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116TH CONGRESS
2D SESSION

H. R. 6092

To direct the Secretary of Veterans Affairs to establish a national clinical pathway for prostate cancer, access to life-saving extending precision clinical trials and research, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 5, 2020

Mr. DUNN (for himself and Mr. CUNNINGHAM) introduced the following bill; which was referred to the Committee on Veterans' Affairs

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A BILL

To direct the Secretary of Veterans Affairs to establish a national clinical pathway for prostate cancer, access to life-saving extending precision clinical trials and research, 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 ''Veteran's Prostate Cancer Treatment and Research Act''.

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) Prostate cancer is the number one cancer diagnosed in the Veterans Health Administration.

(2) A 1996 report published by the National Academy of Sciences, Engineering, and Medicine established a link between prostate cancer and exposure to herbicides, such as Agent Orange.

(3) It is essential to acknowledge that due to these circumstances, certain veterans are made aware that they are high-risk individuals when it comes to the potential to develop prostate cancer.

(4) In being designated as ''high risk'', it is essential that veterans are proactive in seeking earlier preventative clinical services for the early detection and successful treatment of prostate cancer, whether that be through the Veterans Health Administration or through a community provider.

(5) Clinical preventative services and initial detection are some of the most important components in the early detection of prostate cancer for veterans at high risk of prostate cancer.

(6) For veterans with prostate cancer, including prostate cancer that has metastasized, precision oncology, including biomarker-driven clinical trials and innovations underway through the Prostate Cancer Foundation and Department of Veterans Affairs

partnership, represents one of the most promising areas of interventions, treatments, and cures for such veterans and their families.

SEC. 3. DEPARTMENT OF VETERANS AFFAIRS TREATMENT AND RESEARCH OF PROSTATE CANCER.

(a) ESTABLISHMENT OF CLINICAL PATHWAY.—

(1) IN GENERAL.—Not later than 365 days after the date of the enactment of this Act, the Secretary of Veterans Affairs shall establish in the National Surgery Office of the Department of Veterans Affairs a national clinical pathway for all stages of prostate cancer, from early detection to end-of-life care including recommendations regarding the use of transformative innovations, research, and uniform clinical data.

(2) ELEMENTS.—The national clinical pathway established under this subsection shall include the following elements:

(A) A multi-disciplinary plan for the early detection, diagnosis, and treatment of prostate cancer that includes, as appropriate, both Department medical facilities and community-based partners and providers and research centers specializing in prostate cancer, especially

such centers that have entered into partnerships with the Department.

(B) A suggested, but not mandatory, protocol for screening, diagnosis, and treatment or care for subpopulations with evidence-based risk factors (including race, ethnicity, socioeconomic status, geographic location, exposure risks, and genetic risks, including family history).

(C) A suggested treatment protocol timeframe for each point of care based on severity and stage of cancer.

(3) PUBLIC COMMENT PERIOD.—Upon the establishment of a proposed clinical pathway as required under this subsection, the Secretary shall publish the proposed clinical pathway in the Federal Register and provide for a 45-day period for public comments. The Secretary—

(A) may make any such public comments publicly available; and

(B) make changes to the proposed clinical pathway in response to any such comments received using the same process and criteria used to establish the proposed clinical pathway.

(4) COLLABORATION AND COORDINATION.—In establishing the clinical pathway required under this section, the Secretary shall—

(A) provide for consideration of other clinical pathways and research findings of other departments and agencies, including guidelines that are widely recognized and guidelines that are used as the standard for clinical policy in oncology care, such as National Comprehensive Cancer Network guidelines; and

(B) collaborate and coordinate with—

(i) the National Institutes of Health;

(ii) the National Cancer Institute;

(iii) the National Institute on Minority Health and Health Disparities;

(iv) other Institutes and Centers as the Secretary determines necessary;

(v) the Centers for Disease Control and Prevention;

(vi) the Department of Defense;

(vii) the Centers for Medicare and Medicaid Services;

(viii) the Patient-Centered Outcomes Research Institute; and

(ix) the Food and Drug Administration.

(5) PUBLICATION.—The Secretary shall—

(A) publish the clinical pathway established under this subsection on a publicly available Department website; and

(B) regularly update the clinical pathway as needed by review of the medical literature and available evidence-based guidelines at least annually, in accordance with the criteria under paragraph (2).

(b) DEVELOPMENT OF NATIONAL CANCER OF THE PROSTATE CLINICAL CARE IMPLEMENTATION PROGRAM.—

(1) ESTABLISHMENT.—Not later than 90 days after the date of the enactment of this Act, the Secretary shall submit to Congress a plan to establish a comprehensive prostate cancer program.

(2) PROGRAM REQUIREMENTS.—The comprehensive prostate cancer program shall—

(A) be multidisciplinary and include the authority to work across clinical care lines, specialties, and the organizational divisions of the Veterans Health Administration;

(B) receive direct oversight from the Deputy Undersecretary for Health of the Department of Veterans Affairs;

(C) include a yearly program implementation evaluation to facilitate replication for other disease states or in other healthcare institutions;

(D) be metric driven and include the development of quarterly reports on the quality of prostate cancer care, which shall be provided to the leadership of the Department, medical centers, and providers and made publicly available in an electronic form;

(E) made available as national decision support tools in the electronic medical record;

(F) include an education plan for patients and providers; and

(G) be funded appropriately to accomplish the objectives of this Act.

(3) PROGRAM IMPLEMENTATION EVALUATION.—The Secretary shall establish a program evaluation tool as an integral component to learn best practices of multidisciplinary disease-based implementation and to inform the Department and

Congress regarding further use of the disease specific model of care delivery.

(4) PROSTATE CANCER RESEARCH.—The Secretary shall submit to Congress a plan that provides for continual funding through the Office of Research and Development of the Department of Veterans Affairs for supporting prostate cancer research designed to position the Department as a national resource for quality reporting metrics, practice-based evidence, comparative effectiveness, precision oncology, and clinical trials in prostate cancer.

(5) PROSTATE CANCER REAL TIME REGISTRY PROGRAM.—The Secretary, in collaboration with data stewards of the Department of Veterans Affairs, scientists, and the heads of other Departments, agencies, and non-governmental organizations, such as foundations and non-profit organizations focused on prostate cancer research and care, shall establish a real-time, actionable, national prostate cancer registry. Such registry shall be designed—

(A) to establish a systematic and standardized database that enables intra-agency collaboration by which to track veteran patient progress, enable population management pro-

grams, facilitate best outcomes, and encourage future research and further development of clinical pathways, including patient access to precision resources and treatments and access to life-extending precision clinical trials;

(B) to employ novel methods of structuring data, including natural language processing, artificial intelligence, structured data clinical notes, patient reported outcome instruments, and other tools, to ensure that all clinically meaningful data is included; and

(C) to be accessible to—

(i) clinicians treating veterans diagnosed with prostate cancer and being treated for prostate cancer in conjunction with Department medical facilities; and

(ii) researchers.

(c) CLINICAL PATHWAY DEFINED.—In this section, the term ''clinical pathway'' means a health care management tool designed around research and evidence-backed practices that provides direction for the clinical care and treatment of a specific episode of a condition or ailment.

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