

HOUSE BILL 14

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EMERGENCY BILL
(PRE-FILED)

1lr1242

By: **Delegate Kerr**

Requested: October 29, 2020

Introduced and read first time: January 13, 2021

Assigned to: Health and Government Operations

Committee Report: Favorable with amendments

House action: Adopted

Read second time: February 11, 2021

CHAPTER _____

1 AN ACT concerning

2 **Pharmacists – Prescription Drug and Device Labels – Expiration Dates**

3 FOR the purpose of altering the expiration date that is required to be included, except
4 under certain circumstances, on labels on drugs and devices dispensed in the
5 manufacturer's original packaging by a pharmacist; making this Act an emergency
6 measure; and generally relating to pharmacists and labeling requirements for
7 prescription drugs and devices.

8 BY repealing and reenacting, with amendments,

9 Article – Health Occupations

10 Section 12–505

11 Annotated Code of Maryland

12 (2014 Replacement Volume and 2020 Supplement)

13 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,

14 That the Laws of Maryland read as follows:

15 **Article – Health Occupations**

16 12–505.

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

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.



1 (b) In addition to any other information required by law, the label shall include:

2 (1) The date the prescription is filled; and

3 (2) Unless otherwise required by the prescriber:

4 (i) **[An] FOR DRUGS OR DEVICES DISPENSED IN A CONTAINER**
5 **OTHER THAN THE MANUFACTURER'S ORIGINAL PACKAGING, AN** expiration date of the
6 drugs or devices which shall be the lesser of:

7 1. 1 year from the date of dispensing;

8 2. The month and year when the drugs or devices expire;

9 3. The appropriate expiration date for repackaged drugs or
10 devices; or

11 4. A shorter period as determined by the pharmacist;

12 (ii) **FOR DRUGS OR DEVICES DISPENSED IN THE**
13 **MANUFACTURER'S ORIGINAL PACKAGING, AN EXPIRATION DATE OF THE DRUGS OR**
14 **DEVICES WHICH SHALL BE:**

15 1. **THE EXPIRATION DATE SET BY THE MANUFACTURER;**

16 **OR**

17 2. **A SHORTER PERIOD AS DETERMINED BY THE**
18 **PHARMACIST;**

19 [(ii)] (iii) Any appropriate special handling instructions regarding
20 proper storage of the drugs or devices; and

21 [(iii)] (iv) Subject to the provisions of subsection (c) of this section,
22 the name and strength of the drugs or devices.

23 (c) (1) Except as provided in paragraph (2) of this subsection, the label shall
24 indicate the same name for the drug or device as that used by the authorized prescriber.

25 (2) If, under § 12-504 of this subtitle, the pharmacist substitutes a drug or
26 device product for that named by the authorized prescriber, the label shall indicate both
27 the name of the drug or device product and the name of the manufacturer or distributor of
28 the drug or device dispensed.

29 (d) (1) Except as provided in this subsection, if an authorized prescriber
30 dispenses a drug or device, the prescriber shall label each container of the drug or device.

1 (2) In addition to any other information required by law, the authorized
2 prescriber shall include on the label:

3 (i) The name and strength of the drug or device;

4 (ii) The date the prescription is dispensed;

5 (iii) An expiration date of the drug or device which shall be the lesser
6 of:

7 1. 1 year from the date of dispensing;

8 2. The month and year when the drug or device expires; or

9 3. A shorter period as determined by the authorized
10 prescriber; and

11 (iv) Any appropriate special handling instructions regarding proper
12 storage of the drug or device.

13 (3) The labeling requirements of this subsection do not apply if the
14 authorized prescriber dispenses the drug or device:

15 (i) To an inpatient in a hospital or related institution;

16 (ii) In an emergency situation; or

17 (iii) As a sample drug or device dispensed in the regular course of the
18 authorized prescriber's practice.

19 (e) So long as any of the original contents remain in the container, a person may
20 not alter, deface, or remove any label required by this section.

21 ~~SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect~~
22 ~~October 1, 2021.~~

23 SECTION 2. AND BE IT FURTHER ENACTED, That this Act is an emergency
24 measure, is necessary for the immediate preservation of the public health or safety, has
25 been passed by a ye and nay vote supported by three-fifths of all the members elected to
26 each of the two Houses of the General Assembly, and shall take effect from the date it is
27 enacted.