

# HOUSE BILL 512

J1

(0lr0769)

## ENROLLED BILL

— Health and Government Operations/Finance —

Introduced by **Delegates Barron, Bagnall, Buckel, Kipke, R. Lewis, and Szeliga**

Read and Examined by Proofreaders:

\_\_\_\_\_  
Proofreader.

\_\_\_\_\_  
Proofreader.

Sealed with the Great Seal and presented to the Governor, for his approval this

\_\_\_\_\_ day of \_\_\_\_\_ at \_\_\_\_\_ o'clock, \_\_\_\_\_ M.

\_\_\_\_\_  
Speaker.

### CHAPTER \_\_\_\_\_

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

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#### EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.

*Italics indicate opposite chamber/conference committee amendments.*



1 an electronic prescription; authorizing a certain health occupations board to take  
2 certain action against a health practitioner who violates certain provisions of this  
3 Act; authorizing a pharmacist to dispense a drug on a prescription transmitted in a  
4 certain manner under certain circumstances; providing that a pharmacist who  
5 receives certain prescriptions is not required to verify certain information about the  
6 prescription; altering the circumstances under which a pharmacist may refill and  
7 dispense a prescription; making conforming changes; providing for the construction  
8 of certain provisions of this Act; defining a certain term; providing for a delayed  
9 effective date; and generally relating to electronic prescriptions for controlled  
10 dangerous substances.

11 BY repealing and reenacting, without amendments,  
12 Article – Correctional Services  
13 Section 1–101(a), (d), (n), and (o)  
14 Annotated Code of Maryland  
15 (2017 Replacement Volume and 2019 Supplement)

16 BY repealing and reenacting, without amendments,  
17 Article – Criminal Law  
18 Section 5–101(a)  
19 Annotated Code of Maryland  
20 (2012 Replacement Volume and 2019 Supplement)

21 BY adding to  
22 Article – Criminal Law  
23 Section 5–101(p–1)  
24 Annotated Code of Maryland  
25 (2012 Replacement Volume and 2019 Supplement)

26 BY repealing and reenacting, with amendments,  
27 Article – Criminal Law  
28 Section 5–501, 5–504, and 5–701  
29 Annotated Code of Maryland  
30 (2012 Replacement Volume and 2019 Supplement)

31 BY repealing and reenacting, with amendments,  
32 Article – Health – General  
33 Section 21–220  
34 Annotated Code of Maryland  
35 (2019 Replacement Volume)

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

38 Article – Correctional Services

39 1–101.

1 (a) In this article the following words have the meanings indicated.

2 (d) “Correctional facility” means a facility that is operated for the purpose of  
3 detaining or confining adults who are charged with or found guilty of a crime.

4 (n) “State” means:

5 (1) a state, possession, territory, or commonwealth of the United States; or

6 (2) the District of Columbia.

7 (o) (1) “State correctional facility” means a correctional facility that is  
8 operated by the State.

9 (2) “State correctional facility” includes:

10 (i) the Patuxent Institution;

11 (ii) the Baltimore City Detention Center; and

12 (iii) the centralized booking facility in Baltimore City that is operated  
13 by the Division of Pretrial Detention and Services in the Department of Public Safety and  
14 Correctional Services.

15 **Article – Criminal Law**

16 5–101.

17 (a) In this title the following words have the meanings indicated.

18 **(P–1) “ELECTRONIC PRESCRIPTION” MEANS A PRESCRIPTION THAT;**

19 **(1) IS GENERATED ON AN ELECTRONIC APPLICATION AND**  
20 **TRANSMITTED AS AN ELECTRONIC DATA FILE; AND**

21 **(2) IF THE PRESCRIPTION IS FOR A CONTROLLED DANGEROUS**  
22 **SUBSTANCE, COMPLIES WITH THE REQUIREMENTS OF 21 C.F.R. PART 1306.**

23 5–501.

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

27 (1) listed in Schedule II; and

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

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

5 (1) an authorized provider who:

6 (i) is not a pharmacist; and

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

9 (2) a pharmacist if:

10 (i) an emergency exists;

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

14 (iii) federal law authorizes the oral prescription.

15 (c) A prescription for a controlled dangerous substance listed in Schedule II shall  
16 be kept on file in conformity with the requirements for records and inventories under §  
17 5–306 of this title.

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

20 5–504.

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

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

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

28 (2) refilled more than five times.

29 5–701.

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

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

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

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

8 (1) on an authorized provider’s:

9 (I) **ELECTRONIC PRESCRIPTION;**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6 (i) fraud, deceit, or misrepresentation;

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

8 (iii) concealing a material fact;

9 (iv) using a false name or address;

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

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

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

## 16 Article – Health – General

17 21–220.

18 (a) A drug that is intended for use by human beings and is in any of the following  
19 classifications may be dispensed by a pharmacist only on a written **PRESCRIPTION, AN**  
20 **ELECTRONIC PRESCRIPTION, AS DEFINED IN § 5–101 OF THE CRIMINAL LAW**  
21 **ARTICLE**, or AN oral prescription from a health practitioner authorized by law to prescribe  
22 the drug:

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

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

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

1 (b) (1) [A] SUBJECT TO PARAGRAPH (2) OF THIS SUBSECTION AND  
2 SUBSECTION (C) OF THIS SECTION, A prescription may be written or oral OR MADE  
3 THROUGH AN ELECTRONIC PRESCRIPTION.

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

6 (c) (1) EXCEPT AS PROVIDED IN PARAGRAPH (2) OF THIS SUBSECTION, A  
7 HEALTH PRACTITIONER AUTHORIZED BY LAW TO PRESCRIBE A CONTROLLED  
8 DANGEROUS SUBSTANCE WITHIN THE MEANING OF TITLE 5 OF THE CRIMINAL LAW  
9 ARTICLE SHALL ISSUE A PRESCRIPTION FOR A CONTROLLED DANGEROUS  
10 SUBSTANCE USING AN ELECTRONIC PRESCRIPTION, AS DEFINED IN § 5-101 OF THE  
11 CRIMINAL LAW ARTICLE.

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

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

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

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

21 (III) THE PRESCRIPTION IS ISSUED BY A HEALTH PRACTITIONER  
22 OUTSIDE THE STATE;

23 (IV) THE HEALTH PRACTITIONER IS PRESCRIBING AND  
24 DISPENSING THE CONTROLLED DANGEROUS SUBSTANCE DIRECTLY TO THE  
25 PATIENT;

26 (V) THE PRESCRIPTION IS BEING DISPENSED DIRECTLY TO THE  
27 PATIENT IN ACCORDANCE WITH § 12-102(C)(2)(IV) OF THE HEALTH OCCUPATIONS  
28 ARTICLE;

29 ~~(IV)~~ (VI) THE PRESCRIPTION IS FOR AN INDIVIDUAL WHO:

30 1. RESIDES IN A NURSING OR ASSISTED LIVING  
31 FACILITY;

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

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

7                                   4.    ~~IS INCARCERATED IN A STATE~~ DETAINED OR  
8 CONFINED IN A CORRECTIONAL FACILITY, AS DEFINED IN § 1-101 OF THE  
9 CORRECTIONAL SERVICES ARTICLE;

10                               ~~(v)~~ (VII)    THE PRESCRIPTION IS ISSUED BY A LICENSED  
11 VETERINARIAN;

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

16                               ~~(vii)~~ (IX)    THE PRESCRIPTION IS ISSUED FOR A DRUG FOR  
17 WHICH THE FEDERAL FOOD AND DRUG ADMINISTRATION REQUIRES THE  
18 PRESCRIPTION TO CONTAIN CERTAIN ELEMENTS THAT CANNOT BE TRANSMITTED  
19 ELECTRONICALLY;

20                               ~~(viii) THE PRESCRIPTION IS NOT SPECIFIC TO ONE PATIENT,~~  
21 ~~INCLUDING PRESCRIPTIONS THAT ARE;~~

22                                   1.    ~~IN ACCORDANCE WITH A STANDING ORDER;~~

23                                   2.    ~~FOR AN APPROVED PROTOCOL FOR DRUG THERAPY;~~

24                                   3.    ~~FOR COLLABORATIVE DRUG MANAGEMENT;~~

25                                   4.    ~~FOR COMPREHENSIVE MEDICATION MANAGEMENT;~~

26 ~~OR~~

27                                   5.    ~~IN RESPONSE TO A PUBLIC HEALTH EMERGENCY;~~

28                               ~~(ix)~~ (X)    THE PRESCRIPTION PRESCRIBES A DRUG UNDER A  
29 RESEARCH PROTOCOL;

1           ~~(X)~~ (XI)     THE PRESCRIPTION IS ISSUED BY A HEALTH  
2 PRACTITIONER WHO HAS RECEIVED A WAIVER UNDER SUBSECTION (D)(1) OF THIS  
3 SECTION;

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

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

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

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

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

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

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

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

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

4           **(II) ANY WAIVER ISSUED UNDER SUBPARAGRAPH (I) OF THIS**  
5 **PARAGRAPH FOR A GROUP OF HEALTH PRACTITIONERS SHALL APPLY TO A HEALTH**  
6 **PRACTITIONER IN THAT GROUP WITHOUT REQUIRING THE HEALTH PRACTITIONER**  
7 **TO GO THROUGH THE PROCESS ESTABLISHED IN REGULATIONS UNDER PARAGRAPH**  
8 **(1) OF THIS SUBSECTION.**

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

12                   **(I) MAY NOT EXCEED 1 YEAR; AND**

13                   **(II) MAY BE GRANTED FOR THE FOLLOWING REASONS:**

14                           **1. ECONOMIC HARDSHIP;**

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

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

19           **(4) THE SECRETARY MAY ADOPT REGULATIONS ON:**

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

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

27           **(E) THE APPROPRIATE HEALTH OCCUPATIONS BOARD ESTABLISHED**  
28 **UNDER THE HEALTH OCCUPATIONS ARTICLE MAY TAKE DISCIPLINARY ACTION**  
29 **AGAINST A HEALTH PRACTITIONER WHO VIOLATES SUBSECTION (C) OF THIS**  
30 **SECTION.**

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

4 (2) A PHARMACIST WHO RECEIVES A WRITTEN OR ORAL  
5 PRESCRIPTION IS NOT REQUIRED TO VERIFY THAT THE PRESCRIPTION IS AN  
6 AUTHORIZED EXCEPTION TO THE ELECTRONIC PRESCRIPTION REQUIREMENT  
7 UNDER SUBSECTION (C)(2) OF THIS SECTION.

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

12 [(3)] (2) When a prescription is written, a separate prescription form is  
13 required for each controlled dangerous substance. If a pharmacist is otherwise satisfied  
14 that a prescription is valid the pharmacist may fill the prescription if the pharmacist  
15 promptly writes out and files a prescription for each substance and also files the original  
16 prescription.

17 [(4)] (3) A WRITTEN prescription shall be legible.

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

20 (1) The health practitioner's specification in the original prescription as to  
21 how many times it may be refilled; ~~for~~

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

24 ~~(3) AN ELECTRONIC ORDER OF THE HEALTH PRACTITIONER.~~

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

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

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

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

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

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

9           SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect  
10 January 1, ~~2021~~ 2022.

Approved:

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Governor.

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Speaker of the House of Delegates.

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President of the Senate.