificate with the Board

A CHT seeking the bill's exemption must file with the Board a copy of the person's current certification as a hyperbaric technologist in accordance with the rules adopted by the Board. Under the bill, the Board must adopt rules establishing procedures for accepting and storing copies of these hyperbaric technologist certifications. The bill also requires the Board to establish a fee for accepting and storing these certifications, not to exceed \$20.²¹

¹⁸ R.C. 4761.11(A)(11).

¹⁹ R.C. 4761.01(G) and 4761.11(A)(11).

²⁰ R.C. 4761.01(H).

²¹ R.C. 4761.03, 4761.07, and 4761.11.



HISTORY

ACTION	DATE
Introduced	05-15-13
Reported, H. Health & Aging	06-19-13
Passed House (96-1)	06-25-13
Reported, S. Commerce & Labor	03-26-14

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