

(Original Signature of Member)

119TH CONGRESS
2D SESSION

H. R. _____

To amend title 38, United States Code, to empower the Veterans Health Administration to innovate, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. MCGARVEY introduced the following bill; which was referred to the Committee on _____

A BILL

To amend title 38, United States Code, to empower the Veterans Health Administration to innovate, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "'Innovation for VA Technology and Entrepreneurship Act" or the "INNOVATE Act".

SEC. 2. FINDINGS.

Congress finds the following:

(1) The Department of Veterans Affairs offers critical health care services through the Veterans Health Administration (hereinafter, ''VHA''), serving as the largest integrated health care system, largest medical training organization, and one of the largest employers of health care professionals in the United States.

(2) Despite its size, assets, and reach, the VHA struggles to engage with private sector entities, particularly early-stage businesses, due to bureaucratic hurdles.

(3) If provided new authorities through legislation, the VHA is positioned to create a paradigm shift in health care, revitalizing the way it develops and innovates to improve clinical care and access to health care for veterans, and modeling transformational health care to the private sector, ultimately benefitting all Americans.

(4) The Office of Innovation of the VHA will authorize, fund, and streamline processes, enhancing the VHA network of innovation programs and fostering collaboration and partnerships with industry, government, non-profits and academia.

(5) Other transactional authorities and advance market commitments have been successfully em-

ployed by agencies such as NASA, the Department of Defense, the Department of Homeland Security, and ARPA-H, as well as through Operation Warp Speed, to accelerate innovation and deliver critical technologies. Extending these authorities to Department of Veterans Affairs will enable similar breakthroughs in veteran health care.

(6) An Innovation Flexibility Account, established as a multi-sourced fund, is intended to provide VHA with dedicated resources to support innovation initiatives. The Account will enable the collection and management of monies from diverse sources while ensuring that dollars appropriated for direct veteran care remain protected. By providing flexible funding, the Account will sustain partnerships, accelerate development, and expand the deployment of innovative solutions across the VHA.

(7) The National Association of Veterans' Research and Education Foundations (hereinafter, ''NAVREF'') has established a proven framework for advancing research and education through public–private partnerships. Expanding NAVREF's scope to include innovation will strengthen collaboration between the VHA and external partners, enhance the translation of research into practice, and

accelerate the adoption of innovative solutions that improve health care for veterans.

SEC. 3. INNOVATION IN THE VETERANS HEALTH ADMINISTRATION.

(a) ESTABLISHMENT.—Chapter 73 of title 38, United States Code, is amended by adding at the end the following new subchapter (and amending the table of sections at the beginning of such chapter accordingly):

''SUBCHAPTER VI—INNOVATION

''§ 7391. Office of Innovation

''(a) ESTABLISHMENT.—There is in the Veterans Health Administration an Office of Innovation (in this section referred to as the 'Office'). The Office shall be a Federal laboratory, as such term is defined in section 4 of the Stevenson-Wydler Technology Innovation Act of 1980 (Public Law 96–480; 15 U.S.C. 3703). This office shall report directly to the Under Secretary for Health.

''(b) FUNCTION.—The function of the Office is to foster innovation to advance health care and services for veterans and the Nation by—

''(1) researching, developing, and implementing innovative technologies and services to deliver the best health care practicable to veterans;

''(2) assisting, funding, and partnering with non-Department entities that can rapidly accelerate

the research, development, commercialization, and implementation of technologies and services described in paragraph (1);

''(3) coordinating with corporations established under section 7361 of this title to support collaborative development of health care solutions; and

''(4) adopting a comprehensive approach that works across traditional silos to effectively and efficiently—

''(A) use financial and human resources; and

''(B) expedite the development, commercialization, and deployment, of such technologies and solutions.

''(c) ASSISTANT UNDER SECRETARY FOR HEALTH FOR INNOVATION.—The head of the Office is the Assistant Under Secretary for Health for Innovation. The Assistant Under Secretary shall report directly to the Under Secretary for Health.

''(d) ORGANIZATION AND PERSONNEL.—The Office shall be organized in such manner, and its personnel shall perform such duties and have such titles, as the Under Secretary for Health may prescribe pursuant to this subchapter.

''(e) PERFORMANCE MEASUREMENT.—The Assistant Under Secretary shall develop and maintain annual performance metrics for activities carried out under this subchapter, including the following:

''(1) Reduction in time to contract for innovation-related agreements.

''(2) Cost savings or cost avoidance achieved through innovation initiatives.

''(3) Number of innovations piloted and deployed system-wide.

''(4) Measurable improvements in access, quality, or veteran experience attributable to innovation activities.

''(5) Veteran-centered outcome measures, including improvements in health status, functional outcomes, care coordination, and patient-reported experience.

''(f) ENHANCED REPORTING.—(1) The Assistant Under Secretary shall annually submit to the Committees on Veterans' Affairs of the Senate and House of Representatives a report describing—

''(A) activities carried out under this subchapter;

''(B) the status of ongoing innovation projects, including milestones achieved, delays, and barriers encountered;

''(C) expenditures, obligations, and remaining balances associated with innovation initiatives; and

''(D) measurable impacts on access, quality, timeliness, and veteran experience.

''(2) The Assistant Under Secretary shall publish on a publicly available website of the Department, a summary of innovation activities, outcomes, and expenditures in accordance with chapter 57 of this title.

''§ 7392. Other transactional authority

''(a) AUTHORITY.—Pursuant to regulations prescribed by the Under Secretary for Health, the Under Secretary may enter into a transaction—

''(1) other than a contract, cooperative agreement, or grant;

''(2) with any non-Department entity that certifies that such entity—

''(A) is organized under the laws of the United States;

''(B) has its principal place of business in the United States;

''(C) is not owned, controlled by, or subject to the jurisdiction or direction of a foreign adversary, including any entity described in section 4872(d) of title 10; and

''(D) shall not engage with a foreign adversary or such entity in the performance of the transaction;

''(3) that the Under Secretary determines is necessary; and

''(4) the cost to the United States to carry out such agreement does not exceed—

''(A) $10,000,000 (including all options); or

''(B) a greater amount that the senior procurement executive of the Department determines appropriate and justifies in a written report—

''(i) on the bases of necessity, market conditions, and expected benefits; and

''(ii) that the senior procurement executive submits in writing to the Committees on Veterans' Affairs of the Senate and House of Representatives not later than 30 days after entering into the transaction.

''(b) SMALL BUSINESS CONCERNS.—To the extent practicable, a transaction under this subsection shall enable a small business concern, small business concern owned and controlled by veterans, or small business concern owned and controlled by veterans with service-con-

nected disabilities the opportunity to participate in such transaction.

''(c) PRIORITIZATION.—To the extent practicable, the Under Secretary for Health shall use the authority under this section to align with priorities of the Veterans Health Administration, including expanding access to—

''(1) health care in rural areas; and

''(2) mental health care, behavioral health care, and suicide prevention care.

''(d) INTELLECTUAL PROPERTY AND ROYALTY RIGHTS.—(1) An invention created pursuant to a transaction under this subsection shall not be subject to the limitations or requirements of section 203 of title 35.

''(2) A corporation established under section 7361 of this title may participate in a transaction under this section, pursuant to which the corporation may receive, retain, and reinvest royalties, licensing fees, or other income derived from inventions, discoveries, or innovations developed in the course of such transaction, in accordance with applicable Federal law and terms and conditions of the transaction.

''(e) INAPPLICABILITY OF PROHIBITION ON ADVANCES.—A transaction under this subsection shall not be subject to the limitations or requirements of subsections (a) or (b) of section 3324 of title 31.

''(f) REPORTING; TRANSPARENCY.—(1) The Under Secretary for Health shall—

''(A) submit to the Committees on Veterans' Affairs of the Senate and House of Representatives, and publish on a publicly available website of the Department—

''(i) a copy of each determination under subsection (a)(4)(B) not later than 120 days after the date of such determination;

''(ii) not less than quarterly, a report on transactions under this section; and

''(iii) upon request, any information regarding a transaction under this section; and

''(B) ensure that the terms of a transaction under this section permit the Comptroller General of the United States to examine the records relating to such transaction of an entity that enters into, or otherwise participates in the performance, such transaction.

''(2) In this subsection, the term 'determination' means a determination of the Under Secretary or senior procurement executive of the Department to—

''(A) use the authority under this section;

''(B) authorize an amount pursuant to subsection (a)(4)(B);

''(C) waive, modify, or establish a condition related to intellectual property, data rights, or conflict-of-interest safeguards; or

''(D) establish or modify project-specific evaluation criteria or risk mitigation requirements.

''(g) AUDITS.—Not less than once every two years, the Comptroller General shall audit transactions made under this subsection.

''§ 7393. Advance market commitments

''(a) AUTHORITY.—The Under Secretary for Health may enter into an advance market commitment, without regard to the limitations or requirements of subsections (a) or (b) of section 3324 of title 31, under which the Under Secretary shall guarantee to purchase, for a predetermined price, a technology, service, production of, or commodity that addresses an unmet need in the provision of health care to veterans.

''(b) REQUIREMENTS.—An advanced market commitment under this section shall include the following:

''(1) Clearly defined and transparent rules.

''(2) Clear definition of the technology, production, service, or commodity to ensure safety, effectiveness, and feasible delivery.

''(3) Dispute settlement mechanisms.

''(4) The ability to modify the terms of the agreement on the basis of new information regarding the number of veterans to be served with such technology, production, service, or commodity.

''(c) REPORT.—(1) Not later than 120 days after executing an advance market agreement, the Under Secretary shall submit to the Committees on Veterans' Affairs of the Senate and House of Representatives, and publish on a publicly available website of the Department, a report on the status and efficacy of such agreement.

''(2) A report under this subsection shall include the following elements:

''(A) The performance metrics (including delivery timelines, quality measures, and veteran-centered outcome indicators) used to determine whether an advance market commitment helps meets the unmet need.

''(B) The pricing rationale for the commitment, including market analysis, cost assumptions, and justification for the predetermined price.

''(C) An assessment of expected and actual effect on veterans, including improvements in access, health outcomes, or experience.

''(D) Any risks, delays, or barriers identified during execution of the commitment, and the steps taken to mitigate such issues.

"§ 7394. Innovation flexibility account

''(a) ESTABLISHMENT.—There is established an account, to be known as the 'Innovation Flexibility Account' (in this section referred to as the 'Account'), that shall be available to the Under Secretary for Health to carry out this chapter, in addition to such amounts that are otherwise available for innovation.

''(b) AUTHORITY.—To manage the Account, the Under Secretary may—

''(1) accept monies from any existing appropriation or discretionary source within the Department or external source approved by the Department such as research centers, institutes of higher education, nonprofit corporations, charitable organizations, individuals, private companies, and veteran service organizations;

''(2) accept and distribute monies from the Account within the Department as the Under Secretary determines necessary;

''(3) acceptance of external monies shall be subject to applicable ethics, conflict-of-interest, and transparency requirements;

''(4) establish a health care franchise function for the Account: and

''(5) pay for expenses (including information technology, acquisition, advisory, or legal services, whether provided by an employee of the Department or pursuant to an agreement with a non-Department entity) that the Under Secretary determines necessary to carry out the function of innovation, without regard to restrictions on funding type.

''(c) LIMITATION.—In managing the Account, the Under Secretary may not—

''(1) accept monies, directly or indirectly, from—

''(A) a foreign government, foreign political party, or foreign corporation;

''(B) an entity owned or controlled by a foreign government; or

''(C) an individual or entity acting on behalf of, or subject to, the direction of a foreign adversary;

''(2) use appropriated dollars intended for direct veteran care to fund the Account; or

''(3) direct, control, or otherwise influence the selection or execution of a project funded by the Ac-

count on the basis of an external contribution to the Account.

''(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Fund such sums as may be necessary to carry out the function of this chapter.

''(e) AVAILABILITY OF FUNDS.—Monies in the Account shall remain available for five years following the date of receipt.

''(f) REPORTING.—Not later than 180 days after the end of each fiscal year, the Under Secretary for Health shall submit to Congress a report describing deposits into and expenditures from the Account, including the name of each contributor and the purpose and outcomes of funded activities. All records relating to the Account shall be available to the Government Accountability Office for audit and review.

''(g) OVERSIGHT.—Not less than once every two years, the Inspector General of the Department shall audit the Account.

"§ 7395. Oversight and accountability.

''(a) IN GENERAL.—The Under Secretary shall maintain internal controls, monitoring mechanisms, and post-award reviews to ensure that activities under this sub-

chapter comply with applicable law, ethical standards, and performance requirements.

''(b) CONFLICT OF INTEREST.—The Under Secretary for Health shall ensure that each activity under this subchapter is reviewed for conflict of interest, including—

''(1) the disclosure of financial interests;

''(2) mitigation plans for real or perceived conflicts; and

''(3) certification that no individual involved in the selection, negotiation, or administration of the transaction or agreement has a prohibited financial interest in a participating entity.''.

(b) CONFORMING AMENDMENTS.—Section 7361 of title 38, United States Code, is amended—

(1) in subsection (a), by striking ''either research or education or both research and education'' and inserting ''research, education, or innovation under subchapter VI of this chapter, or any combination thereof''; and

(2) in subsection (b)(1), by striking ''research, education, or both'' and inserting ''research, education, or innovation under subchapter VI of this chapter, or any combination thereof''.

(c) IMPLEMENTATION.—Not later than 120 days after the date of the enactment of this Act, the Secretary

of Veterans Affairs shall carry out the amendments made by this section.