Sen. Ellis Written Testimony - SB0078_Finance.pdf
Uploaded by: Arthur Ellis
Position: FAV

Arthur Ellis, CPA
Legislative District 28
Charles County

Deputy Majority Leader

Finance Committee

Vice Chair, Rules Committee

Senate Chair
Joint Committee on the
Management of Public Funds

Senate Chair
Joint Committee on
Workers' Compensation Benefit and
Insurance Oversight

Senate Chair, Charles County Delegation

Chair, Select Committee Southern
Maryland

THE SENATE OF MARYLAND
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Sponsor Written Testimony: Favorable
Senate Bill 0078: Public Health – Prostate-Specific Antigen Testing (Protect Our Prostate Act)

February 10, 2026

Chair Beidle, Vice Chair Hayes, and colleagues of the Senate Finance Committee:

I am pleased to sponsor and request a favorable report on this important public health legislation, which strengthens patient protections and promotes accurate, responsible use of prostate–specific antigen (PSA) testing in Maryland.

According to the American Cancer Society, "about 1 in 8 men will be diagnosed with prostate cancer during their lifetime," and in the United States, an estimated "333,830 new cases" are expected in 2026.[1] The Centers for Disease Control and Prevention (CDC), and the National Cancer Institute suggests that PSA testing is widely used as a screening tool to help detect prostate cancer early, often before symptoms develop. Early detection through PSA testing can lead to timely intervention and improved outcomes for patients; however it is an imperfect tool. Unfortunately, false–positive results are common. About 6%–7% of men have a false-positive PSA test on any given screening round, and only about 25% of men who have a biopsy due to an elevated PSA level are found to have prostate cancer.[2] Because of these findings, there is an urgent need for integrating higher laboratory standards for patients receiving prostate-specific antigen testing.

By promoting standardized laboratory practices and enhanced patient education, Senate Bill 0078 aligns with the core principles of evidence–based screening. For these reasons, I respectfully urge the Senate Finance Committee to issue a favorable report on Senate Bill 0078.

Sincerely,

Arthur Ellis, CPA

[1] American Cancer Society. "Key Statistics for Prostate Cancer." https://www.cancer.org/cancer/types/prostate-cancer/about/key-statistics.html

[2] Grubb RL 3rd, Pinsky PF, Greenlee RT, et al. Prostate cancer screening in the Prostate, Lung, Colorectal and Ovarian cancer screening trial: Update on findings from the initial four rounds of screening in a randomized trial. *BJU International* 2008; 102(11):1524–1530.

SB78_MdPHA.pdf
Uploaded by: Ilona Kabara
Position: FAV

Mission: *To improve public health in Maryland through education and advocacy* ***Vision:*** *Healthy Marylanders living in Healthy Communities*

Testimony In Support of SB0078
Public Health – Prostate–Specific Antigen Testing (Protect Our Prostate Act)
Before the Finance Committee
By: Maryland Public Health Association (MdPHA)
February 12, 2026

Dear Chair Beidle and Members of the Senate Finance Committee,

We submit this written testimony in favorable support of Senate Bill 78, which proposes evidence-based safeguards to improve the accuracy, standardization, and transparency of prostate-specific antigen testing in Maryland.

Prostate-specific antigen (PSA) testing remains a central tool in prostate cancer screening, but it is also well documented as a diagnostic test that carries substantial risks of false-positive results, invasive procedures, and overtreatment. Senate Bill 78, the Protect Our Prostate Act, provides a measured, evidence-based response to these challenges by strengthening safeguards around PSA testing in Maryland.

Medical literature consistently demonstrates that PSA levels are highly sensitive to external factors unrelated to cancer, including ejaculation within 48 hours of testing, urinary tract infections, prostatitis, and recent prostate manipulation. Studies show that ejaculation alone can increase PSA levels in up to 87% of individuals, with effects lasting up to two days [1]. Infections and inflammation can further elevate PSA, increasing the likelihood of misleading results [2]. SB 78 addresses this by requiring clear, written patient preparation guidance, reducing preventable false-positive findings and unnecessary downstream interventions. Published studies estimate PSA false-positive rates ranging from 15% to over 70%, depending on the population and threshold used [3–5]. One real-world cohort study found a false-positive rate of 46.6%, meaning nearly half of men with elevated PSA did not have prostate cancer [6]. These results often lead to invasive prostate biopsies, which carry documented risks including infection, bleeding, hospitalization, and long-term anxiety [7–10].

SB 78 also addresses the lack of standardization in PSA testing methodologies. PSA assays may be calibrated to either the Hybritech or World Health Organization (WHO) standard, yielding results that can differ by 20–25% despite no true biological change [11–12]. By requiring

laboratories to use nationally recognized calibration standards, standardized reporting units, and clear disclosure of assay methodology, SB 78 promotes transparency and safer clinical interpretation. Importantly, the bill does not restrict access to PSA testing nor impose unreasonable burdens on laboratories. Instead, it aligns testing practices with FDA-approved assays, recognized proficiency standards, and best practices recommended by professional medical organizations.

Prostate cancer remains a significant public health concern, and PSA testing continues to play an important role in early detection. SB 78 strengthens that role by improving accuracy, reducing avoidable harm, and supporting informed decision-making. We respectfully urge a favorable report on Senate Bill 78.

The Maryland Public Health Association (MdPHA) is a nonprofit, statewide organization of public health professionals dedicated to improving the lives of all Marylanders through education, advocacy, and collaboration. We support public policies consistent with our vision of healthy Marylanders living in healthy, equitable, communities. MdPHA is the state affiliate of the American Public Health Association, a nearly 145-year-old professional organization dedicated to improving population health and reducing the health disparities that plague our state and our nation.

Maryland Public Health Association (MdPHA)
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[1] Byram Healthcare. (2023). What to avoid before a PSA test. Accessed January 30, 2026. https://www.byramhealthcare.com/blogs/things-to-avoid-before-a-psa-test
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[3] MedStar Health. How doctors are screening smarter for prostate cancer. Accessed January 30, 2026. https://www.medstarhealth.org/news-and-publications/news/screening-smarter-prostate-cancer
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[12] Stephan C. (2009). Prostate cancer: WHO standardization of PSA tests: clinical consequences. Nature reviews. Urology, 6(6), 303–305. https://doi.org/10.1038/nrurol.2009.94

SB 78 Written Testimony.pdf
Uploaded by: Lasava Tidwell
Position: FAV

Committee: Finance

Bill Number: SB 78 – Public Health – Prostate Specific Antigen Testing (Protect our Prostate Act)

Date: February 12, 2026

Chair Beidle, Vice Chair Hayes and Members of the Finance Committee:

My name is Lasava Tidwell and I am here to express my support for SB 78 the *Protect our Prostate Act.* For several years I served as the Co-Chair of Omega Psi Phi Fraternity Incorporated, Pi Omega Graduate Chapter's Staying Alive Community Health Festival Committee. I worked with the Chair, Clarence Jeffers, and RPh, to bring prostate screenings as well as other health related screenings to our underserved West Baltimore Communities. Over a ten-year period prior to Covid we successfully partnered with Chesapeake Urology to bring prostate screenings to black men in the communities we serve. Having had careers in the fields of Microbiology and the Pharmaceutical Industry I know the importance of prostate screenings for early detection of prostate cancer. Again I am here and we are here to express our strong support for SB 78, the *Protect our Prostate Act.*

Research consistently shows black men in the U.S. have the highest prostate cancer incidence and mortality rates, facing a 2.2 - fold higher risk of death and often developing more aggressive disease 3-9 years earlier than other men.

We know prostate–specific antigen testing, while an important tool for the early detection of prostate cancer, is not a definitive diagnostic tool and can produce misleading results that could lead to invasive biopsies or over treatment which can lead to participants anxiety, depression, and stress that impact their quality of life. We also know that the more standardized and more uniform testing requirements will be beneficial to participants and will allow them to make better decisions and achieve better outcomes for themselves and their families. This bill will ensure testing consistency for prostate-specific antigen testing across testing laboratories and home testing kits as well.

We urge you to vote in favor of this bill and help create a safer, healthier and better quality of life for the communities we serve. Thank you for your time and commitment.

Respectfully submitted,

Lasava S. Tidwell, Co-Chair Staying Alive Community Health Festival Committee

Pi Omega Chapter, Omega Psi Phi Fraternity, Incorporated

Leroy Finch Testimony on Protect our Prosate Act [

Uploaded by: Leroy Finch Jr

Position: FAV

Committee: Finance

Bill Number: SB 78 – Public Health – Prostate Specific Antigen Testing (Protect our Prostate Act)

Date: February 12, 2026

Chair Beidle, Vice Chair Hayes and Members of the Finance Committee:

Good afternoon. My name is Leroy Finch Jr, and in February 2023, at the age of 50, I was diagnosed with prostate cancer. It started with a routine PSA test, which revealed higher-than-normal levels for my age. After a biopsy, it was confirmed that I did, in fact, have prostate cancer. Naturally, I was anxious, but my doctor took his time to thoroughly explain the results and helped me understand all my options. This support was crucial as I navigated my next steps.

Together, we discussed several treatment paths, weighing the benefits and risks of each. Ultimately, I chose Active Surveillance, and I am currently getting my PSA levels checked every six months along with an MRI or biopsy every few years, as needed. So far, my cancer has remained confined to a small area within one section of my prostate. If this remains the case, I will continue with Active Surveillance, knowing that my condition is closely monitored.

I am grateful to have a range of options and the ongoing monitoring that allows me to reevaluate my treatment plan every six months. This approach has given me some comfort, knowing that if anything changes, I can quickly address those changes with my doctor.

I fully support this bill because I believe it will help standardize discussions about prostate cancer, PSA screenings, and treatment options. I also believe this bill will ensure that others receive the same thoughtful guidance and care that I did. Thank you.

Respectfully submitted,

Leroy Finch Jr.

Pi Omega Chapter, Omega Psi Phi Fraternity, Inc.

SB0078_Written_Testimony_Dr_Okey_K_Enyia_February
Uploaded by: Okey Enyia
Position: FAV

Written Testimony in Support of SB0078

Maryland Senate Bill 78 (SB0078) – Public Health – Prostate-Specific Antigen Testing (Protect Our Prostate Act)
Senate Finance Committee

Position: FAVORABLE

Submitted by:
Okey K. Enyia, DrPH, MPH
Government Relations Executive | Health Policy Researcher | Founder & CEO, Enyia Strategies, LLC
NIH Research Scholar (All of Us Research Program)
Author, The John Henry Health Equity Playbook: A Four-Year Health Policy Agenda for Men
Deputy Surgeon General, Alpha Phi Alpha Fraternity, Inc.
Chairman, Healthcare Disparities Subcommittee
Chairman, Men's Health & Wellness Committee, Million Men Vote, Inc.
Member, American Public Health Association Men's Health Caucus (Policy Committee)

Chair and Members of the Senate Finance Committee:

Thank you for the opportunity to submit testimony in strong support of SB0078, the Protect Our Prostate Act. This bill represents a commonsense, patient-centered improvement to prostate-specific antigen (PSA) testing practices in Maryland.

This legislation is deeply personal. My father and three uncles are prostate cancer survivors. Like many families, ours has experienced the anxiety, confusion, and uncertainty that can arise from inconsistent PSA testing practices and unclear interpretation of results.

Prostate cancer disproportionately affects Black men. National data show that Black men experience substantially higher incidence and mortality rates compared to White men. These disparities demand policy responses that improve both early detection and the quality of information used to guide care decisions.

SB0078 strengthens PSA testing by:
• Requiring written patient preparation guidance to reduce false or misleading results
• Mandating standardized calibration using internationally recognized reference standards
• Requiring standardized reporting in nanograms per milliliter with assay-specific reference ranges
• Increasing transparency by disclosing assay methodology, manufacturer, and lot number to ordering providers
• Reinforcing quality assurance through participation in recognized proficiency testing programs

These reforms improve clinical decision-making, reduce unnecessary downstream procedures, and enhance patient trust. Importantly, they do so without imposing undue burden on providers or laboratories.

As outlined in my book, The John Henry Health Equity Playbook, improving men's health outcomes requires strengthening health systems and removing avoidable sources of harm—particularly for communities bearing disproportionate risk.

For these reasons, I respectfully urge the Senate Finance Committee to issue a FAVORABLE report on SB0078.

Respectfully submitted,

Dr. Okey K. Enyia

Testimony in support of SB0078 - Protect Our Prost

Uploaded by: Richard KAP Kaplowitz

Position: FAV

SB0078_RichardKaplowitz_FAV

02/12/2026

Richard Keith Kaplowitz
Frederick, MD 21703

TESTIMONY ON SB#/0078- POSITION: FAVORABLE

Public Health – Prostate–Specific Antigen Testing (Protect Our Prostate Act)

TO: Chair Beidle, Vice Chair Hayes, and members of the Finance Committee
FROM: Richard Keith Kaplowitz

My name is Richard Keith Kaplowitz. I am a resident of District 3, Frederick County. I am submitting this testimony in support of SB#/0078, **Public Health – Prostate–Specific Antigen Testing (Protect Our Prostate Act)**

As a person being treated for prostate health with a family history of problems the receipt of accurate reports and information about the testing is critical for me to make informed decisions in consultation with my urologist.

This bill will require certain providers and laboratories to provide certain written information to patients receiving prostate-specific antigen testing; and requiring clinical laboratories that administer prostate-specific antigen tests to follow certain disclosure requirements, use standard calibration for testing assays and report test results in a standard manner, make certain disclosures to ordering providers, and follow guidelines from certain organizations.

This is a consumer protection measure related to processes and procedures for testing and communication of results. As an affected individual by the requirements this bill would implement I believe it to be a necessary step to protect my and other's health.

I respectfully urge this committee to return a favorable report on SB#/0078.

SB0078_UNF_MedChi_PH - Prostate-Specific Antigen T

Uploaded by: Drew Vetter
Position: UNF

MedChi

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Senate Finance Committee
February 12, 2026
Senate Bill 78 – *Public Health – Prostate-Specific Antigen Testing (Protect Our Prostate Act)*
POSITION: OPPOSE

The Maryland State Medical Society (MedChi), the largest physician organization in Maryland, **opposes** Senate Bill 78.

Senate Bill 78 proposes several new requirements governing how health care providers and clinical laboratories administer, disclose, and report prostate-specific antigen (PSA) test results. Specifically, providers and laboratories must provide the patient with written information on the necessary preparation to ensure accurate test results. The bill also includes specific requirements for clinical laboratories that perform PSA tests.

While MedChi strongly supports the importance of PSA testing, we question whether the bill is necessary given that PSA testing is already guided by evidence-based recommendations from nationally recognized organizations, including the American Urological Association, including when testing is recommended and appropriate patient counseling prior to PSA testing. The standard of care already includes shared physician-patient decision-making regarding PSA testing, making the new statutory mandates under this bill redundant. Furthermore, we are concerned that additional requirements for providers and labs may create confusion among patients and lead to reluctance to undergo this critically important testing and discourage appropriate screening from taking place. We are also concerned that the additional requirements may discourage some providers from ordering appropriate screening to avoid violating the new law. Instead, we believe that patients with an elevated PSA should continue to consult their physician or urologist for appropriate counseling and shared decision-making regarding necessary follow-up steps.

We share the sponsor's concern about the evaluation and management of PSA testing and prostate cancer, but believe this bill is duplicative, and the additional requirements are potentially detrimental. For these reasons, MedChi urges an unfavorable report on Senate Bill 78.

For more information call:
Andrew G. Vetter
J. Steven Wise
Danna L. Kauffman
Christine K. Krone
410-244-7000

Public Comment - MD SB78 - Genzen - PSA Testing.pd
Uploaded by: Jonathan Genzen
Position: UNF

ARUP LABORATORIES

A nonprofit enterprise of the University of Utah and its Department of Pathology

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February 9, 2026

Dr. Jonathan R. Genzen
ARUP Laboratories
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Salt Lake City, UT 84108

RE: Maryland Senate Bill 78 – "Protect Our Prostate Act" (MD SB78)

Dear Senator Ellis and members of the Maryland Senate,

I am providing this letter to express my concern that certain aspects of MD SB78 may not be logistically feasible for many clinical laboratories and could actually have unanticipated negative impacts on patient care. I request that you please consider making edits to the bill prior to advancing MD SB78 for further discussion.

As a brief introduction, I serve as Chief Medical Officer and Senior Director of Government Affairs at ARUP Laboratories, a non-profit enterprise of the University of Utah Department of Pathology. ARUP is the nation's largest non-profit clinical reference laboratory, with hospital customers in all 50 states, including Maryland. I am providing this letter in my government affairs capacity at ARUP Laboratories and as a practicing clinical pathologist with expertise in diagnostic testing modalities, including the screening for prostate specific antigen (PSA). My New York State Certificate of Qualification includes Clinical Chemistry testing, which includes the measurement of soluble tumor markers such as PSA.

I have three primary concerns with the proposed legislation, as currently drafted.

1. LOT NUMBER REPORTING REQUIREMENT

My first concern regards the requirement to report "lot number" (i.e., the lot of reagent material used for a particular test) to providers:

> *(4) "DOCUMENT AND DISCLOSE TO THE ORDERING PROVIDER THE TEST METHODOLOGY, MANUFACTURER, AND LOT NUMBER OF THE TESTING ASSAY USED"*

Clinical and Operational Concerns

A clinical laboratory information system (LIS), the computer system used to transmit laboratory data, is not typically configured for the reporting of reagent lot numbers. Reporting of lot numbers to providers is not a federal requirement under CLIA (the Clinical Laboratory Improvement Amendments of 1988) – the federal law that governs clinical laboratory testing across the country – and while documentation of lot

numbers in use are maintained and recorded in most laboratory settings, this is typically only contained within new lot validation paperwork and is not stored in conjunction with patient clinical results.

Reporting of PSA lot numbers to providers with results conceivably could only be conducted using one of two mechanisms: 1) as part of interpretive comments, or 2) as unique data elements typically used for laboratory results. **There are significant problems with using either mechanism for PSA reagent lot number reporting**.

First, interpretive comments for PSA test results are typically hard coded within the LIS and cannot be quickly and easily updated every time a new lot validation is completed and prior to the reagent being put into use (e.g., every few weeks to months, often with short notice based on reagent availability/delivery from manufacturers). For example, reagent changes may occur overnight or during weekends when IT resources may be limited or unavailable.

Second, and more clinically concerning to me as a laboratory director, **reporting lot numbers as discrete data elements could lead to significant patient harm, as clinicians may inadvertently mistake a lot number with an actual PSA result!** Such a "false positive" interpretation by a provider (easy to do, since discrete data elements are often charted in electronic health records in a manner that could easily make them appear to be test results), could erroneously lead to an unnecessary prostate biopsy. I believe this is counter to the intended goal of the legislation.

Fortunately, reporting lot numbers is generally *NOT* considered necessary for clinical laboratory reporting, as assay calibration already adjusts for lot-to-lot variability automatically. If an assay is appropriately calibrated to an international standard (e.g., WHO), the reagent lot used is generally of no clinical benefit to a provider. Reporting of lot numbers for calibrated PSA assays would therefore introduce patient risk with no actual patient benefit.

2. REQUIREMENT FOR FDA APPROVAL

I have additional concerns regarding the unintended impact of another requirement:

> *"(1) USE TESTING ASSAYS THAT HAVE BEEN APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION"*

Clinical and Operational Concerns

First, it is likely that most commercial PSA assays have FDA *clearance* through the 510k pathway, not FDA *approval* through the FDA premarket authorization (PMA pathway). The PMA pathway of FDA approval is typically only required of new, high-risk tests for which a predicate device is not already on the market. PSA assays, however, are well researched and well understood, with many predicate devices already available to compare to. At minimum, I would suggest editing the language to specific "HAVE BEEN CLEARED OR APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION" to remove this limitation.

Second, while most PSA tests are *already* FDA-cleared, there may be other innovative types of prostate cancer screening tests that may *include* PSA measurement, but in conjunction with other markers, algorithms, or calculations that have not necessarily been reviewed in their entirety by the FDA. These types of tests are considered to be laboratory developed tests (LDTs), and they are permissible federally under CLIA. I am concerned that, as written, the act may prohibit access to any such current or future innovative LDTs containing PSA to patients in the state of Maryland.

3. REQUIREMENT FOR WORLD HEALTH ORGANIZATION ASSAY CALIBRATION

I have one final comment regarding the calibration requirement:

> *"(2) IMPLEMENT CALIBRATION OF PROSTATE–SPECIFIC ANTIGEN TEST ASSAYS USING WORLD HEALTH ORGANIZATION INTERNATIONAL STANDARDS OR ANOTHER NATIONALLY RECOGNIZED REFERENCE STANDARD;"*

Clinical and Operational Concerns

Requiring World Health Organization assay calibration (e.g., versus traditional Hybritech calibration) would require revalidations for many PSA and PSA-containing assays in clinical laboratories. Adoption of new calibrations takes time, resources, and frequently "patient re-baselining" to ensure that any switch in calibration is not misinterpreted by clinicians as a change in disease state. Additionally, clinicians need to be educated in new interpretive cutoff values that vary based on calibration of the assay used in their institution. While I am in favor of WHO / international standard calibrations, if this bill is advanced clinical laboratories will need sufficient time prior to enforcement to ensure that revalidation activities (and corresponding educational efforts to inform clinicians about changes in patient results due to new calibrations) are completed in a thorough and appropriate manner. I would suggest that a delayed enactment date (i.e., 12 months) would be sufficient time to complete such activities.

CONCLUSIONS

Given the above concerns, I oppose the bill as written and ask that the Senate remove the requirement for reporting lot number and remove the limitation regarding FDA approval from the proposed legislation. Additionally, I request that a delay in enforcement date be added for the reasons outlined above.

Thank you for your consideration, and please let me know if I can provide any additional information.

Jonathan R. Genzen, MD, PhD, MBA
Chief Medical Officer
Senior Director of Government Affairs

ARUP Laboratories
Email: jonathan.genzen@aruplab.com
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AUA_Opposition Letter _ MD_SB78.pdf
Uploaded by: Mark Edney, MD, MBA
Position: UNF

American Urological Association

January 26, 2026

RE: Opposition to SB 78

Dear Chairwoman Pamela Beidle,

On behalf of the American Urological Association, Inc. (AUA) we are writing to respectfully express our opposition to **SB 78**, legislation that would require providers and clinical laboratories to provide written information to patients each time a Prostate Specific Antigen (PSA) test is ordered, regardless of clinical context or prior counseling. The AUA is a globally engaged organization with more than 22,000 physicians, physician assistants, and advanced practice nursing members practicing in more than 100 countries. Our members represent the world's largest collection of expertise and insight into the treatment of urologic disease. Of the total AUA membership, more than 15,000 are based in the United States, including 297 licensed and practicing Maryland urologists who provide invaluable support to the urologic community by fostering the highest standards of urologic care through education, research, and the formulation of health policy.

We appreciate Senator Ellis's intent to ensure that patients are informed about PSA testing and the possibility of misleading results. However, as written, SB 78 creates substantial administrative and operational burdens without meaningfully advancing patient understanding or clinical accuracy. Our first concern with SB 78 is that the bill imposes excessive and duplicative administrative requirements. SB 78 requires that "if a provider orders a prostate–specific antigen test for a patient during a patient encounter, the provider shall provide written information to the patient relating to the necessary preparation for ensuring accurate test results." This requirement applies each time a prostate–specific antigen test (PSA) is ordered, even when patients undergo multiple PSA tests annually as part of regular monitoring. Such repetitive documentation requirements add unnecessary paperwork to already overburdened clinical workflows and divert limited provider time away from direct patient care.

Optimizing the use of PSA data is essential for accurately identifying men with clinically significant prostate cancer, and this requires allowing clinicians to interpret an inherently variable lab value within the broader context of patient history, risk factors, and complementary diagnostic tools. A burdensome written patient instruction mandate will have no effect on the interpretation of an inherently variable lab value that is best analyzed in the context of other tests and clinical parameters. Imposing additional administrative requirements would only create barriers to timely and efficient diagnosis without improving clinical accuracy. Such barriers to testing risk delaying evaluation for individuals already at elevated risk such as African American men and those with a significant family history of prostate cancer.

We share your commitment to ensuring patients make informed decisions about prostate cancer screening. However, SB 78's mandate for written instructions at every PSA order is unnecessarily

prescriptive, operationally burdensome, and misaligned with clinical best practices. For these reasons, we respectfully urge the Committee to **oppose SB 78.**

Thank you for your consideration. We welcome the opportunity to work together on approaches that better balance patient education with practical care delivery.

Sincerely,

Brian Duty, MD, MBA
Chair, State Advocacy Committee

Mark Edney, MD, MBA
Chair, Public Policy Committee