AMENDMENT TO THE RULES COMMITTEE PRINT OF H.R. 1960

OFFERED BY MR. SESSIONS OF TEXAS

Page 308, after line 21, insert the following:

SEC. 726. PILOT PROGRAM FOR INVESTIGATIONAL TREAT MENT OF MEMBERS OF THE ARMED FORCES
 FOR TRAUMATIC BRAIN INJURY AND POST TRAUMATIC STRESS DISORDER.

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

(b) CONDITIONS FOR APPROVAL.—The approval by
the Secretary for payment for a treatment pursuant to
subsection (a) shall be subject to the following conditions:
(1) Any drug or device used in the treatment
must be approved or cleared by the Food and Drug

1	Administration for any purpose and its use must
2	comply with rules of the Food and Drug Administra-
3	tion applicable to investigational new drugs or inves-
4	tigational devices.
5	(2) The treatment must be approved by the
6	Secretary following approval by an institutional re-
7	view board operating in accordance with regulations
8	issued by the Secretary of Health and Human Serv-
9	ices.
10	(3) The patient receiving the treatment must
11	demonstrate an improvement under criteria ap-
12	proved by the Secretary, as a result of the treatment
13	on one or more of the following:
14	(A) Standardized independent pre-treat-
15	ment and post-treatment neuropsychological
16	testing.
17	(B) Accepted survey instruments including,
18	such instruments that look at quality of life.
19	(C) Neurological imaging.
20	(D) Clinical examination.
21	(4) The patient receiving the treatment must be
22	receiving the treatment voluntarily and based on in-
23	formed consent.
24	(5) The patient receiving the treatment may not
25	be a retired member of the Armed Forces who is en-

titled to benefits under part A, or eligible to enroll
 under part B, of title XVIII of the Social Security
 Act.

4 (c) ADDITIONAL RESTRICTIONS AUTHORIZED.—The 5 Secretary may establish additional restrictions or condi-6 tions for reimbursement as the Secretary determines ap-7 propriate to ensure the protection of human research sub-8 jects, appropriate fiscal management, and the validity of 9 the research results.

(d) AUTHORITY.—The Secretary shall make payments under this section for treatments received by members of the Armed Forces using the authority in subsection
(c)(1) of section 1074 of title 10, United States Code.

14 (e) AMOUNT.—A payment under this section shall be 15 made at the equivalent Centers for Medicare and Medicaid Services reimbursement rate in effect for appropriate 16 treatment codes for the State or territory in which the 17 18 treatment is received. If no such rate is in effect, payment 19 shall be made on a cost-reimbursement basis, as determined by the Secretary, in consultation with the Secretary 2021 of Health and Human Services.

22 (f) DATA COLLECTION AND AVAILABILITY.—

(1) IN GENERAL.—The Secretary shall develop
and maintain a database containing data from each
patient case involving the use of a treatment under

this section. The Secretary shall ensure that the
database preserves confidentiality and that any use
of the database or disclosures of such data are limited to such use and disclosures permitted by law
and applicable regulations.

6 (2) PUBLICATION OF QUALIFIED INSTITU-7 TIONAL REVIEW BOARD STUDIES.—The Secretary 8 shall ensure that an Internet website of the Depart-9 ment of Defense includes a list of all civilian institu-10 tional review board studies that have received a pay-11 ment under this section.

12 (g) Assistance for Members to Obtain Treat-13 ment.—

14 (1) Assignment to temporary duty.—The 15 Secretary of a military department may assign a 16 member of the Armed Forces under the jurisdiction 17 of the Secretary to temporary duty or allow the 18 member a permissive temporary duty in order to 19 permit the member to receive treatment for trau-20 matic brain injury or post-traumatic stress disorder, 21 for which payments shall be made under subsection 22 (a), at a location beyond reasonable commuting dis-23 tance of the permanent duty station of the member. 24 (2) PER DIEM.—A member who is away from

25 the permanent station of the member may be paid

a per diem in lieu of subsistence in an amount not
 more than the amount to which the member would
 be entitled if the member were performing travel in
 connection with a temporary duty assignment.

5 (3) GIFT RULE WAIVER.—The Secretary of De6 fense may waive any rule of the Department of De7 fense regarding ethics or the receipt of gifts with re8 spect to any assistance provided to a member of the
9 Armed Forces for travel or per diem expenses inci10 dental to receiving treatment under this section.

(h) MEMORANDA OF UNDERSTANDING.—The Secretary shall enter into memoranda of understandings with
civilian institutions for the purpose of providing members
of the Armed Forces with treatment carried out by civilian
health care practitioners under treatment—

16 (1) approved by and under the oversight of ci-17 vilian institutional review boards; and

18 (2) that would qualify for payment under this19 section.

(i) OUTREACH.—The Secretary of Defense shall establish a process to notify members of the Armed Forces
of the opportunity to receive treatment pursuant to this
section.

(j) REPORT TO CONGRESS.—Not later than 30 daysafter the last day of each fiscal year during which the Sec-

retary is authorized to make payments under this section,
 the Secretary shall submit to Congress an annual report
 on the implementation of this section and any available
 results on investigational treatment studies authorized
 under this section.

6 (k) TERMINATION.—The authority to make a pay-7 ment under this section shall terminate on the date that 8 is five years after the date of the enactment of this Act. 9 (1) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section 10 11 \$10,000,000 for each fiscal year during which the Secretary is authorized to make payments under this section. 12 13 (m) FUNDING INCREASE AND OFFSETTING REDUC-14 TION.—

15 (1) IN GENERAL.—Notwithstanding the
amounts set forth in the funding tables in division
D, to carry out this section during fiscal year
2014—

(A) the amount authorized to be appropriated in section 1406 for the Defense Health
Program, as specified in the corresponding
funding table in division D, is hereby increased
by \$10,000,000, with the amount of the increase allocated to the Defense Health Pro-

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gram,	as	set	forth	in	the	table	under	section
4501,	to e	earry	v out t	his	secti	ion; ar	nd	

3 (B) the amount authorized to be appro-4 priated in section 301 for Operation and Main-5 tenance, Defense-wide, as specified in the cor-6 responding funding table in division D, is here-7 by reduced by \$10,000,000, with the amount of 8 the reduction to be derived from Line 280, Of-9 fice of the Secretary of Defense as set forth in 10 the table under section 4301.

(2) MERIT-BASED OR COMPETITIVE DECISIONS.—A decision to commit, obligate, or expend
funds referred to in paragraph (1)(A) with or to a
specific entity shall—

15 (A) be based on merit-based selection pro16 cedures in accordance with the requirements of
17 sections 2304(k), 2361, and 2374 of title 10,
18 United States Code, or on competitive proce19 dures; and

20 (B) comply with other applicable provisions21 of law.

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