

119TH CONGRESS
2D SESSION

S. _____

To amend title 38, United States Code, to establish within the Veterans Health Administration an Office of Novel Therapeutics, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. SHEEHY introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend title 38, United States Code, to establish within the Veterans Health Administration an Office of Novel Therapeutics, and for other purposes.

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 “Veterans Health Ad-
5 ministration Novel Therapeutics Preparedness Act”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

8 (1) Emerging therapeutic interventions, includ-
9 ing certain psychedelic-assisted therapies under eval-

1 uation by the Food and Drug Administration as of
2 the date of the enactment of this Act, may signifi-
3 cantly alter the treatment landscape for post-trau-
4 matic stress disorder, depression, and other mental
5 health conditions affecting veterans.

6 (2) The administration of certain emerging
7 therapies may require intensive clinical engagement,
8 interdisciplinary teams, dedicated clinical space,
9 structured preparation, and post-treatment integra-
10 tion that differ substantially from traditional out-
11 patient mental health services.

12 (3) The Department of Veterans Affairs is
13 uniquely positioned to deliver integrated, veteran-
14 centered care that combines medical, mental health,
15 and peer support services within a single system of
16 care.

17 (4) Absent centralized governance and imple-
18 mentation planning, the Department may face
19 delays, safety risks, or inconsistent access following
20 regulatory approval of such therapies.

21 (5) Establishing a dedicated Office of Novel
22 Therapeutics will ensure that the Department is pre-
23 pared to responsibly evaluate, research, and imple-
24 ment emerging treatment modalities consistent with
25 patient safety and evidence-based practice.

1 **SEC. 3. ESTABLISHMENT OF OFFICE OF NOVEL THERA-**
2 **PEUTICS WITHIN VETERANS HEALTH ADMIN-**
3 **ISTRATION.**

4 (a) ESTABLISHMENT.—

5 (1) IN GENERAL.—Chapter 73 of title 38,
6 United States Code, is amended by adding at the
7 end the following new subchapter:

8 **“Subchapter VI—Novel Therapeutics**

9 **“§ 7391. Definitions**

10 “In this subchapter:

11 “(1) CENTER OF EXCELLENCE.— The term
12 ‘center of excellence’ means a medical center of the
13 Department designated under section 7394 of this
14 title as a center of excellence for novel therapeutics
15 to advance research, training, and implementation of
16 emerging therapeutic interventions.

17 “(2) EMERGING THERAPEUTIC INTERVEN-
18 TION.—The term ‘emerging therapeutic intervention’
19 means a pharmacological, biological, or other thera-
20 peutic modality under evaluation or review by the
21 Food and Drug Administration.

22 **“§ 7392. Office of Novel Therapeutics**

23 “(a) ESTABLISHMENT.—There is established within
24 the Veterans Health Administration, under the Office of
25 the Under Secretary for Health, an Office of Novel Thera-
26 peutics (in this section referred to as the ‘Office’).

1 “(b) DIRECTOR.—The head of the Office shall be the
2 Director of the Office of Novel Therapeutics, who shall
3 be appointed by the Under Secretary for Health and who
4 shall—

5 “(1) possess demonstrated expertise in clinical
6 research and implementation science; and

7 “(2) report directly to the Under Secretary for
8 Health.

9 “(c) COORDINATING AUTHORITY.—The Office shall
10 serve as the primary coordinating authority within the
11 Veterans Health Administration for matters relating to
12 emerging and novel therapeutic interventions.

13 “(d) DUTIES.—The Office shall—

14 “(1) develop and oversee national policy, guid-
15 ance, and clinical standards for the evaluation, re-
16 search, and potential implementation by the Vet-
17 erans Health Administration of emerging and novel
18 therapeutic interventions for mental health condi-
19 tions affecting veterans;

20 “(2) develop a national clinical model for the
21 administration of intensive therapeutic interventions,
22 including structured preparation, monitored adminis-
23 tration, and post-administration integration;

24 “(3) develop guidance regarding patient eligi-
25 bility and candidacy for emerging therapeutic inter-

1 ventions, ensuring that utilization management or
2 step therapy requirements do not unduly restrict ac-
3 cess where clinically appropriate;

4 “(4) develop implementation-readiness plans for
5 therapies that may receive approval from the Food
6 and Drug Administration, including—

7 “(A) facility infrastructure requirements;

8 “(B) interdisciplinary team composition
9 standards;

10 “(C) allocation of protected clinical time
11 necessary to safely administer intensive thera-
12 peutic interventions, including full session and
13 integration requirements;

14 “(D) patient safety and adverse event
15 monitoring and response protocols; and

16 “(E) integration with suicide prevention,
17 post-traumatic stress disorder, and substance
18 use disorder programs;

19 “(5) conduct a workforce-readiness assessment
20 to identify clinicians and peer support specialists
21 with prior training or certification relevant to emerg-
22 ing therapeutic interventions and gaps in training,
23 supervision, and clinical capacity necessary to sup-
24 port safe and effective implementation of such inter-
25 ventions;

1 “(6) establish national training and
2 credentialing standards for clinicians administering
3 novel therapeutics;

4 “(7) develop a standardized, competency-based
5 training framework for clinicians and peer support
6 specialists participating in emerging therapeutic
7 interventions, including preparation, monitored ad-
8 ministration, integration, safety monitoring, inter-
9 disciplinary collaboration, and culturally competent
10 care;

11 “(8) distinguish between research protocols and
12 clinical implementation standards to ensure that pa-
13 tient care models are not constrained solely by spon-
14 sor-driven research design;

15 “(9) coordinate with the Office of Research and
16 Development—

17 “(A) to align research priorities with im-
18 plementation-readiness needs;

19 “(B) to recommend specialized review
20 pathways for research involving emerging thera-
21 peutic interventions; and

22 “(C) to develop standards for allocation of
23 protected research time for clinicians partici-
24 pating in research involving emerging thera-
25 peutic interventions, including clarification that

1 patients seen under approved research protocols
2 shall be counted toward standard clinical pro-
3 ductivity metrics;

4 “(10) develop guidance to ensure continuity of
5 care, including—

6 “(A) post-administration integration serv-
7 ices;

8 “(B) incorporation of peer support special-
9 ists; and

10 “(C) coordination with community-based
11 organizations for aftercare support as appro-
12 priate;

13 “(11) identify not fewer than one medical cen-
14 ter in each Veterans Integrated Service Network to
15 develop infrastructure and workforce-readiness for
16 emerging therapeutic models; and

17 “(12) establish criteria for the designation of
18 centers of excellence and oversee compliance with
19 national standards.

20 **“§ 7393. Clinical Implementation Program for Emerg-**
21 **ing Therapeutics**

22 “(a) ESTABLISHMENT.—The Secretary, acting
23 through the Office of Novel Therapeutics, shall establish
24 a Clinical Implementation Program for Emerging Thera-
25 peutics (in this section referred to as the ‘Program’) to

1 evaluate the effectiveness, feasibility, safety, and
2 scalability of emerging therapeutic interventions within
3 the Department.

4 “(b) PURPOSE.—The Program shall—

5 “(1) utilize effectiveness-implementation hybrid
6 models to evaluate both clinical outcomes and real-
7 world implementation factors with respect to emerg-
8 ing therapeutic interventions;

9 “(2) test and refine care delivery models, in-
10 cluding patient eligibility criteria, safety protocols,
11 interdisciplinary team models, and post-administra-
12 tion integration services;

13 “(3) generate real-world evidence to inform po-
14 tential systemwide adoption; and

15 “(4) assess workforce, infrastructure, cost, and
16 operational requirements necessary for broader im-
17 plementation.

18 “(c) COVERED CONDITIONS.—In carrying out the
19 Program, the Secretary may prioritize one or more brain
20 or mental health conditions affecting veterans, including—

21 “(1) post-traumatic stress disorder;

22 “(2) treatment-resistant depression;

23 “(3) substance use disorders;

24 “(4) suicidality;

25 “(5) traumatic brain injury;

1 “(6) repetitive low-level blast exposure;

2 “(7) chronic pain;

3 “(8) co-occurring conditions; and

4 “(9) other clinically appropriate conditions as
5 determined appropriate by the Secretary.

6 “(d) SITE SELECTION.—The Secretary may conduct
7 the Program at—

8 “(1) one or more centers of excellence; and

9 “(2) such other medical centers as the Sec-
10 retary determines appropriate.

11 **“§ 7394. Centers of excellence for novel therapeutics**

12 “(a) DESIGNATION.—The Secretary may designate
13 one or more medical centers of the Department as centers
14 of excellence for novel therapeutics.

15 “(b) FUNCTIONS.—Each center of excellence des-
16 ignated under subsection (a) shall—

17 “(1) serve as a national leader in research, clin-
18 ical training, and implementation of emerging thera-
19 peutic interventions;

20 “(2) develop and disseminate best practices and
21 clinical standards across the Veterans Health Ad-
22 ministration;

23 “(3) provide technical assistance and training
24 to other medical centers of the Department;

1 “(4) integrate interdisciplinary care models, in-
2 cluding peer support and post-administration inte-
3 gration services;

4 “(5) incorporate veteran advisory input into
5 program development; and

6 “(6) coordinate with academic affiliates and ex-
7 ternal research partners, as appropriate.

8 “(c) COORDINATION.—Centers of excellence des-
9 ignated under subsection (a) shall operate in coordination
10 with, and under standards established by, the Office of
11 Novel Therapeutics.

12 **“§ 7395. Veteran Advisory Committee on Novel Thera-**
13 **peutics**

14 “(a) ESTABLISHMENT.—The Secretary shall estab-
15 lish a Veteran Advisory Committee on Novel Therapeutics
16 (in this section referred to as the ‘Committee’) to advise
17 the Office of Novel Therapeutics.

18 “(b) MEMBERSHIP.—The Secretary shall select the
19 members of the Committee, which shall include the fol-
20 lowing:

21 “(1) Veterans with lived experience of mental
22 health treatment furnished by the Department.

23 “(2) Veterans who have participated in clinical
24 research involving emerging therapeutic interven-
25 tions, as applicable.

1 “(3) Family members or caregivers of veterans
2 described in paragraph (1) or (2).

3 “(4) Representatives from academic institutions
4 affiliated with the Department with expertise in clin-
5 ical research, behavioral health, or emerging thera-
6 peutic interventions.

7 “(5) Subject matter experts as determined ap-
8 propriate by the Secretary.

9 “(c) DUTIES.—With respect to the use of novel thera-
10 peutics, the Committee shall provide input on—

11 “(1) patient safety considerations;

12 “(2) informed consent practices;

13 “(3) implementation and access barriers; and

14 “(4) patient-centered care design.

15 **“§ 7396. Interagency coordination**

16 “In carrying out this subchapter, the Secretary shall
17 coordinate with the Secretary of Health and Human Serv-
18 ices, the Commissioner of Food and Drugs, the Adminis-
19 trator of the Centers for Medicare & Medicaid Services,
20 the Secretary of Defense, and the Administrator of the
21 Drug Enforcement Administration to support—

22 “(1) regulatory readiness;

23 “(2) development of reimbursement and billing
24 pathways;

1 “(3) scheduling and rescheduling consider-
2 ations, as appropriate; and

3 “(4) shared data infrastructure for monitoring
4 safety, quality, and outcomes.

5 **“§ 7397. Annual report**

6 “Not less frequently than annually, the Secretary
7 shall submit to Congress a report describing—

8 “(1) research activities of the Department relat-
9 ing to emerging therapeutic interventions;

10 “(2) clinical outcomes and patient-reported out-
11 comes under the Clinical Implementation Program
12 for Emerging Therapeutics under section 7393 of
13 this title;

14 “(3) safety events and adverse outcomes;

15 “(4) workforce readiness and training capacity;

16 “(5) implementation barriers, including staff-
17 ing, procurement, and infrastructure needs; and

18 “(6) recommendations for legislative or admin-
19 istrative action relating to novel therapeutics.”.

20 (2) CLERICAL AMENDMENT.—The table of sec-
21 tions at the beginning of chapter 73 of such title is
22 amended by adding at the end the following:

“SUBCHAPTER VI—NOVEL THERAPEUTICS

“Sec.

“7391. Definitions.

“7392. Office of Novel Therapeutics.

“7393. Clinical Implementation Program for Emerging Therapeutics.

“7394. Centers of excellence for novel therapeutics.

“7395. Veteran Advisory Committee on Novel Therapeutics.

“7396. Interagency coordination.

“7397. Annual report.”.

1 (b) NATIONAL PREPAREDNESS AND IMPLEMENTA-
2 TION STRATEGY.—Not later than 180 days after the date
3 of the enactment of this Act, the Secretary of Veterans
4 Affairs shall submit to Congress a national preparedness
5 and implementation strategy of the Veterans Health Ad-
6 ministration for emerging mental health therapeutics, in-
7 cluding—

8 (1) workforce capacity assessments;

9 (2) facility modification needs;

10 (3) projected timelines for phased implementa-
11 tion; and

12 (4) barriers to implementation.