SENATE BILL 706

J2 1lr1855
CF HB 810

By: **Senator Feldman**
Introduced and read first time: February 3, 2021
Assigned to: Education, Health, and Environmental Affairs

A BILL ENTITLED

AN ACT concerning

Health Occupations – Pharmacists – Laboratory Tests

FOR the purpose of altering the definition of "practice pharmacy" to include the ordering and administering of certain laboratory tests; requiring, on or before a certain date, the State Board of Pharmacy to adopt regulations to authorize pharmacists to order and administer certain laboratory tests; requiring a pharmacist to take certain actions if the results of a certain laboratory test are not within a certain range; requiring the State Board of Pharmacy to report to the General Assembly on or before a certain date; providing for the termination of this Act; defining a certain term; and generally relating to the State Board of Pharmacy and the performance of laboratory tests by pharmacists.

BY repealing and reenacting, with amendments,
Article – Health Occupations
Section 12–101(x)
Annotated Code of Maryland
(2014 Replacement Volume and 2020 Supplement)

BY adding to
Article – Health Occupations
Section 12–513
Annotated Code of Maryland
(2014 Replacement Volume and 2020 Supplement)

Preamble

WHEREAS, Pharmacies are playing a pivotal role in the success of ordering and the administration of consumer–accessible COVID–19 tests; and

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

WHEREAS, It is further recognized that clinical laboratories have been essential in developing COVID–19 tests and running large volumes of needed COVID–19 tests during the COVID–19 pandemic emergency; and

WHEREAS, Cancer and other disease screenings have substantially been reduced and there is a concern that there will be an aftershock of other disease diagnoses and mortalities following the COVID–19 pandemic due to the screening reductions; and

WHEREAS, As a result, there is an increased need for expanded consumer access to COVID–19 tests and other disease screenings due to missed screenings during the pandemic, and anticipated long–term complications among some of those who were infected by the novel coronavirus; now, therefore,

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

Article – Health Occupations

12–101.

(x) (1) "Practice pharmacy" means to engage in any of the following activities:

(i) Providing pharmaceutical care;

(ii) Compounding, dispensing, or distributing prescription drugs or devices;

(iii) Compounding or dispensing nonprescription drugs or devices;

(iv) Monitoring prescriptions for prescription and nonprescription drugs or devices;

(v) Providing information, explanation, or recommendations to patients and health care practitioners about the safe and effective use of prescription or nonprescription drugs or devices;

(vi) Identifying and appraising problems concerning the use or monitoring of therapy with drugs or devices;

(vii) Acting within the parameters of a therapy management contract, as provided under Subtitle 6A of this title;

(viii) Administering vaccinations in accordance with § 12–508 of this title or self–administered drugs in accordance with § 12–509 of this title;

(ix) Delegating a pharmacy act to a registered pharmacy technician, pharmacy student, or an individual engaged in a Board approved pharmacy technician

training program;

(x) Supervising a delegated pharmacy act performed by a registered pharmacy technician, pharmacy student, or an individual engaged in a Board approved pharmacy technician training program;

(xi) Providing drug therapy management in accordance with § 19–713.6 of the Health – General Article; **[**or**]**

(xii) Prescribing and dispensing contraceptive medications and self–administered contraceptive devices approved by the U.S. Food and Drug Administration**; OR**

(XIII) ORDERING AND ADMINISTERING LABORATORY TESTS IN ACCORDANCE WITH REGULATIONS ADOPTED UNDER § 12–513 OF THIS TITLE.

(2) "Practice pharmacy" does not include the operations of a person who holds a permit issued under § 12–6C–03 of this title.

12–513.

(A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.

(2) "HEALTH AWARENESS" MEANS SCREENING FOR MEDICAL CONDITIONS.

(3) "HEALTH AWARENESS" DOES NOT INCLUDE MEDICAL SCREENING FOR A DEFINITIVE DIAGNOSIS.

(B) ON OR BEFORE JANUARY 1, 2022, THE BOARD SHALL ADOPT REGULATIONS AUTHORIZING A PHARMACIST TO ORDER AND ADMINISTER LABORATORY TESTS, WITHOUT A WRITTEN, ORAL, OR ELECTRONICALLY TRANSMITTED PRESCRIPTION FROM AN AUTHORIZED PRESCRIBER, THAT:

(1) ARE USED FOR HEALTH AWARENESS, INCLUDING SCREENING AND EARLY DISEASE DETECTION;

(2) ARE ANALYZED IN A HIGH COMPLEXITY CLINICAL LABORATORY THAT MEETS THE REQUIREMENTS OF THE FEDERAL CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA);

(3) MEASURE BIOMARKERS, INCLUDING:

(I) DEOXYRIBONUCLEIC ACID;

(II) RIBONUCLEIC ACID;

(III) PROTEINS;

(IV) ANTIBODIES;

(V) METABOLITES; OR

(VI) ANY OTHER CLINICAL VALUE THAT MAY ASSIST IN EARLY DETECTION, PREVENTION, OR MITIGATION OF DISEASE;

(4) USE BODILY SPECIMENS THAT CAN BE SAFELY AND EFFECTIVELY COLLECTED AT THE PHARMACY USING COLLECTION PARAPHERNALIA AND PROTOCOLS PROVIDED BY THE HIGH COMPLEXITY CLINICAL LABORATORY, INCLUDING:

(I) CAPILLARY BLOOD;

(II) URINE;

(III) SALIVA;

(IV) NASAL SPECIMENS; AND

(V) EXHALED BREATH; AND

(5) ARE PAID FOR BY A CONSUMER OR AN EMPLOYER OR ARE COVERED BY AN INSURANCE PLAN THAT EXPRESSLY AUTHORIZES THE ORDERING AND ADMINISTERING OF THE LABORATORY TEST BY A PHARMACIST.

(C) IF A PHARMACIST RECEIVES THE RESULTS FROM A LABORATORY TEST ADMINISTERED IN ACCORDANCE WITH REGULATIONS ADOPTED UNDER SUBSECTION (B) OF THIS SECTION THAT ARE NOT WITHIN THE DESIRED RANGE, THE PHARMACIST SHALL PROVIDE:

(1) THE RESULTS OF THE TEST TO THE CONSUMER'S PRIMARY CARE PROVIDER FOR FURTHER EVALUATION; OR

(2) IF A CONSUMER DOES NOT HAVE A PRIMARY CARE PROVIDER, THE CONSUMER WITH A REFERRAL TO A LICENSED INDEPENDENT PRACTITIONER FOR FURTHER EVALUATION.

SECTION 2. AND BE IT FURTHER ENACTED, That, on or before January 1, 2024, the State Board of Pharmacy shall submit a report to the General Assembly, in accordance with § 2–1257 of the State Government Article, on the implementation of Section 1 of this Act, and make recommendations on whether the provisions of Section 1 of this Act should be extended, modified, or terminated.

SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2021. It shall remain effective for a period of 3 years and, at the end of September 30, 2024, this Act, with no further action required by the General Assembly, shall be abrogated and of no further force and effect.