



To: All U.S. Pharmacies

October 2014

From: Dan Langdon, President
AccessaMed, Inc.

The State of the Industry: 2014 White Paper on Accessible Prescription Drug Labeling for the Blind, Visually Impaired and Elderly Communities

It has been more than two years since President Obama signed into law the Food and Drug Administration (FDA) Safety and Innovation Act, promoting drug safety and improving FDA procedures. During this period, the U.S. Access Board responded in 2013 to Section 904 of the Act with *Best Practices* educating pharmacies on how to ensure that blind, visually-impaired and elderly communities have safe, consistent, reliable and independent access to the information of prescription drug container labels. Since last year, AccessaMed has spent time with pharmacies at the National Association of Chain Drug Stores Total Show Expo (NACDS) and the leaders and members of our country's blind organizations, including the American Council for the Blind, America Foundation of the Blind and National Federation for the Blind. These conversations have verified the processes put in place by the FDA have not been even partially executed, let alone enforced. The intent of this white paper is to provide the reader with updated facts so pharmacies can make informed decisions as they look to provide a solution for their blind, visually-impaired and elderly customers as required by the legislation.

BACKGROUND:

On July 9, 2012, President Obama signed into law the Food and Drug Administration Safety and Innovation Act.¹ The law promotes drug safety and improves FDA procedures when reviewing new medicines and medical devices. A provision of the Act, Section 904, authorized the U.S. Access Board to convene a stakeholder working group to develop *Best Practices*, making information on prescription drug container labels accessible to people who are blind or visually-impaired or who are elderly.

The law directed for the U.S. Access Board to convene a working group to develop and report within one year of the enactment of the Act, the *Best Practices* for pharmacies. The determined *Best Practices* are to ensure that blind, visually-impaired and elderly communities have safe, consistent, reliable, and independent access to the information of prescription drug container labels. These findings were published July 10, 2013 by the U.S. Access Board (Exhibit 1).

¹ U.S. Food and Drug Administration, Food and Drug Administration Safety and Innovation Act (2012) <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAAct/SignificantAmendmentsToTheFDCAAct/FDASIA/default.htm>

THE BLIND ORGANIZATIONS ARE TAKING MATTERS INTO THEIR OWN HANDS:

The Law Office of Lainey Feingold engaged in structured negotiations with American Council of the Blind, its affiliates and top U.S pharmacies regarding accessible prescription drug labeling.² The term “structured negotiations” was developed by Lainey Feingold and her co-counsel as an alternative to litigation emphasizing collaboration and focusing on solution.

As a result, the ACB and CVS/pharmacy announced a program in March 2014 to provide a solution for prescriptions ordered by their blind or visually impaired customers for home delivery through its online pharmacy, CVS.com. This settlement was the result of ACB’s collaboration with CVS/pharmacy, the American Foundation for the Blind, and the California Council of the Blind. There is also a separate structured negotiation effort with Caremark to obtain accessible prescription information from that mail-order company. Caremark is connected to CVS but operating as a separate company. Caremark has been a solid structured negotiation partner with the proposed plan to have a solution before the end of the year.

Additionally, the ACB announced a settlement with Walgreens in June 2014, launching a nationwide program offering talking prescription devices to customers with visual impairments. Walgreens is the first in the industry to offer its own exclusive talking prescription device, called the Talking Pill Reminder, at its retail locations nationwide. The device attaches to prescription containers and is provided free of charge with prescription medications that Walgreens dispenses to its pharmacy customers who are blind or visually impaired. The Talking Pill Reminder can be recorded by the customer to speak the information on the customer’s prescription medication label. It also has an audible alarm to remind patients when to take a medication. This initiative was the result of collaboration between ACB and Walgreens, the California Council of the Blind and the Illinois Council of the Blind.

Lainey Feingold is also working with other retail and mail-order pharmacies on the accessible prescription issue, including Rite Aid. In addition to accessible prescription efforts, the law firm is engaged in other structured negotiations with ACB, its affiliates and WellPoint.

STATE GOVERNMENT OFFICIALS ARE TAKING MATTERS INTO THEIR OWN HANDS:

While the FDA Safety and Innovation Act was created on a national scale, we believe the development and implementation effort will greatly rely on the support and urgency from government parties within each state. One example is Massachusetts Bill 427, which was created by Massachusetts State Senator Kathleen O’Connor Ives (Exhibit 2).³ This Bill, *An Act Relative to Prescription Drug Voice Synthesizers*, specifically requires insurance companies that offer prescription drug coverage within the state to insure an audio solution that would speak the contents of the prescription bottle. This Bill was created as a result of one blind constituent who was in need of an accessible prescription labeling solution, but was unable to pay for it. Watch for other states to follow suit.

² Talking Prescription Labels Update – Summer 2014, Law Office of Lainey Feingold (2014)
<http://lflegal.com/2014/07/talking-prescription-labels>

³ Senate Bill No. 472, The 188th General Court of The Commonwealth of Massachusetts (2013)
<https://malegislature.gov/Bills/188/Senate/S472>

THE LACK OF OWNERSHIP BY RESPONSIBLE PARTIES:

According to the National Council on Disability's (NCD) Fiscal Year 2014 Congressional Budget Justification, the FY 2012 Senate Labor-H Appropriation bill approved language for NCD and the Administration on Developmental Disabilities (ADD) regarding monitoring the implementation of the FDA Safety and Innovation Act.⁴ This bill tasked NCD with conducting an informational and educational campaign designed to inform individuals with disabilities, pharmacists, and the public about *Best Practices* associated with access to information on prescription drug container labels for individuals who are blind or visually impaired. To date, the NCD has not put forward any plans to orchestrate forth such campaign. As a result, the intended recipients of this Act have not been properly informed of the requirements of the law, the *Best Practices*, or the pending review from the Comptroller General of the United States.

THE URGENCY AT HAND:

Scheduled to begin in January 2015, 18 months after the completion of the development of *Best Practices* under subsection (a)(3)(A), the Comptroller General of the United States is scoped to conduct a review of the extent to which pharmacies are utilizing the *Best Practices* and the extent to which barriers to accessible information on prescription drug container labels for blind and visually-impaired individuals continue (Exhibit 1).

No later than September 30, 2016, the Comptroller General of the United States shall submit to Congress a report on the review conducted. This report will include recommendations about how best to reduce the barriers experienced by blind and visually-impaired individuals to independently accessing information on prescription drug container labels.

While the FDA Safety and Innovation Act maps out the *Best Practices* for pharmacies, the enforcement tool being used in the structured negotiations is the **Americans with Disabilities Act of 1990 (ADA)**. The ADA prohibits discrimination and ensures equal opportunity for persons with disabilities in employment, state and local government services, public accommodations, commercial facilities, and transportation.⁵ Based on this, pharmacies that are not compliant with the ADA are at risk of being litigated against, just as CVS/pharmacy, Walgreens and Rite Aid have already been.

The political power help by the various state and local blind organizations combined with the enforcement power of the ADA should not be underestimated in achieving the stated goal of providing accessible prescription drug labeling for the blind, visually impaired or elder in this country.

⁴ Fiscal Year 2014 Budget Justification, National Council on Disability (2013)
http://www.ncd.gov/rawmedia_repository/a88c4857_d8b8_4907_a7c0_e23c644409b1?document.docx

⁵ Americans with Disabilities Act of 1990 (Current) <http://www.ada.gov/>

NOTE:

For a copy of the AccessaMed's 2013 White Paper addressing the relevant law, enforcement and published *Best Practices*, please contact AccessaMed at info@accessamed.com or visit our website at www.accessamed.com.

Exhibit 1

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

Working Group Recommendations

Access Board Working Group on Accessible Prescription Drug Container Labels

July 10, 2013

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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 (NCPIE)
- 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 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

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| <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • 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 |
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Exhibit 2

Senate Docket, No. 1018, The Commonwealth of Massachusetts.

SENATE DOCKET, NO. 1018 FILED ON: 1/17/2013

SENATE No. 472

The Commonwealth of Massachusetts

PRESENTED BY:

Kathleen O'Connor Ives

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act relative to prescription drug voice synthesizers.

PETITION OF:

NAME:

Kathleen O'Connor Ives

DISTRICT/ADDRESS:

First Essex

SENATE No. 472

By Ms. O'Connor Ives, a petition (accompanied by bill, Senate, No. 472) of Kathleen O'Connor Ives for legislation relative to prescription drug voice synthesizers. Financial Services.

The Commonwealth of Massachusetts

In the Year Two Thousand Thirteen

An Act relative to prescription drug voice synthesizers.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

SECTION 1. Chapter 175 of the General Laws is hereby amended by inserting after section 47W the following section:-

Section 47X. For the purposes of this section, the following word shall have the following meaning, unless the context clearly otherwise requires: "voice synthesizer", a product that attaches to bottles and or reads electronically a code on the label of a prescription which verbally then converts the textual information encoded by a screen-reader and feeds it to the soundcard for oral reproduction.

Any blanket or general policy of insurance described in subdivision (A), (C) or (D) of section 110 which provides prescription drug insurance, which is delivered or issued for delivery or subsequently renewed by agreement between the insurer and the policyholder within or without the Commonwealth shall provide coverage for the expense of a medically prescribed voice-synthesizer used in connection with a container that would provide audible information of a prescription for use by a person who is legally blind or visually impaired. The policy holder shall be responsible for returning the container to a pharmacist for refill.

SECTION 2. The Commissioner of the Division of Insurance shall adopt regulations to implement and provide information of Chapter 147 Section 47X of the General Laws within 90 days of its effective date.

SECTION 3. Notwithstanding any general or special law to the contrary, an individual, public or private institution, business or other organization that regularly and primarily provides a service to a disabled person may inform the disabled person of the availability of the voice synthesizer referred to in section 47X of chapter 175 of the General Laws.