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S.B. 153
134th General Assembly

Bill Analysis

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Version: As Passed by the Senate

Primary Sponsor: Sen. Hoagland

Daniel DeSantis, Research Analyst

SUMMARY

- Renames the Transcranial Magnetic Stimulation Pilot Program to the Electroencephalogram (EEG) Combined Transcranial Magnetic Stimulation Pilot Program.
- Expands the program to be available to first responders and law enforcement officers.
- Expands the list of disorders and conditions that establish eligibility for treatment under the program.
- Authorizes the program to have up to ten branch sites, and specifies that a branch site may be a mobile unit, or an EEG combined neuromodulation portable unit.
- Requires the Directors of Veterans Services and Mental Health and Addiction Services to adopt additional rules for administration of the program.
- Requires the supplier to create and conduct a clinical trial and to establish and operate a clinical practice.
- Makes an appropriation.

DETAILED ANALYSIS

Background

H.B. 166 of the 133rd General Assembly, effective October 17, 2019, required the Directors of Veterans Services and Mental Health and Addiction Services to establish a three-year pilot program to make transcranial magnetic stimulation available for veterans with

substance use disorders or mental illness. The program must operate in conjunction with a supplier for services selected by the Directors.[1]

Electroencephalogram (EEG) combined transcranial magnetic stimulation pilot program

Treatment and eligibility

The bill alters the description of the treatment to be provided under the program and expands the description of individuals who may be eligible for treatment. Under the bill, the pilot program is to make electroencephalogram (EEG) combined transcranial magnetic stimulation available for veterans, first responders,[2] and law enforcement officers.[3] For purposes of the bill, "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.

The bill also expands the list of disorders and conditions that establish eligibility for treatment under the program. Under current law, treatment may be provided to persons with substance use disorders or mental illness. The bill specifies that treatment also may be provided to individuals with 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. Under the bill, "quality of life issues" means issues affecting human performance including but not limited to issues related to or resulting from problems with cognition and problems maintaining attention, concentration, or focus.[4]

Program locations

The bill requires the Directors of Veterans Services and Mental Health and Addiction Services, by mutual agreement, to choose a location for the pilot program and for up to ten branch sites. Furthermore, the bill specifies that a branch site may be a mobile unit or an EEG combined neuromodulation portable unit if the Directors determine that mobile units or EEG

[1] R.C. 5902.09.

[2] "First responder" means an emergency medical service provider, a firefighter, or any other emergency response personnel, or anyone who has previously served as a first responder. (R.C. 2903.01, not in the bill).

[3] "Law enforcement officer" means a law enforcement officer, a peace officer, or a person authorized to carry firearm who is employed, commissioned, disposed, appointed, or elected in a capacity for this state, a political subdivision of this state, or an agency, department, or instrumentality of this state or a political subdivision of this state. (R.C. 9.69, 109.801, 2901.01, and 2935.01, not in the bill).

[4] R.C. 5902.09(A) and (B).

combined neuromodulation portable units are necessary to expand access to care. Current law, modified by the bill, requires the supplier to choose a location for the pilot program.[5]

Clinical trial and clinical practice

The bill requires that the supplier chosen by the Directors create and conduct a clinical trial, establish and operate a clinical practice, and evaluate outcomes of the clinical trial and the clinical practice. Current law requires the supplier to create, implement, operate, and evaluate outcomes of the pilot program.[6]

Rules

The bill requires that one or both of the Directors adopt all of the following additional rules under the Administrative Procedure Act:

1. A rule requiring adherence to United States Food and Drug Administration regulations governing the conduct of clinical practice and clinical trials;
2. A rule requiring that a peer-to-peer support network be established and made available by the supplier to any individual receiving treatment under the program;
3. A rule establishing 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;
4. A rule requiring 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;
5. A rule requiring 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.

Current law requires that a rule be adopted to require the supplier collect and provide a quarterly report on the clinical protocols and outcomes. The bill clarifies that the report must address the protocols and outcomes of the clinical trial, and of any treatment provided by the clinical practice. And the bill specifies that the report must be provided to the Directors of Veterans Services and Mental Health and Addition Services. The bill requires that the report also be provided to the United States Food and Drug Administration.[7]

[5] R.C. 5902.09(C).

[6] R.C. 5902.09(C).

[7] R.C. 5902.09(E).

Fund

The bill renames the Transcranial Magnetic Stimulation Fund, in the state treasury, as the Electroencephalogram (EEG) Combined Transcranial Magnetic Stimulation Fund.[8]

HISTORY

Action	Date
Introduced	04-06-21
Reported, S. Workforce & Higher Education	06-01-21
Passed Senate (33-0)	06-09-21

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[8] R.C. 5902.09(D).