

## Shortcomings Of Best Practices Report On Drug Labeling

Law360, New York (July 23, 2013, 12:34 PM ET) -- When it was signed into law by President Obama on July 12, 2012, the [Food and Drug Administration Safety Information Act](#), Pub. L. No. 112-144, 126 Stat. 1055 (2012) (FDASIA) was best known for its five-year reauthorization of brand pharmaceuticals user fees and the creation of a new user-fee program for generic and biosimilar products. However, the FDASIA contains a number of additional provisions, some of which relate to improving patient access to medical treatments and technologies.



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Among these is Section 904, which authorizes the [Architectural and Transportation Barriers Compliance Board](#) (access board) to convene a "working group" comprised of an equal number of "consumer and industry advocates" to "develop best practices on access to information on prescription drug container labels for individuals who are blind or visually impaired." Id. § 904(a)(1) & (2).

Congress gave this working group one year to develop a list of "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." Id. § 904(a)(3)(A). The working group was directed to consider best practices for providing prescription label information in Braille; various types of audible formats, including "talking pill bottles" and radio-frequency identification tags; "enhanced visual means," including large fonts; and "other relevant alternatives as determined by the Working Group." Id. § 904(a)(4)(A)(i) – (iv).

Congress also directed the working group to consider whether there exist 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. Id. § 904(a)(4)(B).

The working group first met in January 2013, conducted a number of follow-up conference calls thereafter, issued its final report on June 3, 2013 and presented its final report to the access board on July 10, 2013. A summary of the best practices report's high points follows.

The best practices report builds upon the universal patient-centered prescription drug container label standards developed by the U.S. Pharmacopeial Convention (USP) in 2009.

Among other things, these standards emphasize that prescription drug labels should be organized in a patient-centered manner that features only the most important patient information needed for safe and effective understanding and use and should prominently display “information that is critical for patients’ safe and effective use of medicine” (including the patient's name, drug name and strength, and explicit clear directions for use in simple language). In its report to the access board, the working group recommended that all pharmacies adopt these standards.

The primary point of the best practices report is that pharmacies should be in a position to do more than simply affix standard labels to prescription drug containers. Instead, the report emphasizes that because “the extent of visual impairment varies from person to person,” pharmacies should be equipped to communicate the contents of prescription drug labels in a “variety of delivery methods,” including audible formats, Braille and large print.

The best practices report then goes on to describe best practices for pharmacies when providing prescription label information regardless of format, followed by a more specific description of format-specific practices.

The best practices report begins by making recommendations designed to promote access to prescription drug container label information in all formats. Among other things, the best practices report recommends that pharmacists should do the following:

- Communicate with patients and patient representatives to identify their particular needs and to explain available audible, Braille and large-print format options
- Follow USP label standards
- Maintain sufficient inventory and supplies to provide prescription label information in accessible formats upon request and within the time frame the same prescription would be provided to patients without visual impairments
- Refrain from imposing surcharges or extra fees to cover the cost of providing accessible prescription labels
- Ensure the durability of accessible label format options until the expiration date specified on the prescription drug container label

With respect to providing prescription label information in audible formats, the best practices report recognizes that prescription label information can be translated through the use of digital recorders, RFID chips, QR codes and the like. The report does not designate a preferred approach but simply recommends that pharmacies should “select devices that provide independent, easy to use, start/stop operation, with volume control, and ear bud access for privacy.”

It recommends that pharmacists should speak clearly and record prescription information in settings that minimize background noise and maintain patient privacy and that pharmacists should offer to show patients how to use the device.

With respect to providing prescription label information in Braille, the best practices report recommends that pharmacies provide Braille both in electronic formats, which convert label information into electronic text that can be translated by electronic Braille equipment, as well as in hard copy formats.

The report further recognizes the “challenges” inherent in providing Braille labels at individual pharmacies and recognizes that mail-order and online pharmacies “may be better equipped than local stores to provide hard copy Braille prescription drug container labels.”

Nonetheless, the best practices report suggests that individual pharmacies obtain “on-site Braille embosser capacity and proficiency” if they experience “high demand” for Braille labels, and that they “partner with a pharmacy that has braille prescription drug container labeling capacity” if they only receive “infrequent or occasional requests” for Braille labels.

The report also recommends that Braille labels be embossed “on transparent material” and affixed to drug containers “in order to preserve the legibility of print container labels.”

The best practices report’s recommendations regarding large-font format for accessible prescription labeling is more straightforward. It suggests that pharmacies consider taking the following steps:

- Print label in 18-point bold font.
- Use nonglossy 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 noncondensed, 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 nonglossy, transparent tape.

It is too early to evaluate what effect the working group’s best practices report will have with respect to making prescription drug label information more accessible to individuals with vision impairments. However, we offer the following preliminary observations.

First, the best practices report itself confirms that its recommendations do not have the force of law:

According to Section 904, the best practices are not mandatory. The practices are not to be construed as accessibility guidelines or standards of the Access Board, and the best practices do not 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.

Section 904(b) of the FDASIA directs the comptroller general of the United States to evaluate the extent to which pharmacies utilize the best practices outlined in the working group's best practices report. The comptroller general is to commence its study in approximately January 2016 — some 18 months after promulgation of the best practices report — and to issue a report to Congress no later than Sept. 30, 2016.

The comptroller general's report is to contain “recommendations about how best to reduce the barriers experienced by blind and visually impaired individuals to independently accessing information on prescription drug container labels.” It seems unlikely that Congress or the access board or the [U.S. Department of Justice](#) will be issuing any type enforceable regulations until at least then.

Second, and for a number of reasons, it is unclear just how much influence the best practices report will have as a practical matter. The working group's report does not mention, let alone resolve, whether the alternative methods for communicating the contents of prescription drug labels must comply themselves with prescription drug labeling laws issued by the various states. In addition, and perhaps more importantly, the best practices report establishes aspirational standards without reference to cost.

Third, by recommending that pharmacies adopt the USP's standards to define what information must be provided in accessible formats, the best practices report stops short of mandating that supplemental warnings and other information contained in patient medication guides and other information sheets also be provided in alternative formats.

In addition, incorporating the USP's standards, which distinguish between prescription label information that is “critical for patients' safe and effective use of medicine” and other information that is “less critical but important,” the best practices report may provide some practical guidance in the event that particular auxiliary aids, such as digital voice recorders, do not have sufficient memory to store, translate or communicate all prescription label information.

Retail pharmacies and others who dispense prescription drugs would be well-advised to review the working group's best practices report in detail. At a minimum, it stands as a reminder that the Americans with Disabilities Act, as well as other federal and state laws, obligate retailers to provide appropriate auxiliary aids and services where necessary to ensure effective communication with individuals with disabilities and to ensure that individuals with disabilities are not treated differently than other individuals because of the absence of such aids and services.

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