



COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

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Accessible Accommodations for Visually Impaired Work Group Meeting Agenda *August 16, 2024* 9AM-12pm

<u>TOPIC</u>	<u>PAGES</u>
Call to Order: Cheri Garvin, RPh, Chairman	
• Welcome & Introductions	2
Approval of Agenda	
Call for Public Comment: The work group will receive public comment at this time. The work group will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters.	
Agenda Items:	
• Review charge of meeting consistent with HB 516	3
• Adopt recommended draft regulations for Board of Pharmacy consideration	4-22
• Adopt recommended guidance document for Board of Pharmacy consideration	23-24
Adjourn	

Accessible Accommodations for Visually Impaired Work Group (HB 516)

Chairman: Cheri Garvin, RPh, Board of Pharmacy

Members:

- Shannon Dowdy, PharmD, Board of Pharmacy
- Patricia Richards-Spruill, RPh, Board of Pharmacy
- Sharla Glass, En-Vision America
- Joanne Dial, PharmD, Kaiser Permanente
- Stewart Prost, National Federation of the Blind of Virginia
- Jodi Roth, Virginia Association of Chain Drug Stores
- Dan Aunspach, Director of Rehabilitation Services, Virginia Department of Blind and Visually Impaired
- Jade Ranger, PharmD, Virginia Pharmacist Association
- Cynthia Coffey, PharmD, Virginia Society of Health-System Pharmacists

VIRGINIA ACTS OF ASSEMBLY -- 2024 SESSION

CHAPTER 725

An Act to amend the Code of Virginia by adding a section numbered 54.1-3410.3, relating to prescription drugs; labels; blind and disabled users.

[H 516]

Approved April 8, 2024

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding a section numbered 54.1-3410.3 as follows:

§ 54.1-3410.3. Accessible prescription labels.

A. For the purposes of this section, "prescription reader" means a device that is designed to audibly identify the prescription drug contained on the label of a prescription drug.

B. A pharmacy shall notify each person who identifies themselves or a patient as blind, visually impaired, or otherwise print disabled to whom a prescription drug is dispensed that an accessible prescription label or alternate accommodation is available to the person upon request at no additional cost.

C. If a person informs the pharmacy that he is blind, visually impaired, or otherwise print disabled, and the person requests an accessible prescription label or accommodation, as determined between the pharmacist and the patient, the pharmacy shall:

1. Upon request of a person for an accessible prescription label, provide the person, either at the pharmacy or through mail order, an accessible prescription label fixable to the bottle or container that:

a. Is available to the person in a timely manner comparable to other patient wait times and will remain available for at least the duration of the prescription;

b. Utilizes audible or large print labels or enclosures that are appropriate to the disability and preference of the person making the request;

c. Seeks to attain best practice standards established by the U.S. Access Board; and

d. Is compatible with a prescription reader; or

2. As determined between the pharmacist and patient, provide appropriate counseling and accommodation to the patient and dispense the medication in suitable packaging with sufficient labeling and other information.

2. That the Board of Pharmacy shall adopt initial regulations to implement the provisions of this act no later than December 31, 2024. The Board of Pharmacy's initial adoption of regulations necessary to implement the provisions of this act shall be exempt from the provisions of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia), except that the Board of Pharmacy shall consult with organizations of blind or low-vision consumers and other individuals who are blind, community pharmacists, and other pharmacy stakeholders to assist in the development of necessary regulations and shall provide an opportunity for public comment on the regulations prior to adoption.

3. That the Board of Pharmacy shall issue a guidance document identifying appropriate technologies, packaging, labeling, and counseling for dispensing medications to blind or low-vision patients. In developing guidance documents, the Board of Pharmacy shall consider best practices and formatting suggestions as published and revised by the U.S. Access Board.

Agenda Item: Adopt recommended draft regulations for Board of Pharmacy consideration

Included in Agenda Packet:

- Draft proposed regulation
- Background information:
 - Tennessee Legislation effective 5/9/2022 and Tennessee Regulation
 - Maryland legislation effective 10/1/2023
 - Information from En-Vision America® website solely for educational purposes:
 - Large-Print Labels
 - ScripTalk®
 - BrailleRx™
 - Information regarding Prescription Drug Container Labels from U.S. Access Board
 - Possible questions to consider:
 1. Does the pharmacist need to keep a record of what accommodation is determined to be best?
 2. What if the pharmacist and patient disagree on what accommodation is best?
 3. Should “suitable packaging with sufficient labeling and other information” be interpreted in regulation or guidance? If C1 requires audible or large print that is compatible with a prescription reader, then an example of suitable packaging could be a large-print or braille label that is not compatible with a prescription reader. Should this example be captured in regulation or guidance?

Action Needed:

Motion to recommend to the Board of Pharmacy to adopt the proposed regulation as presented or amended, following a public comment opportunity.

Draft Proposed Regulation

18VAC110-20-351

- A. Prescriptions dispensed to a person who informs the pharmacy that he is blind, visually impaired, or otherwise print disabled shall meet the requirements of § 54.1-3410.3.
- B. If the accommodation involves use of an accessible label, a pharmacist, or person authorized to perform the duties of a pharmacist or pharmacy technician shall affix the label to the drug bottle or container and a pharmacist shall verify the accuracy of the affixed label prior to dispensing to the patient as required in 18VAC110-20-270.

DRAFT

Amendment No. 1 to SB1859

Crowe
Signature of Sponsor

AMEND Senate Bill No. 1859*

House Bill No. 1999

by deleting all language after the caption and substituting:

WHEREAS, the General Assembly finds that thousands of Tennesseans are blind and visually impaired as the result of disease, accident, injuries sustained in the service of our country, genetic causes, or congenital defects; and

WHEREAS, the General Assembly further finds that blind Tennesseans have contributed in no small manner to the prosperity and welfare of the State of Tennessee in the practice of various professions, in the arts, in business, in the sciences, as teachers and instructors, and as parents and caregivers to countless children in this State; and

WHEREAS, the General Assembly further finds and concludes that many blind Tennesseans have limited access to accessible prescription labels; and

WHEREAS, it is the policy of the State of Tennessee to foster the health and preservation of people with disabilities; and

WHEREAS, the General Assembly encourages easy access for blind Tennesseans in both urban and rural settings to prescription information and other related medical information; now, therefore,

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Section 63-10-304, is amended by adding the following new subsection:

(k) The board of pharmacy shall promulgate rules necessary to ensure that an individual who is blind, visually impaired, or otherwise print disabled has appropriate access to prescription labels, bag tags, and medical guides.

SECTION 2: This act takes effect upon becoming a law, the public welfare requiring it.

- (b) Electronic data related to the transmitted order shall be maintained in the pharmacy and shall be deemed the original prescription or medical order meeting all requirements of rule 1140-03-.03 of the rules of the Board.
- (c) The pharmacist receiving any transmitted order shall not knowingly participate in any system that restricts the patient's choice of pharmacy.
- (d) The pharmacist may not provide financial or other remuneration to the prescriber for any prescription transmitted to the dispensing pharmacy. No person or entity, including but not limited to wholesalers, distributors, manufacturers, pharmacists, and pharmacies, shall supply electronic equipment, software, devices, or modems to any prescriber in exchange for transmitting orders.
- (e) The pharmacist shall not use the electronic transmission of orders to circumvent or violate any provision of state or federal drug laws, or the Tennessee Pharmacy Practice Act, or the regulations of the board.
- (f) This rule shall not apply to medical or prescription orders electronically transmitted between pharmacies or medical or prescription orders transmitted by facsimile.
- (g) Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

Authority: T.C.A. §§ 63-10-204, 63-10-304, 63-10-404(19), (26), (29), (30), and (34), 63-10-504, 63-10-504(b)(1) and (2), and 63-10-504(j). **Administrative History:** Original rule filed February 7, 1983; effective March 9, 1983. Amendment filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed August 19, 2002; effective November 2, 2002. Amendments filed November 22, 2016; effective February 20, 2017.

1140-03-.05 AREAS OF RECEIPT AND DISPENSING.

All medical and prescription orders shall be received or accepted and compounded and dispensed from a pharmacy practice site which is in a building permanently located and non-mobile in nature. In case of emergency, the board may waive this rule upon request.

Authority: T.C.A. §§ 63-10-404(4), (11), (19), (28), and (34), 63-10-504(b)(1) and (2), and 63-10-504(j). **Administrative History:** Original rule filed February 7, 1983; effective March 9, 1983. Amendment filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-03-.06 LABELING REQUIREMENTS.

The dispensing label for a medical or prescription order shall bear at least the following information: name and address and telephone number of pharmacy practice site; the medical or prescription order serial number; name of prescriber; name of patient; directions for use; date medical or prescription order originally dispensed, and/or refill date; "poison", "shake", "caution", or other appropriate advisory label; name of product (unless otherwise required by the prescriber); and expiration date of the product (if applicable). All reasonable accommodations for individuals who are blind, visually impaired, or otherwise print-disabled shall be made. This rule shall not apply to medical and prescription orders dispensed by an institutional pharmacy or long-term care pharmacy for administration to inpatients of that institutional facility or long-term care facility, except when medications are dispensed to patients residing in assisted-care living facilities. Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

Chapter 279

(Senate Bill 940)

AN ACT concerning

Pharmacies—Prescription Drugs State Board of Pharmacy - Accessible Prescription Labels, Bag Tags, and Medical Guides for Blind, Visually Impaired, and Print Disabled Individuals - Regulations

FOR the purpose of requiring ~~pharmacies to provide notice to customers of the availability of accessible labels for blind, visually impaired, or otherwise print disabled individuals for prescription drugs and to provide the selected label on request; establishing certain standards for accessible labels and prescription readers to be used with accessible labels;~~ the State Board of Pharmacy to adopt regulations necessary to ensure that individuals who are blind, visually impaired, or otherwise print disabled have appropriate access to prescription labels, bag tags, and medical guides in a certain manner; requiring the Board to give visually impaired individuals an opportunity to provide input regarding the content of the regulations; and generally relating to pharmacies and accessible labels for prescription drugs accessible prescription labels, bag tags, and medical guides for blind, visually impaired, and print disabled individuals.

BY adding to

Article – Health Occupations

Section 12–505.1

Annotated Code of Maryland

(2021 Replacement Volume and 2022 Supplement)

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

Article – Health Occupations

12–505.1.

~~(A) IN THIS SECTION, “PRESCRIPTION READER” MEANS A DEVICE THAT IS DESIGNED TO AUDIBLY CONVEY INFORMATION CONTAINED ON THE LABEL OF A PRESCRIPTION DRUG.~~

~~(B) EACH PHARMACY SHALL PROVIDE NOTICE TO CUSTOMERS THAT AN ACCESSIBLE LABEL FOR BLIND, VISUALLY IMPAIRED, OR OTHERWISE PRINT DISABLED INDIVIDUALS IS AVAILABLE ON REQUEST FOR NO ADDITIONAL COST BY:~~

~~(1) POSTING A NOTICE THAT IS ACCESSIBLE TO BLIND, VISUALLY IMPAIRED, OR OTHERWISE PRINT DISABLED INDIVIDUALS:~~

~~(I) THAT IS CONSPICUOUSLY POSITIONED IN THE PHARMACY AND READABLE BY PHARMACY CUSTOMERS; AND~~

~~(II) IF APPLICABLE, ON THE PHARMACY'S WEBSITE; AND~~

~~(2) PROVIDING VERBAL NOTICE TO EACH CUSTOMER WHO PICKS UP A PRESCRIPTION OR REFILL.~~

~~(C) ON REQUEST OF A CUSTOMER FOR AN ACCESSIBLE LABEL, THE PHARMACIST SHALL:~~

~~(1) EXPLAIN TO THE CUSTOMER THE AVAILABLE ACCESSIBLE LABEL FORMAT OPTIONS; AND~~

~~(2) PROVIDE THE ACCESSIBLE LABEL THAT IS SELECTED BY THE CUSTOMER.~~

~~(D) AN ACCESSIBLE LABEL SHALL:~~

~~(1) PRESERVE THE INTEGRITY OF THE PRINT PRESCRIPTION DRUG CONTAINER LABEL;~~

~~(2) CONTAIN ALL THE LABEL INFORMATION REQUIRED UNDER § 12-505 OF THIS SUBTITLE AND FEDERAL LAW IN THE SAME SEQUENCE AS THE PRINT LABEL, INCLUDING WARNINGS AND CAUTIONS;~~

~~(3) BE DURABLE AND LAST UNTIL THE PRESCRIPTION EXPIRATION DATE;~~

~~(4) BE PROVIDED WITHIN A TIME FRAME COMPARABLE TO INFORMATION PROVIDED TO OTHER CUSTOMERS WITHOUT A VISUAL IMPAIRMENT; AND~~

~~(5) CONFORM TO THE BEST PRACTICES ESTABLISHED BY THE FEDERAL U.S. ACCESS BOARD.~~

~~(E) A PRESCRIPTION READER PROVIDED BY A PHARMACY SHALL BE:~~

~~(1) COMPATIBLE WITH AN ACCESSIBLE LABEL PROVIDED TO A CUSTOMER BY THE PHARMACY; AND~~

~~(2) AVAILABLE TO A CUSTOMER USING AN ACCESSIBLE LABEL FOR THE DURATION OF THE PRESCRIPTION.~~

~~(F) THE BOARD SHALL ADOPT REGULATIONS TO CARRY OUT THIS SECTION.~~

(A) THE BOARD SHALL ADOPT REGULATIONS NECESSARY TO ENSURE THAT AN INDIVIDUAL WHO IS BLIND, VISUALLY IMPAIRED, OR OTHERWISE PRINT DISABLED HAS APPROPRIATE ACCESS TO PRESCRIPTION LABELS, BAG TAGS, AND MEDICAL GUIDES:

(1) AT NO ADDITIONAL COST TO THE INDIVIDUAL;

(2) IN A FORMAT OPTION THROUGH WHICH THE INFORMATION IS FULLY ACCESSIBLE TO THE INDIVIDUAL; AND

(3) WITHIN A TIME FRAME COMPARABLE TO THE TIME FRAME WITHIN WHICH THE INFORMATION IS PROVIDED TO AN INDIVIDUAL WHO IS NOT VISUALLY IMPAIRED.

(B) IN ADOPTING REGULATIONS UNDER SUBSECTION (A) OF THIS SECTION, THE BOARD SHALL GIVE VISUALLY IMPAIRED INDIVIDUALS AN OPPORTUNITY TO PROVIDE INPUT REGARDING THE CONTENT OF THE REGULATIONS.

(C) THE REGULATIONS ADOPTED UNDER SUBSECTION (A) OF THIS SECTION SHALL:

(1) FOLLOW THE GUIDELINES AND RECOMMENDATIONS IN THE “PRESCRIPTION DRUG LABELS: ACTIONS NEEDED TO INCREASE AWARENESS OF BEST PRACTICES FOR ACCESSIBLE LABELS FOR INDIVIDUALS WHO ARE BLIND OR VISUALLY IMPAIRED” REPORT THAT WAS ISSUED BY THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE IN DECEMBER 2016; AND

(2) INCLUDE A METHOD FOR PROVIDING NOTICE TO CUSTOMERS THAT ACCESSIBLE PRESCRIPTION LABELS, BAG TAGS, AND MEDICAL GUIDES ARE AVAILABLE, INCLUDING NOTICE REGARDING THE AVAILABILITY OF THE PRESCRIPTION LABELS, BAG TAGS, AND MEDICAL GUIDES IN AUDIO FORMAT.

SECTION 2. AND BE IT FURTHER ENACTED, That the State Board of Pharmacy shall adopt the regulations required under § 12-505.1 of the Health Occupations Article, as enacted by Section 1 of this Act, on or before January 1, 2025.

SECTION 3. AND BE IT FURTHER ENACTED, That, on or before December 1, 2023, the Maryland Department of Health shall submit to the General Assembly, in accordance with § 2-1257 of the State Government Article, a report on the potential process

for and costs of implementing enhanced professional dispensing fees for providing accessible labels and compliant packaging to blind, visually impaired, and otherwise print disabled individuals.

SECTION ~~2~~ 4. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2023.

Approved by the Governor, May 3, 2023.

Large-Print Labels

The Large Print Label is especially designed for your patients who have low vision or elderly. It presents all vital prescription information in an 18-point font on high-contrast, non-glare, durable media. It features all the same information on a regular label, just in larger font.



You as the pharmacist, print the label, fold it and affix it to the medication. It also features a 2D bar code that can be scanned with a smartphone using the ScriptView app so your patient can audibly access the detailed drug information.

These Large Print Labels meet all the guidelines and recommendations set by the U.S. Access Board's Working Group on Accessible Prescription Labels.

Controlled Substance Safety Labels

A Controlled Substance Safety Label (CSSL) is a solution designed to help reduce the risk of opioid misuse by your patients by reminding them of the risks.

These labels provide easy-to-understand audible and visual access to prescription drug information including SIGs, package inserts, med guides and warnings. This is particularly beneficial for patients who have difficulty understanding printed media, cannot read a printed label or are overwhelmed by the amount of information that comes with Schedule II through V medications.

- Clearly identifies a medication as a controlled substance and provides a safety video to help ensure compliance and adherence
- Distinct label alerts the patient to use extra caution when taking the medication
- Scan of the label's QR code instantly plays a brief safety video, detailing safety tips and warnings in a quick and easy-to-understand audio and visual format



Software/Hardware Features:

- Windows Compatible Software - v1903 (19H1) and higher
- Fast Production and Verification
- Small Hardware Footprint
- Direct Thermal Printing
- Fold Label into Booklet and Attach to Prescription Bottle



Give it a try!

Use your phone to scan the QR code featured on the Controlled Substance Safety Label. A brief safety video detailing drug instructions and warnings will play in your browser.

No phone? No Problem.

View the video [here](#).



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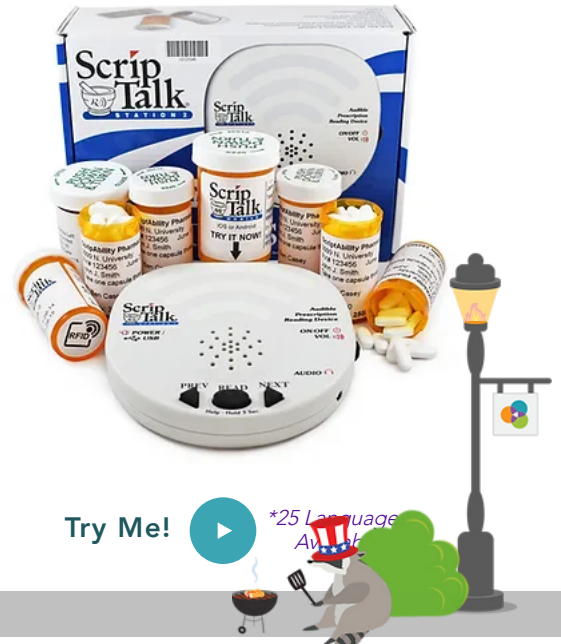
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ScripTalk

Based on RFID text-to-speech technology, ScripTalk Talking Prescription Labels are designed to help you better serve your patients who are blind, visually impaired or print impaired. By using a smartphone app or a ScripTalk Station Reader, your patients can hear all their vital prescription information read out loud, including:

- Drug Name, Dosage & Instructions
- Warnings & Contraindications
- Pharmacy Information
- Doctor Name
- Prescription Number & Date



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Compatible Software (Windows 10 v1903 [19H1] and higher) and integrated with many pharmacy software programs. If you need a specific language for your patient, let us know. We have several [languages available](#).

Study Results **How effective is this solution in improving medication safety and independence for your patients?** The results of an [independent study](#) speak for themselves: Almost all participants (98%) reported feeling safer taking their medications since using ScripTalk.

In 2012, the [FDA Safety and Innovation Act](#) provided a list of best practices for pharmacies to implement to ensure that patients would have a safe, private, independent, reliable and consistent access to prescription label information. ScriptAbility's prescription labeling system helps you meet all of those needs.

How Does ScripTalk Work?

We use cookies on our website to see how you interact with it. By accepting, you agree to our use of such cookies. See [Privacy Policy](#)

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[Click here to request ScripTalk for your pharmacy!](#)[Check Out our ScripTalk ST400 Printer to Cut Creation Time in Half](#)

Several states have adopted laws regarding accessible prescription labels:

- [Oregon](#)
- [Maryland](#)
- [Hawaii](#)
- [Puerto Rico](#)
- [Nevada](#)
- [Tennessee](#)
- [Virginia](#)

Recommendations from the U.S. Access Board:

- [Best Practices for Making Prescription Drug Container Label Information Accessible](#)
- [National Council on Disability \(NCD\) Best Practices Prescription Drug Labeling](#)



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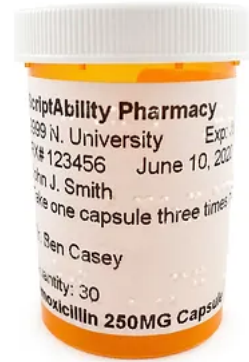
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BrailleRx

These accessible labels are available in an easy-to-access Grade 2 Braille that is on a clear adhesive that fits over the pharmacy labels. You select the data to emboss.

Braille Labels Feature:

- Easy-to-access Grade 2 Braille
- Meet guidelines of US Access Board
- Clear adhesive goes over pharmacy label
- Ideal for Braille readers



ScriptAbility offers Braille labels as an additional solution for accessible pharmacy labels. These labels help ensure compliance and adherence for your blind and visually impaired patients who read Braille. These labels provide quick identification of medications and are often used together with ScripTalk Talking Labels for



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- **Best Practices for Making Prescription Drug Container Label Information Accessible**
<http://www.scriptability.com/wp/wp-content/uploads/2017/09/Best-Practices-for-Making-Prescription-Drug-Container-Label-Information-Accessible.pdf>
- **National Council on Disability (NCD) Best Practices Prescription Drug Labeling**
<http://www.scriptability.com/wp/wp-content/uploads/2017/06/NCD-Best-Practices-2017-Final.pdf>

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Prescription Drug Container Labels

The Board has led the development of advisory guidance on making prescription drug container labels accessible to people who are blind or visually impaired or who are elderly. This initiative was authorized by the [Food and Drug Administration Safety and Innovation Act](#) which President Obama signed into law in July 2012. A provision of the act (section 904) directs the Board to convene a working group to develop best practices for making information on prescription drug container labels accessible to people who are blind or visually impaired.

Shortly after the law was enacted, the Board formed the Working Group on Accessible Prescription Drug Container Labels, an 18-member stakeholder panel comprised of representatives from advocacy organizations and industry. The working group explored various access alternatives, including braille, large print labels, and auditory technologies such as “talking bottles” and radio frequency identification tags. In July 2013, it submitted to the Board its best practice [recommendations](#) for pharmacies on providing independent access to prescription drug container labels. These recommendations are advisory only, not mandatory, and will not have the force of guidelines or standards.

The law directed the National Council on Disability (NCD) to conduct an informational and educational campaign in cooperation with the stakeholder working group to inform the public, including people with disabilities and pharmacists, of the best practices. In June 2016, NCD issued a [brochure](#) on the best practices recommended by the Board’s working group. The law also called upon the Comptroller General to conduct a review to assess the extent to which pharmacies are implementing the best practices and to determine whether barriers to prescription drug labels remain; the [report](#) was completed in December 2016.

Several national pharmacy chains now offer talking prescription information for blind customers: [CVS](#) (including its mail service company [Caremark](#)), [Walmart and Sam’s Club](#), [Walgreens](#), [Rite Aid](#) and [Express Scripts Pharmacy](#).

On March 18, 2014, CVS announced that it is providing ScripTalk talking prescription labels to customers with visual impairments ordering through cvs.com. The CVS initiative will ensure that cvs.com customers who are blind can access the critical health and safety information provided in a standard print prescription label. The Access Board [Working Group’s Final Report](#) Regarding Best Practices for Making Prescription Drug Container Label Information Accessible to Persons who are Blind or Visually-Impaired is referenced in [section 3.2 and 3.5 of the agreement](#) that led to the announcement. The agreement and announcement is the result of Structured Negotiations between CVS and the American Council of the Blind, the California Council of the Blind and the American Foundation for the Blind.



BEST PRACTICES FOR ACCESSIBLE PRESCRIPTION DRUG LABELING:

Pharmacies have a critical role to play to ensure the safety of blind, visually impaired, and elderly customers



Working Group Recommendations

Best Practices for Making Prescription Drug Container Label Information Accessible to Persons Who are Blind or Visually-Impaired or Who are Elderly

Access Board Working Group on Accessible Prescription Drug Container Labels

July 10, 2013

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- [Best Practices to Use for All Formats](#)

- [Format-Specific Best Practices](#)
- [Resources](#)

Legislative Background:

On July 9, 2012, President Obama signed into law the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144, 126 Stat. 993). The law includes measures to promote drug safety and to improve FDA procedures for reviewing new medicines and medical devices.

A provision of the Act, [Section 904](#), authorizes the Access Board to convene a stakeholder working group to develop best practices for making information on prescription drug container labels accessible to people who are blind or visually-impaired or who are elderly. (See 29 U.S.C. 792.) Under the law, representation within the working group must be divided equally between consumer and industry advocates. The Act exempts the working group from the Federal Advisory Committee Act.

The law calls for the working group to develop, no later than 1 year after the date of the enactment of this Act, best practices for pharmacies to ensure that blind and visually-impaired individuals have safe, consistent, reliable, and independent access to the information on prescription drug container labels.

According to Section 904, the best practices are not mandatory. They are not to be construed as accessibility guidelines or standards of the Access Board, nor do they confer any rights or impose any obligations on working group participants or other persons. The law makes it clear that nothing in Section 904 is to be construed to limit or condition any right, obligation, or remedy available under the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et seq.) or any other federal or state law requiring effective communication, barrier removal, or nondiscrimination on the basis of disability.

The law also provides that the working group may make this best practices report publicly available through the internet websites of working group participant organizations, and through other means, in a manner that provides access to interested individuals, including individuals with disabilities. The National Council on Disability will conduct an informational and educational campaign in cooperation with the stakeholder working group to inform the public, including people with disabilities and pharmacists, of the best practices. The Government Accountability Office will undertake a review beginning 18 months after the date of this report to assess the extent to which pharmacies are following the best practices and to what extent barriers to information on prescription drug container labels remain.

Working Group Participant Organizations

In October 2012, the Access Board formed an 18-member working group with representation from national organizations advocating for individuals who are blind, visually-impaired, and older adults, as well as industry groups representing retail, mail order, and independent community pharmacies.

The working group is comprised of representatives of the following organizations:

- AARP
- American Council of the Blind (ACB)
- American Foundation for the Blind (AFB)
- Blinded Veterans Association (BVA)
- Council of Citizens with Low Vision International (CCLVI)
- Express Scripts
- Metropolitan Washington Association of the Deaf Blind (MWADB)
- National Association of Chain Drug Stores
- National Community Pharmacists Association
- National Council on Aging (NCOA)
- National Council on Independent Living (NCIL)
- National Federation of the Blind (NFB)
- National Council on Patient Information and Education (NCPPIE)
- Rite-Aid
- Target
- US Pharmacopeia (USP)
- Walgreens
- Wal-Mart

The working group met in person in Washington, DC, on January 10 and 11, 2013, and subsequently via five teleconferences. The working group explored various alternatives, including braille, large print labels, and various auditory technologies such as “talking bottles” and radio

frequency identification devices. The working group also considered whether there are technical, financial, manpower, or other factors unique to pharmacies with 20 or fewer retail locations which may pose significant challenges to the adoption of the best practices.

Why Are Best Practices Needed?

Persons with visual impairments who cannot read print prescription drug container labels all too often report inadvertently taking the wrong medication, the wrong amount, at the wrong time, and under the wrong instructions, thereby endangering the health and safety of themselves and family members for whom they are caregivers. Without having ready access to their prescription drug container label information, persons with visual impairments are also at risk of taking expired medications, of not being able to obtain refills in a timely manner, and of being unable to detect pharmacy errors. The majority of persons who become blind or visually-impaired do so after age 60, a time when multiple medications are often prescribed and when persons may experience physical and cognitive conditions which heighten the necessity for safe, consistent, reliable, and independent access to prescription drug container label information.

In recent years, various organizations, including US Pharmacopeia (USP), the National Association of Boards of Pharmacy, and the National Council on Patient Information and Education, have recommended the adoption of patient-centered pharmacy practices to improve patient understanding and safe, effective use of prescription medication. Inherently inclusive, patient-centered pharmacy practices promote accessibility, while a one-size-fits-all approach typically creates barriers.

In the context of this report, the term “best practice” refers to a set of working methods that the working group believes is most effective in providing access to prescription drug container label information to customers with blindness and visual impairments, including older adults.

The goal of the best practices for accessible prescription drug container labels is to offer guidance to pharmacies on how to provide accessible prescription drug container labels to patients with visual impairments to enable them to manage their medications independently and privately and have the confidence that they are taking their medications safely, securely, and as prescribed.

What Is a Prescription Drug Container Label?

A prescription drug container label is a legal document that must be prepared by the pharmacist filling the prescription. The pharmacist must ensure the accuracy of the prescription drug container label, and include on the label all elements required by applicable state law.

In 2009, USP determined optimal prescription label content and format to promote safe medication use by critically reviewing factors that promote or distract from patient understanding of prescription drug container label instructions. USP created universal prescription drug container label standards for format, appearance, content, and language (see: [U.S. Pharmacopeial Convention](#)). The best practices in this report build upon the USP universal patient-centered prescription drug container label standards.

Delivery Methods for Providing Accessible Prescription Drug Container Labels

A variety of delivery methods are available for producing accessible prescription drug container labels in audible, braille, and large print formats. Delivery methods include:

- Hard copy braille and large print: A pharmacist filling prescriptions produces hard copy braille and large print labels upon request, and affixes the accessible labels to the prescription drug containers.
- Dedicated electronic equipment: Some equipment is designed specifically to provide accessible prescription drug container labels. Some dedicated electronic methods can be used with containers of various sizes, shapes, and materials. Examples of dedicated electronic methods include:
 - Digital Voice or Text-to-Speech Recorder: This is a small electronic device that a pharmacist affixes to a prescription drug container. When activated by pushing a button on the device, the patient hears the information printed on the prescription drug container label. One device is affixed to each prescription drug container. Some devices also have a USB drive.
 - Radio Frequency Identification Device (RFID): A pharmacist places an RFID tag on a prescription drug container. A patient who is blind or visually-impaired is equipped with a small, dedicated device that, when a container with an RFI Tag is placed over the device, audibly announces the text on the prescription drug container label. This technology may also provide prescription drug container label information in large print, and has a USB drive.
 - Smart devices and computers: Many patients with visual impairments use their own computers and smart devices equipped with electronic braille, large print, and audio technology to access electronic text. Visually impaired computer users, particularly those who are deaf-blind, may request access to prescription drug container labels using their computers and smart devices, either via internet applications (apps) or in combination with dedicated equipment equipped with a USB drive. Methods include pharmacists placing on the prescription drug container a QR code, RFI tag, or other small, electronic unit encoded with the prescription drug container label in electronic text, which visually impaired patients receive on smart devices or computers in

electronic braille, large print, or audible format. Note that using this delivery method does not involve pharmacists embossing a braille label; rather, pharmacists use an electronic delivery method that encodes the prescription drug container label text, which can be displayed via a computer screen, speakers, or an electronic braille display.

Some electronic prescription drug container label delivery methods may also have the capacity to include supplemental information about the prescription medications. In addition, some may have capability to translate prescription drug container label information into several languages.

The key to providing accessible prescription drug container labels is patient-centered communication between pharmacists and patients with blindness and visual impairment and patient representatives. Because the extent of visual impairment varies from person to person, some patients may need prescription drug container labels in an audible format, while others may need braille, and still others may need large print. Additionally, it is important to keep in mind that visually impaired patients who are not computer savvy may need hard copy braille or large print labels, or a dedicated electronic method that is easy to operate.

Best Practices to Use for All Formats

The following best practices promote access to prescription drug container label information in all formats, including audible, braille, and large print labels.

- One of the best things pharmacists can do is to encourage patients and patient representatives to communicate their needs to pharmacists:
 - Advertise a local or, when possible, a toll-free telephone number to promote communication between patients and pharmacists;
 - If pharmacy websites and applications (apps) are made available to patients, ensure website and app accessibility; and
 - When a pharmacist observes a patient or patient representative having reading difficulty, offer education and counseling in a setting that maintains patient privacy.
- Follow universal patient-centered prescription drug container label standards.
- Make available options for accessible prescription drug container labels in audible, braille, and large print formats via methods using, for example, hard copy, dedicated devices, and computers or smart devices.
- Explain to the patient the available accessible prescription drug container label format options, and provide the prescription drug container label in the format option selected by the patient.
- Ensure that duplicate accessible labels preserve the integrity of the print prescription drug container label.
- Subject accessible prescription drug container labels to the same quality control processes used for print labels to ensure accuracy and patient safety.
- Maintain patient privacy in accordance with the Health Insurance Portability and Accountability Act (HIPAA) rules when preparing accessible prescription drug container labels, e.g., record audible labels in a location where patient information cannot be overheard by unauthorized persons.
- In advance, make arrangements to provide accessible prescription drug container labels. For example, maintain a sufficient inventory of supplies necessary to support timely provision of prescription drug container labels in accessible label formats.
- Provide prescription medication with an accessible prescription drug label within the time frame the same prescription would be provided to patients without visual impairments.
- Do not impose a surcharge or extra fee to an individual to cover the cost of providing an accessible drug container label and equipment dedicated for prescription drug container label access.
- Ensure the durability of accessible label format options until the expiration date specified on the prescription drug container label.
- Select a container that best supports the type of accessible label provided.
- For all accessible label formats, including audible formats, ensure that all required information contained on the print prescription drug container label is provided on the accessible label in the same sequence as the print label.
- Include in accessible prescription drug container labels the information on warning labels added to the container at the pharmacist's discretion.

Format-Specific Best Practices

In addition to the best practices listed above, please note the following format-specific best practices.

Audible Prescription Drug Labels

For dedicated equipment, select devices that provide independent, easy to use, start/stop operation, with volume control, and ear bud access for privacy.

If using a voice recorder:

- speak in a clear voice;

- record information in a setting that minimizes background noise and maintains patient privacy.

Offer to show the patient how to operate the audible prescription drug container label.

Braille Prescription Drug Container Labels

Electronic delivery method: Acquire an electronic delivery method using RFI tags, QR codes, or other processes to provide electronic text of the prescription drug container label upon request. Consumers with electronic braille equipment may then access electronic text in braille format.

Note that, as required, the working group considered significant challenges that pharmacies may face in producing drug labels in accessible formats, such as hard copy braille. The working group recognizes that mail order and online pharmacies, because of their centralized structure, large volume, and mail delivery process, may be better equipped than local stores to provide hard copy braille prescription drug container labels. Many mail order and online pharmacies have established a unit with the necessary computer software and braille embossers to produce hard copy braille labels and a protocol to develop pharmacists' proficiency in printing accurate braille labels.

- If a local pharmacy store has a high demand for hard copy braille prescription drug container labels, acquire on-site braille embosser capacity and proficiency.
- If a local pharmacy store receives infrequent or occasional requests for hard copy braille prescription drug container labels, partner with a pharmacy that has braille prescription drug container labeling capacity to provide a hard copy braille prescription drug container label.

When embossing hard copy braille prescription drug container labels:

- Use contracted (Grade 2) braille.
- Emboss braille labels on transparent material in order to preserve the legibility of print container labels. Affix braille label to the prescription drug container with strong adhesive.
- Do not fold braille labels.

Printing Large Print Labels (hard copy):

- Print label in 18-point bold font.
- Use non-glossy paper or other material that is durable and a size that is easy to manipulate.
- Use print with highest possible contrast between text and background color (ideally black text on a white or pale yellow background). If printing on both sides, use material that does not allow print bleed-through from one side to the other.
- Use sentence case, with the initial capital letter followed by lower-case characters.
- Use non-condensed, san-serif font, such as Arial.
- Provide 1.5 line spacing.
- Use horizontal text only.
- Securely affix the large print label to the prescription drug container.
- When covering a large print label with protective tape, use non-glossy, transparent tape.

Resources

[USP Patient-Centered Prescription Label Standards](#)

UMS White Paper, The National Council for Prescription Drug Programs Work Group (WG), 2013

Working Group Participant Organizations

- AARP
- American Council of the Blind (ACB)
- American Foundation for the Blind (AFB)
- Blinded Veterans Association (BVA)
- Council of Citizens with Low Vision International (CCLVI)
- Express Scripts
- Metropolitan Washington Association of the Deaf Blind (MWADB)
- National Association of Chain Drug Stores
- National Community Pharmacists Association
- National Council on Aging (NCOA)
- National Council on Independent Living (NCIL)
- National Council on Patient Information and Education (NCPIE)

- National Federation of the Blind (NFB)
- Rite-Aid
- Target
- US Pharmacopeia (USP)
- Walgreens
- Wal-Mart

Agenda Item: Adopt recommended guidance document for Board of Pharmacy consideration

Action Needed:

Motion to recommend to the Board of Pharmacy to adopt the guidance document as presented or amended.

Virginia Board of Pharmacy

Dispensing Medications to Blind or Low-Vision Patients

In addition to complying with § 54.1-3410.3 and 18VAC110-20-351, pharmacists should refer to the United States Access Board at <https://www.access-board.gov/rx.html> for information regarding various delivery methods for providing accessible prescription drug container labels, best practices to use for all formats, and format-specific best practices such as for audible, braille, and large print labels. Pharmacists should ensure patients are counseled in compliance with § 54.1-3319 and in a manner that identifies and aids their understanding of how to properly use the accessible label or other accommodation provided.

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