

113TH CONGRESS
1ST SESSION

H. R. 2344

To direct the Secretary of Defense to carry out a pilot program for investigational treatment of members of the Armed Forces for traumatic brain injury and post-traumatic stress disorder.

IN THE HOUSE OF REPRESENTATIVES

JUNE 12, 2013

Mr. SESSIONS (for himself and Mr. THOMPSON of California) introduced the following bill; which was referred to the Committee on Armed Services

A BILL

To direct the Secretary of Defense to carry out a pilot program for investigational treatment of members of the Armed Forces for traumatic brain injury and post-traumatic stress disorder.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “TBI Treatment Act”.

1 **SEC. 2. PILOT PROGRAM FOR INVESTIGATIONAL TREAT-**
2 **MENT OF MEMBERS OF THE ARMED FORCES**
3 **FOR TRAUMATIC BRAIN INJURY AND POST-**
4 **TRAUMATIC STRESS DISORDER.**

5 (a) PROCESS.—The Secretary of Defense shall carry
6 out a five-year pilot program under which the Secretary
7 shall establish a process through which the Secretary shall
8 provide payment for investigational treatments (including
9 diagnostic testing) of traumatic brain injury or post-trau-
10 matic stress disorder received by members of the Armed
11 Forces in health care facilities other than military treat-
12 ment facilities. Such process shall provide that payment
13 be made directly to the health care facility furnishing the
14 treatment.

15 (b) CONDITIONS FOR APPROVAL.—The approval by
16 the Secretary for payment for a treatment pursuant to
17 subsection (a) shall be subject to the following conditions:

18 (1) Any drug or device used in the treatment
19 must be approved or cleared by the Food and Drug
20 Administration for any purpose and its use must
21 comply with rules of the Food and Drug Administra-
22 tion applicable to investigational new drugs or inves-
23 tigational devices.

24 (2) The treatment must be approved by the
25 Secretary following approval by an institutional re-
26 view board operating in accordance with regulations

1 issued by the Secretary of Health and Human Serv-
2 ices.

3 (3) The patient receiving the treatment must
4 demonstrate an improvement under criteria ap-
5 proved by the Secretary, as a result of the treatment
6 on one or more of the following:

7 (A) Standardized independent pre-treat-
8 ment and post-treatment neuropsychological
9 testing.

10 (B) Accepted survey instruments including,
11 such instruments that look at quality of life.

12 (C) Neurological imaging.

13 (D) Clinical examination.

14 (4) The patient receiving the treatment must be
15 receiving the treatment voluntarily and based on in-
16 formed consent.

17 (5) The patient receiving the treatment may not
18 be a retired member of the Armed Forces who is en-
19 titled to benefits under part A, or eligible to enroll
20 under part B, of title XVIII of the Social Security
21 Act.

22 (c) ADDITIONAL RESTRICTIONS AUTHORIZED.—The
23 Secretary may establish additional restrictions or condi-
24 tions for reimbursement as the Secretary determines ap-
25 propriate to ensure the protection of human research sub-

1 jects, appropriate fiscal management, and the validity of
2 the research results.

3 (d) AUTHORITY.—The Secretary shall make pay-
4 ments under this section for treatments received by mem-
5 bers of the Armed Forces using the authority in subsection
6 (c)(1) of section 1074 of title 10, United States Code.

7 (e) AMOUNT.—A payment under this section shall be
8 made at the equivalent Centers for Medicare and Medicaid
9 Services reimbursement rate in effect for appropriate
10 treatment codes for the State or territory in which the
11 treatment is received. If no such rate is in effect, payment
12 shall be made on a cost-reimbursement basis, as deter-
13 mined by the Secretary, in consultation with the Secretary
14 of Health and Human Services.

15 (f) DATA COLLECTION AND AVAILABILITY.—

16 (1) IN GENERAL.—The Secretary shall develop
17 and maintain a database containing data from each
18 patient case involving the use of a treatment under
19 this section. The Secretary shall ensure that the
20 database preserves confidentiality and that any use
21 of the database or disclosures of such data are lim-
22 ited to such use and disclosures permitted by law
23 and applicable regulations.

24 (2) PUBLICATION OF QUALIFIED INSTITU-
25 TIONAL REVIEW BOARD STUDIES.—The Secretary

1 shall ensure that an Internet website of the Depart-
2 ment of Defense includes a list of all civilian institu-
3 tional review board studies that have received a pay-
4 ment under this section.

5 (g) ASSISTANCE FOR MEMBERS TO OBTAIN TREAT-
6 MENT.—

7 (1) ASSIGNMENT TO TEMPORARY DUTY.—The
8 Secretary of a military department may assign a
9 member of the Armed Forces under the jurisdiction
10 of the Secretary to temporary duty or allow the
11 member a permissive temporary duty in order to
12 permit the member to receive treatment for trau-
13 matic brain injury or post-traumatic stress disorder,
14 for which payments shall be made under subsection
15 (a), at a location beyond reasonable commuting dis-
16 tance of the permanent duty station of the member.

17 (2) PER DIEM.—A member who is away from
18 the permanent station of the member may be paid
19 a per diem in lieu of subsistence in an amount not
20 more than the amount to which the member would
21 be entitled if the member were performing travel in
22 connection with a temporary duty assignment.

23 (3) GIFT RULE WAIVER.—The Secretary of De-
24 fense may waive any rule of the Department of De-
25 fense regarding ethics or the receipt of gifts with re-

1 spect to any assistance provided to a member of the
2 Armed Forces for travel or per diem expenses inci-
3 dental to receiving treatment under this section.

4 (h) MEMORANDA OF UNDERSTANDING.—The Sec-
5 retary shall enter into memoranda of understandings with
6 civilian institutions for the purpose of providing members
7 of the Armed Forces with treatment carried out by civilian
8 health care practitioners under treatment—

9 (1) approved by and under the oversight of ci-
10 vilian institutional review boards; and

11 (2) that would qualify for payment under this
12 section.

13 (i) OUTREACH.—The Secretary of Defense shall es-
14 tablish a process to notify members of the Armed Forces
15 of the opportunity to receive treatment pursuant to this
16 section.

17 (j) REPORT TO CONGRESS.—Not later than 30 days
18 after the last day of each fiscal year during which the Sec-
19 retary is authorized to make payments under this section,
20 the Secretary shall submit to Congress an annual report
21 on the implementation of this section and any available
22 results on investigational treatment studies authorized
23 under this section.

1 (k) TERMINATION.—The authority to make a pay-
2 ment under this section shall terminate on the date that
3 is five years after the date of the enactment of this Act.

4 (l) AUTHORIZATION OF APPROPRIATIONS.—There is
5 authorized to be appropriated to carry out this section
6 \$10,000,000 for each fiscal year during which the Sec-
7 retary is authorized to make payments under this section.

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