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:

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

Sec. 2. As used in this act:

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

hyperbaric safety principles.

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

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

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

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

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

(*iii*) Is a resident of this state.

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

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

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

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

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

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

recognized pressure-vessel engineering standards.

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

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

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

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

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

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

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

(*i*) American College of Hyperbaric Medicine.

(*ii*) International Board of Undersea Medicine.

(*iii*) International Hyperbaric Association.

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

(*v*) Undersea and Hyperbaric Medical Society.

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

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

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

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

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

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

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

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

(a) Application procedures.

(b) Eligibility criteria subject to section 5.

(c) Selection procedures subject to section 5.

(d) A consideration of the extent to which a provider has used assistance available from other assistance programs before the department makes a grant under this section to the provider. However, a grant must not be denied or delayed solely on the basis that assistance available from other programs has not been used.

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

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

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

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

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

attendants.

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

(3) An eligible veteran is eligible for hyperbaric oxygen therapy under the pilot program if the event that caused the traumatic brain injury or post-traumatic stress disorder meets both of the following:

(a) Is documented as a service-connected disability by the United States Department of Veterans Affairs.

(b) Is documented by a physician.

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

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

(*i*) DD214.

(*ii*) NGB-22.

(*iii*) DD256.

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

(*i*) Each hard-shelled hyperbaric chamber must be constructed in accordance with ASME PVHO-1 and have 510(k) clearance from the

United States Food and Drug Administration for its intended use.

(*ii*) Each hard-shelled hyperbaric chamber must be operated and maintained in accordance with manufacturer guidelines and specifications.

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

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

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

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

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

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

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

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

requirements:

(*i*) Each soft-shelled hyperbaric chamber must have 510(k) clearance from the United States Food and Drug Administration for its intended use.

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

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

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

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

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

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

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

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

(*vi*) Providers operating soft-shelled chambers shall undergo an

independent safety audit not less than every 3 years by a recognized accreditation organization or reviewer with experience evaluating hyperbaric chamber operations or safety practices.

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

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

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

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

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

(D) Any other information required by the department.

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

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

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

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

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

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

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

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

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

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

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

(b) For a soft-shelled hyperbaric chamber, not more than $175.00 per dive and not more than $7,000.00 for a full session of

40 dives.

(6) Each provider must administer Automated Neuropsychological Assessment Metrics procedures following the general guidelines of the American Psychological Association for the distribution and administration of psychological tests. Automated Neuropsychological Assessment Metrics procedures must be administered before treatment, halfway through treatment after 20 dives, and after the completion of a treatment of 40 dives. Automated Neuropsychological Assessment Metrics procedures may be administered by trained proctors under the supervision of individuals with training in psychological testing principles and test administration procedures. Results must be interpreted by qualified medical professionals such as clinical psychologists, neuropsychologists, or physicians with training in psychological testing principles, test administration procedures, and clinical test interpretation.

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

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

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

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

(A) Must include the possibility that new, unanticipated, different, or worse symptoms may result and that the proposed

treatment may hasten death.

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

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

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

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

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

(b) The number of eligible veterans that participated.

(c) The number of providers that participated.

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

(3) In addition to the reports required under subsection (2),

by not later than 6 months after the pilot program ends, the department shall prepare and submit a final cumulative report in the same manner as the report required under subsection (2), containing the information described in subsection (2) for the entire duration of the pilot program.

Enacting section 1. This act does not take effect unless House Bill No. 5457 of the 103rd Legislature is enacted into law.