SENATE BILL 78

J1 6lr1485

(PRE–FILED)

By: **Senator Ellis**
Requested: October 30, 2025
Introduced and read first time: January 14, 2026
Assigned to: Finance

A BILL ENTITLED

AN ACT concerning

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

FOR the purpose of requiring certain providers and laboratories to provide certain written information to patients receiving prostate–specific antigen testing; 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; and generally relating to prostate–specific antigen testing.

BY adding to
Article – Health – General
Section 17–801 through 17–803 to be under the new subtitle "Subtitle 8. Prostate–Specific Antigen Testing"
Annotated Code of Maryland
(2023 Replacement Volume and 2025 Supplement)

Preamble

WHEREAS, 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 overtreatment; and

WHEREAS, Patients undergoing prostate–specific antigen testing should be adequately informed of the potential costs associated with the testing and the implications surrounding false–positive results; now, therefore,

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

EXPLANATION: **CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.**
[Brackets**]** indicate matter deleted from existing law.

Article – Health – General

SUBTITLE 8. PROSTATE–SPECIFIC ANTIGEN TESTING.

17–801.

(A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANING INDICATED.

(B) "CLINICAL LABORATORY" MEANS A FACILITY IN WHICH LABORATORY TESTING IS PERFORMED ON HUMAN SPECIMENS FOR DIAGNOSIS, PREVENTION, OR TREATMENT OF DISEASE.

(C) "PROSTATE–SPECIFIC ANTIGEN TEST" MEANS A LABORATORY BLOOD TEST THAT MEASURES THE CONCENTRATION OF PROSTATE–SPECIFIC ANTIGEN FOR USE IN DIAGNOSING A PROSTATE DISORDER.

17–802.

(A) 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.

(B) IF A CLINICAL LABORATORY OFFERS PROSTATE–SPECIFIC ANTIGEN TESTING WITHOUT A PROVIDER ORDER FROM A PATIENT ENCOUNTER, THE LABORATORY IN WHICH BLOOD IS DRAWN FOR THE TEST SHALL PROVIDE WRITTEN INFORMATION TO THE PATIENT RELATING TO THE NECESSARY PREPARATION FOR ENSURING ACCURATE TEST RESULTS THAT SHALL ALSO BE MADE:

(1) NOT LATER THAN 3 DAYS BEFORE A SCHEDULED APPOINTMENT; AND

(2) AVAILABLE THROUGH IN–PERSON EDUCATION.

17–803.

A CLINICAL LABORATORY ADMINISTERING A PROSTATE–SPECIFIC ANTIGEN TEST SHALL:

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

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

(3) REPORT PROSTATE–SPECIFIC ANTIGEN TEST RESULTS IN NANOGRAMS PER MILLILITER AND INCLUDE ANY REFERENCE RANGE UNIQUE TO THE TESTING ASSAY USED;

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

(5) PARTICIPATE IN A CLINICAL TESTING PROFICIENCY PROGRAM RELATING TO PROSTATE–SPECIFIC ANTIGEN TESTS THAT IS RECOGNIZED BY THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OR THE COLLEGE OF AMERICAN PATHOLOGISTS.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect July 1, 2026.