

# SENATE BILL 166

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By: **Senator Kelley**

Introduced and read first time: January 13, 2020

Assigned to: Finance

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## A BILL ENTITLED

1 AN ACT concerning

2 **Drugs and Devices – Electronic Prescriptions – Controlled Dangerous**  
3 **Substances**

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

30 BY repealing and reenacting, with amendments,

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EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 Article – Criminal Law  
2 Section 5–501, 5–504, and 5–701  
3 Annotated Code of Maryland  
4 (2012 Replacement Volume and 2019 Supplement)

5 BY repealing and reenacting, with amendments,  
6 Article – Health – General  
7 Section 21–220  
8 Annotated Code of Maryland  
9 (2019 Replacement Volume)

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

12 **Article – Criminal Law**

13 5–501.

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

17 (1) listed in Schedule II; and

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

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

22 (1) an authorized provider who:

23 (i) is not a pharmacist; and

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

26 (2) a pharmacist if:

27 (i) an emergency exists;

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

31 (iii) federal law authorizes the oral prescription.

1 (c) A prescription for a controlled dangerous substance listed in Schedule II shall  
2 be kept on file in conformity with the requirements for records and inventories under §  
3 5–306 of this title.

4 (d) A person may not refill a prescription for a controlled dangerous substance  
5 listed in Schedule II.  
6 5–504.

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

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

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

14 (2) refilled more than five times.

15 5–701.

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

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

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

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

23 (1) on an authorized provider’s:

24 (I) **ELECTRONIC PRESCRIPTION;**

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

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

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

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

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

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

7 (1) the name and address of the dispenser;

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

9 (3) the name of the authorized provider; and

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

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

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

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

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

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

20 (i) fraud, deceit, or misrepresentation;

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

22 (iii) concealing a material fact;

23 (iv) using a false name or address;

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

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

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

1 **Article – Health – General**

2 21–220.

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

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

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

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

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

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

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

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

27 (i) **ELECTRONIC PRESCRIBING IS NOT AVAILABLE DUE TO**  
28 **TEMPORARY TECHNOLOGICAL OR ELECTRICAL FAILURE;**

29 (ii) **THE PRESCRIPTION IS TO BE DISPENSED BY A PHARMACY**  
30 **LOCATED OUTSIDE THE STATE;**

31 (iii) **THE PRESCRIBING ENTITY AND DISPENSING ENTITY OF THE**  
32 **DRUG OR DEVICE ARE THE SAME;**

1 (IV) THE PRESCRIPTION IS FOR AN INDIVIDUAL WHO:

2 1. RESIDES IN A NURSING OR ASSISTED LIVING  
3 FACILITY;

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

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

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

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

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

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

20 1. IN ACCORDANCE WITH A STANDING ORDER;

21 2. FOR AN APPROVED PROTOCOL FOR DRUG THERAPY;

22 3. FOR COLLABORATIVE DRUG MANAGEMENT;

23 4. FOR COMPREHENSIVE MEDICATION MANAGEMENT;

24 OR

25 5. IN RESPONSE TO A PUBLIC HEALTH EMERGENCY;

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

28 (X) THE PRESCRIPTION IS ISSUED BY A HEALTH PRACTITIONER

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

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

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

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

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

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

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

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

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

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

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

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

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

8 (I) MAY NOT EXCEED 1 YEAR; AND

9 (II) MAY BE GRANTED FOR THE FOLLOWING REASONS:

10 1. ECONOMIC HARDSHIP;

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

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

15 (4) THE SECRETARY MAY ADOPT REGULATIONS ON:

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

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

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

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

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



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

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

7           **[(3)] (2)** When a prescription is written, a separate prescription form is  
8 required for each controlled dangerous substance. If a pharmacist is otherwise satisfied  
9 that a prescription is valid the pharmacist may fill the prescription if the pharmacist  
10 promptly writes out and files a prescription for each substance and also files the original  
11 prescription.

12           **[(4)] (3)** A **WRITTEN** prescription shall be legible.

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

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

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

19           **(3) AN ELECTRONIC ORDER OF THE HEALTH PRACTITIONER.**

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

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

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

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

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

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

4           SECTION 2. AND BE IT FURTHER ENACTED, That:

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

7           (1) the Maryland Association of Chain Drug Stores;

8           (2) the Maryland Pharmacists Association;

9           (3) the Maryland State Medical Society;

10          (4) the Maryland Hospital Association;

11          (5) the Maryland Nurses Association;

12          (6) the Maryland State Dental Association;

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

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

15          (b) The workgroup shall study, evaluate, and make recommendations relating to  
16 the implementation of the electronic prescription requirement established under §  
17 21–220(c) of the Health – General Article, as enacted by Section 1 of this Act, including by:

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

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

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

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