AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 517
(A-22)

Introduced by: Undersea and Hyperbaric Medical Society

Subject: Safeguard the Public from Widespread Unsafe Use of "Mild Hyperbaric Oxygen Therapy"

Referred to: Reference Committee E

Whereas, There has been a recent proliferation of "mild hyperbaric" activities outside medical facilities in chiropractic centers, wellness centers and health spas. The magnitude of these practices is documented to be widespread, occurring in at least 288 centers in 31 states; and

Whereas Pressure vessels (chambers) employed by these centers are not typically inspected, certified, or approved by the appropriate standards and regulatory agencies including the FDA and ASME (American Society of Mechanical Engineers). Many chambers are being imported from foreign countries. At least two U.S. companies are also involved in design, manufacture, and sales of inadequately designed chambers. In both cases, the manufacturers do not seek the required certification of pressure vessels for human occupancy inappropriately marketing these as medical hyperbaric chambers with no valid FDA 510K clearance; and

Whereas, These treatments are being conducted without physician supervision or prescription. In the event of chamber integrity failure, patients are subject to serious injury and even death by barotrauma. Furthermore, additional complications including hypoglycemic reactions and unrecognized cardiac emergencies can occur and require immediate physician recognition and intervention; and

Whereas, Without regard to the inherent risk of fire in this special environment, most of these facilities operate with chambers installed into business spaces not adherent to the safety regulations of the NFPA (National Fire Protection Association) and not protected by sprinkler systems, alarms or other safety equipment; and

Whereas The staff delivering the actual hyperbaric exposures in "mild hyperbaric facilities" are not receiving comprehensive training in chamber operation, safety and emergency prevention; and

Whereas, Heath Canada has already banned future sales of soft sided mild hyperbaric chambers often used in "mild hyperbaric" applications and called for the recall of those already sold; and

Whereas, These centers often promote and advertise false and misleading applications in the treatment in non-compliance with FDA regulations; therefore be it

RESOLVED, That our American Medical Association oppose the operation of unsafe "Mild Hyperbaric Facilities" (New HOD Policy); and be it further

RESOLVED, That our AMA work with the U.S. Food and Drug Administration and other regulatory bodies to close these facilities until and unless they adopt and adhere to all established safety regulations, adhere to the established principles of the practice of hyperbaric oxygen under the prescription and oversight of a licensed and trained physician, and ensure that staff are appropriately trained and adherent to applicable safety regulations. (Directive to Take Action)

Fiscal Note: Not yet determined

Received: 05/08/22

References:

1. American Society of Mechanical Engineers (ASME) PVHO-1−2012 (Pressure Vessels for Human Occupancy) Revision of ASME PVHO-1–2007)
2. Government of Canada. "Unauthorized soft-shelled hyperbaric chambers may pose serious health risks." Canada.ca, Government of Canada, Oct. 2019, recalls-rappels.canada.ca/en/alert-recall/ unauthorized-soft-shelled-hyperbaric-chambers-may-pose-serious-health-risks.
3. National Fire Protection Association (NFPA) Part 99: Health Care Facilities Code 2021 Edition