HOUSE BILL 14

(PRE-FILED)

1lr1242

By: **Delegate Kerr** Requested: October 29, 2020 Introduced and read first time: January 13, 2021 Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

2 Pharmacists – Prescription Drug and Device Labels – Expiration Dates

FOR the purpose of altering the expiration date that is required to be included, except under certain circumstances, on labels on drugs and devices dispensed in the manufacturer's original packaging by a pharmacist; and generally relating to pharmacists and labeling requirements for prescription drugs and devices.

- 7 BY repealing and reenacting, with amendments,
- 8 Article Health Occupations
- 9 Section 12–505
- 10 Annotated Code of Maryland
- 11 (2014 Replacement Volume and 2020 Supplement)
- 12 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, 13 That the Laws of Maryland read as follows:
- 14

Article – Health Occupations

15 12–505.

16 (a) Except for a drug or device dispensed to an inpatient in a hospital or related 17 institution, each container of a drug or device dispensed shall be labeled in accordance with 18 this section.

- 19 (b) In addition to any other information required by law, the label shall include:
- 20 (1) The date the prescription is filled; and
- 21 (2) Unless otherwise required by the prescriber:

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



HOUSE BILL 14

1 [An] FOR DRUGS OR DEVICES DISPENSED IN A CONTAINER (i) $\mathbf{2}$ OTHER THAN THE MANUFACTURER'S ORIGINAL PACKAGING, AN expiration date of the 3 drugs or devices which shall be the lesser of: 4 1. 1 year from the date of dispensing; 2. The month and year when the drugs or devices expire; $\mathbf{5}$ 6 3. The appropriate expiration date for repackaged drugs or 7 devices; or 8 A shorter period as determined by the pharmacist; 4. FOR 9 **(II)** DRUGS OR DEVICES DISPENSED IN THE MANUFACTURER'S ORIGINAL PACKAGING, AN EXPIRATION DATE OF THE DRUGS OR 1011 **DEVICES WHICH SHALL BE:** 121. THE EXPIRATION DATE SET BY THE MANUFACTURER; 13OR 2. 14 A SHORTER PERIOD AS DETERMINED BY THE 15PHARMACIST; 16 (ii)] **(III)** Any appropriate special handling instructions regarding 17proper storage of the drugs or devices; and 18 (iiii)] **(IV)** Subject to the provisions of subsection (c) of this section, 19the name and strength of the drugs or devices. 20Except as provided in paragraph (2) of this subsection, the label shall (c) (1)21indicate the same name for the drug or device as that used by the authorized prescriber. 22(2)If, under § 12–504 of this subtitle, the pharmacist substitutes a drug or 23device product for that named by the authorized prescriber, the label shall indicate both 24the name of the drug or device product and the name of the manufacturer or distributor of the drug or device dispensed. 2526Except as provided in this subsection, if an authorized prescriber (d) (1)dispenses a drug or device, the prescriber shall label each container of the drug or device. 2728In addition to any other information required by law, the authorized (2)29prescriber shall include on the label: 30 (i) The name and strength of the drug or device; 31 The date the prescription is dispensed: (ii)

 $\mathbf{2}$

HOUSE BILL 14

$rac{1}{2}$	(iii) of:	An expiration date of the drug or device which shall be the lesser
3		1. 1 year from the date of dispensing;
4		2. The month and year when the drug or device expires; or
$5 \\ 6$	prescriber; and	3. A shorter period as determined by the authorized
7 8	(iv) Any appropriate special handling instructions regarding proper storage of the drug or device.	
9 10	(3) The labeling requirements of this subsection do not apply if the authorized prescriber dispenses the drug or device:	
11	(i)	To an inpatient in a hospital or related institution;
12	(ii)	In an emergency situation; or
$\begin{array}{c} 13 \\ 14 \end{array}$	(iii) As a sample drug or device dispensed in the regular course of the authorized prescriber's practice.	
$\begin{array}{c} 15\\ 16\end{array}$	(e) So long as any of the original contents remain in the container, a person may not alter, deface, or remove any label required by this section.	
17 18	SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2021.	

3