

**SUBSTITUTE FOR
HOUSE BILL NO. 5456**

A bill to create a hyperbaric oxygen therapy grant program and pilot program for providing treatment to veterans with traumatic brain injuries or post-traumatic stress disorder; to provide for the powers and duties of certain state governmental officers and entities; and to require the promulgation of rules.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

1 Sec. 1. This act may be cited as the "hyperbaric oxygen
2 therapy pilot program act".

3 Sec. 2. As used in this act:

4 (a) "Accreditation" means a safety or operational review
5 performed by a recognized accrediting organization that conducts
6 evaluations of hyperbaric chamber operations, facility practices,
7 or safety protocols using standards consistent with recognized



1 hyperbaric safety principles.

2 (b) "Chamber attendant" means an individual with training
3 provided by a recognized accrediting organization who is
4 responsible for direct care and supervision of a patient receiving
5 hyperbaric oxygen therapy, including operating and monitoring
6 equipment in accordance with manufacturer, facility, state, and
7 federal guidelines.

8 (c) "Department" means the department of health and human
9 services.

10 (d) "Eligible veteran" means an individual who meets all of
11 the following criteria:

12 (i) Is a veteran as that term is defined in section 1 of 1965
13 PA 190, MCL 35.61.

14 (ii) Is diagnosed with a traumatic brain injury or post-
15 traumatic stress disorder.

16 (iii) Is a resident of this state.

17 (e) "510(k) clearance" means premarket clearance under section
18 510(k) of the federal food, drug, and cosmetic act of 1938, 21 USC
19 360(k).

20 (f) "Fund" means the hyperbaric oxygen therapy fund created in
21 section 3 of the hyperbaric oxygen therapy fund act.

22 (g) "Grant program" means the hyperbaric oxygen therapy grant
23 program created in section 3.

24 (h) "Hard-shelled hyperbaric chamber" means a rigid pressure
25 vessel that meets both of the following requirements:

26 (i) Is constructed in accordance with ASME PVHO-1 and has an
27 ASME PVHO-1 stamp.

28 (ii) Has 510(k) clearance from the United States Food and Drug
29 Administration for its intended use, or meets other federally

1 recognized pressure-vessel engineering standards.

2 (i) "Hyperbaric oxygen therapy" means treatment delivered
3 under increased atmospheric pressure, with or without supplemental
4 oxygen, and prescribed by a physician, physician's assistant, or
5 nurse practitioner.

6 (j) "Nurse practitioner" means an individual who is licensed
7 as a registered professional nurse under part 172 of the public
8 health code, 1978 PA 368, MCL 333.17201 to 333.17242, who has been
9 granted a specialty certification as a nurse practitioner by the
10 Michigan board of nursing under section 17210 of the public health
11 code, 1978 PA 368, MCL 333.17210.

12 (k) "Physician" means a physician who is licensed under part
13 170 or part 175 of the public health code, 1978 PA 368, MCL
14 333.17001 to 333.17097 and 333.17501 to 333.17556.

15 (l) "Physician's assistant" means a physician's assistant who
16 is licensed under part 170 or part 175 of the public health code,
17 1978 PA 368, MCL 333.17001 to 333.17097 and 333.17501 to 333.17556.

18 (m) "Pilot program" means the hyperbaric oxygen therapy pilot
19 program established under section 5.

20 (n) "Provider" means a provider of hyperbaric oxygen therapy.

21 (o) "Recognized accrediting organization" means any of the
22 following:

23 (i) American College of Hyperbaric Medicine.

24 (ii) International Board of Undersea Medicine.

25 (iii) International Hyperbaric Association.

26 (iv) National Board of Diving and Hyperbaric Medical
27 Technology.

28 (v) Undersea and Hyperbaric Medical Society.

29 (p) "Safety director" means a certified individual designated

1 by a provider to perform duties including, but not limited to,
2 overseeing chamber safety procedures, conducting operator training,
3 performing daily safety checks, and ensuring emergency protocol
4 compliance.

5 (q) "Soft-shelled hyperbaric chamber" means a flexible or
6 soft-sided chamber holding valid 510(k) clearance from the United
7 States Food and Drug Administration for its intended use.

8 (r) "Treatment plan" means a hyperbaric oxygen therapy
9 treatment plan.

10 Sec. 3. (1) As part of the pilot program, the department shall
11 create and operate a hyperbaric oxygen therapy grant program. The
12 department may make grants under this section only to a provider
13 chosen by the department under section 5 to assist the provider in
14 providing and paying the costs of hyperbaric oxygen therapy and
15 related diagnostic testing, including, but not limited to,
16 Automated Neuropsychological Assessment Metrics procedures, to
17 eligible veterans under the pilot program. All providers that
18 receive a grant under this section must offer hyperbaric oxygen
19 therapy at no cost to eligible veterans as provided in section 5.

20 (2) The department shall not make a grant under this section
21 until after the department has established the pilot program and
22 promulgated the rules required by section 5.

23 (3) The department shall not make a grant under this section
24 after the pilot program ends.

25 (4) By not later than 12 months after the effective date of
26 this act, the department shall promulgate rules to implement this
27 section under the administrative procedures act of 1969, 1969 PA
28 306, MCL 24.201 to 24.328, that must address all of the following
29 for grants under this section:



1 (a) Application procedures.

2 (b) Eligibility criteria subject to section 5.

3 (c) Selection procedures subject to section 5.

4 (d) A consideration of the extent to which a provider has used
5 assistance available from other assistance programs before the
6 department makes a grant under this section to the provider.

7 However, a grant must not be denied or delayed solely on the basis
8 that assistance available from other programs has not been used.

9 (e) Department oversight and verification of the use of grant
10 money.

11 Sec. 5. (1) The department, in consultation with the
12 department of military and veterans affairs, shall establish a
13 hyperbaric oxygen therapy pilot program to assist each provider
14 that the department approves to provide hyperbaric oxygen therapy
15 and related diagnostic testing to eligible veterans. The pilot
16 program must end 3 years after the first session of hyperbaric
17 oxygen therapy is administered under the program.

18 (2) The department shall issue a request for proposals within
19 this state to provide hyperbaric oxygen therapy to eligible
20 veterans. In determining the providers that will participate in the
21 pilot program, the department shall prioritize existing providers
22 in this state that meet all of the following criteria:

23 (a) Have a medical director who is a licensed medical
24 professional who can prescribe oxygen who provides medical
25 oversight of all hyperbaric oxygen therapy delivered. The medical
26 director must be certified in hyperbaric medicine with a minimum
27 certification of a 40-hour introduction to hyperbaric medicine
28 clinician course.

29 (b) Have a safety director on-site to oversee trained chamber

1 attendants.

2 (c) Follow established treatment protocols for using
3 hyperbaric oxygen therapy to treat traumatic brain injuries and
4 post-traumatic stress disorder.

5 (3) An eligible veteran is eligible for hyperbaric oxygen
6 therapy under the pilot program if the event that caused the
7 traumatic brain injury or post-traumatic stress disorder is
8 documented by a physician.

9 (4) By not later than 12 months after the effective date of
10 this act, the department, after consulting with the department of
11 military and veterans affairs, shall promulgate rules to implement
12 this section under the administrative procedures act of 1969, 1969
13 PA 306, MCL 24.201 to 24.328, that must include standards for all
14 of the following:

15 (a) Confirmation by a provider that an eligible veteran is a
16 veteran eligible for participation in the pilot program by showing
17 1 of the following forms as applicable:

18 (i) DD214.

19 (ii) NGB-22.

20 (iii) DD256.

21 (b) Determination by the department that a provider is
22 eligible to participate in the pilot program with a hard-shelled
23 hyperbaric chamber, including meeting all of the following
24 requirements:

25 (i) Each hard-shelled hyperbaric chamber must be constructed in
26 accordance with ASME PVHO-1 and have 510(k) clearance from the
27 United States Food and Drug Administration for its intended use.

28 (ii) Each hard-shelled hyperbaric chamber must be operated and
29 maintained in accordance with manufacturer guidelines and



1 specifications.

2 (iii) Providers must maintain easily accessible records of all
3 of the following:

4 (A) Each hard-shelled hyperbaric chamber's ASME "U" stamp
5 certification, data plate information, and clinical and operating
6 manual.

7 (B) Proof that a designated safety director is on-site during
8 hyperbaric oxygen therapy services.

9 (C) Documentation that the provider has a medical director
10 responsible for the oversight of the facility's hyperbaric
11 operations.

12 (D) Written policies for management of the hyperbaric
13 facility, including, but not limited to, general operational
14 procedures, emergency procedures, and documentation and maintenance
15 of the equipment that must be accessible to physicians and staff in
16 the workplace, reviewed by all staff at least annually, and revised
17 periodically.

18 (iv) Providers shall obtain accreditation for each hard-shelled
19 chamber from a recognized accreditation organization.

20 (v) Providers shall undergo an independent safety audit not
21 less than every 3 years by a recognized accrediting organization or
22 a reviewer with experience evaluating hyperbaric chamber operations
23 or safety practices.

24 (c) Determination by the department that a provider is
25 eligible to participate in the pilot program with a soft-shelled
26 hyperbaric chamber, including that the provider meets the following
27 requirements:

28 (i) Each soft-shelled hyperbaric chamber must have 510(k)
29 clearance from the United States Food and Drug Administration for

1 its intended use.

2 (ii) Each soft-shelled hyperbaric chamber must be operated and
3 maintained in accordance with manufacturer guidelines and
4 specifications.

5 (iii) The oxygen concentration within each soft-shelled chamber
6 and room in which the soft-shelled chamber operates must not exceed
7 23.5% oxygen.

8 (iv) Providers must maintain easily accessible records of all
9 of the following:

10 (A) Each soft-shelled chamber's serial number, clinical and
11 operating manual, and proof of 510(k) clearance from the United
12 States Food and Drug Administration.

13 (B) Proof that a designated safety director is on-site during
14 hyperbaric oxygen therapy services.

15 (C) Documentation that the provider has a medical director
16 responsible for the oversight of the facility's hyperbaric
17 operations.

18 (D) Written policies for management of the hyperbaric
19 facility, including, but not limited to, general operational
20 procedures, emergency procedures, and documentation and maintenance
21 of the equipment that must be accessible to physicians and staff in
22 the workplace, reviewed by all staff at least annually, and revised
23 periodically.

24 (v) Providers shall obtain accreditation for each soft-shelled
25 chamber from a recognized accreditation organization.

26 (vi) Providers operating soft-shelled chambers shall undergo an
27 independent safety audit not less than every 3 years by a
28 recognized accreditation organization or reviewer with experience
29 evaluating hyperbaric chamber operations or safety practices.



1 (d) Treatment plan requirements, including all of the
2 following:

3 (i) That a provider must submit to the department, before
4 providing hyperbaric oxygen therapy to an eligible veteran, a
5 treatment plan that includes all of the following:

6 (A) A prescription from a physician, physician's assistant, or
7 nurse practitioner. Each patient must be evaluated and cleared by a
8 physician, physician's assistant, or nurse practitioner before
9 receiving hyperbaric oxygen therapy for the first time and any time
10 the patient has a major change in the patient's health status.

11 (B) Verification by the provider that the eligible veteran is
12 eligible under subdivision (a) for participation in the pilot
13 program and voluntarily accepts treatment through the pilot
14 program.

15 (C) An estimate of the cost of the eligible veteran's
16 hyperbaric oxygen therapy.

17 (D) Any other information required by the department.

18 (ii) A requirement that both of the following must occur after
19 the department receives a proposed treatment plan from a provider:

20 (A) Approval or disapproval by the department of the treatment
21 plan within 10 business days.

22 (B) Notice to the provider of approval or disapproval of the
23 treatment plan within 15 business days.

24 (iii) Contingent on the availability of sufficient funding in
25 the fund, approval of each treatment plan that meets the
26 requirements established by the department under this section.

27 (iv) The sources of funding for the estimated cost of
28 hyperbaric oxygen therapy for each eligible veteran whose treatment
29 plan is approved under this section.

1 (e) Criteria for approval of payment for hyperbaric oxygen
2 therapy that has been verified by the department to have been
3 provided under a treatment plan approved under subdivision (d),
4 including both of the following:

5 (i) Whether a drug or device used in the treatment plan has
6 been approved for any purpose by the United States Food and Drug
7 Administration.

8 (ii) A verification that an eligible veteran received the
9 hyperbaric oxygen therapy as demonstrated through billing
10 documentation from the provider, or attendance documentation signed
11 by the provider and the eligible veteran attesting to the receipt
12 of the hyperbaric oxygen therapy.

13 (f) Confidentiality of all individually identifiable patient
14 information of an eligible veteran.

15 (5) A provider shall not bill an eligible veteran for any
16 service provided under the pilot program. A provider shall bill the
17 pilot program and be paid at cost out of a grant made to the
18 provider under the grant program at a rate agreed to between the
19 provider and the department, which may be the current state or
20 federal Centers for Medicare and Medicaid Services rates, but must
21 not be more than the following amounts:

22 (a) For a hard-shelled hyperbaric chamber, not more than
23 \$250.00 per dive and not more than \$10,000.00 for a full session of
24 40 dives.

25 (b) For a soft-shelled hyperbaric chamber, not more than
26 \$175.00 per dive and not more than \$7,000.00 for a full session of
27 40 dives.

28 (6) Each provider must administer Automated Neuropsychological
29 Assessment Metrics procedures following the general guidelines of

1 the American Psychological Association for the distribution and
2 administration of psychological tests. Automated Neuropsychological
3 Assessment Metrics procedures must be administered before
4 treatment, halfway through treatment after 20 dives, and after the
5 completion of a treatment of 40 dives. Automated Neuropsychological
6 Assessment Metrics procedures may be administered by trained
7 proctors under the supervision of individuals with training in
8 psychological testing principles and test administration
9 procedures. Results must be interpreted by qualified medical
10 professionals such as clinical psychologists, neuropsychologists,
11 or physicians with training in psychological testing principles,
12 test administration procedures, and clinical test interpretation.

13 (7) An eligible veteran must provide written informed consent
14 to receive hyperbaric oxygen therapy under the pilot program,
15 subject to all of the following:

16 (a) At a minimum, the written informed consent must include
17 all of the following:

18 (i) An explanation of the products used and treatments given
19 for the traumatic brain injury or post-traumatic stress disorder
20 from which the veteran suffers.

21 (ii) A description of the best and worst potential outcomes of
22 using hyperbaric oxygen therapy and a realistic description of the
23 most likely outcomes. Both of the following apply to the
24 description of potential outcomes:

25 (A) Must include the possibility that new, unanticipated,
26 different, or worse symptoms may result and that the proposed
27 treatment may hasten death.

28 (B) Must be based on the treating provider's knowledge of the
29 proposed treatment in conjunction with an awareness of the

1 veteran's condition.

2 (b) The written informed consent must be signed by the
3 eligible veteran and attested to by the treating provider.

4 Sec. 7. (1) Each provider shall file a quarterly status report
5 concerning the services performed by the provider under the pilot
6 program with the department and the department of military and
7 veterans affairs that must include separate results for treatments
8 using hard shell chambers, soft shell chambers with supplemental
9 oxygen, and soft shell chambers without supplemental oxygen.

10 (2) By not later than 1 year after the pilot program begins
11 and each year after until the pilot program ends, the department,
12 in consultation with the department of military and veterans
13 affairs, shall prepare an annual report and submit it to the
14 governor and the chairpersons of the senate and the house of
15 representatives standing committees on military and veterans
16 affairs. The reports required under this subsection must be made
17 available on the department's website and contain, at a minimum,
18 all of the following information for the pilot program for the
19 applicable reporting period:

20 (a) An evaluation of the effectiveness of the pilot program.

21 (b) The number of eligible veterans that participated.

22 (c) The number of providers that participated.

23 (d) Separate results for treatments using hard shell chambers,
24 soft shell chambers with supplemental oxygen, and soft shell
25 chambers without supplemental oxygen.

26 (3) In addition to the reports required under subsection (2),
27 by not later than 6 months after the pilot program ends, the
28 department shall prepare and submit a final cumulative report in
29 the same manner as the report required under subsection (2),



1 containing the information described in subsection (2) for the
2 entire duration of the pilot program.

3 Enacting section 1. This act does not take effect unless House
4 Bill No. ____ (request no. H03783'25) of the 103rd Legislature is
5 enacted into law.

