J2, C3

0lr2605 CF SB 871

#### By: **Delegates K. Young, Carr, and Kipke** Introduced and read first time: February 5, 2020 Assigned to: Health and Government Operations

## A BILL ENTITLED

1 AN ACT concerning

#### $\mathbf{2}$

## Mail Order and Specialty Drugs – Physician Dispensing

3 FOR the purpose of providing that certain provisions of law do not prohibit a physician 4 from personally dispensing to a patient by mail order certain prescription drugs and  $\mathbf{5}$ devices; prohibiting certain entities, policies, and contracts from imposing certain 6 cost-sharing requirements and conditions on an insured or a certificate holder who 7 uses certain services; requiring certain entities to allow certain insureds, enrollees, 8 and beneficiaries to obtain a covered drug from a certain physician; prohibiting a 9 pharmacy benefits manager from reimbursing a certain physician less than a certain amount: defining certain terms; providing for the application of this Act; providing 1011 for a delayed effective date; and generally relating to physician dispensing of 12prescription drugs.

- 13 BY repealing and reenacting, with amendments,
- 14 Article Health Occupations
- 15 Section 12–102
- 16 Annotated Code of Maryland
- 17 (2014 Replacement Volume and 2019 Supplement)

#### 18 BY repealing and reenacting, with amendments,

- 19 Article Insurance
- 20 Section 15–805, 15–847(a) and (d), 15–1611.1, and 15–1612
- 21 Annotated Code of Maryland
- 22 (2017 Replacement Volume and 2019 Supplement)
- 23 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, 24 That the Laws of Maryland read as follows:
- 24 That the Laws of Maryland read as follows:
- 25

# Article – Health Occupations

26 12–102.

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



1 In this section the following terms have the meanings indicated. (a) (1)"In the public interest" means the dispensing of drugs or devices by a  $\mathbf{2}$ (2)licensed dentist, physician, or podiatrist to a patient when a pharmacy is not conveniently 3 available to the patient. 4  $\mathbf{5}$ "Personally preparing and dispensing" means that the licensed dentist, (3)6 physician, or podiatrist:  $\overline{7}$ (i) Is physically present on the premises where the prescription is filled; and 8 9 (ii) Performs a final check of the prescription before it is provided to 10 the patient. 11 (b) This title does not limit the right of an individual to practice a health 12occupation that the individual is authorized to practice under this article. 13(c)(1)This subsection does not apply to a licensed dentist who obtains a permit from the State Board of Dental Examiners under subsection (h) of this section. 1415(2)This title does not prohibit: 16A licensed veterinarian from: (i) 171. Personally preparing and dispensing the veterinarian's prescriptions; or 18 192. Dispensing, in accordance with § 2-313(c) of the 20Agriculture Article, compounded nonsterile preparations or compounded sterile 21preparations provided by a pharmacy; 22A licensed dentist, physician, or podiatrist from personally (ii) 23preparing and dispensing the dentist's, physician's, or podiatrist's prescriptions when: 241. The dentist, physician, or podiatrist: 25А. Has applied to the board of licensure in this State which licensed the dentist, physician, or podiatrist: 2627Β. Has demonstrated to the satisfaction of that board that the 28dispensing of prescription drugs or devices by the dentist, physician, or podiatrist is in the 29public interest; 30 С. Has received a written permit from that board to dispense 31prescription drugs or devices except that a written permit is not required in order to

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1	dispense starter dosages or samples without charge; and			
$2 \\ 3 \\ 4$	D. Posts a sign conspicuously positioned and readable regarding the process for resolving incorrectly filled prescriptions or includes written information regarding the process with each prescription dispensed;			
$5 \\ 6$	2. The person for whom the drugs or devices are prescribed is a patient of the prescribing dentist, physician, or podiatrist;			
7 8	3. The dentist, physician, or podiatrist does not have a substantial financial interest in a pharmacy; and			
9	4. The dentist, physician, or podiatrist:			
$\begin{array}{c} 10\\ 11 \end{array}$	A. Complies with the dispensing and labeling requirements of this title;			
$\begin{array}{c} 12\\ 13 \end{array}$	B. Records the dispensing of the prescription drug or device			
$14 \\ 15 \\ 16$	C. Allows the Office of Controlled Substances Administration to enter and inspect the dentist's, physician's, or podiatrist's office at all reasonable hours and in accordance with § 12–102.1 of this subtitle;			
17 18 19	D. On inspection by the Office of Controlled Substances Administration, signs and dates an acknowledgment form provided by the Office of Controlled Substances Administration relating to the requirements of this section;			
$20 \\ 21 \\ 22$	E. Except for starter dosages or samples without charge, provides the patient with a written prescription, maintains prescription files in accordance with § 12–403(c)(13) of this title, and maintains a separate file for Schedule II prescriptions;			
$\frac{23}{24}$	F. Does not direct patients to a single pharmacist or pharmacy in accordance with § $12-403(c)(8)$ of this title;			
25 $26$	G. Does not receive remuneration for referring patients to a pharmacist or pharmacy;			
27 $28$	H. Complies with the child resistant packaging requirements regarding prescription drugs under Title 22, Subtitle 3 of the Health – General Article;			
29	I. Complies with drug recalls;			
30 31 32	J. Maintains biennial inventories and complies with any other federal and State record-keeping requirements relating to controlled dangerous substances;			

1 K. Purchases prescription drugs from a pharmacy or 2 wholesale distributor who holds a permit issued by the Board of Pharmacy, as verified by 3 the Board of Pharmacy;

L. Annually reports to the respective board of licensure whether the dentist, physician, or podiatrist has personally prepared and dispensed prescription drugs within the previous year; and

M. Completes ten continuing education credits over a 5-year period relating to the preparing and dispensing of prescription drugs, offered by the Accreditation Council for Pharmacy Education (ACPE) or as approved by the Secretary, in consultation with each respective board of licensure, as a condition of permit renewal;

(iii) A licensed physician from dispensing a topical medication
without obtaining the permit required under item (ii)1C of this paragraph or completing
the continuing education required under item (ii)4M of this paragraph when the physician:

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- 1. Otherwise complies with item (ii) of this paragraph; and
- 152.Has obtained a special written permit under § 14–509 of16this article;
- (iv) A licensed physician who complies with the requirements of item(ii) of this paragraph from personally preparing and dispensing a prescription written by:
- 19 1. A physician assistant in accordance with a delegation 20 agreement that complies with Title 15, Subtitle 3 of this article; or
- 21 2. A nurse practitioner who is authorized to practice under
  22 Title 8, Subtitle 3 of this article and is working with the physician in the same office setting;
  23 or
- 24 (v) A hospital-based clinic from dispensing prescriptions to its 25 patients.
- 26 (d) This title does not prohibit:

(1) A licensed veterinarian from personally dispensing a drug or devicesample to a patient of the veterinarian; or

(2) A licensed dentist, licensed physician, or licensed podiatrist from
 personally dispensing a drug or device sample to a patient of the licensed dentist, licensed
 physician, or licensed podiatrist if:

32 (i) The sample complies with the labeling requirements of § 12–505
33 of this title;

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1	(ii) No charge is made for the sample; and						
$2 \\ 3$	(iii) The authorized prescriber enters an appropriate record in the patient's chart.	:					
$\frac{4}{5}$	(e) (1) This title does not prohibit a dentist, physician, or podiatrist from administering a prescription drug or device in the course of treating a patient.						
6 7 8	means the direct introduction of a single dosage of a drug or device at a given time, whether						
9 10 11	personally dispensing a starter dosage of a prescription drug or device to a patient of the						
12 13	(i) The starter dosage complies with the labeling requirements of § 12–505 of this title;	I					
14	(ii) No charge is made for the starter dosage; and						
$\begin{array}{c} 15\\ 16\end{array}$	(iii) The dentist, physician, or podiatrist enters an appropriate record on the patient's chart.						
17 18	(2) For the purposes of paragraph (1) of this subsection, "starter dosage" means an amount of drug or device sufficient to begin therapy:	,					
19	(i) Of short duration of 72 hours or less; or						
$\begin{array}{c} 20\\ 21 \end{array}$	(ii) Prior to obtaining a larger quantity of the drug or device to complete the therapy.	I					
$\begin{array}{c} 22\\ 23 \end{array}$	(g) This title does not prohibit a dentist, physician, or podiatrist from dispensing a prescription drug or device in the course of treating a patient:	•					
24	(1) At a medical facility or clinic that is operated on a nonprofit basis;						
$\frac{25}{26}$							
$\begin{array}{c} 27\\ 28 \end{array}$							
29 30 31 32	State Board of Dental Examiners that allows the licensed dentist to dispense only prescription strength home fluoride products, dentin/enamel remineralizing products, and						

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1	(1)	The product or rinse is dispensed to a patient of the licensed dentist;					
$2 \\ 3$	(2) The licensed dentist enters an appropriate record in the patient's chart that the product or rinse was dispensed to the patient; and						
4 5	(3) The licensed dentist affixes a label on the product or rinse container that includes:						
6		(i) The name of the patient; and					
7		(ii) Unless already printed on the container:					
8		1. The expiration date of the product or rinse; and					
9		2. The instructions for using the product or rinse.					
10	(i) This	title does not apply to a person who only dispenses:					
11	(1)	Prescription devices that do not contain a prescription drug;					
$\frac{12}{13}$	(2) oxygen;	Prescription devices within which the only prescription drug is medical					
$\begin{array}{c} 14 \\ 15 \end{array}$	(3) Durable medical equipment, as defined by the Centers for Medicare and Medicaid Services; or						
16	(4)	Prosthetics, orthotics, and related supplies.					
17 18							
19	(1)	The patient is receiving pro bono dental care;					
20	(2)	There is no charge for the antibiotics;					
$\begin{array}{c} 21 \\ 22 \end{array}$							
$\begin{array}{c} 23\\ 24 \end{array}$	(4) includes:	The licensed dentist affixes a label on the antibiotic container that					
25		(i) The name of the patient; and					
26		(ii) Unless already printed on the container:					

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1			2. The instructions for taking the antibiotic.				
2	(k) This title does not limit the right of a general merchant to sell:						
3		(1)	Any nonprescription drug or device;				
4		(2)	Any commonly used household or domestic remedy; or				
$5\\6$	otherwise.	(3)	Any farm remedy or ingredient for a spraying solution, in bulk or				
7 8	(L) DISPENSIN		S TITLE DOES NOT PROHIBIT A PHYSICIAN FROM PERSONALLY A PATIENT BY MAIL ORDER:				
9		(1)	A STARTER DOSAGE OF A PRESCRIPTION DRUG OR DEVICE; OR				
10		(2)	AN INITIAL OR REFILL PRESCRIPTION OF A SPECIALTY DRUG.				
$\begin{array}{c} 11\\ 12\\ 13 \end{array}$	•	and t	The Board of Pharmacy, the Board of Dental Examiners, the Board of he Board of Podiatric Medical Examiners annually shall report to the ed Substances Administration:				
$\begin{array}{c} 14 \\ 15 \end{array}$	personally p	(1) prepar	The names and addresses of its licensees who are authorized to e and dispense prescription drugs; and				
$16 \\ 17 \\ 18$			The names and addresses of its licensees who have reported, in ubsection (c)(2)(ii)4L of this section, that they have personally prepared escription drugs within the previous year.				
$\begin{array}{c} 19\\ 20 \end{array}$	[(m)] provisions o	` '	A dentist, physician, or podiatrist who fails to comply with the section governing the dispensing of prescription drugs or devices shall:				
21		(1)	Have the dispensing permit revoked; and				
22		(2)	Be subject to disciplinary actions by the appropriate licensing board.				
23			Article – Insurance				
24	15-805.						
25	(a)	(1)	In this section the following words have the meanings indicated.				
$26 \\ 27 \\ 28$	licensed poo		"Authorized prescriber" means a licensed dentist, licensed physician, or t who is authorized under the Health Occupations Article to prescribe a roduct.				

28 pharmaceutical product.

#### 1 (3) "DISPENSING PHYSICIAN" MEANS A LICENSED PHYSICIAN IN THE 2 STATE WHO HOLDS A VALID DISPENSING PERMIT UNDER TITLE 12, SUBTITLE 1 OF 3 THE HEALTH OCCUPATIONS ARTICLE.

4 [(3)] (4) "Pharmaceutical product" means a drug or medicine that may be 5 prescribed by an authorized prescriber.

6 (b) This section does not apply to a policy or contract that is issued to an employer 7 under a collective bargaining agreement.

8 (c) (1) This subsection applies to each policy or contract that is issued or 9 delivered in the State to an employer or individual by an insurer or nonprofit health service 10 plan and that provides group or individual hospital, medical, or surgical benefits.

11 (2) A policy or contract subject to this subsection that provides 12 reimbursement for a pharmaceutical product prescribed by an authorized prescriber may 13 not establish the amount of reimbursement to the insured or the insured's beneficiary, 14 including copayments and deductibles, based on the identity, practicing specialty, or 15 occupation of the authorized prescriber.

16 (d) (1) This subsection applies to each individual or group policy or contract 17 that is issued or delivered in the State to an employer or individual by an insurer or 18 nonprofit health service plan and that provides benefits for pharmaceutical products.

19 (2) A policy or contract subject to this subsection may not impose a 20 copayment, deductible, or other condition on an insured or certificate holder who uses the 21 services of a community pharmacy that is not imposed when the insured or certificate 22 holder uses the services of a mail order pharmacy, if the benefits are provided under the 23 same program, policy, or contract.

(3) A POLICY OR CONTRACT SUBJECT TO THIS SUBSECTION MAY NOT
IMPOSE A COPAYMENT, A COINSURANCE REQUIREMENT, A DEDUCTIBLE, OR ANY
OTHER CONDITION ON AN INSURED OR A CERTIFICATE HOLDER WHO USES THE
SERVICES OF A DISPENSING PHYSICIAN WHO MAILS OR DELIVERS A SPECIALTY
DRUG TO THE BENEFICIARY THAT IS NOT IMPOSED WHEN THE BENEFICIARY USES
THE SERVICES OF A MAIL ORDER PHARMACY.

30 15-847.

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

32 (2) (i) "Complex or chronic medical condition" means a physical, 33 behavioral, or developmental condition that:

34 1. may have no known cure;

1		2. i	s progressive; or			
$2 \\ 3$	undertreated.	3. c	an be debilitating or fatal if left untreated or			
4	(ii)	"Compl	ex or chronic medical condition" includes:			
<b>5</b>		1. r	nultiple sclerosis;			
6		2. h	nepatitis C; and			
7		3. r	heumatoid arthritis.			
8 9 10	(3) "DISPENSING PHYSICIAN" MEANS A LICENSED PHYSICIAN IN THE STATE WHO HOLDS A VALID DISPENSING PERMIT UNDER TITLE 12, SUBTITLE 1 OF THE HEALTH OCCUPATIONS ARTICLE.					
11 12 13 14	[(3)] (4) "Managed care system" means a system of cost containment methods that an insurer, a nonprofit health service plan, or a health maintenance organization uses to review and preauthorize drugs prescribed by a health care provider for a covered individual to control utilization, quality, and claims.					
15 16	[(4)] <b>(5)</b> affects fewer than:	(i) "	Rare medical condition" means a disease or condition that			
17		1. 2	200,000 individuals in the United States; or			
18		2. a	pproximately 1 in 1,500 individuals worldwide.			
19	(ii)	"Rare n	nedical condition" includes:			
20		1. c	ystic fibrosis;			
21		2. h	nemophilia; and			
22		3. n	nultiple myeloma.			
23	<b>[</b> (5) <b>] (6)</b>	"Specia	lty drug" means a prescription drug that:			
$\begin{array}{c} 24 \\ 25 \end{array}$	(i) condition or a rare medie	-	ribed for an individual with a complex or chronic medical ion;			
26	(ii)	costs \$6	300 or more for up to a 30–day supply;			
27	(iii)	is not ty	pically stocked at retail pharmacies; and			

requires a difficult or unusual process of delivery to the 1 (iv) 1.  $\mathbf{2}$ patient in the preparation, handling, storage, inventory, or distribution of the drug; or 3 2. requires enhanced patient education, management, or support, beyond those required for traditional dispensing, before or after administration of 4 the drug.  $\mathbf{5}$ 6 (1) Subject to § 15–805 of this subtitle [and], notwithstanding § 15–806 of (d) 7 this subtitle, AND EXCEPT AS PROVIDED IN PARAGRAPH (2) OF THIS SUBSECTION, nothing in this article or regulations adopted under this article precludes an entity subject 8 to this section from requiring a covered specialty drug to be obtained through: 9 10 a designated pharmacy or other source authorized under the [(1)] (I) Health Occupations Article to dispense or administer prescription drugs; or 11 12[(2)] **(II)** a pharmacy participating in the entity's provider network, if the 13entity determines that the pharmacy: 14(i) 1. meets the entity's performance standards; and [(ii)] **2**. accepts the entity's network reimbursement rates. 1516 (2) AN ENTITY SUBJECT TO THIS SECTION SHALL ALLOW AN INSURED 17OR ENROLLEE TO OBTAIN A COVERED SPECIALTY DRUG FROM A DISPENSING 18 PHYSICIAN. 19 15 - 1611.1.20IN THIS SECTION, "DISPENSING PHYSICIAN" MEANS A LICENSED (A) 21PHYSICIAN IN THE STATE WHO HOLDS A VALID DISPENSING PERMIT UNDER TITLE 2212, SUBTITLE 1 OF THE HEALTH OCCUPATIONS ARTICLE. 23Except as provided in subsection [(b)] (C) of this section, a pharmacy [(a)] **(B)** 24benefits manager may not require that a beneficiary use a specific pharmacy or entity to 25fill a prescription if: 26(1)the pharmacy benefits manager or a corporate affiliate of the pharmacy benefits manager has an ownership interest in the pharmacy or entity; or 2728(2)the pharmacy or entity has an ownership interest in the pharmacy benefits manager or a corporate affiliate of the pharmacy benefits manager. 2930 [(b)] (C) (1) [A] EXCEPT AS PROVIDED IN PARAGRAPH (2) OF THIS 31SUBSECTION, A pharmacy benefits manager may require a beneficiary to use a specific pharmacy or entity for a specialty drug as defined in § 15–847 of this title. 32

1(2)A PHARMACY BENEFITS MANAGER SHALL ALLOW A BENEFICIARY2TO OBTAIN A SPECIALTY DRUG FROM A DISPENSING PHYSICIAN.

3 (D) A PHARMACY BENEFITS MANAGER MAY NOT IMPOSE A COPAYMENT, A 4 COINSURANCE REQUIREMENT, A DEDUCTIBLE, OR ANY OTHER CONDITION ON A 5 BENEFICIARY WHO USES THE SERVICES OF A DISPENSING PHYSICIAN WHO MAILS OR 6 DELIVERS A SPECIALTY DRUG TO THE BENEFICIARY THAT IS NOT IMPOSED WHEN 7 THE BENEFICIARY USES THE SERVICES OF A MAIL ORDER PHARMACY.

8 15-1612.

9 (A) IN THIS SECTION, "DISPENSING PHYSICIAN" MEANS A LICENSED 10 PHYSICIAN IN THE STATE WHO HOLDS A VALID DISPENSING PERMIT UNDER TITLE 11 12, SUBTITLE 1 OF THE HEALTH OCCUPATIONS ARTICLE.

- 12 [(a)] (B) (1) [This] EXCEPT AS PROVIDED IN SUBSECTION (C) OF THIS 13 SECTION, THIS section does not apply to reimbursement:
- 14 **[**(1)**] (I)** for specialty drugs;
- 15 [(2)] (II) for mail order drugs; or

16 [(3)] (III) to a chain pharmacy with more than 15 stores or a 17 pharmacist who is an employee of the chain pharmacy.

18 [(b)] (2) A pharmacy benefits manager may not reimburse a pharmacy or 19 pharmacist for a pharmaceutical product or pharmacist service in an amount less than the 20 amount that the pharmacy benefits manager reimburses itself or an affiliate for providing 21 the same product or service.

# (C) A PHARMACY BENEFITS MANAGER MAY NOT REIMBURSE A DISPENSING PHYSICIAN WHO MAILS OR DELIVERS A SPECIALTY DRUG IN AN AMOUNT LESS THAN THE AMOUNT THAT THE PHARMACY BENEFITS MANAGER REIMBURSES ITSELF OR AN AFFILIATE FOR PROVIDING THE SAME PRODUCT OR SERVICE.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall apply to all policies, contracts, and health benefit plans issued, delivered, or renewed in the State on or after January 1, 2021.

29 SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect 30 January 1, 2021.