

## **PROPOSAL**

**Maryland Register**

**Issue Date: June 27, 2025**

**Volume 52 • Issue 13 • Pages 672-673**

**ELF Docket Number: 25-103**

# **Title 10**

## **MARYLAND DEPARTMENT OF HEALTH**

### **Subtitle 34 BOARD OF PHARMACY**

#### ***10.34.43 Prescription Labeling for Blind, Visually Impaired, and Print Disabled Individuals***

*Authority: Health Occupations Article, §12-501.1 Annotated Code of Maryland*

##### **Notice of Proposed Action**

[25-103-P]

The Acting Secretary of Health proposes to adopt new Regulations .01—.03 under a new chapter, **COMAR 10.34.43 Prescription Labeling for Blind, Visually Impaired, and Print Disabled Individuals**. This action was considered by the Board of Pharmacy at a public meeting held on December 18, 2024, notice of which was given by publication on the Board's website at <https://health.maryland.gov/pharmacy/Pages/index.aspx> pursuant to General Provisions Article, §3-302(c), Annotated Code of Maryland.

##### **Statement of Purpose**

The purpose of this action is to adopt regulations according to the mandate in SB 940 FY 2023 and Health Occupations Article, §12-505.1, Annotated Code of Maryland related to prescription labeling for visually impaired, blind, and print disabled individuals.

##### **Estimate of Economic Impact**

**I. Summary of Economic Impact.** This regulatory action implements SB940 (2023) which requires pharmacies in the State to provide certain prescription labels for visually impaired, blind, and print disabled individuals. The Board estimates that the economic impact, while indeterminate may potentially be significant.

These new requirements will result in an increased expense for pharmacies which may not have the economic resources to obtain and maintain the equipment required to produce prescription labeling for visually impaired individuals. The impact on these small pharmacies may be significant. Further, the Board anticipates that these increased expenses may be passed on to all consumers.

For a pharmacy which opts to lease equipment to comply with requirements, it is anticipated that the cost will be approximately \$2,600 per year. Further, the Board estimates that any costs associated with maintaining the equipment to print the labels and to purchase the labels will likely increase over time.

##### **II. Types of Economic Impact.**

<b>Impacted Entity</b>	<b>Revenue</b> (R+/R-)	<b>Magnitude</b>
	<b>Expenditure</b> (E+/E-)	
A. On issuing agency:	NONE	
B. On other State agencies:	NONE	
C. On local governments:	NONE	
<b>Benefit (+)</b> <b>Cost (-)</b>		<b>Magnitude</b>

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D. On regulated industries or trade groups:	Pharmacies	(-)	Indeterminable
E. On other industries or trade groups:		NONE	
F. Direct and indirect effects on public:		NONE	

### **III. Assumptions.** (Identified by Impact Letter and Number from Section II.)

D. (a) The Board estimates that there are 2,104 pharmacies in the State, 458 of these are independent pharmacies.

(b) The economic impact is difficult for the Board to determine given the variety of avenues in which a pharmacy could implement these regulations such as purchase of equipment, lease of equipment, or other collaborative arrangement to give the pharmacy access to equipment to provide these specialized labels. The Board estimates that yearly lease fees will be approximately \$2,600 per pharmacy per year for those pharmacies which choose to lease equipment. Lease is only one avenue of compliance with these regulations, therefore, the true economic impact is indeterminable but may be significant.

#### **Economic Impact on Small Businesses**

The proposed action has a meaningful economic impact on small businesses. An analysis of this economic impact follows:

This proposed action will have a potentially significant impact on smaller pharmacies in the State. The Board has worked to ensure the implementation of SB940 (2023) will meet the requirements of the legislation while considering the interests and needs of smaller pharmacies in the State. While pharmacies will need to use special equipment to become and remain compliant with the law, the Board has not dictated the manner in which small pharmacies are required to be compliant. Small pharmacies may choose to purchase equipment, lease equipment, or enter into other cooperative arrangements which may minimize the cost of implementation. The cost of implementation may still be significant and may cause financial strain on small and community pharmacies that serve rural and urban areas. The true economic impact is difficult for the Board to precisely estimate as there are many possible manners for implementation – one manner, lease of equipment is estimated to have a yearly cost of \$2,600 per pharmacy. Assuming every small pharmacy in the State (458) chooses to lease equipment, the economic impact may be as high as \$1,190,800.

#### **Impact on Individuals with Disabilities**

The proposed action has an impact on individuals with disabilities as follows:

This will have a positive impact on visually impaired, blind, and print disabled individuals. It will allow them to have multiple options available to receive their medications and instructions in a manner that suits their individual needs.

#### **Opportunity for Public Comment**

Comments may be sent to Jordan Fisher Blotter, Director, Office of Regulation and Policy Coordination, Maryland Department of Health, 201 West Preston Street, Room 534 Baltimore, Maryland 21201, or call 410-767-0938, or email to [mdh.regs@maryland.gov](mailto:mdh.regs@maryland.gov). Comments will be accepted through July 28, 2025. A public hearing has not been scheduled.

#### **.01 Definitions.**

*A. In this chapter, the following terms have the meanings indicated.*

*B. Terms Defined.*

(1) "Bag tag" means a receipt that may contain patient demographic information, drug information, and cost which is affixed to the bag containing the prescription drug vial or package.

(2) "Blind" means:

- (a) A visual acuity not exceeding 20/200 in the better eye with corrective lenses; or
- (b) A visual field of which the widest diameter subtends an angle of not more than 20 degrees.

(3) "Board" means the State Board of Pharmacy.

(4) "Medical guide" means a medication guide approved by the Food and Drug Administration (FDA) as part of the prescription drug labeling for certain drugs when the FDA determines that:

- (a) Patient labeling could prevent serious adverse reactions;
- (b) The drug has serious risks that could affect the patient's decision to use, or to continue to use, the product; or
- (c) Patient adherence to the directions for use is crucial to the drug's effectiveness.

(5) "Pharmacy" means an establishment holding a permit under Health Occupations Article, §12-401, Annotated Code of Maryland.

(6) "Prescription label" means a label affixed to a prescription drug vial or package that contains the information required by State and federal laws, including any warnings or other information contained in auxiliary labels.

(7) "Print disabled individual" means an individual who cannot effectively read print because of a visual, physical, perceptual, developmental, cognitive, or learning disability.

(8) "Visually impaired individual" means an individual who has difficulty seeing even when wearing glasses,

**.02 General Requirements.**

A. A pharmacy shall adopt policies and procedures necessary to ensure that a blind, visually impaired, or print disabled individual has appropriate access to prescription labels, bag tags, and medical guides:

- (1) At no additional cost to the individual;
- (2) In a format through which the information is fully accessible to the individual;
- (3) Within a timeframe comparable to the timeframe within which the information is provided to an individual who is not blind, visually impaired, or print disabled; and
- (4) That contains the same information provided in a standard print prescription label, bag tag, or medical guide.

B. A prescription labeling, bag tag, or medical guide alternative provided under this chapter shall be in addition to the standard print prescription labeling, bag tag, or medical guide dispensed with a prescription drug.

**.03 Prescription Labeling, Bag Tag, and Medical Guide Alternative—Requirements.**

A. A pharmacist shall, upon request, provide at least one of the following alternative formats consistent with the needs of the blind, visually impaired, or print disabled individual:

- (1) Audio;
- (2) Braille;
- (3) Digital format; or
- (4) Large print.

B. A pharmacy shall implement policies and procedures to ensure that pharmacy staff provide verbal notice to any patient who may be blind, visually impaired, or print disabled that alternative prescription labeling, bag tags, and medical guides are available at no additional cost.

C. Notification Requirements.

(1) A pharmacy shall notify the public that alternative prescription labeling, bag tags, and medical guides are available for blind, visually impaired, or print disabled individuals at no additional cost.

(2) A pharmacy shall provide the information required by §C(1) of this regulation by:

- (a) Posting signage in a conspicuous location;
- (b) If applicable, including the information in the pharmacy's telephone recording; and
- (c) If applicable, including the information on the pharmacy's website .

D. The Board may take disciplinary action against a pharmacy or pharmacist for a violation of this chapter.

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Acting Secretary of Health