SENATE BILL 166

J1 0lr0770
CF 0lr0769

By: **Senator Kelley**
Introduced and read first time: January 13, 2020
Assigned to: Finance

A BILL ENTITLED

AN ACT concerning

Drugs and Devices – Electronic Prescriptions – Controlled Dangerous Substances

FOR the purpose of authorizing certain controlled dangerous substance prescriptions to be dispensed on an electronic prescription; requiring, except under certain circumstances, a certain health practitioner to issue a prescription for a controlled dangerous substance electronically; authorizing an authorized prescriber to issue a written or oral prescription for a controlled dangerous substance only under certain circumstances; requiring the Secretary of Health, in collaboration with the Maryland Health Care Commission, to adopt certain regulations regarding a certain waiver that includes certain provisions; authorizing the Secretary to issue a waiver that applies generally to a certain group of health practitioners or drugs; providing that a certain waiver shall apply to a certain health practitioner without requiring the health practitioner to go through a certain process; authorizing the Secretary to adopt certain regulations regarding certain exceptions to the requirement to issue an electronic prescription; requiring a certain health occupations board to take certain action against a health practitioner who violates certain provisions of this Act; authorizing a pharmacist to dispense a drug on a prescription transmitted in a certain manner under certain circumstances; providing that a pharmacist who receives certain prescriptions is not required to verify certain information about the prescription; altering the circumstances under which a pharmacist may refill and dispense a prescription; requiring the Maryland Health Care Commission to convene a certain workgroup; requiring the workgroup to study, evaluate, and make recommendations on certain matters; requiring the workgroup to report its findings and recommendations to certain committees of the General Assembly on or before a certain date; making conforming changes; providing for the construction of certain provisions of this Act; providing for a delayed effective date; providing for the termination of certain provisions of this Act; and generally relating to electronic prescriptions for controlled dangerous substances.

BY repealing and reenacting, with amendments,

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

Article – Criminal Law
Section 5–501, 5–504, and 5–701
Annotated Code of Maryland
(2012 Replacement Volume and 2019 Supplement)

BY repealing and reenacting, with amendments,
Article – Health – General
Section 21–220
Annotated Code of Maryland
(2019 Replacement Volume)

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

Article – Criminal Law

5–501.

(a) Except as provided in subsection (b) of this section, a person may not dispense a controlled dangerous substance without a written prescription **OR AN ELECTRONIC PRESCRIPTION** from an authorized provider if the substance is:

(1) listed in Schedule II; and

(2) a drug to which § 21–220 of the Health – General Article applies.

(b) A controlled dangerous substance to which subsection (a) of this section applies may be dispensed without a written prescription **OR AN ELECTRONIC PRESCRIPTION** by:

(1) an authorized provider who:

(i) is not a pharmacist; and

(ii) dispenses the controlled dangerous substance directly to an ultimate user; or

(2) a pharmacist if:

(i) an emergency exists;

(ii) the pharmacist dispenses the drug under regulations of the Department on an oral prescription that the pharmacist reduces promptly to writing and keeps on file; and

(iii) federal law authorizes the oral prescription.

(c) A prescription for a controlled dangerous substance listed in Schedule II shall be kept on file in conformity with the requirements for records and inventories under § 5–306 of this title.

(d) A person may not refill a prescription for a controlled dangerous substance listed in Schedule II.

5–504.

(a) Except when dispensed directly to an ultimate user by an authorized provider who is not a pharmacist, a controlled dangerous substance listed in Schedule III or Schedule IV that is a drug to which § 21–220 of the Health – General Article applies may not be dispensed without a written **PRESCRIPTION, AN ELECTRONIC PRESCRIPTION,** or **AN** oral prescription.

(b) Unless renewed by the authorized provider, the prescription may not be:

(1) filled or refilled more than 6 months after the date of prescription; or

(2) refilled more than five times.

5–701.

(a) Sections 5–701 through 5–704 of this subtitle apply to:

(1) the sale of prescription drugs by a manufacturer, wholesale distributor, retail pharmacist, or jobber to a person not legally qualified or authorized to purchase and hold prescription drugs for use or resale; and

(2) an authorized provider's assistant who is not licensed to administer prescription drugs.

(b) A person may not dispense a prescription drug except:

(1) on an authorized provider's:

(I) ELECTRONIC PRESCRIPTION;

[(i)**] (II)** written prescription; or

[(ii)**] (III)** oral prescription that the pharmacist reduces to writing and files; or

(2) by refilling a written **PRESCRIPTION, AN ELECTRONIC PRESCRIPTION,** or **AN** oral prescription that is authorized:

(i) by the authorized provider in the original prescription; or

(ii) by oral direction that the pharmacist reduces to writing and files.

(c) A person may not dispense a prescription drug by filling or refilling a written **PRESCRIPTION, AN ELECTRONIC PRESCRIPTION,** or **AN** oral prescription of an authorized provider unless the drug bears a label that, in addition to any requirements of the Department or federal law, contains:

(1) the name and address of the dispenser;

(2) the serial number and date of the prescription;

(3) the name of the authorized provider; and

(4) if stated in the prescription, the name and address of the patient and the directions for use.

(d) Except as otherwise provided under this title, a person may not:

(1) manufacture, distribute, or possess with intent to distribute a prescription drug;

(2) affix a false or counterfeit label to a package, container, or other receptacle containing a prescription drug;

(3) omit, remove, alter, or obliterate a label or symbol that is required by federal, State, or local law on a prescription drug; or

(4) obtain or attempt to obtain a prescription drug by:

(i) fraud, deceit, or misrepresentation;

(ii) the counterfeiting or altering of a prescription or written order;

(iii) concealing a material fact;

(iv) using a false name or address;

(v) falsely assuming the title of or falsely representing that the person is a manufacturer, distributor, or authorized provider; or

(vi) making or issuing a false or counterfeit prescription or written order.

(e) A person who violates this section is guilty of a misdemeanor and on conviction is subject to imprisonment not exceeding 2 years or a fine not exceeding $1,000 or both.

Article – Health – General

21–220.

(a) A drug that is intended for use by human beings and is in any of the following classifications may be dispensed by a pharmacist only on a written **PRESCRIPTION, AN ELECTRONIC PRESCRIPTION,** or **AN** oral prescription from a health practitioner authorized by law to prescribe the drug:

(1) A habit–forming drug to which § 21–218(b)(1) of this subtitle applies.

(2) A drug that because of its toxicity or other potentiality for harmful effect, the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a health practitioner who is authorized by law to administer such a drug.

(3) A drug that is limited by an approved application under § 355 of the federal act or § 21–223 of this subtitle to use under the professional supervision of a health practitioner authorized by law to administer such a drug.

(b) (1) **[**A**] SUBJECT TO PARAGRAPH (2) OF THIS SUBSECTION AND EXCEPT AS PROVIDED IN SUBSECTION (C) OF THIS SECTION, A** prescription may be written or oral.

(2) [However, a**] A** pharmacist may not dispense a drug on an oral prescription unless the pharmacist promptly writes out and files the prescription.

(C) (1) EXCEPT AS PROVIDED IN PARAGRAPH (2) OF THIS SUBSECTION, A HEALTH PRACTITIONER AUTHORIZED BY LAW TO PRESCRIBE A CONTROLLED DANGEROUS SUBSTANCE WITHIN THE MEANING OF TITLE 5 OF THE CRIMINAL LAW ARTICLE SHALL ISSUE A PRESCRIPTION ELECTRONICALLY.

(2) A HEALTH PRACTITIONER MAY ISSUE A WRITTEN OR, IF AUTHORIZED BY STATE AND FEDERAL LAW, ORAL PRESCRIPTION FOR A CONTROLLED DANGEROUS SUBSTANCE ONLY IF:

(I) ELECTRONIC PRESCRIBING IS NOT AVAILABLE DUE TO TEMPORARY TECHNOLOGICAL OR ELECTRICAL FAILURE;

(II) THE PRESCRIPTION IS TO BE DISPENSED BY A PHARMACY LOCATED OUTSIDE THE STATE;

(III) THE PRESCRIBING ENTITY AND DISPENSING ENTITY OF THE DRUG OR DEVICE ARE THE SAME;

(IV) THE PRESCRIPTION IS FOR AN INDIVIDUAL WHO:

1. RESIDES IN A NURSING OR ASSISTED LIVING FACILITY;

2. IS RECEIVING CARE THROUGH A HOSPICE OR PALLIATIVE CARE PROGRAM AND THE PRESCRIPTION IS RELATED TO THE CARE PROVIDED; OR

3. IS RECEIVING CARE AT AN OUTPATIENT RENAL DIALYSIS FACILITY AND THE PRESCRIPTION IS RELATED TO THE CARE PROVIDED;

(V) THE PRESCRIPTION IS ISSUED BY A LICENSED VETERINARIAN;

(VI) THE PRESCRIPTION INCLUDES ELEMENTS THAT ARE NOT SUPPORTED BY THE MOST RECENT VERSION OF THE NATIONAL COUNCIL FOR PRESCRIPTION DRUG PROGRAMS PRESCRIBER/PHARMACIST INTERFACE SCRIPT STANDARD;

(VII) THE PRESCRIPTION IS ISSUED FOR A DRUG FOR WHICH THE FEDERAL FOOD AND DRUG ADMINISTRATION REQUIRES THE PRESCRIPTION TO CONTAIN CERTAIN ELEMENTS THAT CANNOT BE TRANSMITTED ELECTRONICALLY;

(VIII) THE PRESCRIPTION IS NOT SPECIFIC TO ONE PATIENT, INCLUDING PRESCRIPTIONS THAT ARE:

1. IN ACCORDANCE WITH A STANDING ORDER;

2. FOR AN APPROVED PROTOCOL FOR DRUG THERAPY;

3. FOR COLLABORATIVE DRUG MANAGEMENT;

4. FOR COMPREHENSIVE MEDICATION MANAGEMENT; OR

5. IN RESPONSE TO A PUBLIC HEALTH EMERGENCY;

(IX) THE PRESCRIPTION PRESCRIBES A DRUG UNDER A RESEARCH PROTOCOL;

(X) THE PRESCRIPTION IS ISSUED BY A HEALTH PRACTITIONER

WHO HAS RECEIVED A WAIVER UNDER SUBSECTION (D)(1) OF THIS SECTION;

(XI) THE PRESCRIPTION IS ISSUED BY A HEALTH PRACTITIONER WHO REQUESTED A WAIVER UNDER SUBSECTION (D)(1) OF THIS SECTION AND THE DEPARTMENT HAS NOT ISSUED A WAIVER TO THE PRACTITIONER OR HAS NOT REJECTED THE PRACTITIONER'S REQUEST FOR A WAIVER;

(XII) THE HEALTH PRACTITIONER ISSUING THE PRESCRIPTION OR THE DRUG FOR WHICH THE PRESCRIPTION IS ISSUED FALLS UNDER A WAIVER ISSUED BY THE SECRETARY UNDER SUBSECTION (D)(2) OF THIS SECTION;

(XIII) THE PRESCRIPTION IS ISSUED BY A HEALTH PRACTITIONER WHO WRITES A LOW VOLUME OF PRESCRIPTIONS FOR CONTROLLED DANGEROUS SUBSTANCES, AS DETERMINED BY THE MARYLAND HEALTH CARE COMMISSION; OR

(XIV) THE PRESCRIPTION IS ISSUED BY A HEALTH PRACTITIONER UNDER CIRCUMSTANCES IN WHICH, ALTHOUGH THE PRACTITIONER HAS THE ABILITY TO ISSUE AN ELECTRONIC PRESCRIPTION AS REQUIRED BY PARAGRAPH (1) OF THIS SUBSECTION, THE HEALTH PRACTITIONER REASONABLY DETERMINES THAT:

1. IT WOULD BE IMPRACTICABLE FOR THE PRACTITIONER TO PRESCRIBE THE DRUG OR DEVICE BY ELECTRONIC PRESCRIPTION IN A TIMELY MANNER; AND

2. THE DELAY WOULD ADVERSELY IMPACT THE PATIENT'S MEDICAL CONDITION.

(3) THIS SUBSECTION MAY NOT BE CONSTRUED TO LIMIT THE RIGHT OF A PATIENT TO DESIGNATE A SPECIFIC PHARMACY TO DISPENSE A PRESCRIBED DRUG OR DEVICE TO THE INDIVIDUAL.

(D) (1) THE SECRETARY SHALL ADOPT REGULATIONS, IN COLLABORATION WITH THE MARYLAND HEALTH CARE COMMISSION, TO ESTABLISH A PROCESS FOR THE DEPARTMENT TO ISSUE A WAIVER FROM THE ELECTRONIC PRESCRIPTION REQUIREMENTS IN SUBSECTION (C)(1) OF THIS SECTION.

(2) (I) THE SECRETARY MAY ISSUE A WAIVER THAT APPLIES GENERALLY TO A GROUP OF HEALTH PRACTITIONERS OR DRUGS THAT MEET CONDITIONS SPECIFIED BY THE SECRETARY.

(II) ANY WAIVER ISSUED UNDER SUBPARAGRAPH (I) OF THIS

PARAGRAPH FOR A GROUP OF HEALTH PRACTITIONERS SHALL APPLY TO A HEALTH PRACTITIONER IN THAT GROUP WITHOUT REQUIRING THE HEALTH PRACTITIONER TO GO THROUGH THE PROCESS ESTABLISHED IN REGULATIONS UNDER PARAGRAPH (1) OF THIS SUBSECTION.

(3) EXCEPT FOR A WAIVER ISSUED UNDER PARAGRAPH (2) OF THIS SUBSECTION, THE REGULATIONS ADOPTED UNDER PARAGRAPH (1) OF THIS SUBSECTION SHALL SPECIFY THAT A WAIVER:

(I) MAY NOT EXCEED 1 YEAR; AND

(II) MAY BE GRANTED FOR THE FOLLOWING REASONS:

1. ECONOMIC HARDSHIP;

2. TECHNOLOGICAL LIMITATIONS THAT ARE NOT REASONABLY WITHIN THE CONTROL OF THE HEALTH PRACTITIONER; OR

3. ANY OTHER EXCEPTIONAL CIRCUMSTANCES AS DEMONSTRATED BY THE HEALTH PRACTITIONER.

(4) THE SECRETARY MAY ADOPT REGULATIONS ON:

(I) WHICH TEMPORARY TECHNOLOGICAL OR ELECTRICAL FAILURES CONSTITUTE AN EXCEPTION TO THE REQUIREMENT TO ISSUE AN ELECTRONIC PRESCRIPTION UNDER SUBSECTION (C)(1) OF THIS SECTION; AND

(II) THE CIRCUMSTANCES UNDER WHICH A HEALTH PRACTITIONER IS EXEMPT FROM THE REQUIREMENT TO ISSUE AN ELECTRONIC PRESCRIPTION UNDER SUBSECTION (C)(1) OF THIS SECTION BECAUSE THE PRESCRIPTION WILL BE DISPENSED BY A PHARMACY LOCATED OUTSIDE THE STATE.

(E) THE APPROPRIATE HEALTH OCCUPATIONS BOARD ESTABLISHED UNDER THE HEALTH OCCUPATIONS ARTICLE SHALL TAKE DISCIPLINARY ACTION AGAINST A HEALTH PRACTITIONER WHO VIOLATES SUBSECTION (C) OF THIS SECTION.

(F) (1) A PHARMACIST MAY DISPENSE A DRUG ON A WRITTEN OR ORAL PRESCRIPTION FOR A CONTROLLED DANGEROUS SUBSTANCE THAT MEETS THE REQUIREMENTS OF THIS SECTION.

(2) A PHARMACIST WHO RECEIVES A WRITTEN OR ORAL PRESCRIPTION IS NOT REQUIRED TO VERIFY THAT THE PRESCRIPTION IS AN

AUTHORIZED EXCEPTION TO THE ELECTRONIC PRESCRIPTION REQUIREMENT UNDER SUBSECTION (C)(2) OF THIS SECTION.

[(2)**] (G) (1) [**A**]** **IF A** prescription for a controlled dangerous substance within the meaning of Title 5 of the Criminal Law Article **IS WRITTEN, IT** may not be written on a preprinted prescription form that states the name, quantity, or strength of the controlled dangerous substance.

[(3)**] (2)** When a prescription is written, a separate prescription form is required for each controlled dangerous substance. If a pharmacist is otherwise satisfied that a prescription is valid the pharmacist may fill the prescription if the pharmacist promptly writes out and files a prescription for each substance and also files the original prescription.

[(4)**] (3)** A **WRITTEN** prescription shall be legible.

[(c)**] (H)** A pharmacist may not refill and dispense a prescription unless the refilling is authorized by:

(1) The health practitioner's specification in the original prescription as to how many times it may be refilled; **[**or**]**

(2) An oral order of the health practitioner that promptly is written out and filed by the pharmacist**; OR**

(3) AN ELECTRONIC ORDER OF THE HEALTH PRACTITIONER.

[(d)**] (I)** The dispensing of a drug without complying with the requirements of this section is the dispensing of a misbranded drug.

[(e)**] (J)** (1) A drug that is subject to the prescription requirements of this section is misbranded if, at any time before it is dispensed, its label does not bear the statement "Caution: Federal Law Prohibits Dispensing Without Prescription", or "Caution: State Law Prohibits Dispensing Without Prescription".

(2) A drug to which the prescription requirements of this section do not apply is misbranded if, at any time before it is dispensed, its label bears the caution statement quoted in paragraph (1) of this subsection.

[(f)**] (K)** (1) The prescription requirements of this section do not apply to any drug that is exempted under a rule or regulation adopted by the Secretary.

(2) The Secretary, by rule or regulation, may exempt any drug from the requirements of this section if the Secretary finds that, as to the drug, the requirements of this section are not necessary for the protection of the public health.

(3) The Secretary, by rule and regulation, may exempt from the requirements of this section any drug that is removed from the prescription requirements of the federal act by a rule or regulation adopted under that act.

SECTION 2. AND BE IT FURTHER ENACTED, That:

(a) The Maryland Health Care Commission shall convene a workgroup of interested stakeholders, including:

(1) the Maryland Association of Chain Drug Stores;

(2) the Maryland Pharmacists Association;

(3) the Maryland State Medical Society;

(4) the Maryland Hospital Association;

(5) the Maryland Nurses Association;

(6) the Maryland State Dental Association;

(7) the Maryland Affiliate of the American College of Nurse Midwives; and

(8) the Maryland Society of Oral and Maxillofacial Surgeons.

(b) The workgroup shall study, evaluate, and make recommendations relating to the implementation of the electronic prescription requirement established under § 21–220(c) of the Health – General Article, as enacted by Section 1 of this Act, including by:

(1) identifying the successes and challenges of implementing the electronic prescription requirement and the use of prescription drug discount cards; and

(2) recommending options for increasing the electronic prescribing of prescriptions.

(c) On or before January 1, 2022, the workgroup shall report its findings and recommendations to the Senate Finance Committee and the House Health and Government Operations Committee in accordance with § 2–1257 of the State Government Article.

SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect January 1, 2021. Section 2 of this Act shall remain effective for a period of 1 year and 6 months and, at the end of June 30, 2022, Section 2 of this Act, with no further action required by the General Assembly, shall be abrogated and of no further force and effect.