SENATE BILL NO. 1234

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the House Committee on Health, Welfare and Institutions

on February 14, 2023)

(Patron Prior to Substitute--Senator Cosgrove)

A BILL to establish a pilot program for transcranial magnetic stimulation.

Be it enacted by the General Assembly of Virginia:

1. § 1. That the Department of Behavioral Health and Development Services (the Department) shall establish a pilot program to make electroencephalogram (EEG) combined transcranial magnetic stimulation available for veterans, first responders, and law-enforcement officers, including agents of the Department of Defense and the Central Intelligence Agency, with substance use disorders, mental illness, sleep disorders, traumatic brain injuries, sexual trauma, post-traumatic stress disorder and accompanying comorbidities, concussions or other brain trauma, or other quality of life issues.

§ 2. The Department shall choose a location for the pilot program and up to 10 branch sites and shall enter into a contract for the purchase of services related to the pilot program. A branch site may be a mobile unit or an EEG combined neuromodulation portable unit if the Department determines that mobile units or EEG combined neuromodulation portable units are necessary to expand access to care. The contract shall include provisions requiring the supplier to create and conduct a clinical trial, to establish and operate a clinical practice, to evaluate outcomes of the clinical trial and the clinical practice, to expend payments received from the state as needed for purposes of the program, and to report quarterly regarding the pilot program to the Chairmen of the Senate Committee on Education and Health and the House Committee on Health, Welfare and Institutions.

§ 3. The State Board of Behavioral Health and Developmental Services (the Board) shall adopt regulations as necessary to administer this act, including regulations that:

A. Require adherence to the U.S. Food and Drug Administration regulations governing the conduct of clinical practice and clinical trials;

B. Require that a peer-to-peer support network be established and made available by the supplier to any individual receiving treatment under the program;

C. Establish that the program protocol will be to use adapted stimulation frequency and intensity modulation based on a daily EEG and motor threshold testing, as well as clinical symptoms and signs and biometrics;

D. Require that each individual who receives treatment under the program also must receive pre- and post-neurophysiological monitoring, with EEG and autonomic nervous systems assessments; daily checklists of symptoms of alcohol, opioid, or other substance use; and weekly medical counseling and wellness programming, and also must participate in the peer-to-peer support network established by the supplier;

E. Require that protocols and outcomes of the clinical trial, and of any treatment provided by the clinical practice, must be collected and reported quarterly in a report provided by the supplier;

F. Require that any individual who receives treatment at the clinical practice be eligible for a minimum of two electroencephalograms during the course of the individual's treatment; and

G. Require that the report required by this act include a thorough accounting of the use and expenditure of all funds received from the state under this act.

§ 4. As used in this act:

"Electroencephalogram (EEG) combined transcranial magnetic stimulation" means treatment in which transcranial magnetic stimulation (TMS) frequency pulses are tuned to the patient's physiology and biometric data, at the time of each treatment, using a pre- and post-TMS EEG.

"Quality of life issues" means issues affecting human performance, including issues related to or resulting from problems with cognition and problems maintaining attention, concentration, or focus.

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