United States Government Accountability Office

Report to Congressional Addressees

December 2016

PRESCRIPTION DRUG LABELS

Actions Needed to Increase Awareness of Best Practices for Accessible Labels for Individuals Who Are Blind or Visually Impaired

Accessible Version

GAO-17-115

GAO Highlights

Highlights of GAO-17-115, a report to congressional addressees

December 2016

PRESCRIPTION DRUG LABELS

Actions Needed to Increase Awareness of Best Practices for Accessible Labels for Individuals Who are Blind or Visually Impaired

Why GAO Did This Study

About 7.4 million Americans are blind or visually impaired and may face difficulty reading prescription drug container labels. FDASIA required the U.S. Access Board to develop best practices for accessible labels and NCD to conduct an informational campaign on these best practices.

FDASIA also included a provision for GAO to review pharmacies' implementation of these best practices. This report examines: the extent to which pharmacies can and do provide accessible labels and implement the best practices; pharmacy challenges; and the extent to which NCD conducted its informational campaign, among others.

GAO collected information from 55 stakeholders, including 4 PBMs used by large insurers; 9 of the largest chain pharmacy companies; 18 randomly selected individual retail pharmacy locations in 4 states with varying levels of visually impaired residents; and 24 others, such as state regulating bodies and advocacy and industry groups. GAO sent a web-based questionnaire to PBMs, chain pharmacy companies, and individual retail pharmacy locations. GAO also interviewed stakeholders and reviewed state regulations and documents from NCD.

What GAO Recommends

NCD should assign responsibility for conducting campaign activities and evaluate these activities. NCD neither agreed nor disagreed with the recommendation but indicated that it is taking steps to address this issue.

View GAO-17-115. For more information, contact John Dicken at (202) 512-7114 or dickenj@gao.gov

What GAO Found

GAO found that some pharmacies can provide accessible prescription drug labels, which include labels in audible, braille, and large print formats and are affixed to prescription drug containers.

- **Mail order pharmacies:** Four pharmacy benefit managers (PBMs) used by large insurers that GAO contacted reported that they can provide accessible labels through their mail order pharmacies.
- **Retail pharmacies:** Six of the 9 largest chain pharmacy companies and 8 of the 18 selected individual retail pharmacy locations GAO contacted also reported that they can provide accessible labels through their store-based retail pharmacies.

The percent of prescriptions dispensed with accessible labels was generally low—less than one percent of all prescriptions dispensed—according to some PBMs and chain pharmacy companies that GAO contacted. With regard to best practices, a working group convened by the U.S. Access Board—a federal agency that promotes accessibility for individuals with disabilities—developed and published 34 best practices for accessible labels. Four PBMs, six chain pharmacy companies, and eight individual retail pharmacy locations GAO contacted reported that they have generally implemented most of the 34 best practices for accessible labels. However, stakeholders GAO contacted said that individuals who are blind or visually impaired continue to face barriers accessing drug label information, including identifying pharmacies that can provide accessible labels.

Stakeholders GAO contacted identified four key challenges that pharmacies faced in providing accessible labels or implementing the best practices: (1) lack of awareness of the best practices; (2) low demand and high costs for providing accessible labels; (3) technical challenges for providing these labels; and (4) an absence of requirements to implement the best practices. Many stakeholders identified greater dissemination of the best practices as a step, among others, that could help address some of these challenges.

The National Council on Disability (NCD)—the federal agency responsible for conducting an informational campaign on the best practices, as required by the Food and Drug Administration Safety and Innovation Act (FDASIA)—has conducted limited campaign activities. Primarily in 2013 and 2014, NCD used its website and social media to disseminate an agency statement and press releases on the best practices. However, most stakeholders GAO spoke with said they had no communication with NCD about its campaign, and some said they were unaware of the best practices. Agency officials provided GAO with an original plan for conducting campaign activities through 2014, but most activities were not conducted. During the course of our review, NCD developed a corrective action plan for conducting future campaign activities. However, neither plan assigned responsibilities for conducting these activities nor does the agency have plans to evaluate them, which is inconsistent with federal internal control standards. Without assigning responsibilities and developing an evaluation plan, NCD will be unable to adjust its action plan and assess whether the information on the best practices is effectively reaching its target audience.

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Abbreviations

FDASIA	Food and Drug Administration Safety and Innovation Act
NCD	National Council on Disability
PBM	pharmacy benefit manager
PSAO	pharmacy services administrative organization

RFID	Radio Frequency Identification

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U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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December 9, 2016

The Honorable Lamar Alexander
Chairman
The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor & Pensions
United States Senate

The Honorable Fred Upton
Chairman
The Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Edward J. Markey
United States Senate

As of 2014, according to an analysis of U.S. Census Bureau survey data, about 7.4 million Americans were blind or visually impaired—individuals who have serious difficulty seeing even when wearing glasses.[1] These individuals may be unable to read or have difficulty independently reading a standard print prescription drug container label—a document prepared by the pharmacist filling a prescription, typically affixed to a medication bottle, and containing information about and for using a medication. Individuals are more likely to experience vision loss as they age. Also, as of 2014, according to the analysis of U.S. Census Bureau survey data, over 3 million Americans that were blind or visually impaired were aged 65 and older and this number is likely to increase with an aging

[1]Yang Tan Institute on Employment and Disability, Cornell University, *2014 Disability Status Report: United States*, (Ithaca, N.Y.: 2016). Another analysis estimated that as many as 21 million Americans 18 years or older were blind or had trouble seeing even when wearing glasses or contacts in 2012. See Department of Health and Human Services, Centers for Disease Control and Prevention, *Summary Health Statistics for U.S. Adults: National Health Interview Study, 2012,* DHHS Publication No. 2014-1588 (Hyattsville, Md.: February 2014).

population.[2] Older individuals are more likely to be prescribed multiple medications and may experience physical and cognitive conditions that increase the need for safe, consistent, reliable, and independent access to prescription drug container label information. Individuals whose vision precludes them from reading standard print prescription drug container labels may be at risk of taking the wrong medication or incorrectly following instructions found on the labels of their medications, thus endangering their health and safety.

The Food and Drug Administration Safety and Innovation Act (FDASIA) authorized the U.S. Access Board, a federal agency that promotes accessibility for people with disabilities, to convene a stakeholder working group to develop best practices for making information on prescription drug container labels accessible to individuals who are blind or visually impaired (henceforth referred to as the best practices).[3] The working group published its report on the U.S. Access Board's website in July 2013, which included information on delivering prescription drug container label information through audible, braille, and large print labels—collectively referred to as accessible labels—and the best practices for formatting these labels.[4] These best practices are voluntary and offer guidance to pharmacies on how to provide accessible labels to individuals who are blind or visually impaired.[5] Further, these best practices are

[2]Yang Tan Institute on Employment and Disability, *2014 Disability Status Report: United States.* Another analysis estimated that over 5 million Americans 65 or older were blind or had trouble seeing even when wearing glasses or contacts in 2012. See Department of Health and Human Services, Centers for Disease Control and Prevention, *Summary Health Statistics for U.S. Adults.* The number of Americans aged 65 and older increased about 28 percent from 36.2 million in 2004 to 46.2 million in 2014, and the number of Americans aged 65 years and older is projected to more than double to 98 million by 2060. See Administration on Aging, Administration for Community Living, Department of Health and Human Services, *A Profile of Older Americans: 2015* (Washington, D.C.: 2015).

[3]Pub. L. No. 112-144, § 904(a)(3), 126 Stat. 993, 1090 (2012).

[4]U.S. Access Board Working Group on Accessible Prescription Drug Container Labels, *Best Practices for Making Prescription Drug Container Label Information Accessible to Persons Who are Blind or Visually-Impaired or Who are Elderly* (Washington, D.C.: July 10, 2013), accessed November 23, 2015, http://www.access-board.gov/guidelines-and-standards/health-care/about-prescription-drug-container-labels/working-group-recommendations.

[5]FDASIA provides that the best practices are not to be construed to limit or condition any right, obligation, or remedy available under the Americans with Disabilities Act of 1990 or any other federal or state law requiring effective communication, barrier removal, or nondiscrimination on the basis of disability.

consistent with certain practices included in agreements between some companies that operate pharmacies and advocacy groups representing individuals who are blind or visually impaired.[6] FDASIA also required the National Council on Disability (NCD)—a federal agency that advises the President, Congress, and other federal agencies on policies and practices affecting people with disabilities—to conduct a campaign to inform and educate individuals with disabilities, pharmacists, and the public about the best practices after they were published.[7]

FDASIA also included a provision for us to review pharmacies' implementation of the best practices and examine barriers that individuals who are blind or visually impaired continue to face in accessing information on prescription drug container labels. We briefed your staff on our preliminary findings in September 2016. This report contains information shared during that briefing and examines:

1. the extent to which pharmacies can and do provide accessible prescription drug container labels to individuals who are blind or visually impaired and have implemented the best practices;
2. barriers that individuals who are blind or visually impaired face in accessing prescription drug container label information after publication of the best practices, as identified by stakeholders;
3. challenges that affect pharmacies' provision of accessible labels or implementation of the best practices and steps that could address these challenges, as identified by stakeholders; and
4. the extent to which NCD has conducted its informational campaign on the best practices.

To examine our first three research objectives, we collected and analyzed information from 55 stakeholders. Our review included mail order pharmacies, which dispense prescriptions from a central location and deliver prescriptions directly to customers, and retail pharmacies with store-based locations, which are generally accessible to the public on a walk-in basis. Retail pharmacies included both chain pharmacies (those with four or more locations under common ownership) and independent

[6]For example, an agreement effective from February 1, 2016 through June 30, 2016 required one company to make audible prescription drug container labels available upon request. Such agreements may vary in terms of the companies participating, activities specifically required, geographic scope, and duration.

[7]Pub. L. No. 112-144, § 904(a)(5), 126 Stat. 1091.

pharmacies (those with three or fewer retail locations under common ownership). We collected information from the following stakeholders:

- Four pharmacy benefit managers (PBM) that manage prescription drug benefits for the four largest private insurers that sponsor Medicare Part D plans based on enrollment as of March 2016.[8] PBMs may operate mail order pharmacies and assemble networks of retail pharmacies.[9]
- Nine of the ten largest chain pharmacy companies based on the number of retail pharmacy locations as of March 2016.[10] Chain pharmacy companies include traditional pharmacy companies, supermarkets, and mass merchandizers.
- Three of the largest pharmacy services administrative organizations (PSAO) based on the number of independent pharmacies in their retail pharmacy network as of 2011.[11] PSAOs provide administrative services for networks of retail pharmacies and generally represent independent pharmacies.
- Four state pharmacy regulating bodies (e.g., state boards of pharmacy) that oversee the practice of pharmacy in California,

[8]Medicare Part D provides voluntary, outpatient prescription drug coverage for Medicare, the federally financed health insurance program for eligible individuals 65 years and older, certain individuals with disabilities, and individuals with end-stage renal disease; and is administered by the Centers for Medicare & Medicaid Services. Based on data from the Centers for Medicare & Medicaid Services, these four Medicare Part D sponsors' health plans represented about 60 percent of total Medicare Part D enrollment as of March 2016, which were the most recent available data at the time we began collecting data.

[9]Our four selected PBMs had about 60,000 or more pharmacies in their retail pharmacy networks.

[10]Based on data from the National Council for Prescription Drug Programs—a nonprofit that develops pharmacy industry standards and maintains data on pharmacies—the number of retail pharmacies operated by these chain pharmacy companies ranged from about 480 to over 9,700 pharmacies. We used National Council for Prescription Drug Programs data to select chain pharmacy companies as of March 2016, which were the most recent available data at the time we began collecting data. We compared this list of pharmacies to data from the National Association of Chain Drug Stores—which represents companies that operate chain pharmacies—on their members as of March 2016 and reconciled any differences between these two lists.

[11]The number of retail pharmacies that these three PSAOs represented ranged from about 1,900 to about 4,100 pharmacies in 2011. We used data we previously reported to select PSAOs and used market research from 2016 to verify that these PSAOs continue to be among the largest in terms of the number of independent pharmacies in their networks. See GAO, *Prescription Drugs: The Number, Role and Ownership of Pharmacy Service Administrative Organizations,* GAO-13-176 (Washington, D.C.: Jan. 29, 2013).

Florida, Illinois, and Massachusetts. We selected states that were geographically diverse, that had varying levels of visually impaired residents as of 2013, and based on other stakeholders' recommendations.[12]

- Eighteen randomly selected individual retail pharmacy locations—including chain and independent pharmacies that were licensed in California, Florida, Illinois, and Massachusetts—the four states for which we interviewed the state pharmacy regulating bodies.[13]
- Seventeen other stakeholders, including the U.S. Access Board and NCD; pharmacy accreditation or standard-setting organizations; advocacy groups for individuals who are blind or visually impaired; industry groups that represent pharmacies, pharmacists, or physicians; and vendors that develop and sell technologies that produce accessible labels. We selected these organizations because of their participation in the U.S. Access Board working group, because of other stakeholders' recommendations, or because they may affect pharmacies' prescription drug container labeling practices.

To collect information from stakeholders, we conducted interviews with most of these stakeholders; administered a web-based questionnaire to the selected PBMs, chain pharmacy companies, and individual retail pharmacy locations; and reviewed key documents. We analyzed questionnaire responses from the 4 PBMs, 7 of the 9 chain pharmacy companies, and the 18 individual retail pharmacy locations. These responses included information on the extent to which mail order and retail pharmacies can provide accessible labels and implemented specific

[12]The number of visually impaired individuals residing in these four states ranged from about 137,000 residents in Massachusetts to about 791,000 residents in California. Collectively, visually impaired residents in these four states represented about 23 percent of the total number of visually impaired individuals in the United States as of 2013. This was the most recent analysis on the visually impaired from the Employment and Disability Institute, which annually produces disability statistics, at the time we began collecting data. See Employment and Disability Institute, Cornell University, *2013 Disability Status Report: United States* (Ithaca, N.Y.: 2014); and, for example, Employment and Disability Institute, Cornell University, *2013 Disability Status Report: Massachusetts*, (Ithaca, N.Y.: 2014) and Employment and Disability Institute, Cornell University, *2013 Disability Status Report:* California (Ithaca, N.Y.: 2014).

[13]We obtained a listing of active retail pharmacies licensed in each of the four states as of May or June 2016 and sent a web-based questionnaire to 38 randomly selected individual chain and independent pharmacy locations in metropolitan and non-metropolitan areas. Of these 38 pharmacies, 18 submitted responses, including 10 chain and 8 independent pharmacies.

best practices as of March 2016, when we began data collection.[14] (See app. I for more information on the web-based questionnaire that we administered to PBMs, chain pharmacy companies, and individual retail pharmacy locations.) We also reviewed documents that we collected from stakeholders—including state pharmacy regulations; company pharmacy policies; and pharmacy standards—as well as relevant peer-reviewed articles published within the past 5 years and other key reports.

To examine the extent to which NCD has conducted its informational campaign on the best practices, we collected information on steps NCD has taken to conduct its campaign, including steps to plan and document campaign activities, the agency's progress in conducting these activities, and steps taken to assess the effectiveness of the campaign. To collect this information, we reviewed NCD documents—such as a brochure and press releases—and interviewed agency officials. Additionally, we interviewed some of the stakeholders previously mentioned about their communication with NCD about its campaign.

Our findings on the extent to which pharmacies have provided accessible labels and implemented the best practices are not generalizable to all pharmacies. For example, our review included mail order and retail pharmacies in the commercial market; therefore, our findings may not be applicable to other types of pharmacies, such as those operated by federal health systems, including through the Department of Veterans Affairs.[15] Further, our findings on individual retail pharmacy locations are limited to a small random sample in the four selected states. Additionally, our findings on barriers that individuals who are blind or visually impaired face in accessing information on prescription drug container labels, pharmacy challenges for providing accessible labels or implementing the best practices, and steps that could address these challenges represent the views of the pharmacies and other stakeholders from which we collected information and cannot be generalized.

[14]Of the nine selected chain pharmacy companies, two declined to provide responses to our web-based questionnaire. However, we collected information from both companies that did not respond to our web-based questionnaire on the accessible labels their retail pharmacies can provide, with one of these companies also providing information on the specific best practices it implemented for these labels.

[15]According to agency officials, the Department of Veterans Affairs can provide audible labels at all of its medical center pharmacies; however, we did not assess the extent to which these medical center pharmacies have implemented the best practices.

We took several steps to ensure that the data used to produce this report were sufficiently reliable. We reviewed relevant documents to learn about their sources, including methods for collecting and checking data and limitations of the data, and compared these data to other published sources to the extent possible. Also, we spoke with officials who were knowledgeable about these data. We determined that all data sources that we used were sufficiently reliable for our purposes.

We conducted this performance audit from November 2015 to December 2016 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

As of July 2014, about 60,000 community retail pharmacies in the United States dispensed prescription drugs of which approximately 66 percent were chain retail pharmacies and the remaining 34 percent were independent pharmacies, according to an industry study.[16] In 2015, retail pharmacies dispensed about 4 billion prescriptions, while mail order pharmacies dispensed over 200 million prescriptions, according to one study.[17]

Entities That May Affect Pharmacies' Labeling Practices

Pharmacies' prescription drug container labeling practices may be affected by several types of entities:

- **PBMs** that help many third-party payers—such as health plans—manage their prescription drug benefits by operating mail order pharmacies, assembling retail pharmacy networks that include both chain and independent pharmacies, and providing other services. PBMs issue corporate policies that govern their mail order pharmacy operations and enter into contracts with retail pharmacies in their networks that set forth the terms and conditions for dispensing prescriptions to health plan enrollees.

[16]National Association of Chain Drug Stores, "Community Retail Pharmacy Outlets by Location," *Chain Drug Review* (New York, N.Y.: Oct. 26, 2015).

[17]IMS Institute for Healthcare Informatics, *Medicines Use and Spending in the U.S.: A review of 2015 and Outlook to* 2020 (Parsippany, N.J.: April. 2016).

- **Chain pharmacy companies** that operate chain retail pharmacies with four or more locations. These companies issue corporate policies that govern their retail pharmacy operations.
- **PSAOs** that provide a broad range of administrative services to networks of retail pharmacies, including contract negotiation with third-party payers. To establish these networks, PSAOs enter into contracts with retail pharmacies—generally independent pharmacies—that set forth the duties and obligations of the PSAO and each pharmacy.
- **State pharmacy regulating bodies** that oversee the practice of pharmacy through activities such as licensing pharmacies and issuing regulations. According to the National Association of Boards of Pharmacy, which represents state boards of pharmacy, as of February 2016, only one state—Massachusetts—requires pharmacies to provide large-print labels to individuals who are visually impaired and elderly upon request.[18]
- **Pharmacy accreditation organizations** that certify pharmacies meet a predetermined set of standards for pharmacy care or functions, which may include elements for providing services to individuals who are blind or visually impaired.[19]

Other entities may also develop or disseminate guidance on prescription drug container labels that may affect pharmacies' labeling practices. For example, standard-setting organizations may develop prescription drug container labeling standards and entities, such as state pharmacy regulating bodies, can incorporate these standards into their pharmacy labeling requirements.[20] Industry groups representing pharmacies or pharmacists and advocacy groups for individuals who are blind or visually impaired also may develop guidance, including prescription drug container labeling guidance, or use tools, such as newsletters or website postings, to disseminate guidance or other information to their members.

[18]Mass. Gen. Laws ch. 94C, § 21 (2016).

[19]For example, URAC developed accreditation standards intended to address pharmacy communications with populations who have physical impairments, including visual impairments.

[20]For example, in 2012, the U.S. Pharmacopeial Convention initially published standards for patient-centered prescription drug container labels to promote patient understanding, and these standards were updated in 2016. See U.S. Pharmacopeial Convention, *Prescription Container Labeling,* First Supplement to USP 39-NF 34 (Rockville, Md.: August 2016).

Accessible Labels

Accessible labels can make information on prescription drug container labels more easily available to individuals who are blind or visually impaired. Pharmacies can purchase hardware and software from private technology vendors to produce labels in audible, braille, and large print formats. Audible labels allow individuals to hear prescription drug container label information. Technologies for audible labels include talking pill bottles that allow pharmacists to create a voice or digital recording of label information and tags that can be encoded with label information, affixed to prescription drug containers, and are read out by a separate device. Braille labels allow individuals who are blind or visually impaired to read prescription drug container label information by touch, and large print labels enhance the size of label text for easier viewing. Pharmacists can produce hard copy braille or large print labels and affix them to the prescription drug container. See figure 1 for examples of accessible labels.

Figure 1: Examples of Accessible Prescription Drug Container Labels

Audible labels

Audible labels allow individuals to hear prescription drug container label information.

This audible label is two inches long, one inch wide, and affixed to the prescription drug container using an adhesive. Pharmacists use software to record up to a 60 second digital message that contains prescription drug container label information and customized dosage instructions. Individuals press a button to hear this digital message.

This audible label uses a Radio Frequency Identification (RFID) tag, which contains a thin antenna and microchip embedded within the tag. This tag is programmed with all the printed prescription drug container label information and attached to the bottom of the container. Individuals place the RFID tag over a separate device, which reads the prescription drug container label information in a digital voice. The device has a headphone jack for private listening and buttons to adjust volume and start, stop, and move through the digital message.

Braille labels

A braille label allows individuals to read prescription drug container label information by touch. This hard copy braille label is a clear tape that is affixed to the prescription drug container label over the original label so the original label can still be read. Prescription drug container label information is provided in braille in a line-by-line format.

Large print labels

A large print label allows individuals to view prescription drug container label information in an enhanced font size. This large print booklet type label is affixed to the prescription drug container and can be printed in 12- to 26-point, san-serif font with 1.5 line spacing. This label text also has high contrast with the background.

Sources: © Accessamed, Inc. (top image); En-Vision America (bottom three images); GAO (analysis). | GAO-17-115

Note: We analyzed vendor-reported information on their technologies for prescription drug container labels in audible, braille, and large print formats. Other technology vendors also have other technologies available for producing prescription drug container labels in accessible formats. Braille is a system of one to six raised dots arranged in cells to represent letters, words, numbers, or symbols.

Best Practices Related to Accessible Labels

In 2012, the U.S. Access Board convened an 18-member working group to develop best practices to make prescription drug container label information accessible to individuals who are blind or visually impaired. This working group included representatives from mail order pharmacies; chain pharmacy companies; advocacy groups for individuals who are blind or visually impaired; and industry groups representing pharmacies and pharmacists. The working group's July 2013 report identified 34 best practices. These best practices offer guidance to pharmacists on how to deliver and provide accessible labels and their adoption is voluntary. The

best practices include those that promote access to prescription drug container label information in all accessible labels formats as well as those specific to audible, braille, and large print formats. For example, one best practice that applies to all accessible label formats is for pharmacies to not impose an extra fee to individuals to cover the cost of providing accessible labels or equipment dedicated for prescription drug container label access.

Some Pharmacies Can Provide Accessible Labels but Dispensed Few of Them and Have Implemented Most of the U.S. Access Board's Best Practices

Mail Order Pharmacies and Some Retail Pharmacies Can Provide Accessible Labels

The mail order pharmacies operated by the 4 PBMs, some retail pharmacies operated by the 9 chain pharmacy companies, and some of the 18 individual chain and independent retail pharmacy locations that we contacted for this review said they can provide accessible labels as of March 31, 2016.[21] For example, officials from the 4 PBMs reported their mail order pharmacies generally can provide accessible labels, including audible, braille, and large print labels. Similarly, officials from 6 of the 9 nine chain pharmacy companies reported their retail pharmacies can provide accessible labels. Additionally, officials from 8 of the 18 randomly selected individual chain and independent retail pharmacy locations reported they can provide accessible labels. Of the 8 individual retail pharmacy locations that reported that they can provide accessible labels, officials from more chain pharmacies—7 pharmacies—reported being

[21]After March 31, 2016, officials from one PBM told us they can provide large print labels through its mail order pharmacies. Further, officials from three chain pharmacy companies told us that they are considering providing accessible labels through their retail pharmacies.

able to provide accessible labels than independent pharmacies—1 pharmacy.[22] Furthermore, officials from the PBMs more often reported that their mail order pharmacies can provide audible and braille labels, while officials from the chain pharmacy companies and individual retail pharmacy locations more often reported that their retail pharmacies can provide audible labels. (See table 1.)

Table 1: Number of Selected Pharmacy Benefit Mangers (PBM), Chain Pharmacy Companies, and Individual Retail Pharmacy Locations That Reported They Can Provide Accessible Labels through Their Pharmacies, as of March 31, 2016

Accessible label formats	PBMs (n=4)	Chain pharmacy companies (n=9)	Individual retail pharmacy locations (n=18)
At least one format	4	6	8
Audible	4	5	6
Braille	4	2	2
Large print	2[a]	2	6

Source: GAO analysis of information provided by selected PBMs, chain pharmacy companies, and individual retail pharmacy locations. | GAO-17-115

Note: We collected information from 4 PBMs on the operation of their mail order pharmacies, 9 chain pharmacy companies on the operation of their retail pharmacies, and 18 individual retail pharmacy locations that included both chain and independent pharmacies.

[a]Officials from one PBM told us they began providing large print labels through their mail order pharmacies after March 31, 2016.

The four PBMs that can provide accessible labels through their mail order pharmacies dispensed prescriptions with these labels from a central location and delivered them directly to customers. These PBMs used the same technologies to provide audible and braille labels, but differed in how they can provide large print labels through their mail order pharmacies. See table 2 for more information on how these PBMs can provide accessible labels through their mail order pharmacies.

[22]Of the 18 individual retail pharmacy locations that responded to our questionnaire, 10 were chain pharmacies and 8 were independent pharmacies.

Table 2: Four Selected Pharmacy Benefit Managers (PBM) Can Provide Accessible Labels through Their Mail Order Pharmacies, as of March 31, 2016

Four PBMs' mail order pharmacies dispense prescriptions with accessible labels from a central location and deliver them directly to the customer. Pharmacies provide these labels to individuals upon request or if pharmacy staff identify an individual as someone who could benefit from accessible labels. These labels include audible labels that digitally record prescription drug container label information that can be scanned and audibly read by a separate device; and braille labels that are a clear tape, embossed with braille, and affixed over the original standard print prescription drug container label. Additionally, two of these PBMs' mail order pharmacies can also provide large print labels in a booklet format that is affixed to the drug container. The other two PBM's mail order pharmacies cannot provide large print labels. However, one of these PBM's mail order pharmacies can make other accommodations by providing prescription drug container label information in large print on a piece of paper that is not affixed to the drug container.[a]

Source: GAO analysis of information provided by four PBMs. | GAO-17-115

Note:

[a]Officials from the other PBM told us they began providing large print labels through their mail order pharmacies after March 31, 2016.

The six chain pharmacy companies that can provide accessible labels through their retail pharmacies varied in terms of the accessible label formats they can provide, the number of retail locations that can provide them, and timeframes for providing prescriptions with these labels. For example, officials from one chain pharmacy company reported to us their retail locations can provide accessible labels in all formats, while others reported to us their retail locations can provide accessible labels in one or two formats. Also, officials from five companies reported to us that they can provide accessible labels in all retail locations, while officials from one company reported they can provide accessible labels in one retail location. Further, some of these companies can provide prescriptions with accessible labels available with same-day pickup, while others delivered them directly to customers. Officials from the three chain pharmacy companies that cannot provide accessible labels reported that they can make other accommodations, such as providing information on a separate piece of paper in large print. See table 3 for more information on how selected chain pharmacy companies can provide accessible labels.

Table 3: Six of Nine Selected Chain Pharmacy Companies Can Provide Accessible Labels through Their Retail Pharmacies, as of March 31, 2016

Five chain pharmacy companies can provide accessible labels at all of their retail locations	• One company's retail pharmacies can provide audible, braille, and large print labels upon request. Retail locations can provide two types of audible labels. One audible label allows pharmacy staff to voice record prescription drug container label information that can be played back at a later time by pushing a button and prescriptions with these labels are available for same-day pickup. Additionally, retail locations can provide another type of audible label that digitally records prescription drug container label information that can be scanned and audibly read by a separate device; braille labels that are a clear tape, embossed with braille, and affixed over the original standard print prescription drug container label; and large print labels in a booklet format. These labels are generated at a central location, delivered to retail pharmacies, and prescriptions with these labels are not available for same-day pickup.
	• One company's retail pharmacies can provide audible labels and braille labels upon request. Retail pharmacies can provide audible labels that digitally record prescription drug container label information that can be scanned and audibly read by a separate device. Prescriptions with audible labels are available for same-day pickup at some retail locations; other retail locations can provide prescriptions with these labels through the company's mail order pharmacy and deliver them directly to customers.[a] Also, all retail locations can provide braille labels that are a clear tape, embossed with braille, and affixed over the original standard print prescription drug container label through the company's mail order pharmacy.[b]
	• Two companies can provide audible labels upon request.
	  • One company's retail pharmacies can provide audible through its mail order pharmacy and deliver the prescriptions directly to the customers. Retail locations can provide audible labels that digitally record prescription drug container label information that can be scanned and audibly read by a separate device.[b]
	  • The other company's retail pharmacies can provide audible labels that allow pharmacy staff to voice record prescription drug container label information that can be played back at a later time by pushing a button. Prescriptions with these labels are available for same-day pickup.[b]
	• One company's retail pharmacies' standard print prescription drug container label is a large print label that includes information in an enhanced font size.

One chain pharmacy company can provide accessible labels in one of its retail locations	One company can provide audible labels that digitally record prescription drug container label information that can be scanned and audibly read by a separate device at one of its retail locations upon request. Further, officials stated that their company may consider providing these labels at additional locations. When an individual requests an audible label at a retail location that cannot provide these labels, the company refers the individual to another nearby retail location that can provide the labels or, if there are no nearby retail locations that can provide such labels, it will consider providing audible labels at that location in the future.
Three chain pharmacy companies cannot provide accessible labels, but their retail locations can make other accommodations	All three companies' retail pharmacies can provide prescription drug container label information in large print on a piece of paper that is not affixed to the drug container.

Source: GAO analysis of information provided by nine chain pharmacy companies. | GAO-17-115

Notes:

[a]When a retail location that provides audible labels through the company's mail order pharmacy receives a request for such labels, the company will begin the process of implementing technology in that retail location to make prescriptions with audible labels available for same-day pickup.

[b]While retail pharmacies cannot provide large print labels, they can provide prescription drug container label information in large print on a piece of paper that is not affixed to the drug container.

Mail Order and Retail Pharmacies Dispensed Few Prescriptions with Accessible Labels

Officials from the four PBMs and three of the six chain pharmacy companies that can provide accessible labels through their pharmacies reported that the percent of prescriptions dispensed with such labels was generally low—less than 1 percent. For example, officials from one PBM stated their mail order pharmacy dispensed an average of about 21,000 prescriptions with accessible labels out of about 11.5 million total prescriptions dispensed each month during the first quarter of calendar year 2016. Officials from another PBM stated that they dispensed about 1,200 prescriptions with accessible labels out of about 3 million total prescriptions dispensed each month during the first quarter of 2016. Similarly, officials from one chain pharmacy company stated that their retail pharmacy locations dispensed an average of about 240 prescriptions with accessible labels out of about 6.5 million total prescriptions dispensed each month during the first quarter of 2016. Officials from the three remaining chain pharmacy companies could not provide us with the percent of prescriptions dispensed with accessible labels. However, officials from one of these companies stated that one of their retail locations dispensed prescriptions with accessible labels to 6 to 10 individuals who are blind or visually impaired each month and dispensed between 3,200 and 5,600 total prescriptions each month during the first quarter of 2016.

Mail Order and Retail Pharmacies Reported Implementing Most of the Best Practices for Accessible Labels

Officials from the four PBMs, six chain pharmacy companies, and eight individual retail pharmacy locations that we contacted and that can provide accessible labels reported that their mail order and retail pharmacies have generally implemented most of the 34 best practices for these labels. Of these 34 best practices, 14 apply to all accessible labels (henceforth referred to as all-format best practices), 3 apply to audible labels, 7 apply to braille labels, and 10 apply to large print labels.

All-Format Best Practices

Officials from the four PBMs, four of the six chain pharmacy companies, and eight individual retail pharmacy locations generally reported that their mail order and retail pharmacies have implemented most of the 14 all-format best practices for accessible labels.[23] These all-format best practices include specific recommendations to promote access to prescription drug container label information in all available formats—including audible, braille, and large print labels—and include practices

[23]Two chain pharmacy companies that can provide accessible labels did not provide us with information on the all-format best practices implemented in their retail pharmacies.

such as pharmacists encouraging patients and their representatives to communicate their needs to the pharmacist. All selected PBMs, chain pharmacy companies, and individual retail pharmacy locations that provide accessible labels implemented practices such as making prescription drug container labels available in various accessible formats, as well as using the same quality control processes for prescription drug container labels in accessible formats as print prescription drug container labels. See table 4 for further detail on all-format best practices implemented in pharmacies by selected PBMs, chain pharmacy companies, and individual retail pharmacy locations.

Table 4: All-Format Best Practices Implemented by Selected Pharmacy Benefit Managers (PBM), Chain Pharmacy Companies, and Individual Retail Pharmacy Locations That Can Provide Accessible Labels through Their Pharmacies, as of March 31, 2016

All-format best practices	PBMs (n=4)	Chain pharmacy companies (n=4)	Individual retail pharmacy locations (n=8)
1. Encouraging patients and patient representatives to communicate their needs to pharmacists.	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
			Implemented
			Implemented
			Implemented
			No Answer
2. Following universal patient-centered prescription drug container label standards for the format, appearance, content, and language of prescription medication instructions to promote patient understanding.	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
			Implemented
			Implemented
			Not Implemented
			No Answer
3. Making 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.	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
			Implemented
			Implemented
			Implemented
			Implemented

All-format best practices	PBMs (n=4)	Chain pharmacy companies (n=4)	Individual retail pharmacy locations (n=8)
4. Explaining the accessible format options available for prescription drug container labels to the patient, and providing the prescription drug container label in the format selected by the patient.	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
			Implemented
			Implemented
			Implemented
			Not Implemented
5. Ensuring that duplicate prescription drug container labels in accessible formats preserve the integrity of the print prescription drug container label.	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
			Implemented
			Implemented
			Not Implemented
			Not Implemented
6. Subjecting prescription drug container labels in accessible formats to the same quality control processes used for print prescription drug container labels to ensure accuracy and patient safety.	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
			Implemented
			Implemented
			Implemented
			Implemented
7. Maintaining patient privacy in accordance with the Health Insurance Portability and Accountability Act rules when preparing prescription drug container labels in accessible formats.	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
			Implemented
			Implemented
			Implemented
			Not Implemented

All-format best practices	PBMs (n=4)	Chain pharmacy companies (n=4)	Individual retail pharmacy locations (n=8)
8. Making arrangements in advance to provide prescription drug container labels in accessible formats.	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
			Implemented
			Implemented
			Not Implemented
			Not Implemented
9. Providing prescription medication with an accessible prescription drug container label format in the same time frame as a prescription would be provided to patients without visual impairments.	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
	Implemented	Not Implemented	Implemented
	Implemented	Not Implemented	Implemented
			Implemented
			Not Implemented
			Not Implemented
			Not Implemented
10. Providing accessible prescription drug container labels and any dedicated equipment free of charge to individuals requesting them.	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
			Implemented
			Implemented
			Implemented
			Not Implemented
11. Ensuring the durability of accessible label formats until the expiration date specified on the prescription drug container label.	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
			Implemented
			Implemented
			Implemented
			Not Implemented

All-format best practices	PBMs (n=4)	Chain pharmacy companies (n=4)	Individual retail pharmacy locations (n=8)
12. Selecting a container that best supports the type of accessible label provided.	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
			Implemented
			Implemented
			Implemented
			Not Implemented
13. Ensuring 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.	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
	Not Implemented	Not Implemented	Implemented
			Implemented
			Implemented
			Implemented
			Not Implemented
14. Including information on warning labels added to the container at the pharmacist's discretion in an accessible format on the prescription drug container label.	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
	Not Implemented	Not Implemented	Implemented
	Not Implemented	Not Implemented	Implemented
			Implemented
			Implemented
			Implemented
			Not Implemented

Source: GAO analysis of information provided by four PBMs, four chain pharmacy companies, and eight individual retail pharmacy locations. | GAO-17-115

Note: Two additional chain pharmacy companies that can provide accessible labels did not provide us with information on the all-format best practices implemented in their retail pharmacies. Some of the language for the best practices in this table was modified from the U.S. Access Board's report for purposes of conducting our web-based questionnaire. See U.S. Access Board Working Group on Accessible Prescription Drug Container Labels, *Best Practices for Making Prescription Drug Container Label Information Accessible to Persons Who are Blind or Visually-Impaired or Who are Elderly* (Washington, D.C.: July 10, 2013).

Format-Specific Best Practices

Officials from the four PBMs, five of the six chain pharmacy companies, and eight individual retail pharmacy locations told us that their mail order and retail pharmacies implemented most of the applicable format-specific best practices for audible, braille, and large print labels.[24] These format-specific best practices include specific recommendations on how to

[24]One chain pharmacy company that can provide accessible labels did not provide us with information on the format-specific best practices implemented in its retail pharmacies.

provide these labels and some of these practices only apply under certain circumstances. For example, six of the seven format-specific best practices for braille prescription drug container labels only apply to hard copy braille labels. The most commonly implemented applicable format-specific best practices across the PBMs, chain pharmacy companies, and individual retail pharmacy locations included speaking in a clear voice when recording an audible label, using transparent materials when embossing braille labels, and printing text in the highest possible contrast for large print labels. See tables 5 through 7 for further detail on the audible, braille, and large print format-specific best practices implemented by PBMs, chain pharmacy companies, and individual retail pharmacy locations.

Audible Format-Specific Best Practices

Table 5: Audible Format-Specific Best Practices Implemented by Selected Pharmacy Benefit Managers (PBM), Chain Pharmacy Companies, and Individual Retail Pharmacy Locations That Can Provide Audible Labels through Their Pharmacies, as of March 31, 2016

Audible format-specific best practices	PBMs (n=4)	Chain pharmacy companies (n=4)	Individual retail pharmacy locations (n=6)
1. Offering to show patients how to operate the audible label.	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
	Not Implemented	Implemented	Implemented
			Implemented
			Not Implemented
2. For dedicated equipment provided to the patient, selecting devices that provide independent, easy to use, start/stop operation, with volume control, and ear bud access for privacy.	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
	Implemented	Implemented	Not Implemented
	Implemented	Not Implemented	Not Implemented
			Not Implemented
			Not Applicable
3. If using a voice recorder, ensuring the label information is spoken in a clear voice in a setting that minimizes background noise and maintains patient privacy.	Not Applicable	Implemented	Implemented
	Not Applicable	Implemented	Implemented
	Not Applicable	Not Applicable	Implemented
	Not Applicable	Not Applicable	Not Applicable
			Not Applicable
			Not Applicable

Source: GAO analysis of information provided by four PBMs, four chain pharmacy companies, and six individual retail pharmacy locations. | GAO-17-115

Note: One additional chain pharmacy company that can provide audible labels did not provide information on the audible format-specific best practices implemented in retail pharmacies. For two audible format-specific best practices (numbers 2 and 3), respondents had the option to select “not

applicable" if a particular practice did not apply. Some of the language for the best practices in this table was modified from the U.S. Access Board's report for purposes of conducting our web-based questionnaire. See U.S. Access Board Working Group on Accessible Prescription Drug Container Labels, *Best Practices for Making Prescription Drug Container Label Information Accessible to Persons Who are Blind or Visually-Impaired or Who are Elderly* (Washington, D.C.: July 10, 2013).

Braille Format-Specific Best Practices

Table 6: Braille Format-Specific Best Practices Implemented by Selected Pharmacy Benefit Managers (PBM), Chain Pharmacy Companies, and Individual Retail Pharmacy Locations That Can Provide Braille Labels through Their Pharmacies, as of March 31, 2016

Braille format-specific best practices	PBMs (n=4)	Chain pharmacy companies (n=2)	Individual retail pharmacy locations (n=2)
1. For patients with electronic braille equipment, providing electronic delivery methods.	Implemented Implemented Implemented Not Applicable	Not Implemented Not Implemented	Implemented Not Applicable
2. For pharmacies with low demand for hard copy braille, partnering with other pharmacies that have the capacity to provide hard copy braille prescription drug container labels.	Not Applicable Not Applicable Not Applicable Not Applicable	Implemented Not Implemented	Implemented Implemented
3. For pharmacies with high demand for hard copy braille, having an onsite hard copy braille embosser in pharmacies.	Implemented Implemented Implemented Not Applicable	Implemented Not Implemented	Not Applicable Not Applicable
4. When embossing braille labels, using contracted (grade 2) braille.	Implemented Implemented Implemented Not Implemented	Implemented Not Implemented	Implemented Not Applicable
5. When embossing braille labels, using transparent materials in order to preserve the legibility of print prescription drug container labels.	Implemented Implemented Implemented Implemented	Implemented Implemented	Implemented Not Applicable
6. When embossing braille labels, affixing braille labels to the prescription drug container with strong adhesive.	Implemented Implemented Implemented Implemented	Implemented Implemented	Implemented Not Applicable
7. When embossing braille labels, not folding labels.	Implemented Implemented Implemented Implemented	Implemented Implemented	Implemented Not Applicable

Source: GAO analysis of information provided by four PBMs, two chain pharmacy companies, and two individual retail pharmacy locations. | GAO-17-115

Note: Grade 2 braille is a space-saving braille system where dots are arranged in cells to represent words or contractions. For all braille format-specific best practices, respondents had the option to select "not applicable" if a particular practice did not apply. Some of the language for the best practices in this table was modified from the U.S. Access Board's report for purposes of conducting our web-based questionnaire. See U.S. Access Board Working Group on Accessible Prescription Drug Container Labels, *Best Practices for Making Prescription Drug Container Label Information Accessible to Persons Who are Blind or Visually-Impaired or Who are Elderly* (Washington, D.C.: July 10, 2013).

Large Print Format-Specific Best Practices

Table 7: Large Print Format-Specific Best Practices Implemented by Selected Pharmacy Benefit Managers (PBM), Chain Pharmacy Companies, and Individual Retail Pharmacy Locations That Can Provide Large Print Labels through Their Pharmacies, as of March 31, 2016

Large print format-specific best practices	PBMs[a] (n=2)	Chain pharmacy companies (n=2)	Individual retail pharmacy locations (n=6)
1. Printing labels in 18-point bold font.	Implemented	Implemented	Implemented
	Implemented	Not Implemented	Implemented
			Implemented
			Implemented
			Implemented
			Implemented
2. Printing labels in a non-condensed, san-serif font.	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
			Implemented
			Implemented
			Implemented
			Implemented
3. Printing labels using 1.5 line spacing.	Implemented	Implemented	Implemented
	Implemented	Not Implemented	Implemented
			Implemented
			Implemented
			Implemented
			Not Implemented
4. Printing labels using sentence case capitalization, with a capitalized first letter followed by lower-case letters.	Implemented	Implemented	Implemented
	Implemented	Not Implemented	Implemented
			Implemented
			Not Implemented
			Not Implemented
			Not Implemented

Large print format-specific best practices	PBMs[a] (n=2)	Chain pharmacy companies (n=2)	Individual retail pharmacy locations (n=6)
5. Printing labels exclusively in horizontal text.	Implemented	Implemented	Implemented
	Implemented	Not Implemented	Implemented
			Implemented
			Implemented
			Implemented
			Not Implemented
6. Printing labels using the highest possible contrast between text and background color.	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
			Implemented
			Implemented
			Implemented
			Implemented
7. Printing labels on non-glossy paper or other material that is durable and easy to manipulate.	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
			Implemented
			Implemented
			Implemented
			Implemented
8. Securely affixing labels to the prescription drug container.	Implemented	Implemented	Implemented
	Implemented	Implemented	Implemented
			Implemented
			Implemented
			Implemented
			No Answer
9. When labels are printed on both sides, printing labels on material that does not allow print bleed-through.	Implemented	Implemented	Implemented
	Implemented	Not Applicable	Implemented
			Implemented
			Not Applicable
			Not Applicable
			Not Applicable
10. When protective tape is used, covering labels in tape that is non-glossy and transparent.	Implemented	Implemented	Not Implemented
	Not Applicable	Not Applicable	Not Applicable
			Not Applicable
			Not Applicable
			Not Applicable
			Not Applicable

Source: GAO analysis of information provided by two PBMs, two chain pharmacy companies, and seven individual retail pharmacy locations. | GAO-17-115

Note: For two large print format-specific best practices (numbers 9 and 10), respondents had the option to select “not applicable” if a particular practice did not apply. Some of the language for the best practices in this table was modified from the U.S. Access Board’s report for purposes of

conducting our web-based questionnaire. See U.S. Access Board Working Group on Accessible Prescription Drug Container Labels, *Best Practices for Making Prescription Drug Container Label Information Accessible to Persons Who are Blind or Visually-Impaired or Who are Elderly* (Washington, D.C.: July 10, 2013).

aOfficials from one additional PBM told us they began providing large print labels through their mail order pharmacies after March 31, 2016. This company's mail order pharmacies have implemented most of the applicable large-print format specific best practices for these labels.

Stakeholders Reported That Individuals Who Are Blind or Visually Impaired Continue to Face Barriers Accessing Prescription Label Information

Stakeholders we contacted most often identified three key barriers that individuals who are blind or visually impaired continue to face in accessing prescription drug container label information even after the publication of the best practices in 2013.[25] Some of these stakeholders told us that the best practices have reduced some barriers to accessing prescription drug container label information for individuals who are blind or visually impaired by increasing pharmacies' awareness of these barriers or encouraging more pharmacies to provide accessible labels. However, other stakeholders told us that the types of barriers that individuals who are blind or visually impaired face have not changed.

Inability to identify medications independently. Stakeholders told us that individuals who are blind or visually impaired continue to face barriers identifying medications independently. Without accessible labels, individuals who are blind or visually impaired will need to rely on a pharmacist or caregiver to help them identify medications. For example, some stakeholders said that pharmacists may offer medication counseling, such as allowing individuals who are blind or visually impaired to feel the size, shape, and weight of their medication and answering questions about dosage or side effects. Pharmacists may also place rubber bands on some prescription drug containers or use differently sized containers to help individuals who are blind or visually impaired identify different medications by their containers. However, according to some stakeholders, these alternative methods may not be reliable; for example, a rubber band may be removed from a prescription drug container or caregivers may not understand medication directions. Further, stakeholders stated that if accessible labels are not securely

[25]We analyzed information collected through interviews and questionnaire responses from selected stakeholders, including 4 PBMs; 9 chain pharmacy companies; 4 states; 18 randomly selected individual retail pharmacy locations; and 17 other stakeholders. These 17 other stakeholders included federal agencies; accreditation and standard setting organizations; advocacy groups for individuals who are blind or visually impaired; industry groups representing pharmacies, pharmacists, or physicians; and technology vendors. We defined key barriers as those cited by at least 10 stakeholders.

affixed to the prescription drug containers, then they can fall off and get mixed up, which could increase individuals' risk for medication errors.

Inability to identify pharmacies that can provide accessible labels. Stakeholders told us that individuals who are blind or visually impaired generally do not know which pharmacies can provide accessible labels. Many stakeholders stated that the inability to identify pharmacies that can provide these labels stems from limited or no efforts to advertise accessible labels in pharmacies and no centralized database that provides information on pharmacies that can provide these labels. While officials from the four selected PBMs reported taking steps to inform individuals who are blind or visually impaired about the accessible labels that their mail order pharmacies can provide—such as two PBMs reporting training customer service representatives to ask specific questions to identify individuals who could benefit from prescriptions with accessible labels and help them identify the accessible label that would best fit their needs—other selected stakeholders that operate pharmacies told us that they do not advertise the accessible labels their pharmacies can provide. Specifically, officials from 2 of our 9 selected chain pharmacy companies and 4 of 18 individual retail pharmacy locations that submitted questionnaire responses reported to us that they generally do not advertise the accessible labels their pharmacy can provide, or that customers need to ask pharmacists about these labels in order to have them included on the prescription containers. Officials from an advocacy group also reported that individuals who are blind or visually impaired continue to be unable to identify pharmacies that can provide accessible labels because there is no centralized database that provides information on which pharmacies can provide such labels. Officials from the two technology vendors told us that they compiled information on retail pharmacies that can provide accessible labels sold by their companies; however, their databases are limited to locations that can provide their specific products and do not include retail pharmacy locations that can provide accessible labels made by other technology vendors.

Inability to obtain prescriptions with accessible labels on the same day as requested. Stakeholders told us that individuals who are blind or visually impaired may be unable to obtain prescriptions with accessible labels on the same day as requested. For example, officials from two chain pharmacy companies stated that individuals who are blind or visually impaired can work with retail pharmacy staff to order prescriptions with accessible labels through mail order pharmacies and have these accessible prescriptions sent directly to these individuals at a later date. Further, officials from these chain pharmacy companies reported that it

may take up to 72 hours from the time an individual requests a prescription with an accessible label to the time the individual receives that prescription. Officials from one advocacy group raised concerns that this delay in obtaining prescriptions through the mail order pharmacy is unreasonable for certain time-sensitive prescriptions that must be dispensed immediately, such as antibiotics to treat an infection.

Stakeholders Identified Pharmacy Challenges and Steps for Providing Accessible Labels or Implementing the U.S. Access Board's Best Practices

Stakeholders most often identified four key challenges that pharmacies had in providing accessible labels or implementing the best practices and identified steps that could address some of these challenges.[26]

Lack of awareness of the best practices. Stakeholders identified lack of awareness of the best practices by pharmacies and others as a key challenge:

- **Pharmacies (including pharmacists and pharmacy staff).** Federal agencies, advocacy groups, technology vendors, and an accreditation organization told us that pharmacies were not aware of the best practices. Further, officials from 7 of 18 individual retail pharmacy locations stated that they first learned about the best practices when we contacted them. Additionally, some stakeholders told us that individuals who are blind or visually impaired are generally unaware of the best practices and, as a result, may not request accessible labels at their pharmacies.
- **Other stakeholders.** Other stakeholders that could affect pharmacies' labeling practices or provide medical services to individuals who are blind or visually impaired were unaware of the best practices. For example, the four states and an industry group representing physicians told us that they were unaware of the best practices prior to our contact with them. After our outreach, one state published an article about the best practices in its newsletter and discussed these practices with pharmacists, pharmacy staff, and the public at two public meetings in May and July 2016.

[26]We analyzed information collected through interviews and questionnaire responses from selected stakeholders, including 4 PBMs; 9 chain pharmacy companies; 3 PSAOs; 4 states; 18 randomly selected individual retail pharmacy locations; and 17 other stakeholders. These 17 other stakeholders included federal agencies; accreditation and standard setting organizations; advocacy groups for individuals who are blind or visually impaired; industry groups representing pharmacies, pharmacists, or physicians; and technology vendors. We defined key challenges as those cited by at least 10 stakeholders.

Of those stakeholders who identified this challenge, many stated that greater dissemination of information on the best practices could increase awareness of the best practices.[27] Additionally, NCD officials told us that they would continue to disseminate information on the best practices as long as stakeholders remained unaware of them.

Low demand and high costs for providing accessible labels. Another challenge that stakeholders identified is that pharmacies had low demand and incurred high costs to provide accessible labels. Officials from five chain pharmacy companies and four individual retail pharmacy locations told us that they have had relatively few or no customer requests for accessible labels.[28] Some stakeholders reported that the demand for these labels does not justify the costs to provide accessible labels. These costs include staff costs—such as training or the time needed to produce these labels—as well as the costs associated with the technology required to produce the labels—such as purchasing software, printers, or labels. Two stakeholders told us that the initial costs to purchase this technology may range from a few hundred to a few thousand dollars for each individual retail pharmacy location. Further, these pharmacy locations may incur ongoing costs, such as annual fees of up to a few hundred dollars to cover technical assistance and other services or fees of up to a few dollars to purchase additional accessible labels. Additionally, many stakeholders stated that it may be costly for larger chain pharmacy companies to implement technology and train staff in many locations, while smaller independent pharmacies may have difficulty absorbing the costs of purchasing the new technology they need to produce accessible labels.

Of those stakeholders who identified this challenge, some stated that financial support for pharmacies, such as third-party reimbursement, could address high costs that pharmacies incur to provide accessible labels that meet the best practices. These stakeholders stated that there is currently no direct financial support for providing these labels and these

[27]We found that some stakeholders have taken steps to disseminate information on the best practices. For example, officials from an industry group representing pharmacists published an article about the best practices in its member newsletter. Additionally, officials from an advocacy group for individuals who are blind or visually impaired stated that it informed its members about the best practices at a national convention.

[28]This is consistent with our finding that prescriptions with accessible labels accounted for less than one percent of all prescriptions dispensed across pharmacies operated by the four selected PBMs and three of the seven chain pharmacy companies.

labels are provided free of charge to customers.[29] Officials from four chain pharmacy companies told us that pharmacies may be willing to provide accessible labels that meet the best practices if third parties, such as health plans, were willing to reimburse or share in the costs of producing these labels. Additionally, officials from one industry group representing pharmacists stated that pharmacies may be more willing to provide accessible labels that meet the best practices if grant money were available to cover costs for producing these labels.

Technical challenges for providing accessible labels. Stakeholders identified some technical challenges for providing accessible labels that meet the best practices. For example, officials from one state and four chain pharmacy companies told us that pharmacies face challenges fitting all the required prescription label information in large print formats on small prescription drug containers.[30] Officials from one technology vendor stated that printing the large print labels in a booklet form, which can then be affixed to the prescription drug container, could address this challenge. Additionally, officials from a chain pharmacy company, a state regulating body, and a federal agency told us that pharmacists typically cannot independently verify information on braille labels to ensure their accuracy.[31] Specifically, three stakeholders expressed concern that pharmacists who cannot read braille cannot determine if the braille translation is accurate and therefore must rely on the accuracy of the braille technology to translate prescription label information to braille.

Absence of requirements to implement the best practices. Stakeholders told us that some pharmacies are not implementing the best practices, given an absence of requirements to do so by applicable corporate policies, contracts, state regulations, or accreditation standards.

- **Corporate pharmacy policies.** Officials from all four PBMs and four of the nine chain pharmacy companies told us that they incorporated

[29]Officials from the Centers for Medicare & Medicaid Services and the Department of Veterans Affairs confirmed that they do not provide additional reimbursement to retail pharmacies for dispensing prescriptions with accessible labels.

[30]One of the all-format best practices states that all required information contained on the print prescription drug container labels should be provided on the accessible labels in the same sequence as the print label.

[31]One of the all-format best practices states that accessible labels should be subjected to the same quality control processes used for print labels to ensure accuracy and patient safety.

some, but not all, of the best practices into their corporate policies that pharmacies must follow. However, officials from three chain pharmacy companies told us that their corporate policies do not include any of the best practices and their retail pharmacies cannot offer any services for individuals who are blind or visually impaired other than what has been approved at the corporate level.[32]

- **Contracts with retail pharmacies.** Officials from all four PBMs and all three PSAOs told us that their contracts with retail pharmacies in their networks do not require pharmacies to implement the best practices.
- **Pharmacy accreditation standards.** Officials from two accreditation organizations told us that their pharmacy standards do not incorporate the best practices. Pharmacies must comply with standards for the accreditation processes they choose to undergo. Two accreditation organizations reported that they have standards that address services for individuals with disabilities, but these standards are not specific to drug labeling for the visually impaired and do not incorporate the best practices.
- **State regulations.** Officials from all four states told us that their state's regulations do not incorporate the best practices. They also stated that they did not have any plans to update their current regulations to incorporate the best practices; however, officials from one state told us that they may consider doing so in the future. Massachusetts does have a law requiring the provision of large print labels to the visually impaired and elderly upon request, but the font size requirement differs from that of the best practices.[33]

Of those stakeholders who identified this challenge, most stakeholders told us that more pharmacies may implement the best practices if corporate pharmacy policies or pharmacy accreditation standards incorporated them. For example, officials from three chain pharmacy companies, one advocacy group, one industry group, and one technology vendor told us that pharmacies could implement the best practices if corporate pharmacy policies included them. Further, officials from two individual retail pharmacy locations stated that they require corporate approval to implement any technologies to produce accessible labels that meet the best practices. Additionally, officials from one PBM and one

[32]We did not receive information about corporate pharmacy policies from two of the nine chain pharmacy companies.

[33]See Mass. Gen. Laws ch. 94C, § 21 (2016).

technology vendor told us that more pharmacies would implement the best practices if pharmacy accreditation standards incorporated them.

NCD Has Conducted Limited Campaign Activities, but Has Not Assigned Responsibilities for Future Activities Nor Evaluated Its Activities

We found that NCD conducted limited campaign activities from July 2013 through August 2016 to inform and educate pharmacies (including pharmacists and pharmacy staff), individuals who are blind or visually impaired, and the public about the best practices. For example, prior to the publication of the U.S. Access Board working group's report, NCD sent emails to members of the working group to solicit ideas on how the agency could coordinate with working group members to disseminate information on the best practices once they were published. From July 2013 through February 2016, NCD issued an agency statement and two press releases through its website, listserv, and online social media about the best practices and pharmacies' agreements with advocacy groups to provide accessible labels; hosted a conference call with three advocacy groups to discuss how they could conduct outreach as part of NCD's campaign; and published a blog post on accessible labels.[34] However, the agency did not conduct any campaign activities in 2015. From June through August 2016, NCD developed a brochure on some of the best practices, disseminated the brochure through its website, and coordinated with the U.S. Access Board, one industry group representing pharmacists, and one chain pharmacy company to disseminate this brochure. See table 8 for a timeline of NCD's campaign activities.

Table 8: National Council on Disability's (NCD) Informational Campaign Activities after Publication of the U.S. Access Board's Best Practices

2013	**July:** Issued agency statement about publication of best practices and disseminated statement via its website, its listserv, and social media, such as Facebook. **November:** Held conference call with three advocacy groups to discuss outreach for campaign.
2014	**March:** Issued a press release about the best practices and a pharmacy's agreement with advocacy groups to provide accessible labels and disseminated press release via its website, its listserv, and social media. Also, published blog post on accessible labels from the perspective of an individual who is blind.[a]
2015	No reported campaign activities.

[34]NCD officials stated that the agency's listserv has about 3,000 subscribers, such as members of advocacy groups for individuals who are blind or visually impaired. They tracked the number of likes on their Facebook posts or number of retweets on their Twitter posts.

2016	**February:** Issued a press release about the best practices and a pharmacy's agreement with advocacy groups to provide accessible labels and disseminated press releases via its website, its listserv, and social media. **June-August:** Developed brochure on best practices, disseminated brochure via website, and coordinated with the U.S. Access Board, one industry group, and one chain pharmacy company to also disseminate brochure.

Source: GAO analysis of NCD campaign activities. | GAO-17-115

Note:

The U.S. Access Board working group published its report on the best practices on July 10, 2013. See U.S. Access Board Working Group on Accessible Prescription Drug Container Labels, *Best Practices for Making Prescription Drug Container Label Information Accessible to Persons Who are Blind or Visually-Impaired or Who are Elderly* (Washington, D.C.: July 10, 2013).

aThe blog post was published on Disability.Blog, the blog for Disability.gov, a federal website for information on disability programs and services.

Most of the selected stakeholders we spoke with—including PBMs, chain pharmacy companies, states, and advocacy groups—have not had any communication with NCD about its campaign, and, as previously discussed, some were unaware of the best practices. When we first interviewed NCD officials in February 2016, they could not provide us with a fully developed and documented plan for conducting and evaluating the agency's campaign nor did they do so in subsequent follow-up we had with them through August 2016. However, in September 2016 during a meeting to review NCD's campaign activities, officials told us they had developed a plan in December 2013 for conducting campaign activities that were to occur throughout 2014. These activities consisted of developing a virtual toolkit for stakeholders to use for planning their own outreach, according to documentation NCD provided. However, we determined that NDC did not conduct most of these activities. Subsequent to our September 2016 meeting, officials provided us with a corrective action plan with timeframes for conducting future campaign activities through fiscal year 2017, including some of the activities that NCD did not conduct in 2014. The development of this corrective action plan is a positive step to conduct campaign activities. However, neither the original plan nor the corrective action plan assigned responsibilities for campaign activities. This is inconsistent with federal internal control standards, which indicate that an agency should assign responsibilities to achieve its objectives. Given that most of the activities NDC originally planned for 2014 never occurred, this lack of specificity regarding responsibilities is concerning because it does not provide assurance that the agency will conduct future campaign activities as planned. Further, officials could not provide us any plans for how they will evaluate the agency's campaign activities. NCD officials stated that the agency has not evaluated nor has any plans to evaluate its campaign activities, other than tracking the number of likes or retweets on its social media posts. Federal internal control standards indicate that an agency should design and execute a plan to evaluate its activities, document evaluation results,

and identify corrective actions to address identified deficiencies.[35] In the absence of a formal evaluation plan, NCD officials will be unable to determine the effectiveness of their campaign activities and make adjustments, as needed.

Conclusions

The U.S. Access Board published best practices to make information on prescription drug container labels accessible to the about 7.4 million Americans who are blind or visually impaired. However, there continues to be a lack of awareness among a variety of stakeholders that these best practices exist. NCD, the agency charged with conducting a campaign to inform and educate stakeholders of these practices, has not had an effective plan to conduct its campaign and, consequently, conducted limited activities from July 2013 through August 2016. For example, the agency did not conduct most of its planned campaign activities in 2014 and conducted no activities in 2015. Although NCD now has a corrective action plan for activities it intends to conduct through fiscal year 2017, it has not assigned responsibilities for these activities and has not developed an evaluation strategy for its activities, which is inconsistent with federal internal control standards. Without ensuring these elements are in place, NCD will be unable to adjust its corrective action plan and assess whether the information it is providing on the best practices are effectively reaching its target audience.

Recommendation for Executive Action

The Executive Director of NCD should assign responsibilities for conducting future campaign activities and develop an evaluation plan for its activities.

Agency Comments and Our Evaluation

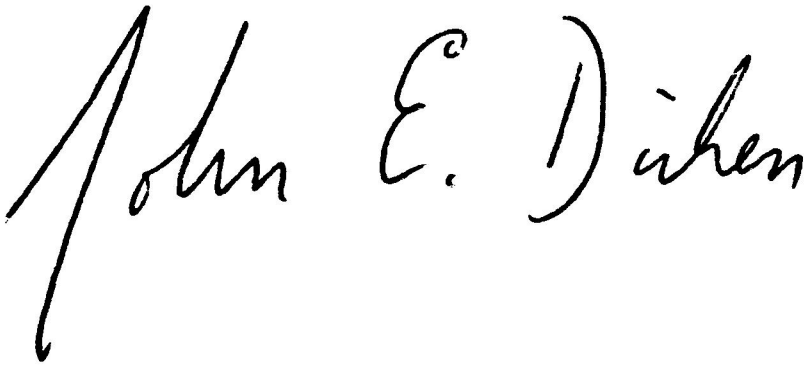
We provided a draft of this report to the U.S. Access Board and NCD for comment. Both agencies provided written comments, which we have reprinted in appendixes II and III, respectively. The U.S. Access Board said that it found our report to be complete and accurate. In its written comments, NCD did not specifically state whether it agreed with our recommendation, but signaled its intention to revise its corrective action plan for conducting campaign activities through fiscal year 2017. NCD stated that it has reassessed its plan and is taking action to ensure

[35]See GAO, *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: September 2014). Internal control is a process effected by an entity's oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved.

ongoing compliance with federal internal control standards. NCD also provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the appropriate congressional committees, the Executive Director of the U.S. Access Board, the Executive Director of the National Council on Disability, and other interested parties. In addition, the report is available at no charge on the GAO website at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or dickenj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix IV.



John E. Dicken
Director, Health Care

Appendix I: Description of Web-Based Questionnaire

We developed a web-based questionnaire that included questions on

1. the extent to which pharmacies can provide accessible labels and have implemented the specific U.S. Access Board's best practices for making information on prescription drug container labels accessible to individuals who are blind or visually impaired (henceforth referred to as best practices);
2. barriers that individuals who are blind or visually impaired face in accessing information on prescription drug container labels; and
3. factors that affect pharmacies' implementation of the best practices and steps that could address any implementation challenges.

We sent this questionnaire to pharmacy benefit managers (PBM) that operate mail order pharmacies that centrally fill prescriptions and send them directly to individuals; chain pharmacy companies that operate retail pharmacies in traditional pharmacies locations, supermarkets, and mass merchandise stores; and individual retail pharmacy locations—including chain pharmacies (those with four or more locations under common ownership) and independent pharmacies (those with three or fewer retail locations under common ownership):

- Four PBMs that manage prescription drug benefits for the four largest private insurers that sponsor Medicare Part D plans as of March 2016.[1] To select PBMs, we analyzed Medicare Part D contract and enrollment data as of March 2016 from the Centers for Medicare & Medicaid Services, which were the most recent available data at the time began our work. Using these data, we identified the four private insurers that sponsor Medicare Part D plans with the largest percentage of Medicare Part D enrollment as of March 2016—representing a total of about 60 percent of Medicare Part D enrollees—and selected the four PBMs that managed the prescription drug benefits for these private insurers.
- Nine of the 10 largest chain pharmacy companies as of March 2016. To select these companies, we obtained data from the National

[1]Medicare Part D provides voluntary, outpatient prescription drug coverage for Medicare, the federally financed health insurance program for eligible individuals 65 years and older, certain individuals with disabilities, and individuals with end-stage renal disease; and is administered by the Centers for Medicare & Medicaid Services. PBMs are companies that help third-party payers—such as private insurers—manage their prescription drug benefits by operating mail order pharmacies, assembling retail pharmacy networks that include both chain and independent pharmacies, and providing other services.

Council of Prescription Drug Programs on the 16 chain pharmacy companies with the most retail pharmacy locations as of March 2016, which were the most recent available data at the time we began our data collection.[2] We compared this list of pharmacies to data from the National Association of Chain Drug Stores on their members as of March 2016 and reconciled any differences between these two lists of data.[3] We contacted the 10 largest chain pharmacy companies based on their number of retail pharmacy locations, which ranged from about 480 to over 9,700, and 9 agreed to participate in our study.

- Thirty-eight individual retail pharmacy locations that included both chain and independent pharmacies in metropolitan and non-metropolitan areas in the four states for which we interviewed the state pharmacy regulating bodies—California, Florida, Illinois, and Massachusetts. To make our selection, we obtained data as of May and June 2016 on the active licensed retail pharmacies in each of the four states—including pharmacy name, the county in which the pharmacies were located, and pharmacy license number.[4] Then, using the U.S. Department of Agriculture's 2013 Rural-Urban Continuum Codes data, which classifies counties by their population size and degree of urbanization, we coded pharmacies by the county in which they were located.[5] We used the coded data to create two randomized lists—one for pharmacies in metropolitan counties and a second for pharmacies in non-metropolitan counties—to use for

[2]The National Council for Prescription Drug Programs is a nonprofit organization that develops pharmacy industry standards and maintains data on pharmacies.

[3]The National Association of Chain Drug Stores is an industry group that represents companies that operate chain pharmacies.

[4]We excluded pharmacies that were located out of state or did not have a county name listed in the original data file we obtained from the state pharmacy regulating body.

[5]The Rural-Urban Continuum Codes are a classification scheme that distinguishes metropolitan counties by the population size of their metropolitan area and non-metropolitan counties by degree of urbanization and adjacency to a metropolitan area. Each county in the U.S. is assigned a code that ranges from one (meaning that the county is in a metropolitan area with a population of one million people or more) to nine (meaning that the county is rural, has a urban population of less than 2,500 people, and is not adjacent to a metropolitan area).

selection.[6] Using these lists, we targeted two independent and two chain pharmacies from metropolitan counties, since most pharmacies were located in metropolitan areas, and one independent and one chain from non-metropolitan counties.

During the development of our questionnaire, we pretested it with two randomly selected individual retail pharmacy locations (one chain and one independent pharmacy) to ensure that our questions and response choices were clear, appropriate, and answerable. We then made changes to the content of the questionnaire based on feedback obtained from the pretests.

We administered the web-based questionnaire from July 2016 through September 1, 2016 and received responses from the 4 selected PBMs, 7 of the 9 selected chain pharmacy companies, and 18 of 38 randomly selected individual retail pharmacy locations. The 18 individual retail pharmacy locations represented 10 chain and 8 independent pharmacies in both metropolitan and non-metropolitan areas in all four of our selected states.

[6]We defined metropolitan counties as those coded with Rural-Urban Continuum Codes one through three and non-metropolitan counties as those coded with Rural-Urban Continuum Codes four through nine. Data on retail pharmacies located in Florida did not contain data on the county, but rather zip codes, in which pharmacies are located. We used a crosswalk from the Centers for Medicare & Medicaid Services that allowed us to match zip codes to counties to identify counties in which the pharmacies were located.

Appendix II: Comments from the U.S. Access Board

UNITED STATES ACCESS BOARD

1331 F Street, NW
Suite 1000
Washington, DC
20004-1111

Voice
202-272-0080

TTY
202-272-0082

Fax
202-272-0081

Web
www.access-board.gov

November 17, 2016

John E. Dicken
Director, Health Care
U.S. General Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Dicken:

Thank you for the opportunity to review the draft report, "Prescription Drug Labels: Actions Needed to Increase Awareness of Best Practices for Accessible Labels for Individuals Who Are Blind or Visually Impaired".

The Access Board was pleased to lead the development of advisory guidance on making prescription drug container labels accessible to people who are blind or visually impaired or who are elderly as directed by Congress in the Food and Drug Administration Safety and Innovation Act. We took our responsibility seriously and completed the best practices within the 1-year period set out in the legislation. We could not have done our work without the outstanding assistance of our 18-member stakeholder panel comprised of representatives from advocacy organizations and industry and with staff assistance from the Department of Justice.

In regard to the Access Board's role in the legislation through the development of the best practices, I found your report complete and accurate. We would be happy to work with the National Council on Disability on any additional outreach and informational campaign activities to help improve awareness and adoption of the best practices.

Sincerely,

David M. Capozzi
Executive Director

A FEDERAL AGENCY COMMITTED TO ACCESSIBLE DESIGN

Appendix III: Comments from the National Council on Disability

National Council on Disability

An independent federal agency making recommendations to the President and Congress to enhance the quality of life for all Americans with disabilities and their families.

November 21, 2016

John E. Dicken
Director, Health Care
Government Accountability Office

Dear Mr. Dicken:

Thank you for the opportunity to review the draft report entitled "Prescription Drug Labels: Actions Needed to Increase Awareness of Best Practices for Accessible Labels for Individuals Who Are Blind or Visually Impaired" (GAO-17-115). We appreciate your consideration of our technical comments which we provided prior to the completion of the final report.

We have reviewed GAO's recommendation to NCD in this report and have reassessed our corrective action plan pursuant to federal internal control standards. NCD's management is partnering with the Center for Audit Excellence to ensure ongoing compliance with internal control standards and application of the Green Book principles and attributes.

Respectfully,

Rebecca Cokley

Rebecca Cokley
Executive Director

1331 F Street, NW ■ Suite 850 ■ Washington, DC 20004
202-272-2004 Voice ■ 202-272-2074 TTY ■ 202-272-2022 Fax ■ www.ncd.gov

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

John E. Dicken (202) 512-7114 or dickenj@gao.gov

Staff Acknowledgments

In addition to the contact named above, individuals making key contributions to this report include Rashmi Agarwal, Assistant Director; Kristin Ekelund, Analyst-in-Charge; Melissa Duong; and John Lalomio. Also contributing were George Bogart, Carolyn Fitzgerald, Laurie Pachter, and Vikki Porter.

Appendix V: Accessible Data

Agency Comment Letters

Comments from the U.S. Access Board

November 17, 2016

John E. Dicken Director, Health Care

U.S. General Accountability Office 441 G Street, NW

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David M. Capozzi Executive Director

Comments from the National Council on Disability

November 21, 2016

John E. Dicken Director, Health Care

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Respectfully,

Rebecca Cokley Executive Director

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