

To: All U.S. Pharmacies

November 2014

From: Dan Langdon, President
AccessaMed, Inc.

A Toothless Tiger or an Enforceable Law? The Implementation of Accessible Prescription Drug Labeling.

After publishing last month's State of the Industry white paper, we received feedback from our readers asking us to clarify the difference and relationships between the **Food and Drug Administration Safety and Innovation Act (FDASIA)**, the **Access Board's Best Practices**¹ and the **American's with Disabilities Act of 1990 (ADA)**². In addition to the need for a clearer understanding on what the legal requirements, pharmacies are left to determine how to cover the cost of this added service of accessible prescription drug labeling. Whether pharmacies decide to create an in-house solution or select products or services from an outside vendor, there are costs associated with providing a solution for their visually impaired customers. We have made it our mission to not only provide a better understanding of the FDASIA Access Board's Best Practices vs. ADA, but to provide ideas that can help cover the cost of accessible labeling solutions.

The Tough Questions: What's Toothless and What's Enforceable?

- A. Are the Best Practices made by the FDASIA Access Board mandatory?
According to Marsha Mazz, United States Access Board Director, Office of Technical and Information Services, the Access Board was convened under the auspices of the Food and Drug Administration Safety and Innovation Act to develop Best Practices. It did not, however, authorize these Best Practices to be mandatory requirements. Although the Access Board's recommendations for Best Practices remain recommendations, not requirements, people with disabilities have certain protections under the ADA that could result in a requirement that a pharmacy provides an accessible labeling solution³.
- B. What does the ADA say about this topic? Who enforces the ADA?
Under the Department of Justice (DOJ), the ADA Title III Regulations require public accommodations, including pharmacies, to make "reasonable modifications" in policies, practices, and procedures in order to avoid discrimination on the basis of disability⁴. To ensure that individuals with disabilities are not excluded, denied services, segregated or otherwise treated differently than other individuals, the ADA regulations require public accommodations to provide "auxiliary aids and services" and to ensure "effective communication" with

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

² Americans with Disabilities Act of 1990 (Current) <http://www.ada.gov>

³ Marsha Mazz (personal communication, October 16, 2014)

⁴ Americans with Disabilities (Current) http://www.ada.gov/regs2010/titleIII_2010/titleIII_2010_withbold.htm; § 36.202

individuals with disabilities⁵. Taken together, these requirements might logically conclude that there is a requirement to provide an accessible labeling solution.

C. How is an ADA law enforced?

The DOJ enforces an ADA laws upon a citizen's request. As referenced in last month's white paper, one example is from the Law Office of Lainey Feingold, who has engaged in structured negotiations with the American Council of the Blind, its affiliates and top U.S pharmacies regarding accessible prescription drug labeling⁶. 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. Additionally, the ACB announced a settlement with Walgreens in June 2014, launching a nationwide program offering talking prescription devices to customers with visual impairments.

D. Can any customers be charged for accessible prescription drug labeling?

ADA Title III Regulations also address surcharges under Subpart C, Charges, stating that a public accommodation may not impose a surcharge on a particular individual with a disability or any group of individuals with disabilities to cover the costs of measures, such as the provision of auxiliary aids, barrier removal, alternatives to barrier removal, and reasonable modifications in policies, practices, or procedures, that are required to provide that individual or group with the nondiscriminatory treatment required by the Act or this part⁷.

With that said, this does not completely eliminate the ability to charge any customers that are outside of this group that electively choose to use an accessible labeling solution. To better define who is considered disabled, one might look to the DOJ definition. The DOJ states that an individual with a disability is defined by the ADA as a person who has a physical or mental impairment that substantially limited one or more major life activities, a person who has a history or record of such an impairment, or a person who is perceived by others as having an impairment⁸.

E. Can this cost be absorbed by insurance?

For private insurance carriers, we recommend pharmacies attempt to use CPT Code T1505-01. The description of this code includes "Electronic medication compliance management device, includes all components and accessories, not otherwise classified," while the -01 is the indicator for pharmacies⁹.

⁵ Americans with Disabilities (Current) http://www.ada.gov/regs2010/titleIII_2010/titleIII_2010_withbold.htm; § 36.203

⁶ Talking Prescription Labels Update – Summer 2014, Law Office of Lainey Feingold (2014) <http://llegal.com/2014/07/talking-prescription-labels>

⁷ Americans with Disabilities (Current) http://www.ada.gov/regs2010/titleIII_2010/titleIII_2010_withbold.htm; § 36.301

⁸ U.S. Department of Justice, A Guide to Disability Rights Laws (2009) <http://www.ada.gov/cguide.htm>

⁹ American Medical Association (Current) <https://ocm.ama-assn.org>

F. How does a pharmacy recoup the cost of this fee, if they can't charge customers and it isn't covered by insurance?

As mentioned above, there can be opportunities to recoup the cost of accessible labeling.

- Sell the accessible labeling solution as an add-on service for items that are not prescription, including over the counter and every day toiletry items. Not only does this allow Pharmacies to recoup cost but may provide your customers a more personalized pharmacy experience.
- Create a premier program for new and existing customer to be part of for a fee (i.e. one time, monthly, annually). A program of this nature can offer a variety of additional services, features and products that would not be available outside of the program, including the accessible labeling solution.
- Encourage your sales team to do presentations to independent living facilities to promote your accessible prescription labeling solution as a means to capture new business. This could be used for mail order services as well as for those who are still able to come into the pharmacy themselves.
- Host an in-store 'Demonstration Day' to preview your accessible labeling solution and sign-up new/existing customers for the service. While this may not directly recoup your costs, you have the potential of new customers coming in to purchase items other than their prescriptions (i.e. toothpaste, shampoo, deodorant).

Closing Remarks: A Few Words from Our Legal Team

The management of AccessaMed Inc.™ has reviewed the existing legal requirements for pharmacies to provide means of access to prescription information to sight impaired customers. This is a fast developing field with a patchwork of state laws and regulations that pharmacies need to consider. AccessaMed management believes that the nominal cost of the DAL when used with prescriptions for sight impaired customers will be a cost of compliance necessary to offer services and products to sight impaired consumers. The federal legal requirement (for not imposing a surcharge for devices such as AccessaMed's DAL) are clear as found at CFR Section 36.301(c), where a "public accommodation" is defined as including pharmacies:

"(c) Charges. A public accommodation may not impose a surcharge on a particular individual with a disability or any group of individuals with disabilities to cover the costs of measures, such as the provision of auxiliary aids, barrier removal, alternatives to barrier removal, and reasonable modifications in policies, practices, or procedures, that are required to provide that individual or group with the nondiscriminatory treatment required by the Act or this part."

AccessaMed is confident that the DAL and base station units will be accepted among the product representing "best practices" for pharmacies providing prescription information accessibility to sight impaired customers. AccessaMed will constantly seek to work with our customers in many state jurisdictions on compliance issues for sight impaired patients as this field develops. The DAL and base station products now offered by AccessaMed provide a readily and available compliance solution to our pharmacy customers to serve sight impaired consumers.

Note:

For a copy of the AccessaMed's State of the Industry White Paper on Accessible Prescription Drug Labeling that addresses the relevant laws, enforcement and published *Best Practices*, [please read it online now.](#)