

119TH CONGRESS  
2D SESSION

# S. 4220

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

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## IN THE SENATE OF THE UNITED STATES

MARCH 26, 2026

Mr. SHEEHY (for himself, Mr. GALLEG0, Ms. DUCKWORTH, and Mr. BOOZMAN) introduced the following bill; which was read twice and referred to the Committee on Veterans' Affairs

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## 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-

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

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

“(A) facility infrastructure requirements;

“(B) interdisciplinary team composition  
standards;

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

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

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

“(5) conduct a workforce-readiness assessment  
to identify clinicians and peer support specialists  
with prior training or certification relevant to emerg-  
ing therapeutic interventions and gaps in training,  
supervision, and clinical capacity necessary to sup-  
port safe and effective implementation of such inter-  
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 igned 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.

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