Chapter 489

(House Bill 14)

AN ACT concerning

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; making this Act an emergency measure; and generally relating to pharmacists and labeling requirements for prescription drugs and devices.

BY repealing and reenacting, with amendments,

Article – Health Occupations

Section 12-505

Annotated Code of Maryland

(2014 Replacement Volume and 2020 Supplement)

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

Article - Health Occupations

12 - 505.

- (a) Except for a drug or device dispensed to an inpatient in a hospital or related institution, each container of a drug or device dispensed shall be labeled in accordance with this section.
 - (b) In addition to any other information required by law, the label shall include:
 - (1) The date the prescription is filled; and
 - (2) Unless otherwise required by the prescriber:
- (i) [An] FOR DRUGS OR DEVICES DISPENSED IN A CONTAINER OTHER THAN THE MANUFACTURER'S ORIGINAL PACKAGING, AN expiration date of the drugs or devices which shall be the lesser of:
 - 1. 1 year from the date of dispensing;
 - 2. The month and year when the drugs or devices expire;

OR

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

- 4. A shorter period as determined by the pharmacist;
- (II) FOR DRUGS OR DEVICES DISPENSED IN THE MANUFACTURER'S ORIGINAL PACKAGING, AN EXPIRATION DATE OF THE DRUGS OR DEVICES WHICH SHALL BE:
 - 1. THE EXPIRATION DATE SET BY THE MANUFACTURER;

2. A SHORTER PERIOD AS DETERMINED BY THE PHARMACIST;

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

- [(iii)] (IV) Subject to the provisions of subsection (c) of this section, the name and strength of the drugs or devices.
- (c) (1) Except as provided in paragraph (2) of this subsection, the label shall indicate the same name for the drug or device as that used by the authorized prescriber.
- (2) If, under § 12–504 of this subtitle, the pharmacist substitutes a drug or device product for that named by the authorized prescriber, the label shall indicate both the name of the drug or device product and the name of the manufacturer or distributor of the drug or device dispensed.
- (d) (1) Except as provided in this subsection, if an authorized prescriber dispenses a drug or device, the prescriber shall label each container of the drug or device.
- (2) In addition to any other information required by law, the authorized prescriber shall include on the label:
 - (i) The name and strength of the drug or device;
 - (ii) The date the prescription is dispensed;
- (iii) An expiration date of the drug or device which shall be the lesser of:
 - 1. 1 year from the date of dispensing;
 - 2. The month and year when the drug or device expires; or

- 3. A shorter period as determined by the authorized prescriber; and
- (iv) Any appropriate special handling instructions regarding proper storage of the drug or device.
- (3) The labeling requirements of this subsection do not apply if the authorized prescriber dispenses the drug or device:
 - (i) To an inpatient in a hospital or related institution;
 - (ii) In an emergency situation; or
- (iii) As a sample drug or device dispensed in the regular course of the authorized prescriber's practice.
- (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.

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

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

Enacted under Article II, § 17(c) of the Maryland Constitution, May 30, 2021.