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Chesapeake UROLOGY

The most personal care for life's most personal issues.

February 26, 2020

The Honorable Delores G. Kelley
Chair, Finance Committee

Miller Senate Office Building, 3 East
11 Bladen St., Annapolis, MD 21401 - 1991

SUPPORT SB 661 Health Insurance – Prostate Cancer Screening – Prohibiting Cost Sharing

Dear Madame Chairman Kelley:

As a practicing urologist in Maryland, I am asking for your support for SB 661 to eliminate cost sharing for prostate cancer screening with the PSA blood test. Urologists diagnose and treat most forms of prostate cancer and taking care of men with the disease constitutes a major part of my clinical practice. While early detection is important for all types of illness, this is particularly salient for prostate cancer. There is a 99% chance of surviving at least 10 years when men are diagnosed with localized disease as opposed to less than 30% survival when men are diagnosed with metastatic prostate cancer. Most cancer screening occurs in the primary care setting and the PSA test is the main screening tool used to find prostate cancer. Easy access to this simple blood test is essential to diagnosing this cancer at a stage where management is likely to be successful.

Chesapeake Urology is the largest provider of urologic care in Maryland. In 2018, almost 2,500 Marylanders were diagnosed with prostate cancer within our practice. We continue to see, with dismay, the detrimental effects of decreased PSA testing in our patients. Over the past 7 years, the number of patients presenting to our practice with incurable prostate cancer has increased by over 60%, representing an additional 100+ men/year. Treatment at this stage of the disease is more difficult for patients and more costly for payors. Removing obstacles to effective prostate cancer screening will save the lives of men in our state.

Thank you for the opportunity to provide testimony, and I urge your support of SB 661.
Sincerely,

Alan L. Kaplan, MD, MBA
Chesapeake Urology Associates

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SB 661 SUPPORT

Part III - Administrative, Procedural, and Miscellaneous

Notice 2004-23

PURPOSE

This notice provides a safe harbor for preventive care benefits allowed to be provided by a high deductible health plan (HDHP) without satisfying the minimum deductible under section 223(c)(2) of the Internal Revenue Code.

BACKGROUND

Section 1201 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, added section 223 to the Internal Revenue Code to permit eligible individuals to establish Health Savings Accounts (HSAs) for taxable years beginning after December 31, 2003.

Among the requirements for an individual to qualify as an eligible individual under section 223(c)(1) (and thus to be eligible to make tax-favored contributions to an HSA) is the requirement that the individual be covered under an HDHP. An HDHP is a health plan that satisfies certain requirements with respect to minimum deductibles and maximum out-of-pocket expenses. Generally, an HDHP may not provide benefits for any year until the deductible for that year is satisfied. However, section 223(c)(2)(C) provides a safe harbor for the absence of a preventive care deductible. That section states, "[a] plan shall not fail to be treated as a high deductible health plan by reason of failing to have a deductible for preventive care (within the meaning of section 1871 of the Social Security Act, except as otherwise provided by the Secretary)." An HDHP may therefore provide preventive care benefits without a deductible or with a deductible below the minimum annual deductible. On the other hand, there is no requirement in section 223 that an HDHP provide benefits for preventive care or provide preventive care with a deductible below the minimum annual deductible.

PREVENTIVE CARE SAFE HARBOR

Preventive care for purposes of section 223(c)(2)(C) includes, but is not limited to, the following:

- Periodic health evaluations, including tests and diagnostic procedures ordered in connection with routine examinations, such as annual physicals.

- Routine prenatal and well-child care.

- Child and adult immunizations.
- Tobacco cessation programs.
- Obesity weight-loss programs.
- Screening services (see attached APPENDIX).

However, preventive care does not generally include any service or benefit intended to treat an existing illness, injury, or condition (See below for request for comments regarding drug treatments.)

INTERACTION WITH STATE LAW HEALTH CARE REQUIREMENTS

Section 220(c)(2)(B)(ii) allows a high deductible health plan for purposes of an Archer Medical Savings Account to provide preventive care without a deductible if required by State law. However, section 220 does not define preventive care for this purpose. Section 223(c)(2)(C), for purposes of an HSA, does not condition the exception for preventive care on State law requirements. State insurance laws often require health plans to provide certain health care without regard to a deductible or on terms no less favorable than other care provided by the health plan. The determination of whether health care that is required by State law to be provided by an HDHP without regard to a deductible is "preventive" for purposes of the exception for preventive care under section 223(c)(2)(C) will be based on the standards set forth in this notice and other guidance issued by the IRS, rather than on how that care is characterized by State law.

COMMENTS REQUESTED

Notice 2004-2, 2004-2 I.R.B. 269, requested comments concerning the appropriate standard for preventive care in section 223(c)(2)(C). We continue to request comments on the appropriate standard for preventive care, and in particular, recommendations concerning any benefit or service that should be added to those set forth in this notice and appendix. In addition, we request comments on the extent to which benefits provided by an employee assistance program, mental health program or wellness program may qualify as preventive care, including comments regarding the scope of treatments provided as benefits through counseling and health assessments. In particular, we request comments on the extent to which drug treatments, either solely by prescription or as part of an overall treatment regimen should be treated as preventive care and the appropriate standards for differentiating between drug treatments that would be considered preventive care and those that would not be considered preventive care.

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DRAFTING INFORMATION

The principal author of this notice is Shoshanna Tanner of the Office of Division Counsel/Associate Chief Counsel (Tax Exempt and Government Entities). For further information regarding this notice contact Ms. Tanner on (202) 622-6080 (not a toll-free call).

APPENDIX
Safe Harbor Preventive Care Screening Services

Cancer Screening
Breast Cancer (e.g., Mammogram)
Cervical Cancer (e.g., Pap Smear)
Colorectal Cancer
Prostate Cancer (e.g., PSA Test)
Skin Cancer
Oral Cancer
Ovarian Cancer
Testicular Cancer
Thyroid Cancer

Heart and Vascular Diseases Screening
Abdominal Aortic Aneurysm
Carotid Artery Stenosis
Coronary Heart Disease
Hemoglobinopathies
Hypertension
Lipid Disorders

Infectious Diseases Screening
Bacteriuria
Chlamydial Infection
Gonorrhea
Hepatitis B Virus Infection
Hepatitis C
Human Immunodeficiency Virus (HIV) Infection
Syphilis
Tuberculosis Infection

Mental Health Conditions and Substance Abuse Screening
Dementia
Depression
Drug Abuse
Problem Drinking
Suicide Risk
Family Violence

Metabolic, Nutritional, and Endocrine Conditions Screening
Anemia, Iron Deficiency
Dental and Periodontal Disease
Diabetes Mellitus
Obesity in Adults
Thyroid Disease

Musculoskeletal Disorders Screening
Osteoporosis

Obstetric and Gynecologic Conditions Screening
Bacterial Vaginosis in Pregnancy
Gestational Diabetes Mellitus
Home Uterine Activity Monitoring
Neural Tube Defects
Preeclampsia
Rh Incompatibility
Rubella
Ultrasonography in Pregnancy

Pediatric Conditions Screening
Child Developmental Delay
Congenital Hypothyroidism
Lead Levels in Childhood and Pregnancy
Phenylketonuria
Scoliosis, Adolescent Idiopathic

Vision and Hearing Disorders Screening
Glaucoma
Hearing Impairment in Older Adults
Newborn Hearing

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The Honorable Delores G. Kelley
Chair, Finance Committee
3 East Miller Senate Office Building
11 Bladen Street
Annapolis, MD 21401

SUPPORT
Senate Bill 661 (HB 852) Health Insurance- Prostate Cancer Screening- Prohibiting Cost Sharing

Dear Madame Chairman Kelley,

I hope this letter finds you in good health and good spirits. My name is Robert Ginyard. I am the Chairman of the Board of Directors of ZERO: The End of Prostate Cancer. I am a husband, civic leader, lover of life, father of two beautiful daughters, and a prostate cancer survivor. Ten years ago, I was diagnosed with prostate cancer and was successfully treated for the disease through a combination of surgery, followed by radiation treatment and hormone therapy.
I am alive today, I believe, because of my wife's insistence on me getting a PSA as part of my annual checkup, and a primary care physician who was cognizant of the importance of PSA testing given my family history of the disease and that I am African American.

Let's be honest, most men do not voluntarily raise their hands and yell out that they want to go to the doctor. For those brave souls who do, we should make sure that are no obstacles to PSA screenings. How can we do that? By passing Senate Bill 661.Here's why:

- Parity. Currently, there is no cost sharing for mammograms. Also, through the ACA, there is no cost sharing for cervical cancer screenings. Prohibiting cost sharing for PSA test would eliminate the cost burden for men to receive the test just as women do not have a cost burden for mammograms and cervical cancer screenings.
- Mortality- Prostate cancer deaths are on the rise in the U.S. New reporting from the American Cancer Society shows that in 2020, the number of men who will die from prostate cancer will hit a record high over the last two decades, with an increase of 5 percent since last year. When caught early, a man diagnosed with prostate cancer has a 99 percent chance of survival; this is three times higher than when the cancer is found in an advanced stage, which has only a 30 percent rate of survival.
- Public Health and Health Disparities- African American men are at an increased risk for developing prostate cancer over white men and other men of color. One in six African American men will develop prostate cancer in their lifetime. Overall, African American men are 1.8 times more likely to be diagnosed with – and 2.2 times more likely to die from – prostate cancer than white men. African American men are also slightly more likely than white men to be diagnosed with advance disease.

- Cost- Removing barriers to the PSA screening test and diagnosing prostate cancer at an earlier stage is much more cost effective than treating late stage prostate cancer.

Thank you for the opportunity to provide testimony on SB 661, I/we urge your support of SB 661.

Best regards,

Robert Ginyard,
Chairman of the Board of Directors, ZERO: The End Prostate Cancer

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SB 661 SUPPORT

ZERO
THE END OF PROSTATE CANCER

ZEROCANCER.ORG

Main Phone: 202-463-9455
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The Need for State-Based Prostate Cancer Screening Legislation

In 2012 the United States Preventive Services Task Force (USPSTF or Task Force) updated their screening recommendations for both breast cancer and prostate cancer, recommending against the screening for both cancers. In response, after outrage amongst the breast cancer community, Congress passed Protecting Access to Lifesaving Screenings Act (PALS Act) which circumvented the USPSTF recommendation[1], allowing for the cohort of women the Task Force recommended against mammography screening the ability to receive regular mammograms with no cost-sharing requirements. As more men die of prostate cancer, it is time for the states to fill the gap created by the Task Force allowing men to access common sense screenings to catch prostate cancer while it is still treatable.

Background on the UPSPTF

Established in 1984, the USPSTF was created to make evidence-based recommendations for clinical preventive services to primary care professionals, patients, and families. The sixteen members of the Task Force are appointed volunteers and representing the fields of primary care – specialists (such as urologists and oncologists) do not sit on the panel, which is within the Agency for Healthcare Research and Quality (AHRQ) at the Department of Health and Human Services' (HHS). The Task Force is an independent body, and its work does not require AHRQ or HHS approval.

For years, USPSTF recommendations have been widely referred to in the medical community and used to decide which preventive services physicians and their patients should use. While in some cases insurance companies use these recommendations to decide what to cover under their policies, this coverage was not mandated, and decisions were left largely to providers. The Affordable Care Act (ACA) required private insurance plans to cover USPSTF recommended preventive services without any patient cost sharing (such as copayments, co-insurance, or deductibles), removing a significant obstacle for individuals in need of preventive services. The result of this change has been that those screening tools receiving an A or B rating from USPSTF have benefited from increased access, while other screening tools have experienced a marked decrease in access coupled with confusion over screening best practices[2].

The Problem with the USPSTF PSA Rating

Prostate cancer has very few, if any, symptoms before late stage disease – which only has a 30 percent survival rate. The PSA blood test is an affordable and currently irreplaceable tool to alert providers to the possible presence of prostate cancer before it metastasizes into a fatal diagnosis. In 2012, the USPSTF gave prostate specific antigen (PSA) screening for prostate cancer a "D" rating for all men. That recommendation on contradicted practice guidance issued by the American Urological Association, the National Comprehensive Cancer Network (NCCN), the American Society of Clinical Oncology (ASCO), and the American College of Physicians-American Society of Internal

[1] H.R.2029 - Consolidated Appropriations Act, 2016, https://www.congress.gov/bill/114th-congress/house-bill/2029/text

[2] MacDonald, A. (2011, October 7). New prostate cancer screening recommendation generates controversy and confusion. Retrieved from https://www.health.harvard.edu/blog/new-prostate-cancer-screening-recommendation-generates-controversy-and-confusion-201110073569.

Medicine. The NCCN guidelines, which ZERO endorses, recommend baseline screening beginning as early as age 45[3].

The USPSTF's justification for the "D" rating was due to concerns about false-positives and overtreatment for an often, slow growing cancer. The USPSTF based its 2012 recommendation primarily on two studies of mostly older white men and concluded that the harms of overtreatment outweighed the benefits of early screening (the recommendation emphasized that many men in this category have slow-growing tumors and may die of something else). However, the USPSTF recommendation applied to all age groups and races. The USPSTF did not consider the benefits of screening for younger men (who are more likely to have an aggressive form of the disease), men with a genetic marker or family history of disease, or African-American men, who have almost double the incidence and death rates as their white counterparts.

The lack of nuance in this approach disturbed many in the medical community and has created significant mixed messages about the benefits of screening for prostate cancer. After this recommendation, prostate cancer screening decreased, as did diagnoses of localized prostate cancers, whereas diagnoses of metastatic prostate cancer remained stable[4]. Many experts agree that more men will die because their cancer will not be detected in time to be treated successfully. In fact, **after decades of declining death rates, 2,000 more men are expected to die of prostate cancer in 2019 than in 2018.**

In 2018, the USPSTF issued a new recommendation, upgrading the PSA test a "C" rating for men ages 55-69 and a "D" rating for men 70 and over[5]. The "C" rating suggests that providers should offer the test for high-risk men in that category, but it does not require insurance coverage of the test. The "D" rating for men 70 and above means the PSA test is <u>not</u> recommended for older men – no matter their life expectancy or state of health.

While the USPSTF says that generating data to understand the specific risks and benefits of screening for African Americans and men with a family history is a national priority[6], there are several barriers to the completion of such studies in the near future. Since prostate cancer is slow growing, a comprehensive research study could take twenty years to generate data necessary to make a recommendation. In addition, it is extremely difficult to enroll a sufficient number of African Americans or men with a family history in research trials, and many are concerned such a cohort would not be large enough to support conclusive findings.

<u>The Solution</u>

In the 2018 recommendation report, the USPSTF stated, "given the large disparities in prostate cancer mortality in African American men" filling the PSA screening data gap for this population as well as for men with a family history of the disease, including whether to screen them at a younger age "should be a national priority". Further, the Task Force included this national prioritization language in their "Eighth Annual Report to Congress on High-Priority Evidence Gaps for Clinical Preventive Services".

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[3] National Comprehensive Cancer Network Early Detection for Prostate Cancer Guidelines, https://www.nccn.org/patients/guidelines/prostate/17/

[4] MacDonald, A. (2011, October 7). New prostate cancer screening recommendation generates controversy and confusion. Retrieved from https://www.health.harvard.edu/blog/new-prostate-cancer-screening-recommendation-generates-controversy-and-confusion-201110073569.

[5] USPSTF Screening: Prostate Cancer Recommendation, 2018

[6] Eighth Annual Report to Congress on High-Priority Evidence Gaps for Clinical Preventive Services

Considering the many barriers a comprehensive study sufficient for the Task Force would require, including ethical concerns, the time period required of the study, as well as the well-documented challenges in African-American enrollment, we recognize there is no appropriate path forward to fill this glaring research gap.

To that end, ZERO – The End of Prostate Cancer is proposing legislation that would allow, similarly to mammography, men to receive prostate cancer screenings without any burdensome cost-sharing requirements. Further, this legislation would allow men in these highest risk groups to receive prostate cancer screenings at a younger age, catching the disease while it is still treatable and helping fill the USPSTF's "national priority" research gap.

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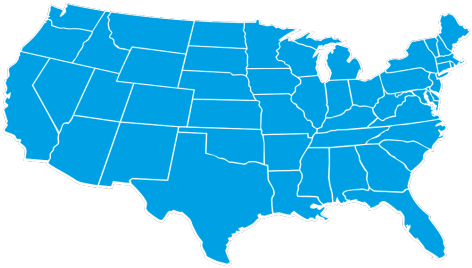
SB 661 SUPPORT
2019 Prostate Cancer Facts & Statistics

Mid-Atlantic Chapter



Nationwide Incidence Rate

1 in 9 men will be diagnosed during his lifetime
2.9M men currently diagnosed

This year in the United States…
New cases: 174,650
Deaths: 31,620

Veterans are 1.5x more likely to get prostate cancer

African-American men are 2.2x more likely to die of prostate cancer

Incidence Rate in Maryland

125.7 in every 100,000 men diagnosed
20.2 in every 100,000 men die from the disease

This year in Maryland…
New cases: 3,810
Deaths: 550

National Rankings by State:
#8 for prostate cancer incidents
#16 for prostate cancer deaths

Source: *Estimates based on 2019 data from the American Cancer Society.*

ZERO's Impact in Maryland

Patient Programs

ZERO helped provide co-pay assistance to advanced prostate cancer patients:

$2,480,455.14 total provided to
604 men in Maryland.

Upcoming Invitations to Speak to Constituents

Baltimore – September 22

ZERO — The End of Prostate Cancer is the leading national nonprofit with the mission to end prostate cancer. ZERO advances research, improves the lives of men and families, and inspires action. Visit our website: www.zerocancer.org.

ZERO Contact:
Matt Marks
Government Relations & Advocacy Manager
matt@zerocancer.org | 202-664-4342

2019 Prostate Cancer Facts & Statistics

Mid-Atlantic Chapter

CDMRP Grants in Maryland

Year introduced: 1997
Total Grants to Date: 188
Total Grant Awards to through FY 2017*: $92.1M

**PCRP data for FY 2018 has not been posted yet*

Grant Recipient	Year	Amount
John Hopkins University	2013	$6,055,088.00
John Hopkins University	2009	$2,590,809.32
John Hopkins University	2013	$2,022,501.00
John Hopkins University	2014	$1,699,782.00
National Cancer Institute	2017	$1,461,572.00

CDC's National Comprehensive Cancer Control Program (NCCCP) funding in Maryland:

• Goal 1: Reduce the burden of cancer in Maryland.
• Objective 1: By 2020, reduce age-adjusted cancer incidence rates to reach the following targets: Prostate: 87.3 per 100,000 (2012 Baseline: 112.0 per 100,000).
• Objective 2: By 2020, reduce age-adjusted cancer mortality rates to reach the following targets: Prostate: 11.2 per 100,000 (2012 Baseline: 20.4 per 100,000).
• Objective 3: By 2020, increase the proportion of men ages 55 to 69 who have discussed the advantages and disadvantages of the prostate-specific antigen (PSA) test to screen for prostate cancer with their healthcare provider to 38.2% of Maryland men ages 55 to 69 (2012 Baseline: 34.7% of Maryland men ages 55 to 69). Target Setting Method: 10% Increase.
• Objective 4: By 2020, reduce disparities in cancer incidence and mortality to reach the following targets: Prostate Incidence: White: 68.7 per 100,000 (2012 baseline: 97.5 per 100,000), Black: 130.9 per 100,000 (2012 baseline: 159.7 per 100,000). Prostate mortality: White: 10.0 per 100,000 (2012 baseline: 17.4 per 100,000), Black: 13.5 per 100,000 (2012 baseline: 35.5 per 100,000).

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Chesapeake Urology Associates

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Heart and Vascular Diseases Screening
Abdominal Aortic Aneurysm
Carotid Artery Stenosis
Coronary Heart Disease
Hemoglobinopathies
Hypertension
Lipid Disorders

Infectious Diseases Screening
Bacteriuria
Chlamydial Infection
Gonorrhea
Hepatitis B Virus Infection
Hepatitis C
Human Immunodeficiency Virus (HIV) Infection
Syphilis
Tuberculosis Infection

Mental Health Conditions and Substance Abuse Screening
Dementia
Depression
Drug Abuse
Problem Drinking
Suicide Risk
Family Violence

Metabolic, Nutritional, and Endocrine Conditions Screening
Anemia, Iron Deficiency
Dental and Periodontal Disease
Diabetes Mellitus
Obesity in Adults
Thyroid Disease

Musculoskeletal Disorders Screening
Osteoporosis

Obstetric and Gynecologic Conditions Screening
Bacterial Vaginosis in Pregnancy
Gestational Diabetes Mellitus
Home Uterine Activity Monitoring
Neural Tube Defects
Preeclampsia
Rh Incompatibility
Rubella
Ultrasonography in Pregnancy

Pediatric Conditions Screening
Child Developmental Delay
Congenital Hypothyroidism
Lead Levels in Childhood and Pregnancy
Phenylketonuria
Scoliosis, Adolescent Idiopathic

Vision and Hearing Disorders Screening
Glaucoma
Hearing Impairment in Older Adults
Newborn Hearing

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Let's be honest, most men do not voluntarily raise their hands and yell out that they want to go to the doctor. For those brave souls who do, we should make sure that are no obstacles to PSA screenings. How can we do that? By passing Senate Bill 661.Here's why:

- Parity. Currently, there is no cost sharing for mammograms. Also, through the ACA, there is no cost sharing for cervical cancer screenings. Prohibiting cost sharing for PSA test would eliminate the cost burden for men to receive the test just as women do not have a cost burden for mammograms and cervical cancer screenings.
- Mortality- Prostate cancer deaths are on the rise in the U.S. New reporting from the American Cancer Society shows that in 2020, the number of men who will die from prostate cancer will hit a record high over the last two decades, with an increase of 5 percent since last year. When caught early, a man diagnosed with prostate cancer has a 99 percent chance of survival; this is three times higher than when the cancer is found in an advanced stage, which has only a 30 percent rate of survival.
- Public Health and Health Disparities- African American men are at an increased risk for developing prostate cancer over white men and other men of color. One in six African American men will develop prostate cancer in their lifetime. Overall, African American men are 1.8 times more likely to be diagnosed with – and 2.2 times more likely to die from – prostate cancer than white men. African American men are also slightly more likely than white men to be diagnosed with advance disease.

- Cost- Removing barriers to the PSA screening test and diagnosing prostate cancer at an earlier stage is much more cost effective than treating late stage prostate cancer.

Thank you for the opportunity to provide testimony on SB 661, I/we urge your support of SB 661.

Best regards,

Robert Ginyard,
Chairman of the Board of Directors, ZERO: The End Prostate Cancer

ZERO_FAV_SB661
Uploaded by: Brown, Patrice
Position: FAV

SB 661 SUPPORT

ZERO
THE END OF PROSTATE CANCER

ZEROCANCER.ORG

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The Need for State-Based Prostate Cancer Screening Legislation

In 2012 the United States Preventive Services Task Force (USPSTF or Task Force) updated their screening recommendations for both breast cancer and prostate cancer, recommending against the screening for both cancers. In response, after outrage amongst the breast cancer community, Congress passed Protecting Access to Lifesaving Screenings Act (PALS Act) which circumvented the USPSTF recommendation[1], allowing for the cohort of women the Task Force recommended against mammography screening the ability to receive regular mammograms with no cost-sharing requirements. As more men die of prostate cancer, it is time for the states to fill the gap created by the Task Force allowing men to access common sense screenings to catch prostate cancer while it is still treatable.

Background on the UPSPTF

Established in 1984, the USPSTF was created to make evidence-based recommendations for clinical preventive services to primary care professionals, patients, and families. The sixteen members of the Task Force are appointed volunteers and representing the fields of primary care – specialists (such as urologists and oncologists) do not sit on the panel, which is within the Agency for Healthcare Research and Quality (AHRQ) at the Department of Health and Human Services' (HHS). The Task Force is an independent body, and its work does not require AHRQ or HHS approval.

For years, USPSTF recommendations have been widely referred to in the medical community and used to decide which preventive services physicians and their patients should use. While in some cases insurance companies use these recommendations to decide what to cover under their policies, this coverage was not mandated, and decisions were left largely to providers. The Affordable Care Act (ACA) required private insurance plans to cover USPSTF recommended preventive services without any patient cost sharing (such as copayments, co-insurance, or deductibles), removing a significant obstacle for individuals in need of preventive services. The result of this change has been that those screening tools receiving an A or B rating from USPSTF have benefited from increased access, while other screening tools have experienced a marked decrease in access coupled with confusion over screening best practices[2].

The Problem with the USPSTF PSA Rating

Prostate cancer has very few, if any, symptoms before late stage disease – which only has a 30 percent survival rate. The PSA blood test is an affordable and currently irreplaceable tool to alert providers to the possible presence of prostate cancer before it metastasizes into a fatal diagnosis. In 2012, the USPSTF gave prostate specific antigen (PSA) screening for prostate cancer a "D" rating for all men. That recommendation on contradicted practice guidance issued by the American Urological Association, the National Comprehensive Cancer Network (NCCN), the American Society of Clinical Oncology (ASCO), and the American College of Physicians-American Society of Internal

[1] H.R.2029 - Consolidated Appropriations Act, 2016, https://www.congress.gov/bill/114th-congress/house-bill/2029/text

[2] MacDonald, A. (2011, October 7). New prostate cancer screening recommendation generates controversy and confusion. Retrieved from https://www.health.harvard.edu/blog/new-prostate-cancer-screening-recommendation-generates-controversy-and-confusion-201110073569.

Medicine. The NCCN guidelines, which ZERO endorses, recommend baseline screening beginning as early as age 45[3].

The USPSTF's justification for the "D" rating was due to concerns about false-positives and overtreatment for an often, slow growing cancer. The USPSTF based its 2012 recommendation primarily on two studies of mostly older white men and concluded that the harms of overtreatment outweighed the benefits of early screening (the recommendation emphasized that many men in this category have slow-growing tumors and may die of something else). However, the USPSTF recommendation applied to all age groups and races. The USPSTF did not consider the benefits of screening for younger men (who are more likely to have an aggressive form of the disease), men with a genetic marker or family history of disease, or African-American men, who have almost double the incidence and death rates as their white counterparts.

The lack of nuance in this approach disturbed many in the medical community and has created significant mixed messages about the benefits of screening for prostate cancer. After this recommendation, prostate cancer screening decreased, as did diagnoses of localized prostate cancers, whereas diagnoses of metastatic prostate cancer remained stable[4]. Many experts agree that more men will die because their cancer will not be detected in time to be treated successfully. In fact, **after decades of declining death rates, 2,000 more men are expected to die of prostate cancer in 2019 than in 2018.**

In 2018, the USPSTF issued a new recommendation, upgrading the PSA test a "C" rating for men ages 55-69 and a "D" rating for men 70 and over[5]. The "C" rating suggests that providers should offer the test for high-risk men in that category, but it does not require insurance coverage of the test. The "D" rating for men 70 and above means the PSA test is <u>not</u> recommended for older men – no matter their life expectancy or state of health.

While the USPSTF says that generating data to understand the specific risks and benefits of screening for African Americans and men with a family history is a national priority[6], there are several barriers to the completion of such studies in the near future. Since prostate cancer is slow growing, a comprehensive research study could take twenty years to generate data necessary to make a recommendation. In addition, it is extremely difficult to enroll a sufficient number of African Americans or men with a family history in research trials, and many are concerned such a cohort would not be large enough to support conclusive findings.

<u>The Solution</u>

In the 2018 recommendation report, the USPSTF stated, "given the large disparities in prostate cancer mortality in African American men" filling the PSA screening data gap for this population as well as for men with a family history of the disease, including whether to screen them at a younger age "should be a national priority". Further, the Task Force included this national prioritization language in their "Eighth Annual Report to Congress on High-Priority Evidence Gaps for Clinical Preventive Services".

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[3] National Comprehensive Cancer Network Early Detection for Prostate Cancer Guidelines, https://www.nccn.org/patients/guidelines/prostate/17/

[4] MacDonald, A. (2011, October 7). New prostate cancer screening recommendation generates controversy and confusion. Retrieved from https://www.health.harvard.edu/blog/new-prostate-cancer-screening-recommendation-generates-controversy-and-confusion-201110073569.

[5] USPSTF Screening: Prostate Cancer Recommendation, 2018

[6] Eighth Annual Report to Congress on High-Priority Evidence Gaps for Clinical Preventive Services

Considering the many barriers a comprehensive study sufficient for the Task Force would require, including ethical concerns, the time period required of the study, as well as the well-documented challenges in African-American enrollment, we recognize there is no appropriate path forward to fill this glaring research gap.

To that end, ZERO – The End of Prostate Cancer is proposing legislation that would allow, similarly to mammography, men to receive prostate cancer screenings without any burdensome cost-sharing requirements. Further, this legislation would allow men in these highest risk groups to receive prostate cancer screenings at a younger age, catching the disease while it is still treatable and helping fill the USPSTF's "national priority" research gap.

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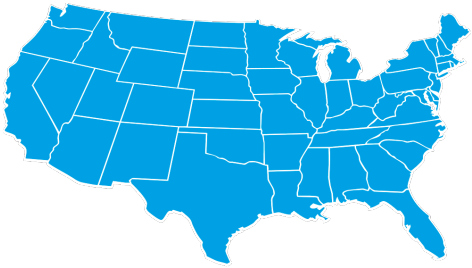
Position: FAV

SB 661 SUPPORT
2019 Prostate Cancer Facts & Statistics

Mid-Atlantic Chapter



Nationwide Incidence Rate

1 in 9 men will be diagnosed during his lifetime
2.9M men currently diagnosed

This year in the United States…
New cases: 174,650
Deaths: 31,620

Veterans are 1.5x more likely to get prostate cancer

African-American men are 2.2x more likely to die of prostate cancer

Incidence Rate in Maryland

125.7 in every 100,000 men diagnosed
20.2 in every 100,000 men die from the disease

This year in Maryland…
New cases: 3,810
Deaths: 550

National Rankings by State:
#8 for prostate cancer incidents
#16 for prostate cancer deaths

Source: *Estimates based on 2019 data from the American Cancer Society.*

ZERO's Impact in Maryland

Patient Programs

ZERO helped provide co-pay assistance to advanced prostate cancer patients:

$2,480,455.14 total provided to
604 men in Maryland.

Upcoming Invitations to Speak to Constituents

Baltimore – September 22

ZERO — The End of Prostate Cancer is the leading national nonprofit with the mission to end prostate cancer. ZERO advances research, improves the lives of men and families, and inspires action. Visit our website: www.zerocancer.org.

ZERO Contact:
Matt Marks
Government Relations & Advocacy Manager
matt@zerocancer.org | 202-664-4342

2019 Prostate Cancer Facts & Statistics

Mid-Atlantic Chapter

CDMRP Grants in Maryland

Year introduced: 1997
Total Grants to Date: 188
Total Grant Awards to through FY 2017*: $92.1M

**PCRP data for FY 2018 has not been posted yet*

Grant Recipient	Year	Amount
John Hopkins University	2013	$6,055,088.00
John Hopkins University	2009	$2,590,809.32
John Hopkins University	2013	$2,022,501.00
John Hopkins University	2014	$1,699,782.00
National Cancer Institute	2017	$1,461,572.00

CDC's National Comprehensive Cancer Control Program (NCCCP) funding in Maryland:

• Goal 1: Reduce the burden of cancer in Maryland.
• Objective 1: By 2020, reduce age-adjusted cancer incidence rates to reach the following targets: Prostate: 87.3 per 100,000 (2012 Baseline: 112.0 per 100,000).
• Objective 2: By 2020, reduce age-adjusted cancer mortality rates to reach the following targets: Prostate: 11.2 per 100,000 (2012 Baseline: 20.4 per 100,000).
• Objective 3: By 2020, increase the proportion of men ages 55 to 69 who have discussed the advantages and disadvantages of the prostate-specific antigen (PSA) test to screen for prostate cancer with their healthcare provider to 38.2% of Maryland men ages 55 to 69 (2012 Baseline: 34.7% of Maryland men ages 55 to 69). Target Setting Method: 10% Increase.
• Objective 4: By 2020, reduce disparities in cancer incidence and mortality to reach the following targets: Prostate Incidence: White: 68.7 per 100,000 (2012 baseline: 97.5 per 100,000), Black: 130.9 per 100,000 (2012 baseline: 159.7 per 100,000). Prostate mortality: White: 10.0 per 100,000 (2012 baseline: 17.4 per 100,000), Black: 13.5 per 100,000 (2012 baseline: 35.5 per 100,000).

ZERO — The End of Prostate Cancer is the leading national nonprofit with the mission to end prostate cancer. ZERO advances research, improves the lives of men and families, and inspires action. Visit our website: www.zerocancer.org.

ZERO Contact:
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MedChi, MDCSCO_Danna Kauffman_FAV_SB0661
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MedChi

MDCSCO
MARYLAND/DISTRICT OF COLUMBIA SOCIETY OF CLINICAL ONCOLOGY

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TO: The Honorable Delores G. Kelley, Chair
Members, Senate Finance Committee
The Honorable Malcolm Augustine

FROM: Danna L. Kauffman
Pamela Metz Kasemeyer
J. Steven Wise
Richard A. Tabuteau

DATE: February 26, 2020

RE: **SUPPORT** – Senate Bill 661 – *Health Insurance – Prostate Cancer Screening – Prohibition Cost-Sharing*

On behalf of the Maryland State Medical Society and the Maryland/District of Columbia Society of Clinical Oncology (MDCSCO), we **support** Senate Bill 661.

Prostate cancer can often be found early by testing for prostate-specific antigen (PSA) levels in a blood test or during a digital rectal exam. According to the American Urological Association, prostate cancer is the second-leading cause of cancer deaths for men in the United States, with about 1 in 9 men being diagnosed with prostate cancer in their lifetime.

Recognizing this, Maryland law already requires carriers to provide coverage for the expenses incurred in conducting a medically recognized diagnostic examination which includes a digital rectal exam and a blood test called the prostate–specific antigen test: (1) for men who are between 40 and 75 years of age; (2) when used for the purpose of guiding patient management in monitoring the response to prostate cancer treatment; (3) when used for staging in determining the need for a bone scan in patients with prostate cancer; or (4) when used for male patients who are at high risk for prostate cancer.

However, while these tests are covered, copays and other cost-sharing requirements still apply. Eliminating co-pays and other cost-sharing will hopefully increase utilization, thereby detecting prostate cancer early, which will ultimately reduce medical costs and, more importantly, save lives. A favorable report is requested.

For more information call:
Danna L. Kauffman
Pamela Metz Kasemeyer
J. Steven Wise
Richard A. Tabuteau
410-244-7000

Sen. Augustine_FAV_SB661
Uploaded by: Senator Augustine, Senator Augustine
Position: FAV

MALCOLM AUGUSTINE
Legislative District 47
Prince George's County

Finance Committee
Energy and Public Utilities Subcommittee

Senate Chair, Joint Committee on the Management of Public Funds

THE SENATE OF MARYLAND
ANNAPOLIS, MARYLAND 21401

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February 26, 2020

The Honorable Delores G. Kelley
Chair, Senate Finance Committee
3 East Miller Senate Office Building
Annapolis, MD 21401

SUPPORT
SB 661 Health Insurance – Prostate Cancer Screening – Prohibiting Cost Sharing

Dear Chairman Kelley:

Thank you for presiding over today's hearing regarding SB 661, a bill I am proud to sponsor. SB 661 would prohibit burdensome and unnecessary cost-sharing for prostate cancer screening. When caught early, prostate cancer has a likelihood of survival, which is why it's crucial to make disease screening accessible and affordable.

I'm proud that Maryland has a current law that requires insurers to cover prostate-specific-antigen (PSA) screening tests. This simple blood test can detect the presence of prostate cancer in the body. However, insurers may still apply cost-sharing to PSAs in the form of copayments, deductibles, and coinsurance to patients. I am asking that members of this esteemed legislative body consider prohibiting any form of cost-sharing on PSA screenings, to save the lives of men across this fine state.

This year in Maryland, prostate cancer will be the most commonly diagnosed cancer among men, and is second in overall cancer diagnoses only compared to breast cancer in women in the state. Prostate cancer is similar genetically to breast cancer and has nearly the same incidence rates for women as prostate cancer for men. Currently, through an act of Congress, there is no cost-sharing for mammograms. Also, through the ACA, there is no cost-sharing for cervical cancer screenings. Given the similarities of these diseases in prevalence and scientific makeup, it would only be fair to prohibit cost-sharing for PSA tests. This would eliminate the cost burden for men to receive the test, just as women do not have a cost burden for mammograms and cervical cancer screenings.

In 2019, Maryland had the eighth-highest prostate cancer incidence rate in the country. This may be in part due to the high African American male population in this state African American men are at an increased risk for developing prostate cancer over white men and other men of color. One in six African American men will develop

MALCOLM AUGUSTINE
Legislative District 47
Prince George's County

Finance Committee
Energy and Public Utilities Subcommittee

Senate Chair, Joint Committee on the Management of Public Funds

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prostate cancer in his lifetime. African American men are 1.8 times more likely to be diagnosed with—and 2.2 times more likely to die from—prostate cancer than white men. African American men are also slightly more likely than white men to be diagnosed with advanced disease. Prohibiting cost-sharing for PSA screening can potentially alter these statistics, and help African American men catch the disease early, and beat it.

It's especially important to make screening for this awful disease accessible and affordable since prostate cancer deaths are on the rise. New reporting from the American Cancer Society shows that in 2020, the number of men who will die from prostate cancer will hit a record high over the last two decades, with an increase of 5 percent since just last year. When caught early, prostate cancer has a 99 percent chance of survival; this is three times higher than when prostate cancer is found in an advanced stage, which has only a 30 percent rate of survival. By making the PSA test accessible and affordable, more Maryland men can have their lives saved from cancer.

Removing barriers to the PSA screening test and diagnosing prostate cancer at an earlier stage is much more cost-effective than treating late-stage prostate cancer. We are all here today because we care about the lives and wellbeing of Maryland citizens. I encourage you to consider the lifesaving and life changing impact SB 661 could have on the men of Maryland.

Thank you for the opportunity to provide testimony on SB 661. **I urge your support of SB 661.**

Sincerely,

Senator Malcolm Augustine
Democrat, District 47, Prince George's County

MD Health Care Comm_INFO_SB 661
Uploaded by: Renfrew, Megan
Position: INFO

STATE OF MARYLAND

Andrew N. Pollak
CHAIR

Ben Steffen
EXECUTIVE DIRECTOR

MARYLAND HEALTH CARE COMMISSION

4160 PATTERSON AVENUE – BALTIMORE, MARYLAND 21215
TELEPHONE: 410-764-3460 FAX: 410-358-1236

February 24, 2020

The Honorable Delores G. Kelley
Chair, Senate Finance Committee
3 East, Miller Senate Office Building
Annapolis, MD 21401

RE: SB 661 – Health Insurance – Prostate Cancer Screening – Prohibiting Cost-Sharing - INFORMATION

Dear Chair Kelley:

The Maryland Health Care Commission ("Commission") is pleased to provide the Senate Finance Committee with information related to Senate Bill 661 (SB 661). SB 661 would modify the mandate that health insurers cover certain prostate cancer screening services[1] to 1) prohibit carriers from imposing cost-sharing requirements on these services or 2) reducing or eliminating of health insurance coverage doe to the benefit mandate related to prostate cancer screening services. The current prostate cancer screening mandate applies to males between 40 and 75 years of age.

In response a request from Health and Government Operations Committee Vice-Chair Peña-Melnyk in December, the Commission used the Maryland Medical Care Data Base (MCDB), to estimate the impact of mandating the elimination these cost-sharing requirements. The Commission estimates that the elimination of cost-sharing will add about $0.03 per member per month (PMPM) to fully insured health care premiums (or about $0.35 per year), approximately one quarter of the total PMPM of allowed charges for prostate cancer screening in fully-insured health benefit plans in Maryland.[2]

[1] Specifically, Insurance Article §15-825 requires that insurers, nonprofit health service plans, and health maintenance organizations cover digital rectal exams and the prostate-specific antigen (PSA) test.
[2] For purposes of this analysis, the Commission assumed that the elimination of cost-sharing would only apply to the 40-75 year old male population impacted by the prostate cancer screening mandate, but that the PMPM premium costs would impact all fully-insured health insurance plan members (i.e. no age restriction). This analysis included the fully insured individual market, small group market, and large group market (including the Federal employees Health Benefits Program).

Note: The Maryland Health Care Commission is an independent State agency. The position of the Commission may differ from the Maryland Department of Health.

Table 1: Utilization and Cost of Prostate Cancer Screening.					
Study Year	**No. of Services per 1,000 Members**	**Utilization Trend**	**Cost per Service (age 40 – 75)**	**PMPM**	
				Allowed Charges	**Member Cost Share**
2018	79	5.2%	$17.7	$0.12	**$0.03**
2017	75	8.7%	$18.4	$0.12	**$0.03**
2016	69		$17.6	$0.10	**$0.03**

As shown in table 1, the results of our analysis indicate that the cost impact, if the member out of pocket (OOP) cost requirements for the PSA screening and DRE were eliminated, is about $0.03 per member per month (PMPM). We would expect this cost to remain relatively flat over time, as there was little to no variation in the member OOP costs over the last three years (2016 - 2018). The cost per service for the 40 to 75 age range (at about $18) and the PMPM allowed charges across the entire fully-insured population (at about $0.12) have been relatively stable over the last three years despite modest increases in utilization over this time period.

About 23% (283,036 members per month on average) of the entire 2018 private fully-insured population is between ages 40 and 75 (inclusive). Of that 23%, about 31.8% (or 89,983 males) had a prostate cancer screening during 2018. These 89,983 males are about 7.3% of the fully-insured population.

The Commission does not believe that the elimination of member cost-sharing will fuel excessive demand for the test because of the emphasis on shared decision making in accessing the value of the PSA screening.

For more detail on this analysis, a copy of the Commission's January 27, 2020 letter to Delegate Peña-Melnyk is enclosed.

I hope you find this information useful. Please feel free to contact me at (410) 764-3566 or Ben.Steffen@maryland.gov, or Megan Renfrew, Government Affairs and Special Projects, at (410) 764-3483 or Megan.Renfrew@maryland.gov if you have any questions.

Sincerely,

Ben Steffen
Executive Director
Maryland Health Care Commission

Enclosure

Note: The Maryland Health Care Commission is an independent State agency, and the position of the Commission may differ from the position of the Maryland Department of Health.

STATE OF MARYLAND

Andrew N. Pollak, MD
CHAIR

Ben Steffen
EXECUTIVE DIRECTOR

MARYLAND HEALTH CARE COMMISSION

4160 PATTERSON AVENUE – BALTIMORE, MARYLAND 21215
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January 27, 2020

The Honorable Joseline Peña-Melnyk
Vice Chair, Health and Government Operations Committee
Maryland House of Delegates
6 Bladen St., Room 241
Annapolis, MD 21401-1991

RE: Request for Cost Estimate to Eliminate Cost Sharing for Prostate Cancer Screening

Dear Vice-Chair Peña-Melnyk:

The Maryland Health Care Commission (MHCC) is pleased to submit this response to your December 12, 2019 letter requesting a study to estimate the cost impact of eliminating the cost sharing requirements for the prostate specific antigen (PSA) screening test and digital rectal examination (DRE). Pursuant to Insurance Article §15-825, Annotated Code of Maryland, this member out-of-pocket (OOP) cost elimination would apply to all males between 40 and 75 years of age. The MHCC estimates that the elimination of cost-sharing will add about $0.03 per member per month or about $0.35 per year to privately insured health care premiums.

MHCC used the Maryland Medical Care Data Base (MCDB), the main component of Maryland's Multi-Payer Claims Database, as the data source for this analysis. Specifically, institutional files (outpatient only), professional services files, and eligibility files were used. The MCDB population is all Maryland residents who are enrolled in private fully-insured health plans. For purposes of this analysis, only the claims experience for males between 40 and 75 years of age were selected from the MCDB, since the cost elimination would only apply to that cohort. However, when calculating the per member per month (PMPM) costs, the entire fully insured population (i.e., no age restriction) including the individual market, the small group market, and the large group market including those covered in the Federal Employees Health Benefits (FEHB) Program, was used to calculate member exposure. Finally, the CPT codes used in this analysis included: 84152, 84153, G0102, and G0103.

As shown in the table below, the results of our analysis indicate that the cost impact, if the member out of pocket (OOP) cost requirements for the PSA screening and DRE were eliminated, is about $0.03 per member per month (PMPM). We would expect this cost to remain relatively flat with modest increases in utilization for men between ages 40 and 75 since there was little to no variation in the member OOP costs over the last three years (2016 - 2018). The cost per service for the 40 to 75 age range (at about $18) and the PMPM allowed charges across the entire fully-insured population (at about $0.12) have been relatively stable over the last three years despite increases in utilization.

Study Year	No. of Services per 1,000 Members	Utilization Trend	Cost per Service (age 40 – 75)	PMPM	
				Allowed Charges	Member Cost Share
2018	79	5.2%	$17.7	$0.12	**$0.03**
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2016	69		$17.6	$0.10	**$0.03**

About 23% (283,036 members per month on average) of the entire 2018 private fully-insured population is between ages 40 and 75 (inclusive). Of that 23%, about 31.8% (or 89,983 males) had a prostate cancer screening during 2018. These 89,983 males are about 7.3% of the fully-insured population.

Using the average 2018 PMPM premiums by market ($547 for individual, $448 for small group, and $485 for fully-insured large group) from MHCC's "*Study of Mandated Health Insurance Services as Required Under Insurance Article §15-1502"* the estimated cost for eliminating the member cost-sharing is about 0.01% of premium across all markets (individual, small group, and fully-insured large group). Although the costs for the illness burden for the privately fully-insured population, level of benefit coverage, and medical management will vary by insurance market due to differences in health insurance carrier medical management and care coordination, information from carriers is not available to quantify such differences. Therefore, the same estimated PMPM premium impact for each market was used across all carriers.

MHCC does not believe that the elimination of member cost-sharing will fuel excessive demand for the test because of the emphasis on shared decision making in accessing the value of the PSA screening.

The U.S. Preventive Services Task Force (USPSTF), the organization that makes recommendations about the effectiveness of specific preventive care services for patients without visible related signs or symptoms, gives PSA screening a C rating (there is at least moderate certainty of net benefit) for men aged 55 to 69 years. They advise that the decision to undergo periodic PSA screening for prostate cancer should be an individual one, made in consultation with a clinician taking into account a patient's assessment of benefits and harms and factoring in risks based on family history, race/ethnicity, comorbid medical conditions, and patient values about the benefits and harms of screening. The USPSTF recognizes the test offers a small potential benefit of reducing the chance of death from prostate cancer but also emphasizes that

some men will experience potential harms of screening, including false-positive results that require additional testing and possible prostate biopsy; overdiagnosis and overtreatment; and treatment complications, such as incontinence and erectile dysfunction.

The American Cancer Society (ACS) takes a more proactive approach to screening but also emphasizes individual decision making in assessing benefits versus risks with the option for screening presented to patients beginning at age 50 or who are at average risk of prostate cancer; beginning at age 45 for men at high risk for developing prostate cancer (including African American men who have a first-degree relative with prostate cancer); and beginning at age 40 for men with more than one first-degree relative who had prostate cancer at an early age. The American Urological Association's (AUA) recommendations largely parallel those of the ACS with the exception that they do not distinguish between men at high and the highest risks.

African American men have a higher incidence of prostate cancer, increased prostate cancer mortality, and earlier age of diagnoses compared to white American men. This observation is attributable to a greater risk of developing preclinical prostate cancer and a higher likelihood that a preclinical tumor will spread. The ACS and AUA believe it is reasonable for African American men to consider to begin shared decision-making about PSA screening at earlier ages and to consider screening at annual intervals. Also of note, none of the standard-setting organizations recommend routine PSA screening for men over age 70 with no symptoms.

If you have any questions related to these findings, please do not hesitate to contact me at 410-764-3566 or ben.steffen@maryland.gov.

Sincerely,

Ben Steffen
Executive Director

cc: Megan Renfrew, Chief of Government Relations and Special Projects, MHCC