

24 August 2020

To: *(Each addressee will receive a separate letter)*

Chair and Members of Appropriate House and Senate Committees

Secretary of Defense

Secretary of HHS

Administrator of CMS

Secretary of DHS

Secretary of Interior

Secretary of Transportation

Governor of Florida

Governor of Alabama

Governor of California

Governor of Hawaii

American Hospital Association

We are writing to express our concern about the decreasing availability of emergent access to hyperbaric oxygen (HBO₂) therapy in many areas of the United States, including a growing number of major population centers.

A number of disorders – including diving-related, thromboembolic, iatrogenic (caused by medical investigation or treatment), traumatic, and infectious conditions – may cause loss of life, permanent neurological damage, permanent loss of vision, or loss of an extremity if not treated emergently with hyperbaric oxygen.

Delays in obtaining HBO₂ treatment reduce or eliminate the possibility of obtaining a good outcome for these patients. Each year in the United States, there are approximately 400 serious cases of decompression illness in divers; almost 1,000 reported cases of arterial gas embolism (gas bubbles in the arteries, or AGE) occurring as a result of medical or surgical procedures; 50,000 cases of carbon monoxide poisoning; 6,200 cases of acute blindness due to occlusion of the central retinal artery; and 13,000 cases of life-threatening soft tissue infections. Failure to provide prompt access to HBO₂ therapy for these conditions is a clear departure from the evidence-based, best-practice standard of care.

There are approximately three million recreational scuba divers in the U.S. In the unlikely event that they suffer a diving-related injury, they trust that the U.S. medical system will provide state-of-the-art care for their injuries, but the steadily

decreasing number of hyperbaric treatment facilities in the U.S. willing to treat them emergently for decompression sickness or arterial gas embolism often places them at much greater risk than they realize. In May of 2020, a retired Marine Corps aviator made a dive to 70 feet for 20 minutes off the coast of Pensacola, Florida. He was battling a large speared fish near the end of his dive. After surfacing, he experienced serious neurological symptoms that were indicative of a diving-related injury, but none of the five hyperbaric treatment facilities in Pensacola currently provide the emergency HBO₂ therapy that he badly needed. Knowing that no hyperbaric treatment facilities in the city or in the rest of Northwest Florida would treat the injured diver, his dive buddy, a retired Navy flight surgeon, arranged for him to be transported to the hyperbaric facility at Springhill Medical Center, in Mobile, Alabama, the closest treatment facility that offers emergency HBO₂ therapy, where he was treated successfully. This facility continues to offer emergent HBO₂ despite the fact that it is not financially advantageous to do so. (The owners of the Springhill facility, the Wallace family, do this as a public service for the Gulf Coast diving community.) As described in the attached white paper, treatment delays such as occurred during this patient's care, are one of the most significant risk factors for a negative outcome when treating patients with decompression sickness or arterial gas embolism.

This reduced capability to provide emergency treatment for diving accidents also impacts local fire and police forces, many of which have diving rescue teams; federal law enforcement agencies; fish and wildlife services, park service and other state and federal agencies with dive teams; as well as military divers conducting training operations in areas away from the location of their unit chamber; all of these divers also would not be able to receive optimal care if there is no emergent HBO₂ treatment available in proximity to their operations.

There are approximately 1,300 hyperbaric treatment facilities (each of which has one or more hyperbaric chambers) that currently provide HBO₂ therapy in the United States. As recently as two decades ago, the large majority of hyperbaric treatment facilities were available to provide emergent HBO₂ treatments on a 24/7 basis, but today, fewer than 10% of these facilities offer emergency HBO₂ treatment, and some of those facilities do so only intermittently. Electively scheduled patients being treated for wound healing deficiencies dominate the remainder of chamber usage, with some additional chambers used in support of civilian and military diving operations.

As a business enterprise the scheduled wound care model is much more profitable than emergent HBO₂ therapy. In the past, hospitals and other hyperbaric treatment

facilities underwrote the additional costs associated with providing 24/7 access to emergent HBO₂ as a public service for patients who require it. Now, because of funding and staffing considerations, as well as concern for legal liability, most hyperbaric treatment facilities have ceased to provide 24/7 access to emergent HBO₂ therapy.

There is an urgent need to correct this decreasing availability in the U.S. health care system and make emergent HBO₂ available to those patients who require it. This will require the identification and implementation of strategies to incentivize hyperbaric treatment facilities to offer emergent HBO₂ therapy. Options for accomplishing this include:

- 1) direct federal or state grants to hyperbaric treatment facilities that offer emergent HBO₂;
- 2) indemnification from legal liability for hyperbaric treatment facilities and medical providers who provide emergent HBO₂ to divers and other patients who require it;
- 3) recognition of the public service performed by the hyperbaric treatment facilities that offer HBO₂ on an emergent basis when indicated;
- 4) favorable consideration with respect to Medicare, Medicaid, and private insurance reimbursements to hyperbaric treatment facilities and medical providers that offer HBO₂ on an emergent basis when indicated, including carve-outs to inpatient DRG (diagnosis-related group) payments;
- 5) incentives for military hyperbaric facilities to provide emergent HBO₂ to civilian patients through emphasis on the training benefit to military providers that this accomplishes; third-party reimbursement for emergency HBO₂ therapy provided to civilian patients by military hyperbaric facilities; and indemnification of the military facility from lawsuits resulting from this public service activity.

In addition, there should be federal support for non-profit organizations willing to operate around the clock assisting any patient who needs emergent HBO₂ therapy by identifying the nearest hyperbaric treatment facility that is capable of providing this treatment and helping to arrange transportation to it. Since chamber availability may vary based on ongoing HBO₂ treatments, staffing issues, and chamber maintenance operations, the ability to quickly determine which hyperbaric treatment facility is the most appropriate for a particular emergency

patient in a specific geographic area is critical to optimal care. It should likewise be a national health care priority to ensure that there is adequate funding for fellowship education in Hyperbaric Medicine so that appropriately trained physicians will be reliably available to oversee the HBO₂ therapy provided by these hyperbaric treatment facilities.

Please see the attached white paper for additional detail on this important aspect of emergency health care. We would like to have representatives from our organizations meet with you regarding this worsening deficiency in the U.S. health care system.

Sincerely,

Academy of Underwater Arts and Sciences

American Board of Wound Healing

American College of Emergency Physicians

American College of Hyperbaric Medicine

American College of Surgeons

Divers Alert Network

National Board of Diving & Hyperbaric Medical Technology

Professional Association of Diving Instructors

Texas Medical Association

Undersea and Hyperbaric Medical Society

University of California San Diego Division of Hyperbaric Medicine and Wound Care

Access to Emergent Hyperbaric Oxygen (HBO₂) Therapy: An Urgent Problem in Health Care Delivery in the United States

24 August 2020

Background

A number of disorders – including diving-related, embolic, iatrogenic (caused by medical investigation or treatment), traumatic, and infectious conditions – may cause loss of life, permanent neurological damage, loss of an extremity, or permanent loss of vision if not treated promptly with HBO₂ therapy. Delays in initiating HBO₂ reduce or eliminate the possibility of survival or full recovery for patients suffering from these conditions (*Moon 2019, Sadler 2019, Beevor 2016, Vann 2011*).

Conditions That Require Emergent HBO₂ Therapy

- decompression sickness (DCS)
- diving-related arterial gas embolism (AGE)
- iatrogenic AGE resulting from laparoscopic surgery, central venous catheters, and a wide range of other invasive medical and surgical procedures
- carbon monoxide poisoning
- central retinal artery occlusion (CRAO)
- life-threatening soft tissue infections (e.g., necrotizing fasciitis and clostridial myositis and myonecrosis (gas gangrene) (*Moon 2019, Nicholson 2018, Shaw 2014, Soh 2012*)).

- failing skin flaps (*Moon 2019*).

Hyperbaric Treatment Facilities in the U.S.

The Undersea and Hyperbaric Medical Society (UHMS) estimates that there are approximately 1,300 hyperbaric treatment facilities (each of which has one or more hyperbaric chambers) in the United States that provide HBO₂ therapy (*Personal communication - Mr. John Peters - 3 Feb 20*). These facilities may be located in hospitals, free-standing medical clinics, or may be located with military or commercial diving operations.

Hyperbaric Treatment Facility Availability to Provide HBO₂ Therapy

Fewer than 10% of these 1,300 hyperbaric treatment facilities, however, provide emergent HBO₂ on a 24/7 basis to patients who need it. The number of hyperbaric treatment facilities in the U.S. that offer emergent HBO₂ (on at least an intermittent basis) is 99 according to the list provided by the Divers Alert Network (DAN). The number of hyperbaric treatment facilities in the U.S. that offer full-time access to emergent HBO₂ therapy (*provided by Mr. Dick Clarke, President of the National Board of Diving & Hyperbaric Medical Technology*) as of June 2020 is 78, with several treatment facilities having just dropped their 24/7 emergent HBO₂ availability in the last several weeks (*Personal communication: Dr. Jim Chimiak – 29 May 2020; personal communication Mr. Dick Clarke – 19 June 2020*). The remaining hyperbaric treatment facilities are used to provide scheduled HBO₂ to facilitate wound healing or are intended to support commercial or military diving operations; these latter facilities are typically not available to take emergency patients other than those arising from within their company or unit.

Two decades ago almost all hyperbaric treatment facilities provided emergent HBO₂ therapy to patients when needed. The growing prevalence of provision of HBO₂ therapy as a venture capital-owned, for-profit enterprise, however, has changed this landscape dramatically (*Clarke 2017*). In addition to the remuneration consideration, there are a number of other considerations that may factor into organizations' decisions not to make their hyperbaric treatment facilities available to provide emergent HBO₂ therapy:

- Providing 24/7 access to emergent HBO₂ therapy requires that a hyperbaric-trained physician and chamber operators be available on short recall at all times;
- Maintaining training and certification to treat conditions that require emergent HBO₂ imposes an added training and compliance burden on the hyperbaric facility;
- The arrival of an emergent HBO₂ patient may interrupt scheduled (and reimbursable) non-emergent HBO₂ sessions;
- Emergent HBO₂ patients may have no insurance coverage and their treatment may be at the hyperbaric facility's expense;
- Treating emergent patients who may experience bad outcomes even when HBO₂ is provided appropriately increases the liability exposure of the hyperbaric facility;

- Some emergent HBO₂ patients may require critical care support during their HBO₂ treatment, and many hyperbaric treatment facilities do not have the necessary expertise or equipment to support this level of care (*Clarke 2017*).

Impact of Delays to HBO₂ Therapy When Required

What happens when patients who require emergent HBO₂ do not receive it quickly? That depends on the condition.

- DCS patients may suffer preventable permanent neurologic disability or death (see the two attached publications).
- Diving-related AGE patients may suffer preventable permanent neurologic disability or death.
- Iatrogenic AGE patients may suffer preventable permanent neurologic disability or death.
- Carbon monoxide poisoning patients may suffer preventable permanent neurologic disability or death.
- Central retinal artery occlusion patients may suffer preventable and permanent blindness in the affected eye.
- Patients with life-threatening soft tissue infections (e.g., necrotizing fasciitis) or clostridial myositis and myonecrosis (gas gangrene) may require amputation of affected extremities or suffer preventable death from overwhelming sepsis that might not have occurred if prompt HBO₂ had been available.

Burden of Death and Disability When Indicated Emergent HBO₂ Therapy Is Not Available

As noted above, failure to assure the availability of emergent HBO₂ for patients who require it may result in preventable loss of life, cases of preventable permanent neurological impairment, preventable cases of blindness, and preventable instances of limb loss. An approximation of the magnitude of these avoidable bad outcomes and the conditions that will cause them is provided below.

- Serious (neurological or pulmonary) decompression sickness (DCS) and diving-related arterial gas embolism (AGE) – approximately 400 cases per year (*Personal communication – Dr. Jim Chimiak, Medical Director, Divers Alert Network - 21 March 2020*).
- Iatrogenic AGE resulting from laparoscopic surgery, central venous catheters, etc.) complicates 2.65 per 100,000 hospitalizations, with a mortality rate of

21% (*Bessereau 2010*). There were 36,353,946 hospital admissions in the U.S. in 2018 (*AHA website accessed 26 May 2020* <https://www.aha.org/statistics/fast-facts-us-hospitals>). This results in an estimated 963 cases of iatrogenic AGE in the U.S. annually.

- Carbon monoxide poisoning – “Every year, at least 430 people die in the U.S. from accidental CO poisoning. Approximately 50,000 people in the U.S. visit the emergency department each year due to accidental CO poisoning.” (*CDC website 10 May 2020*)
- Central retinal artery occlusion (CRAO) – the annual incidence of CRAO is 1.9 cases per 100,000 people in the U.S. (*Leavitt 2011*). With a current U.S. population of 331 million people, this would produce an estimated 6,289 cases of CRAO annually.
- Necrotizing soft tissue infections (also called NSTI or necrotizing fasciitis), including clostridial myonecrosis (gas gangrene) – The incidence of NSTI in the United States is estimated at 13,000 cases per year (*Anaya 2007*).

Military Hyperbaric Chambers: A Special Circumstance

Hyperbaric chambers that are intended to support military diving or hypobaric operations are a special circumstance. Their primary mission is not to provide routine health care but to be available should active-duty military members require emergent HBO₂, typically for diving- or aviation-related DCS or AGE. There is no DoD-wide directive at present that requires these chambers to provide emergent HBO₂ to non-military patients, nor is there one that forbids them from doing so. The availability of military hyperbaric chambers for this purpose, then, is at present left to the discretion of the commanding officer of the facility that operates the chamber.

Disincentives for military chambers to provide treatment for non-military patients who require emergent HBO₂ include:

- The DoD can be sued by non-military patients (or their families) treated by a military chamber if there is a bad outcome.
- If the chamber is being used to treat a non-military patient, then it is not available to treat injured military divers or aviators for that treatment period (usually 5-6 hours), possibly delaying military exercises until the chamber is available.
- Providing 24/7 coverage for emergent HBO₂ entails a significant demand on the chamber crew and their supervising physician, preventing them from being away from the chamber location for official travel or personal leave. It

would also not allow the supervising physician and chamber team to engage in recreational activities that would preclude their emergent recall for an HBO₂ treatment.

On the other hand, there are benefits that might be realized by the military should their hyperbaric chambers be made available to treat non-military emergent HBO₂ therapy patients:

- The experience gained in conducting emergent HBO₂ for non-military patients would increase the skills and expertise of the chamber team in the management of diving-related diseases and make them better able to treat future military diving accident victims.
- Procedures could be established to allow the military to be reimbursed for emergent HBO₂ provided to civilians who require it. This is done at present in military treatment facilities that provide trauma care for civilian patients, and serves to benefit the local community as well as to enhance the trauma skills of the military providers.
- Just as with sending the USNS ships *Comfort* and *Mercy* to assist in the treatment of non-military COVID-19 patients in New York and Los Angeles, the knowledge that military personnel are providing critically important emergency care generates a significant measure of goodwill toward the military.

Lastly, an important point in considering whether to use military chambers to provide emergent HBO₂ is that the chamber availability does not have to be an “all or nothing” decision. As noted by the DAN medical leadership, the availability of a particular chamber to conduct HBO₂ therapy is always dependent on chamber staffing and maintenance considerations and whether the chamber is currently engaged in a treatment. Thus, a military chamber may be declared “up” for emergent HBO₂ treatments only for designated periods of time, and DAN would direct emergency patients accordingly. The customized tasking function performed by DAN also provides the opportunity to direct patients who are judged likely to require intensive care support to chambers that are capable of providing that level of support (*Personal communication - Dr. Jim Chimiak - 5 May 20*).

Incentivizing Hyperbaric Treatment Facilities to Provide Emergent HBO₂ Therapy

Optimizing the ability of the U.S. health care system to make emergent HBO₂ available to those patients who require it will require the identification and implementation of strategies to incentivize hyperbaric treatment facilities to offer emergent HBO₂. Options for accomplishing this include:

- 1) direct federal or state grants to hyperbaric treatment facilities that offer emergent HBO₂;
- 2) indemnification from legal liability for hyperbaric treatment facilities and medical providers who provide emergent HBO₂ to divers and other patients who require it;
- 3) recognition of the public service performed by the hyperbaric treatment facilities that offer HBO₂ on an emergent basis when indicated;
- 4) favorable consideration with respect to Medicare, Medicaid, and private insurance reimbursements to hyperbaric treatment facilities and medical providers that offer HBO₂ on an emergent basis when indicated, including carve-outs to inpatient DRG (diagnosis-related group) payments;
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Attachment 1

Beevor H, Frawley G: Iatrogenic cerebral gas embolism: analysis of the presentation, management and outcomes of patients referred to The Alfred Hospital Hyperbaric Unit. *Diving Hyperb Med* 2016;46:15-21.

Attachment 2

Sadler C, Latham E, Hollidge M, Boni B, Brett K: Delayed hyperbaric oxygen therapy for severe arterial gas embolism following scuba diving: a case report. *Undersea Hyperb Med* 2019;46:197-202.