

**Suspend the Rules and Pass the Bill, HR. 6092**

**(The amendment strikes all after the enacting clause and inserts a new text)**

116<sup>TH</sup> CONGRESS  
2<sup>D</sup> 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.

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## 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.

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”.

1 **SEC. 2. FINDINGS.**

2 Congress makes the following findings:

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

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

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

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

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

23 (6) For veterans with prostate cancer, including  
24 prostate cancer that has metastasized, precision on-  
25 cology, including biomarker-driven clinical trials and  
26 innovations underway through the Prostate Cancer

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

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

7 (a) ESTABLISHMENT OF CLINICAL PATHWAY.—

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

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

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

17 (F) include an education plan for patients  
18 and providers.

19 (3) PROGRAM IMPLEMENTATION EVALUA-  
20 TION.—The Secretary shall establish a program  
21 evaluation tool as an integral component to learn  
22 best practices of multidisciplinary disease-based im-  
23 plementation and to inform the Department and  
24 Congress regarding further use of the disease spe-  
25 cific model of care delivery.

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

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

20                   (A) to establish a systematic and standard-  
21                   ized database that enables intra-agency collabo-  
22                   ration by which to track veteran patient  
23                   progress, enable population management pro-  
24                   grams, facilitate best outcomes, and encourage  
25                   future research and further development of clin-



1           ical pathways, including patient access to preci-  
2           sion resources and treatments and access to  
3           life-extending precision clinical trials;

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

10                   (C) to be accessible to—

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

15                           (ii) researchers.

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