

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

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.

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 “Veteran’s Prostate
5 Cancer Treatment and Research Act”.

6 **SEC. 2. FINDINGS.**

7 Congress makes the following findings:

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

3 (2) A 1996 report published by the National
4 Academy of Sciences, Engineering, and Medicine es-
5 tablished a link between prostate cancer and expo-
6 sure to herbicides, such as Agent Orange.

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

11 (4) In being designated as “high risk”, it is es-
12 sential that veterans are proactive in seeking earlier
13 preventative clinical services for the early detection
14 and successful treatment of prostate cancer, whether
15 that be through the Veterans Health Administration
16 or through a community provider.

17 (5) Clinical preventative services and initial de-
18 tection are some of the most important components
19 in the early detection of prostate cancer for veterans
20 at high risk of prostate cancer.

21 (6) For veterans with prostate cancer, including
22 prostate cancer that has metastasized, precision on-
23 cology, including biomarker-driven clinical trials and
24 innovations underway through the Prostate Cancer
25 Foundation and Department of Veterans Affairs

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

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

6 (a) ESTABLISHMENT OF CLINICAL PATHWAY.—

7 (1) IN GENERAL.—Not later than 365 days
8 after the date of the enactment of this Act, the Sec-
9 retary of Veterans Affairs shall establish in the Na-
10 tional Surgery Office of the Department of Veterans
11 Affairs a national clinical pathway for all stages of
12 prostate cancer, from early detection to end-of-life
13 care including recommendations regarding the use of
14 transformative innovations, research, and uniform
15 clinical data.

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

19 (A) A multi-disciplinary plan for the early
20 detection, diagnosis, and treatment of prostate
21 cancer that includes, as appropriate, both De-
22 partment medical facilities and community-
23 based partners and providers and research cen-
24 ters specializing in prostate cancer, especially

1 such centers that have entered into partner-
2 ships with the Department.

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

9 (C) A suggested treatment protocol time-
10 frame for each point of care based on severity
11 and stage of cancer.

12 (3) PUBLIC COMMENT PERIOD.—Upon the es-
13 tablishment of a proposed clinical pathway as re-
14 quired under this subsection, the Secretary shall
15 publish the proposed clinical pathway in the Federal
16 Register and provide for a 45-day period for public
17 comments. The Secretary—

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

20 (B) make changes to the proposed clinical
21 pathway in response to any such comments re-
22 ceived using the same process and criteria used
23 to establish the proposed clinical pathway.

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

4 (A) provide for consideration of other clin-
5 ical pathways and research findings of other de-
6 partments and agencies, including guidelines
7 that are widely recognized and guidelines that
8 are used as the standard for clinical policy in
9 oncology care, such as National Comprehensive
10 Cancer Network guidelines; and

11 (B) collaborate and coordinate with—

12 (i) the National Institutes of Health;

13 (ii) the National Cancer Institute;

14 (iii) the National Institute on Minor-
15 ity Health and Health Disparities;

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

18 (v) the Centers for Disease Control
19 and Prevention;

20 (vi) the Department of Defense;

21 (vii) the Centers for Medicare and
22 Medicaid Services;

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

1 (ix) the Food and Drug Administra-
2 tion.

3 (5) PUBLICATION.—The Secretary shall—

4 (A) publish the clinical pathway estab-
5 lished under this subsection on a publicly avail-
6 able Department website; and

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

12 (b) DEVELOPMENT OF NATIONAL CANCER OF THE
13 PROSTATE CLINICAL CARE IMPLEMENTATION PRO-
14 GRAM.—

15 (1) ESTABLISHMENT.—Not later than 90 days
16 after the date of the enactment of this Act, the Sec-
17 retary shall submit to Congress a plan to establish
18 a comprehensive prostate cancer program.

19 (2) PROGRAM REQUIREMENTS.—The compre-
20 hensive prostate cancer program shall—

21 (A) be multidisciplinary and include the
22 authority to work across clinical care lines, spe-
23 cialties, and the organizational divisions of the
24 Veterans Health Administration;

1 (B) receive direct oversight from the Dep-
2 uty Undersecretary for Health of the Depart-
3 ment of Veterans Affairs;

4 (C) include a yearly program implementa-
5 tion evaluation to facilitate replication for other
6 disease states or in other healthcare institu-
7 tions;

8 (D) be metric driven and include the devel-
9 opment of quarterly reports on the quality of
10 prostate cancer care, which shall be provided to
11 the leadership of the Department, medical cen-
12 ters, and providers and made publicly available
13 in an electronic form;

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

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

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

20 (3) PROGRAM IMPLEMENTATION EVALUA-
21 TION.—The Secretary shall establish a program
22 evaluation tool as an integral component to learn
23 best practices of multidisciplinary disease-based im-
24 plementation and to inform the Department and

1 Congress regarding further use of the disease spe-
2 cific model of care delivery.

3 (4) PROSTATE CANCER RESEARCH.—The Sec-
4 retary shall submit to Congress a plan that provides
5 for continual funding through the Office of Research
6 and Development of the Department of Veterans Af-
7 fairs for supporting prostate cancer research de-
8 signed to position the Department as a national re-
9 source for quality reporting metrics, practice-based
10 evidence, comparative effectiveness, precision oncol-
11 ogy, and clinical trials in prostate cancer.

12 (5) PROSTATE CANCER REAL TIME REGISTRY
13 PROGRAM.—The Secretary, in collaboration with
14 data stewards of the Department of Veterans Af-
15 fairs, scientists, and the heads of other Depart-
16 ments, agencies, and non-governmental organiza-
17 tions, such as foundations and non-profit organiza-
18 tions focused on prostate cancer research and care,
19 shall establish a real-time, actionable, national pros-
20 tate cancer registry. Such registry shall be de-
21 signed—

22 (A) to establish a systematic and standard-
23 ized database that enables intra-agency collabo-
24 ration by which to track veteran patient
25 progress, enable population management pro-

1 grams, facilitate best outcomes, and encourage
2 future research and further development of clin-
3 ical pathways, including patient access to preci-
4 sion resources and treatments and access to
5 life-extending precision clinical trials;

6 (B) to employ novel methods of structuring
7 data, including natural language processing, ar-
8 tificial intelligence, structured data clinical
9 notes, patient reported outcome instruments,
10 and other tools, to ensure that all clinically
11 meaningful data is included; and

12 (C) to be accessible to—

13 (i) clinicians treating veterans diag-
14 nosed with prostate cancer and being
15 treated for prostate cancer in conjunction
16 with Department medical facilities; and

17 (ii) researchers.

18 (c) **CLINICAL PATHWAY DEFINED.**—In this section,
19 the term “clinical pathway” means a health care manage-
20 ment tool designed around research and evidence-backed
21 practices that provides direction for the clinical care and
22 treatment of a specific episode of a condition or ailment.

○