II

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S. 3775

To improve prostate cancer screening and treatment, particularly in medically underserved communities, and for other purposes.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 14, 2010

Mr. TESTER (for himself and Mr. VOINOVICH) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To improve prostate cancer screening and treatment, particularly in medically underserved communities, 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 ''Prostate Research, Outreach, Screening, Testing, Access, and Treatment Effectiveness Act of 2010'' or the ''PROSTATE Act of 2010''.

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) In 2009, prostate cancer was the second leading cause of cancer death among men.

(2) In 2009, more than 190,000 new patients were diagnosed with and more than 27,000 men died from prostate cancer.

(3) In 2009, approximately 2,000,000 people in the United States were living with a diagnosis of prostate cancer and its consequences.

(4) While prostate cancer generally affects older men, younger men are also at risk of the disease. When prostate cancer appears in early middle age it frequently takes on a more aggressive form.

(5) There are significant racial, ethnic, population, and geographic disparities with respect to prostate cancer in the United States.

(6) African-Americans have prostate cancer mortality rates that are more than double the prostate cancer mortality rates among Whites.

(7) Certain veterans populations may have nearly twice the incidence of prostate cancer than the general population of the United States.

(8) Underserved rural and highly rural populations have higher rates of mortality than urban populations.

(9) Urologists are specialists who diagnose and treat the vast majority of prostate cancer patients.

(10) Investments in basic and translational research have proved promising for the prevention, diagnosis, and treatment of prostate cancer.

(11) There are many unanswered questions regarding prostate cancer.

(12) It is not fully understood how much of the known disparities in prostate cancer rates among differing communities are attributable to disease etiology, access to care, or education and awareness of matters relating to prostate cancer.

(13) The causes of prostate cancer are unknown.

(14) There are no treatments that can durably arrest growth or cure prostate cancer once it has metastasized.

(15) A significant proportion (approximately 23 to 54 percent) of cases of prostate cancer may be clinically indolent or over-diagnosed, resulting in significant over treatment.

(16) Good information regarding how to differentiate accurately, early on, between aggressive and indolent forms of prostate cancer is generally unavailable, resulting in significant over treatment.

(17) More accurate tests for prostate cancer—

(A) will minimize the physical, psychological, financial, and emotional trauma that men and their families face; and

(B) could increase efficiencies in public and private health care systems that result in the saving of billions of dollars.

(18) Treatment of prostate cancer has been identified by the Centers for Medicare and Medicaid Services under the Physician Feedback Program established under section 1848(n) of the Social Security Act (42 U.S.C. 1395w–4(n)) as one of eight highest volume, highest cost areas of health care in the United States.

SEC. 3. SENSE OF CONGRESS ON ACCESS TO AND PROVISION AND COORDINATION OF HEALTH CARE FOR DIAGNOSIS AND TREATMENT OF PROSTATE CANCER.

It is the sense of Congress that—

(1) innovative and cost-efficient methods to improve access to high-quality health care by underserved, rural, and highly rural populations should take advantage of advances in telehealth to diagnose and treat prostate cancer;

(2) a coordinated effort between specialists and primary care physicians is essential to provide the most effective diagnosis and treatment plan for prostate cancer patients;

(3) prostate cancer research and health care programs across Federal agencies should be coordinated—

(A) to improve transparency and accountability;

(B) to encourage the translation of research into practice;

(C) to identify and implement best practices; and

(D) to foster an integrated and consistent focus on effective prevention, diagnosis, and treatment of prostate cancer.

SEC. 4. INTERAGENCY PROSTATE CANCER COORDINATION AND EDUCATION TASK FORCE.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Veterans Affairs shall, in conjunction with the Secretary of Defense and the Secretary of Health and Human Services, establish a task force

on the coordination of Federal activities relating to prostate cancer.

(2) DESIGNATION.—The task force established under paragraph (1) shall be known as the ''Interagency Prostate Cancer Coordination and Education Task Force'' (in this section referred to as the ''Task Force'').

(b) MEMBERSHIP.—

(1) COMPOSITION.—The Task Force shall be composed as follows:

(A) Such representatives of the Department of Veterans Affairs and such program areas of the Department as the Secretary of Veterans Affairs considers appropriate for the purpose of coordinating a uniform Federal message relating to prostate cancer screening and treatment.

(B) Such representatives of the Department of Defense as the Secretary of Defense considers appropriate for such purpose.

(C) Such representatives of the Department of Health and Human Services as the Secretary of Health and Human Services considers appropriate for such purpose, including representatives of the following:

(i) The National Institutes of Health.

(ii) National research institutes and centers, including the National Cancer Institute, the National Institute of Allergy and Infectious Diseases, and the Office of Minority Health.

(iii) The Centers for Medicare and Medicaid Services.

(iv) The Food and Drug Administration.

(v) The Centers for Disease Control and Prevention.

(vi) The Agency for Healthcare Research and Quality.

(vii) The Health Resources and Services Administration.

(2) MEETINGS.—The Task Force shall meet at the call of the Secretary of Veterans Affairs, but not less frequently than twice each year.

(c) DUTIES.—

(1) SUMMARY OF ADVANCES IN FEDERAL PROSTATE CANCER RESEARCH.—The Task Force shall develop a summary of advances in prostate cancer research supported or conducted by Federal agencies

relevant to the diagnosis, prevention, and treatment of prostate cancer.

(2) LIST OF BEST PRACTICES FOR TREATMENT OF PROSTATE CANCER.—The Task Force shall develop a list of best practices for treatment of prostate cancer that warrant broader adoption in health care programs.

(3) SHARE AND COORDINATE.—The Task Force shall share and coordinate information on existing Federal research and health care program activities relating to prostate cancer, including by carrying out the following with respect to such research and health care program activities:

(A) Determining how to improve existing research and health care programs.

(B) Identifying any gaps in the overall research inventory and in health care programs.

(C) Identifying opportunities to promote translation of research into practice.

(D) Maximizing the impact of existing efforts by identifying opportunities for collaboration and leveraging of resources in research and health care programs that serve those susceptible to or diagnosed with prostate cancer.

(4) COMPREHENSIVE STRATEGY AND ADVICE ON SOLICITATION OF PROPOSALS.—The Task Force shall develop a comprehensive interagency strategy on, and advise relevant Federal agencies in, the solicitation of proposals for collaborative, multidisciplinary research and health care programs relating to prostate cancer, including proposals to evaluate factors that may be related to the etiology of prostate cancer, that would—

(A) result in innovative approaches to studying emerging scientific opportunities or eliminating knowledge gaps in research to improve the prostate cancer research portfolio of the Federal Government;

(B) outline key research questions, methodologies, and knowledge gaps;

(C) expand the number of research proposals and health care programs that involve collaboration between two or more Federal agencies, national research institutes, or national centers, including proposals for Common Fund research described in section 402(b)(7) of the Public Health Service Act (42 U.S.C. 282(b)(7)) to improve the prostate cancer research portfolio of the Federal Government;

(D) expand the number of collaborative, multidisciplinary, and multi-institutional research grants relating to prostate cancer; and

(E) encourage such collaborations to include coordination with other robust Federal and private health care services research and health care programs that have successfully addressed prostate cancer education, outreach, and awareness among medically underserved populations.

(5) COORDINATED MESSAGE.—The Task Force shall develop a coordinated message related to screening and treatment for prostate cancer to be reflected in educational and beneficiary materials for Federal health programs as such materials are updated.

(6) RECOMMENDATIONS AND REPORT.—

(A) IN GENERAL.—Not later than two years after the date of the establishment of the Task Force, the Task Force shall submit to the Secretary of Veterans Affairs, the Secretary of Defense, and the Secretary of Health and Human Services a report on the matters described in subparagraph (B).

(B) MATTERS.—The matters described in this subparagraph are the following:

(i) Appropriate changes to research and health care programs of the Federal Government, including recommendations to improve the research portfolio of the Department of Veterans Affairs, Department of Defense, National Institutes of Health, and other Federal agencies, to ensure that scientifically based strategic planning is implemented in support of prostate cancer research and health care program priorities.

(ii) How to ensure that the prostate cancer research and health care program activities of the Department of Veterans Affairs, the Department of Defense, the National Institutes of Health, and other Federal agencies are free of unnecessary duplication.

(iii) How to improve public participation in decisions relating to prostate cancer research and health care programs to increase the involvement of patient advocacy, community organizations, and medical as-

sociations representing a broad geographical area.

(iv) How best to disseminate information on prostate cancer research and progress achieved by health care programs.

(v) How to expand partnerships between public entities, including Federal agencies, and private entities to encourage collaboration between such entities and agencies in prostate cancer research and health care delivery.

(vi) How to assess any cost savings and efficiencies realized through any activities identified or supported pursuant to this Act and recommending expansion of those activities that have proven most promising for the prevention, diagnosis, and treatment of prostate cancer.

(C) ELEMENTS.—The report required by subparagraph (A) shall include the following:

(i) The recommendations of the Task Force on the matters described in subparagraph (B).

(ii) A prioritized ranking of the recommendations.

(iii) A description of the funding necessary to carry out each of the recommendations included in the report.

(d) APPOINTING EXPERT ADVISORY PANELS.—The Task Force shall appoint expert advisory panels to obtain input and concurrence from individuals and organizations from the medical, research, and health care delivery communities with expertise in prostate cancer diagnosis, treatment, and research, including practicing urologists, primary care providers, and individuals with expertise in education and outreach to medically underserved populations.

SEC. 5. PROSTATE CANCER RESEARCH.

(a) PROGRAM ESTABLISHMENT.—The Secretary of Veterans Affairs shall, in coordination with the Secretary of Defense and the Secretary of Health and Human Services, establish and carry out a program to coordinate and intensify prostate cancer research.

(b) PROGRAM ACTIVITIES.—In carrying out the program required by subsection (a), the Secretary of Veterans Affairs shall—

(1) carry out research to develop advances in improved early detection, diagnostic, and prognostic methods and tests, including—

(A) biomarkers and an improved prostate cancer screening blood test; and

(B) improvements or alternatives to the prostate specific antigen test and additional tests to distinguish indolent from aggressive disease;

(2) carry out research to better understand the etiology of prostate cancer to improve prevention efforts, including an analysis of—

(A) susceptibility and lifestyle factors proven to be involved in higher rates of prostate cancer, such as obesity and diet; and

(B) the role in which belonging to different ethnic, racial, geographic, and socioeconomic groups, such African-American, Latino, and American Indian populations, as well as those living in rural and highly rural areas, has on the incidence of prostate cancer and mortality from prostate cancer;

(3) expand basic research into prostate cancer, including studies of fundamental molecular and cellular mechanisms;

(4) identify and provide clinical testing of novel agents for the prevention and treatment of prostate cancer;

(5) establish clinical registries for prostate cancer; and

(6) utilize the National Institute of Biomedical Imaging and Bioengineering and the National Cancer Institute for assessment of appropriate imaging services and technologies.

(c) MATTERS ADDRESSED.—In carrying out the program required by subsection (a), the Secretary shall address the following:

(1) The racial, ethnic, and geographic disparities in the incidence and mortality rates of prostate cancer.

(2) The barriers, if any, regarding access to care and participation in clinical trials that are specific to racial, ethnic, and other underserved populations.

(3) Such outreach and education as the Secretary considers necessary to raise awareness of prostate cancer in the communities of racial, ethnic, and other underserved populations.

(4) The availability of and utilization of appropriate imaging services and technologies by racial, ethnic, and other underserved populations.

(d) GRANTS FOR ELIGIBLE ENTITIES THAT SERVE MEDICALLY UNDERSERVED POPULATIONS.—The Secretary shall carry out the program required by subsection

(a) through the award of grants to entities that are eligible to apply for at least 1 grant under any Federal program.

(e) COMPARATIVE EFFECTIVENESS RESEARCH.—In carrying out the program required by subsection (a), the Secretary shall integrate and build upon existing knowledge gained from comparative effectiveness research.

SEC. 6. INCORPORATION OF PROSTATE CANCER TREATMENT INTO FEDERAL TELEHEALTH PROGRAMS.

(a) IN GENERAL.—Whenever practicable, the Secretary of Veterans Affairs, the Secretary of Defense, and the Secretary of Health and Human Services shall incorporate prostate cancer prevention, diagnosis, and treatment for medically underserved populations into the telehealth programs of the Department of Veterans Affairs, the Department of Defense, and the Department of Health and Human Services, respectively.

(b) POPULATIONS.—In providing prostate cancer prevention, diagnosis, and treatment via telehealth programs under this section, the Secretary of Veterans Affairs, the Secretary of Defense, and the Secretary of Health and Human Services shall give priority to the provision of such prevention, diagnosis, and treatment to populations—

(1) in medically underserved areas, particularly areas that include populations consisting predomi-

nantly of Indians, Alaska Natives, African-Americans, Hawaii Natives and other Pacific Islanders, Asians, and Latinos; and

(2) in rural and highly rural areas.

(c) DELIVERY OF HEALTH CARE.—In providing prostate cancer prevention, diagnosis, and treatment via telehealth programs under this section, the Secretary of Veterans Affairs, the Secretary of Defense, and the Secretary of Health and Human Services shall—

(1) promote the efficient use of specialist care through better coordination of primary care and physician extender teams in medically underserved areas; and

(2) more effectively employ tumor boards to better counsel patients.

(d) EVALUATION.—In providing prostate cancer prevention, diagnosis, and treatment via telehealth programs under this section, the Secretary of Veterans Affairs, the Secretary of Defense, and the Secretary of Health and Human Services shall evaluate the following:

(1) The effectiveness and efficiency of diagnosing and treating prostate cancer using telehealth services in medically underserved, rural, highly rural, and tribal areas, including the use of tumor boards to facilitate better patient counseling.

(2) The collaborative uses of health care professionals and the integration of a range of telehealth and other technologies in the provision of health care in medically underserved communities.

(3) The effectiveness of improving the capacity of non-medical providers and non-specialized medical providers to provide health care services for prostate cancer in medically underserved, rural, highly rural, and tribal areas, including—

(A) the use of innovative medical home models with collaboration between urologists and primary care physicians; and

(B) coordination of care through the efficient use of primary care physicians and physician extenders.

(e) REPORT.—

(1) IN GENERAL.—Not later than five years after the date of the enactment of this Act, the Secretary of Veterans Affairs, the Secretary of Defense, and the Secretary of Health and Human Services shall submit to Congress a report on their activities under this section.

(2) ELEMENTS.—The report required by paragraph (1) shall include the following:

(A) A description of the outcomes of the activities carried out under this section.

(B) An assessment of the effectiveness and efficiency of using telehealth services to provide health care in medically underserved communities.

(C) The recommendations, if any, of the Secretary concerned as to whether the Federal Government should increase the use of telehealth services to deliver health care to medically underserved communities.

(f) DEFINITIONS.—In this section:

(1) MEDICAL HOME MODEL.—The term ''medical home model'' means a model of care in which each patient has an ongoing relationship with a personal physician who leads a health care team that includes a specialist and takes collective responsibility for patient care. Such team is responsible for providing all the patient's health care needs and, when needed, arranges for appropriate care with qualified physicians who are not part of such team.

(2) PHYSICIAN EXTENDER.—The term ''physician extender'' means a trained health care professional who provides quasi-autonomous health care

under a particular physician's license. Such term includes physician assistants and nurse practitioners.

(3) PRIMARY CARE AND PHYSICIAN EXTENDER TEAM.—A ''primary care and physician extender team'' is the collaboration of a primary care physician and one or more physician extenders working in collaboration with a urologist for the care of the prostate cancer patient.

(4) TELEHEALTH.—The term ''telehealth'' means technology-based professional consultations, patient monitoring, patient training services, clinical observation, assessment, or treatment, and any additional services that utilize technologies specified in the Healthcare Common Procedure Coding System of the Centers for Medicare and Medicaid Services.

(5) TUMOR BOARD.—The term ''tumor board'' means a group of physician experts in a particular disease or condition who convene to discuss a particular case, normally one that is challenging or complex, in order to drawn upon the collective expertise of the group to reach consensus on a recommended course of treatment.

SEC. 7. NATIONAL EDUCATION CAMPAIGN FOR PROSTATE CANCER AWARENESS.

(a) NATIONAL EDUCATION CAMPAIGN REQUIRED.—The Secretary of Veterans Affairs shall carry out a national education campaign to encourage men to seek prostate cancer prevention, diagnosis, and treatment when appropriate.

(b) MANNER.—The Secretary shall carry out the national education campaign required by subsection (a) through the development and distribution of educational materials and through public service announcements in a manner that is consistent with the findings and recommendations of the Interagency Prostate Cancer Coordination and Education Task Force established under section 4.

(c) AVAILABILITY OF EDUCATIONAL MATERIALS AND PUBLIC SERVICE ANNOUNCEMENTS IN COMMUNITIES WITH HIGHER INCIDENCE OF PROSTATE CANCER.—In carrying out the national education campaign required by subsection (a), the Secretary shall ensure that such educational materials and public service announcements required by subsection (b) are more readily available in communities with higher than average rates of incidence of prostate cancer and rates of mortality from prostate cancer.

(d) GRANTS.—In carrying out the national education campaign required by subsection (a), the Secretary shall award grants to private nonprofit organizations to test alternative outreach and education strategies.

SEC. 8. DEFINITIONS.

In this Act:

(1) HIGHLY RURAL.—The term ''highly rural'', with respect to an area, means that the area consists of a county or counties having a population density of less than seven persons per square mile.

(2) RURAL.—The term ''rural'', with respect to an area, means the area is a rural area as classified by the Director of the Bureau of the Census.

SEC. 9. AUTHORIZATION OF APPROPRIATIONS.

There is authorized to be appropriated to carry out this Act, such sums as necessary for each of fiscal years 2012 through 2016.

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