HOUSE BILL 1416

J1 8lr2974
CF 8lr3358

By: **Delegate Saab**
Introduced and read first time: February 9, 2018
Assigned to: Health and Government Operations

A BILL ENTITLED

AN ACT concerning

Drugs and Devices – Electronic Prescriptions – Requirements

FOR the purpose of requiring, except under certain circumstances, a certain health practitioner to issue a prescription electronically; authorizing an authorized prescriber to issue a written or oral prescription 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 adopt certain regulations regarding certain exceptions to the requirement to issue an electronic prescription; establishing a certain penalty; 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; making conforming changes; and generally relating to electronic prescriptions for drugs and devices.

BY repealing and reenacting, with amendments,
Article – Health – General
Section 21–220
Annotated Code of Maryland
(2015 Replacement Volume and 2017 Supplement)

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

Article – Health – General

21–220.

(a) A drug that is intended for use by human beings and is in any of the following

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

classifications may be dispensed by a pharmacist only on **[**a**]** **AN ELECTRONIC,** written**,** or 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 prescription may be written or oral. However, a pharmacist may not dispense a drug on an oral prescription unless the pharmacist promptly writes out and files the prescription.**]**

(B) (1) EXCEPT AS PROVIDED IN PARAGRAPH (2) OF THIS SUBSECTION, A HEALTH PRACTITIONER AUTHORIZED BY LAW TO PRESCRIBE A DRUG OR DEVICE SHALL ISSUE A PRESCRIPTION ELECTRONICALLY.

(2) A HEALTH PRACTITIONER MAY ISSUE A WRITTEN OR ORAL PRESCRIPTION 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 INCLUDES ELEMENTS THAT ARE NOT SUPPORTED BY THE MOST RECENT VERSION OF THE NATIONAL COUNCIL FOR PRESCRIPTION DRUG PROGRAMS PRESCRIBER/PHARMACIST INTERFACE SCRIPT STANDARD;

(V) 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;

(VI) 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;

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

(VIII) THE PRESCRIPTION IS ISSUED BY A HEALTH PRACTITIONER WHO HAS RECEIVED A WAIVER UNDER SUBSECTION (C) OF THIS SECTION; OR

(IX) 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 IMPRACTICAL FOR THE PATIENT TO OBTAIN THE PRESCRIBED DRUG OR DEVICE BY ELECTRONIC PRESCRIPTION IN A TIMELY MANNER; AND

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

(C) (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 (B)(1) OF THIS SECTION.

(2) 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.

(3) 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 (B)(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 (B)(1) OF THIS SECTION BECAUSE THE PRESCRIPTION WILL BE DISPENSED BY A PHARMACY LOCATED OUTSIDE THE STATE.

(D) (1) SUBJECT TO PARAGRAPH (2) OF THIS SUBSECTION, A HEALTH PRACTITIONER WHO VIOLATES SUBSECTION (B)(1) OF THIS SECTION IS SUBJECT TO AN ADMINISTRATIVE FINE OF $250 PER VIOLATION.

(2) A HEALTH CARE PRACTITIONER MAY NOT BE ASSESSED ADMINISTRATIVE FINES UNDER PARAGRAPH (1) OF THIS SUBSECTION IN A CALENDAR YEAR THAT IN THE AGGREGATE EXCEED $5,000.

(E) (1) A PHARMACIST MAY DISPENSE A DRUG ON A WRITTEN OR ORAL PRESCRIPTION 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 (B)(2) OF THIS SECTION.

[(2)**] (F) (1)** A prescription for a controlled dangerous substance within the meaning of Title 5 of the Criminal Law Article 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)**] (G)** 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)**] (H)** The dispensing of a drug without complying with the requirements of this section is the dispensing of a misbranded drug.

[(e)**] (I)** (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)**] (J)** (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 this Act shall take effect October 1, 2018.