Assessment of Audible Prescription Drug Labels

REPORT TO THE MINNESOTA STATE LEGISLATURE

4/1/25

Assessment of Accessible Drug Labels

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DEPARTMENT OF HEALTH

Protecting, Maintaining and Improving the Health of All Minnesotans

Minnesota Senate

Health and Human Services Committee

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The Honorable Paul Utke, Ranking Member, 2403 Minnesota Senate Building

Human Services Committee

The Honorable John Hoffman, Chair, 2111 Minnesota Senate Building

The Honorable Jim Abeler, Ranking Member, 2207 Minnesota Senate Building

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Commerce Finance and Policy Committee

The Honorable Tim O'Driscoll, Co-Chair, 2nd Floor, Centennial Office Building

The Honorable Kaohly Vang Her, Ranking Member, 5th Floor, Centennial Office Building

April 1, 2025

To the Honorable Chairs and Ranking Members,

As directed by the Legislature (Minnesota Laws of 2024, chapter 127, article 60, section 24), the Minnesota Department of Health (MDH), in consultation with the Board of Pharmacy, assessed prescription drug container labels for people who cannot use standard printed labels, large print, or Braille drug container labels.

Enclosed is MDH's report of pharmacies' capacity to provide audible labels and vendors of audible drug container technology. Consistent with the requirements of the law, MDH:

- Approximated the number of outpatient pharmacies currently providing audible drug container labels.
- Estimated the costs of adopting audible container labels.
- Offered recommendations for policy makers to consider concerning the adoption of new requirements

In addition, MDH offered a number of considerations the Legislature may wish to consider as it weighs balancing the establishment of new requirements with the burden associated with those requirements.

This report is available on the Accessible Prescription Drug Labels webpage (https://www.health.state.mn.us/data/economics/rxlabels/index.html).

A list of pharmacies with the type of accessible prescription drug container labels they make available is also online. MDH is required to update this list on a quarterly basis throughout 2025: Pharmacies with Accessible Labels (Excel) (https://www.health.state.mn.us/data/rxtransparency/docs/rxlabels.xlsx).

Questions or comments on the report may be directed to Stefan Gildemeister, the state health economist, at (651) 201-4520, or health.Rx@state.mn.us.

Sincerely,

/s/ Brooke Cunningham

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Executive summary

The 2024 Legislature directed the Minnesota Department of Health (MDH), in consultation with the Board of Pharmacy, to assess prescription drug container labels for Minnesotans who cannot use standard printed, large print, or Braille (Minnesota Laws of 2024, chapter 127, article 60, section 24).[1] For the purposes of this report, MDH considers these to be audible container labels. The goals of the assessment were to: 1) approximate the number of outpatient pharmacies in Minnesota currently providing audible drug container labels, and 2) approximate the costs of providing audible container labels.

Patients need access to label information on prescription drugs to avoid medication errors, including taking the wrong medication or incorrect dose. It is important that drug container labels are accessible to all individuals, including for those who are blind, DeafBlind, or visually impaired. The risk of vision impairment increases with age, and the number of medications prescribed to individuals also tends to increase with age. Considering that the population of Minnesota is aging, the issue of accessible labels may be of particular and growing importance. Notably, the percent of the population of Minnesota over the age of 65 years was about 14% in 2015. It is expected to increase to 25% by the year 2030. While Braille or large print is appropriate for some, others cannot access Braille or large print and need an alternative—such as an audible drug container label, where the content of a label is read audibly for patients (or their caregivers).

Methods and data sources

To inform this assessment of audible drug container labels, MDH conducted a survey of Minnesota community/outpatient pharmacies and held informational conversations with key stakeholders. MDH reached out to all pharmacies licensed in Minnesota and collected data from 863 outpatient pharmacies. Key stakeholder and data sources for this assessment included: disability advocacy groups, pharmacies (including both small, independent pharmacies and larger, chain pharmacies), pharmacy trade associations, and vendors of audible label technology.

Results

Approximately 40% of outpatient pharmacies that responded to the survey currently provide audible container labels. Most of the pharmacies currently providing audible labels are larger chains or health care systems, rather than independent pharmacies. Of the pharmacies that provide audible container labels, approximately 60% were located in-state (as opposed to out-of-state mail order pharmacies). Approximately 60% of pharmacies currently providing audible labels reported the label is provided the same day as the patient's request. Most can provide the label within one to three days of the patient's request.

Pharmacies largely bear the cost of audible container labels. The costs are primarily front-loaded in start-up costs, including purchasing required equipment (e.g., radio-frequence identification [RFID] printers) and supplies to produce audible labels. Annual and ongoing costs include software and technical support. Pharmacies and

[1] Minnesota Laws of 2024, chapter 127, article 60, section 24 (https://www.revisor.mn.gov/laws/2024/0/Session+Law/Chapter/127/)

vendors of audible label technology reported a wide range of costs, and the approximate average costs are listed below.

- Start-up: $4,000
- Annual cost: $2,500
- Cost per label (most commonly an RFID sticker): $3.00

Implementation Challenges

For pharmacies not currently providing audible labels, the main concern relates to the needed financial commitment. These pharmacies also consider the need for technical support, training, and guidance regarding types of labels, vendors, and processes for providing labels.

Exact data characterizing the need for audible labels (as opposed to large print or Braille) were not available for this report, whether specific to Minnesota patients or nationally. However, both chain and independent pharmacies expressed concerns that the costs of providing labels were significant relative to low utilization of services.

Pharmacies expressed concerns about monopolistic pricing as there is currently one vendor of audible label technology, aside from large chain pharmacies that have the resources to develop proprietary technology (e.g., CVS Pharmacy).

With the general pace of technological advancements, the current audible label technology appears somewhat outdated and financially inefficient. Pharmacies wondered whether centralizing audible label solutions could represent effective alternatives to serve patient needs while reducing the burden on individual pharmacies. They recognized such a solution would have to overcome potential delays for patients.

Recommendations

Based on findings from this assessment of community/outpatient pharmacies, MDH recommends the following:

- **Recommendation 1**: All Minnesotans should have access to prescription drug container labels that meet their needs and are available in their preferred format, including audible labels.
- **Recommendation 2**: Any audible label requirement should not add to the financial challenges already faced by small chain and independent pharmacies.
- **Recommendation 3**: Minnesota should explore audible label technologies that are less expensive and easier for pharmacies to implement. If this creates delays, pharmacies should be required to provide patients information on where they can obtain an audible container label.
- **Recommendation 4:** The Legislature should develop estimates for audible container label demand.
- **Recommendation 5:** Any audible label requirement should include clear requirements, including specifications about which types of medications, which modes of administering medications, which settings, what information must be included with the audible label, and timeliness.

Considerations

In weighing potential policy development, legislators should consider the following additional questions:

1. Should certain small and medium-sized pharmacies be granted a longer adoption window to implement technology, training, and other resources needed to provide audible labels?
2. Should there be a requirement for a dual-language option to expand accessibility to those who are not English proficient?
3. Are there opportunities for developing alternative approaches, including developing a centralized program for distributing audible label readers?
4. Are there other gaps in service—either related to the patients' ability to effectively use a prescription drug label or for the blind, Deafblind, and hard of hearing community—that could be simultaneously addressed, thus creating opportunities for efficiency?
5. What are the risks for errors in audible labeling, and how can they be addressed to reduce potential patient harm?

Introduction

Prescription drug medications are an essential component of health care for many Minnesotans. Access to information about prescriptions is critically important for patients to take the correct type and dosage of their medications. Many patients or caregivers can relate to the complexity of managing medications. This is especially true for people with any access impairments—including vision impairments—and for those taking multiple medications. As people age, they have a higher likelihood of developing vision impairment as well as a higher likelihood of being prescribed multiple medications. Making drug container labels accessible to those who are blind or visually impaired is important, particularly considering the aging population in Minnesota.

Minnesota is working to meet these needs with new legislation requiring pharmacies to provide large print or Braille labels (Minnesota Statutes, section 151.212, subdivision 4).[2] While large print or Braille meets some patients' needs, certain patients need alternatives. The main alternative format currently available for patients who cannot effectively use large print or Braille labels is an audible container label. This is typically a radio-frequency identification (RFID) sticker on a drug container that can be scanned and read aloud using a reader device or phone.

Minnesota does not currently require pharmacies to provide audible container labels, as some other states do. To consider expanding the current accessible label requirement to include audible labels, the Legislature directed the Minnesota Department of Health (MDH), in partnership with the Board of Pharmacy, to assess outpatient pharmacies and vendors of audible label technology—including the approximate number of pharmacies in Minnesota currently providing audible labels and the resources needed for those that do not currently provide audible labels.

Because MDH staff are not subject matter experts on audible container labels, MDH conducted this assessment by surveying outpatient pharmacies, consulting with experts at the Board of Pharmacy, and gathering information from a range of key stakeholders.

This report summarizes the results of the assessment by describing the current landscape for accessible drug container labels for those who cannot effectively use Braille or large print (i.e., audible drug container labels); characterizing the perspectives, needs, and preferences of stakeholders; and presenting recommendations and considerations for ways to expand the availability of these services. This report is one part of a broader effort to improve accessibility and equity for the blind and visually impaired, improve health outcomes by reducing adverse health events, and to support pharmacies in providing accessible drug container labels.

[2] Minnesota Statutes, section 151.212, subdivision 4 (https://www.revisor.mn.gov/statutes/cite/151.212)

Assumptions and terminology

Based on available accessible label technology, the law's language, and stakeholder conversations, MDH interprets "accessible labels to individuals who cannot access large print or Braille labels" to mean audible drug container labels for the purposes of this report. The statute does not mention accessible audible label options for those who are not English proficient.

Individuals accessing drug labels includes patients, as well as caregivers or family members of those who are prescribed medications. Accessing label information can also be important for first responders or Emergency Medical Technicians (EMTs). For simplicity, this report uses the term "patient," but should be considered to represent all individuals who need access to drug container information.

"Drug container" refers to any type of packaging of medications, including but not limited to bottles, boxes, blister packs, vials, pre-filled syringes, and tubes. While a consideration for possible future requirements, MDH assumes for this report any labeling requirement that applies to typical prescription drug container labels would also apply to an audible prescription drug container (see Minnesota Statutes, section 151.212).[3] It is also assumed any audible label would be provided in addition to—and not in lieu of—a typical printed label. For example, drug containers should have a standard print label affixed to the container, as well as an audible label RFID sticker (or alternative audible label technology).

[3] Minnesota Statutes, section 151.212 (https://www.revisor.mn.gov/statutes/cite/151.212)

Minnesota legislation and policy context

Federal policy context

At the federal level, the 2012 Food and Drug Administration Safety and Innovation Act (Public Law 112-144, 126 Stat. 993)[4] included a directive to the US Access Board to develop recommendations on making drug container labels accessible to people who are blind or visually impaired. The Access Board published their recommendations and best practices in 2013.[5] Then in 2016, the Government Accountability Office (GAO) published a congressional report entitled "Prescription Drug Labels: Actions Needed to Increase Awareness of Best Practices for Accessible Labels for Individuals Who are Blind or Visually Impaired,"[6] which expanded on the Access Board's work and detailed pharmacies' capacity to implement the best practices outlined by the Access Board. Since 2016, 11 states, including Minnesota, enacted laws related to pharmacies providing accessible drug container labels.[7]

Minnesota legislation

Adding to existing prescription drug label requirements, Minnesota enacted a law in 2024 requiring all pharmacies in the state to provide accessible drug container labels in large print or Braille format, depending on the needs and preferences of the patient (Minnesota Statutes, section 151.212, subdivision 4).[8] A requirement to universally make available audible labels was ultimately not included in the legislation due to concerns about the feasibility of implementing it.

Recognizing the need for drug container labels to be accessible by blind and visually impaired individuals who cannot access large print or Braille and considering the costs and resources needed to provide audible labels, the Minnesota Legislature directed MDH to gather additional information to inform policymakers on this matter as described below (Minnesota Laws of 2024, chapter 127, article 60, section 24)[9]:

> "The commissioner of health, in consultation with the Board of Pharmacy, must conduct an assessment of licensed outpatient pharmacies and vendors of audible container labels and prescription readers to determine: (1) the approximate number of such pharmacies currently providing accessible labels to

[4] Public Law 112-144, 126 Stat. 993 (https://www.congress.gov/112/plaws/publ144/PLAW-112publ144.pdf)

[5] U.S. Access Board. (2013, July). Prescription Drug Container Labels. (https://www.access-board.gov/rx.html#working-group-recommendations)

[6] U.S. Government Accountability Office (2016, December). Prescription Drug Labels: Actions Needed to Increase Awareness of Best Practices for Accessible Labels for Individuals Who are Blind or Visually Impaired. (https://www.gao.gov/products/gao-17-115)

[7] Stay Safe Rx. Stay Safe Rx: Accessible Prescription Label Laws Timeline. (https://www.staysaferx.org/p/accessible-prescription-laws-time-line.html)

[8] Minnesota Statutes, section 151.212 (https://www.revisor.mn.gov/statutes/cite/151.212)

[9] Minnesota Laws 2024, chapter 127 (https://www.revisor.mn.gov/laws/2024/0/Session+Law/Chapter/127/)

individuals who cannot access large print or Braille labels; and (2) the approximate cost to such pharmacies to provide accessible labels to individuals who cannot access large print or Braille labels. By January 15, 2025, the commissioner must submit a report to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services finance and policy. The report must include the assessment results and recommendations for providing accessible labels to those who cannot access large print or Braille labels."

This report details the findings from the assessment of pharmacies and vendors of audible label technology.

Other states

The Minnesota law requiring pharmacies to provide large print and Braille drug container labels aligns with similar initiatives in other states. While this is not a comprehensive list, several states that have adopted similar laws in recent years include:

- **California**: AB-1902 Prescription drug labels: accessibility
  - Requires pharmacies to provide large print, Braille, or audible labels upon request.
  - Does not apply to institutional pharmacies, correctional facilities, or veterinary prescriptions.
- **Colorado**: HB24-1115 Prescription Drug Label Accessibility
  - Requires pharmacies to provide an electronic label affixed to the drug container that transmits the label information, provide a prescription drug reader at no cost to the patient, provide Braille or large print, or provide another method recommended by the US Access Board.
  - Colorado enacted a Prescription Accessibility Grant Program to financially support pharmacies in complying with the new regulations.[10]
- **Hawaii**: SB608 SD1 Relating to Prescription Drugs
  - Like Colorado, this law requires an electronic label affixed to the drug container, a prescription reader at no cost to the patient, or another method recommended by the US Access Board.
- **Virginia**: HB 516 Prescription drugs; labels provided for blind and disabled users
  - Pharmacies are required to notify patients who identify as blind or visually impaired that an accessible label or alternate accommodation is available.
  - Accessible labels include large print, Braille, or audible labels provided at the store or by mail order. Other accommodations such as daily pill packaging can be made.[11]

In general, these laws require pharmacies to provide a label in the format requested by the patient (large print, Braille, or audible), in a timely manner, at no additional cost, and to make reasonable efforts to inform patients of the services available. The state laws are largely consistent with the US Access Board best practices and GAO

[10] Colorado Department of Public Health & Environment. Prescription Accessibility Grant Program. (https://cdphe.colorado.gov/chronic-disease-prevention/prescription-accessibility-grant-program)

[11] Virginia Governor Signs Accessible Prescription Labeling into Law. (2024, April). Stay Safe Rx: Virginia Governor Signs Accessible Prescription Labeling into Law. (https://www.staysaferx.org/2024/04/virginia-governor-signs-accessible.html)

recommendations regarding accessible drug container labels. Translating drug container labels for patients who are not English proficient is required in some states such as Ohio (Rule 4729:5-2-05).[12]

[12] Ohio Rule 4729:5-2-05 (https://codes.ohio.gov/ohio-administrative-code/rule-4729:5-2-05)

Background

Patient need

According to 2019 census data, an estimated 84,900 people in Minnesota have vision difficulty.[13] Vision impairments vary and as such, the needs of patients vary regarding the type of accessible labels required. In other words, one label type is not sufficient for this whole population. While Braille or large print is appropriate for some individuals, others who cannot effectively use Braille or large print may need technology that audibly reproduces key information on labels (e.g., an audible drug container label). Sufficient data were not available to quantify the number or share of individuals who are blind or visually impaired who cannot effectively use large print or Braille.

The risk of vision impairment increases with age, and the number of medications prescribed to individuals also tends to increase with age. Considering the population of Minnesota is aging,[14] it is particularly important to consider the growing needs of older adults and the potential increase in need for audible labels. Notably, the percent of the population of Minnesota over the age of 65 years was about 14% in 2015 and is expected to increase to 25% by the year 2030.[15]

Audible label technology

Audible labels currently available at outpatient pharmacies are typically RFID or Quick Response (QR) code stickers attached to the drug container. A pharmacist encodes the electronic label with the prescription drug information and affixes the label on the container.[16] Patients can scan the RFID or QR code with an electronic reader device or smartphone app which will read the drug information to the patient. Figure 1 depicts an RFID label and the electronic device that scans and reads the prescription drug information. En-Vision America, a privately-held company, developed this technology—named ScripTalk®—more than 20 years ago and has remained the leading provider of audible label technology nationwide.[17] The most significant technological

[13] American Federation for the Blind. (2020, September). (https://www.afb.org/research-and-initiatives/statistics/state-specific-stats/minnesota).

[14] Minnesota State Demographic Center. (2016, March). Demographic Considerations for Long-Range & Strategic Planning for the State of Minnesota's Executive and Legislative Leaders. [demographic-considerations-planning-for-mn-leaders-msdc-march2016_tcm36-219453.pdf (https://mn.gov/admin/assets/demographic-considerations-planning-for-mn-leaders-msdc-march2016_tcm36-219453.pdf)]

[15] Minnesota Department of Human Services. (2017, September). Aging Data Profiles. (https://mn.gov/dhs/partners-and-providers/news-initiatives-reports-workgroups/aging/aging-2030/data-profiles/)

[16] Audible labels are typically affixed to the container and not the cap to avoid accidentally mixing caps.

[17] En-Vision America. (2024). (https://www.envisionamerica.com/about-us).

advancement since its inception is En-Vision America's smartphone app, which most patients prefer as opposed to the reader device, according to MDH's consultation with a representative from Envision America.

Figure 1: ScripTalk® Electronic Container Label with Prescription Reader Device

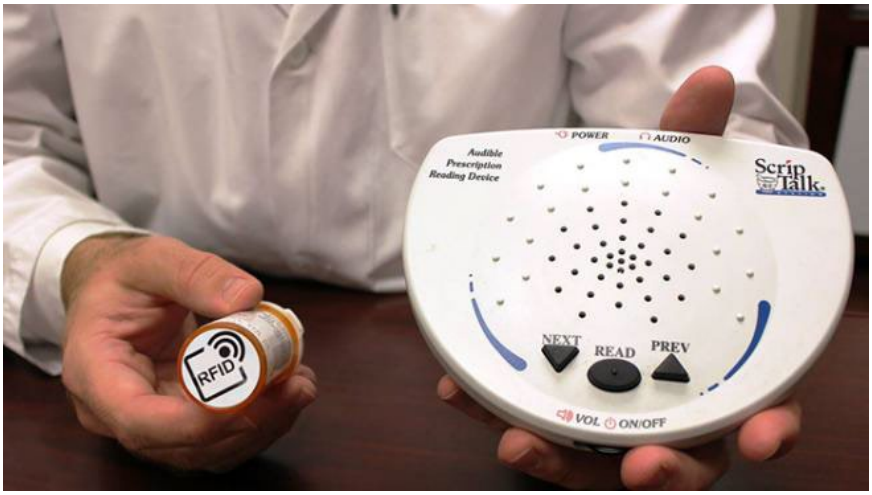

Image source: https://drugstorenews.com/retail-news/walmart-sams-club-expand-en-vision-americas-scriptalk-labels

The process for a patient acquiring an audible label from this vendor typically begins with the patient requesting an audible label from the pharmacy. The patient completes a request form, either provided by the pharmacy or En-Vision America. En-Vision America provides the patient with a prescription reader device at no cost to the patient on free loan or provides information on how to use the free ScripTalk® App on the patient's own smartphone. Most patients opt to use the mobile app and do not require the reader device. Both the reader device and smartphone app can be programmed to read 25 different languages.

Approximately five years ago, CVS Pharmacy collaborated with En-Vision America to develop its proprietary Spoken Rx® audible label technology, which functions similarly to ScripTalk®. CVS provides one talking label device per patient at no cost, and pharmacists are trained to encode RFID labels when dispensing medications to patients who have requested audible labels. Walgreens, another large chain pharmacy, introduced a different type of audible label in 2014. Walgreens developed a store-branded *Talking Pill* Reminder, which is an electronic device that attaches to a drug container label. Prescription drug information can be recorded audibly on the device, and it includes an alarm to remind patients when to take their medication.

Patients can also obtain audible container labels from mail order pharmacies. For example, Accessible Pharmacy[18] is an online pharmacy that specializes in accessible prescription drug container labels and packaging. Accessible Pharmacy provides En-Vision America accessible label options. Less commonly utilized options include a reader device purchased from Amazon and provided to the patient by the pharmacy upon the patient's request, or Tel-Rex—a small audio recorder that allows the pharmacist to record prescription information and send the recording to the patient.

[18] Accessible Pharmacy (https://accessiblepharmacy.com/)

Alternatively, patients can use text to speech technologies not specifically designed for reading prescription drug information but serve the purpose. Smartphone apps—such as Be My Eyes—can read prescription drug labels, even if they are affixed to a cylindrical container.

Pharmacies in Minnesota

In 2023 (the latest available data), there were about 2,100 pharmacies licensed by the Minnesota Board of Pharmacy. This includes nearly 500 chain community pharmacies, roughly 150 non-chain community pharmacies, and about 400 non-resident pharmacies (other pharmacy types include hospital, home health care, long-term care, nuclear, and veterinary).[19] "Non-resident pharmacy" refers to any pharmacy located outside of the state of Minnesota and mails or ships medications to Minnesota. These pharmacies are required to be licensed in Minnesota and were included in the survey for this assessment. Consistent with national trends, the number of Minnesota community/outpatient pharmacies has declined in recent years. Between 2010 – 2021, 34% of all pharmacies operating in Minnesota during that time period closed, and while there were some new pharmacies added, the state had a net loss of pharmacies.[20] In 2023, it was reported that Minnesota had lost more independent pharmacies in the prior decade than any other state.[21] Pharmacies facing financial difficulties continue to close, leaving "pharmacy deserts" where residents have limited access to prescription drugs and in-person drug consultation through physical pharmacy locations. According to a 2024 MDH report, nearly half a million Minnesotans live in a low-pharmacy access area.[22]

A recent study found that nationally, independent pharmacies have a higher risk for closure compared to chain pharmacies.[20] While independent pharmacies have been hit hardest, they are not the only ones struggling with losses. Big chain pharmacies—including CVS and Walgreens—are also closing stores nationwide, viewed by the companies as unprofitable. Minnesota pharmacy advocates are voicing concerns about pharmacy closures and advocating to change polices.[23]

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[19] Minnesota Board of Pharmacy. (2023, July). Licensing and Registration Statistics. (https://mn.gov/boards/pharmacy/resourcesfaqs/licensingandregistration.jsp)

[20] Guadamuz, J. S., Alexander, G. C., Kanter, G. P., & Dima Mazen Qato. (2024, December). More US Pharmacies Closed Than Opened In 2018–21; Independent Pharmacies, Those In Black, Latinx Communities Most At Risk. Health Affairs, 43(12), 1703–1711. https://doi.org/10.1377/hlthaff.2024.00192.

[21] Ramstad, E. (2023, December). Ramstad: Minnesota is losing independent pharmacies, victims of scale, efficiency. https://www.startribune.com/minnesota-is-losing-independent-pharmacies-victims-scale-and-efficiency-drugstore-consolidation-pbms/600324746.

[22] Minnesota Department of Health. (2024, July). (https://www.health.mn.gov/diseases/cardiovascular/documents/pharmacy.pdf).

[23] DePass, D. (2024, November). More Minnesotans face 'pharmacy deserts' with chain drugstore closures. https://www.startribune.com/pharmacies-closing-pharmacy-deserts-growing-health-care-access-walgreens-cvs/601173628.

Assessment

Goals & objectives of assessment

Following legislative direction, the goals and objectives of this assessment were to:

1. Enumerate the number of outpatient pharmacies in Minnesota currently providing audible drug container labels.
2. Delineate the cost to such pharmacies to provide audible container labels.
3. Provide recommendations for providing audible labels.

Research methods & data sources

For this report, MDH sought data and information from several sources, including pharmacies, pharmacy trade associations, vendors of accessible label technology, and advocacy groups for the blind and visually impaired. MDH engaged these stakeholders throughout the fall of 2024 in open-ended discussions and through a survey of pharmacies. This report synthesizes the data MDH collected, and the data informs the recommendations in this report.

Consultations

MDH collaborated with the **Board of Pharmacy** throughout this project. Staff of the Board helped to gather insights on the current landscape, including pharmacies' current capacity to provide accessible drug container labels, and anticipated barriers to providing such labels. The Board also identified key stakeholders, provided background, and consulted on the report and recommendations.

MDH met with representatives from the **Minnesota Commission of the Deaf, DeafBlind & Hard of Hearing,** the **National Federation of the Blind of MN, and the Minnesota State Services for the Blind** who shared important information and considerations from the perspective of those who are blind, visually impaired, or DeafBlind. Key information included: the needs and preferences of consumers, contextualizing and quantifying the issue, identifying other stakeholders and vendors of accessible label technology, and other considerations for MDH's recommendations.

MDH met with the primary vendor of audible label technology, **En-Vision America**, to discuss the available technology, costs of audible labels, their capacity to provide accessible labels to pharmacies and meet increasing demand, additional information on other vendors and stakeholders, barriers and facilitators pharmacies face regarding accessible labels, and other key considerations and recommendations.

MDH held meetings with representatives from two large chain pharmacies (**CVS and Walgreens**) and one medium-sized chain pharmacy (**ThriftyWhite)**. These representatives clarified their processes for providing accessible labels, the types of labels available to those who cannot access large print or Braille, the associated costs to the pharmacy and patients, insights on the utilization/demand for audible labels, and other important information from their experience providing audible container labels.

Staff from pharmacy trade associations, the **Minnesota Pharmacy Alliance** and the **Minnesota Pharmacists Association**, also shared insights during a meeting with MDH. Representatives from these groups advocated on behalf of pharmacies, particularly small and independent pharmacies, and shared key considerations and recommendations regarding this legislation.

Pharmacy survey

In November 2024, MDH administered a **web-based survey to all pharmacies** licensed in the state of Minnesota. The survey included questions related to the requirements of the new accessible label requirement (Minnesota Statutes, section 151.212, subdivision 4.) and audible labels for this assessment. It was distributed to all 2,096 licensed pharmacies (excluding correctional facilities) and MDH received responses for 998 pharmacies (a 48% response rate). In accordance with the legislation, MDH analyzed data collected from the **outpatient pharmacies** (863 survey responses of the 1,759 total licensed outpatient pharmacies, a 49% response rate) to inform the recommendations in this report. Community/outpatient pharmacies dispense drugs to patients for home use, and some of these additionally dispense to providers administering drugs in outpatient and long-term care settings, and veterinarians dispensing drugs to pet and livestock owners.

The objectives of the audible label portions of the survey were to: determine the approximate number of pharmacies currently providing audible container labels; explore the process, timeliness, and costs associated with providing audible labels; and identify what resources and supports would be needed for pharmacies who are not currently providing audible labels. Pharmacies also had an opportunity to share any additional information in an open-text response via the survey.

Limitations

Due to incomplete participation by pharmacies and time constraints associated with producing this report, MDH was not able collect data from all outpatient pharmacies licensed in Minnesota. Notably, some large chain pharmacies did not submit survey responses for all their locations. [24]

Results

Current capacity to provide audible labels

The MDH survey to pharmacies found:

- **Most pharmacies licensed in Minnesota do not currently provide audible labels.**
  - Approximately 40% (341 pharmacies) of outpatient pharmacies that responded to the survey currently provide audible container labels.
- **Many pharmacies providing audible labels are non-residential (meaning out-of-state, primarily mail order).**

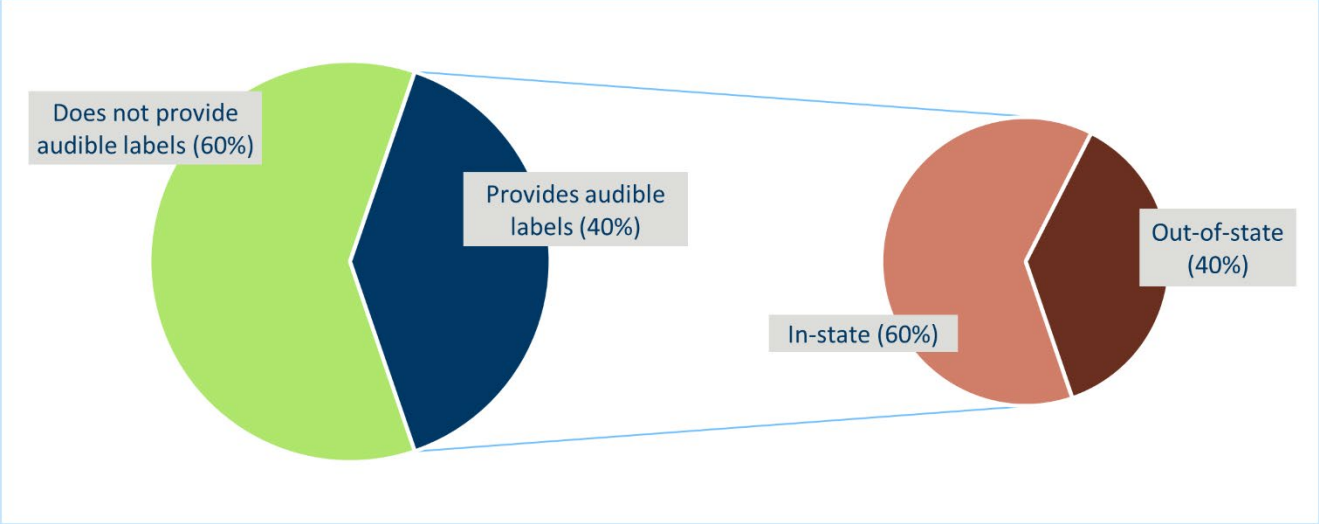
[24] MDH did not receive survey data from all licensed outpatient/community pharmacies. Notably, data is missing from large chain pharmacies Walgreens and Costco.

  - Of the survey respondents providing audible labels (341 pharmacies), approximately 60% (214 pharmacies) are in Minnesota, and 40% (127 pharmacies) have an out-of-state address.

- **Most pharmacies providing audible labels are large chain pharmacies.**
  - Among the in-state pharmacies reporting they currently provide audible container labels (214 pharmacies), all were large chain pharmacies or affiliated with a large health care system (e.g., Essentia Health), as opposed to small chain or independent pharmacies.[25]
  - Notably, CVS pharmacy has 127 locations in Minnesota, all of which provide audible labels (making up 60% of in-state pharmacies providing audible labels).

Figures 2 and 3 display these survey results. Figure 4 depicts the geographic distribution of pharmacies providing audible labels. While there is coverage throughout much of the state, there are still large areas without any pharmacy and particularly without access to a pharmacy providing audible labels.

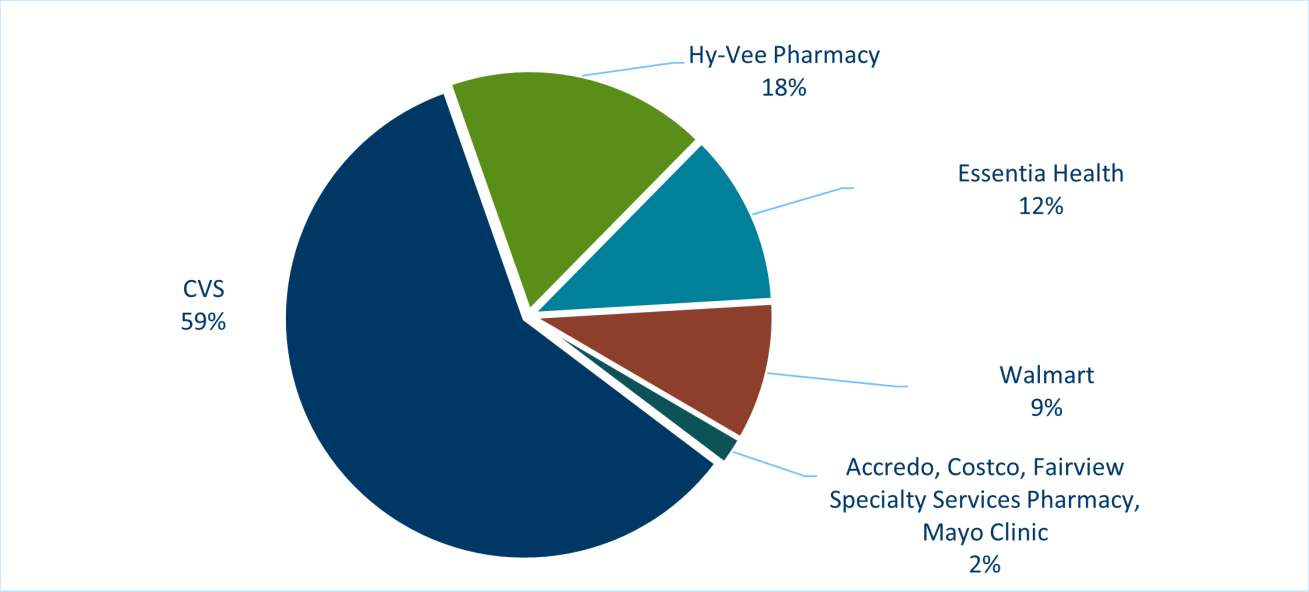
Figure 2: Portion of outpatient pharmacies currently providing audible container labels (Total N=863 pharmacies)



Source: MDH, Health Economics Program analysis of 2024 pharmacy survey data reported to MDH.

[25] In this report, "independent pharmacy" is defined as a pharmacy that has only one location, and "chain pharmacy" refers to a pharmacy that has multiple locations according to survey responses.

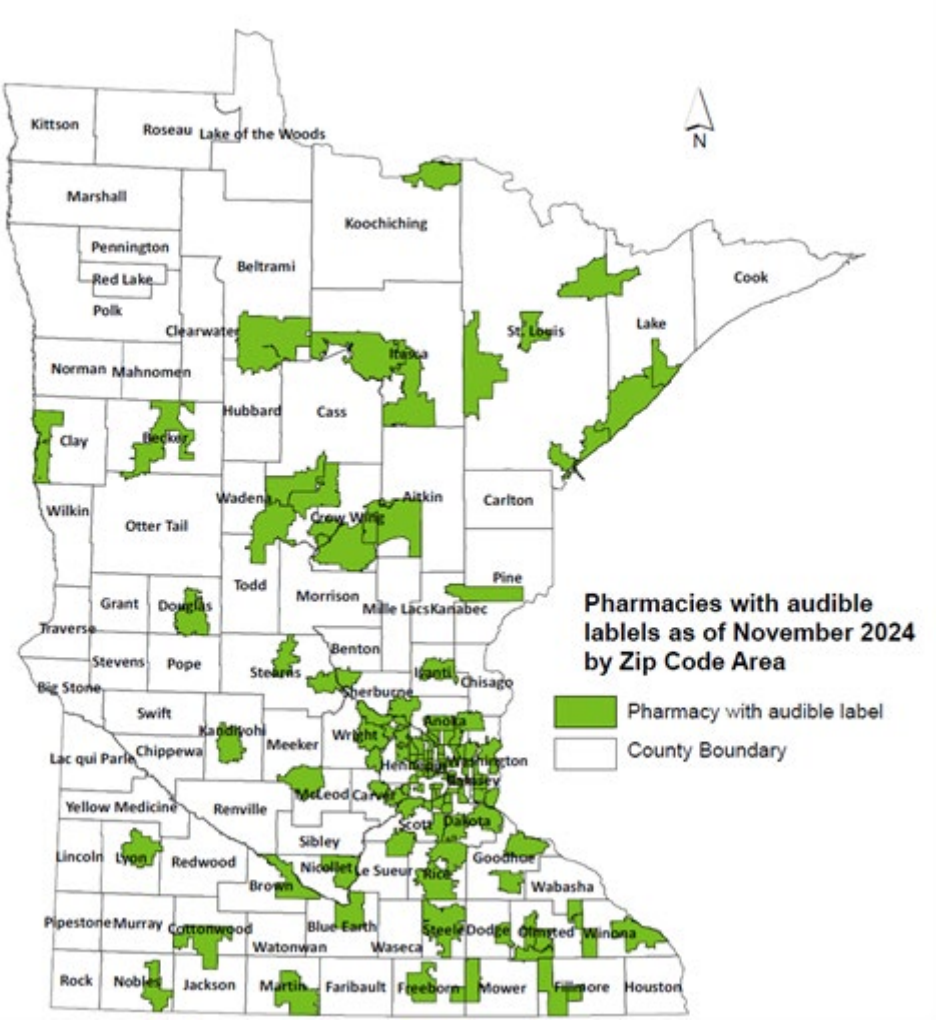
Figure 3: In-state pharmacies currently providing audible container labels (214 pharmacies)



Source: MDH, Health Economics Program analysis of 2024 pharmacy survey data reported to MDH.

Note: MDH did not receive full data from large chain pharmacies Walgreens and Costco.

Figure 4: Geographic distribution of in-state pharmacies currently providing audible container labels (214 pharmacies)



Source: MDH, Health Economics Program analysis of 2024 pharmacy survey data reported to MDH.

Pharmacy setting

While the audible label assessment focuses on community/outpatient pharmacies, many of these pharmacies serve in other capacities, including providing medication to hospital patients. There was significant concern expressed in the survey and consultations about aligning any requirement with patient needs in appropriate settings. In other words, survey respondents who represented pharmacies that do not dispense medications directly to patients for self-administration felt the requirements to provide accessible container labels would not be meaningful, as staff administer these drugs. Types of pharmacies representing that view included outpatient infusion centers and long-term care/assisted living facilities. One survey respondent commented:

> "Some consideration to **narrow the scope to true outpatient prescriptions** would be appreciated. For example, prescriptions dispensed by a community/outpatient or mail order pharmacy directly to a patient or their immediate care provider in an independent care environment."

However, patient advocates are concerned about certain types of pharmacies—such as long-term care facilities and outpatient infusion centers—being exempted from accessible label requirements. One facility may provide multiple types of care, including medications administered by health care professionals and medications self-administered by patients. Considering that a pharmacy may have multiple methods of administering medications, patient advocates emphasized that audible label requirements or exemptions should not be universally applied by pharmacy type. Rather, it should be considered whether audible label requirements and exemptions should apply to certain methods of administering medications.

Costs of providing audible labels

As with all support services, there is a cost associated with providing audible container labels to patients. The following costs, at this point, appear to be carried by pharmacies:

- **Start-up costs:** purchasing supplies and equipment (e.g., programmer to encode RFID stickers, printers to produce stickers, reader devices), software, and staff training.
- **Annual and ongoing costs**: ongoing software subscription, IT support, and licensing fees for audible label technology.

  Cost per label: labels are typically purchased as a roll of 250 – 500 RFID stickers.

The cost of providing audible container labels is largely front-loaded in start-up costs. The patient's label reader device, which ranges from $100 - $300, and is typically provided one time by the vendor at no cost to the patient. Presumably, vendors recover the cost of these devices through their contracts with pharmacies. As an example of pharmacy-chain solutions, Walgreen's Talking Pill Reminder is sold in stores, where vouchers are available to patients to cover the cost of the device, which is currently listed at $9.99.

According to a conversation with a representative from En-Vision America, a small pharmacy can get set up for approximately $2,000, pay annual licensing fees, and pay approximately $2.20 per label. However, a representative from the Minnesota Pharmacists Association estimated that start-up costs are greater than $2,000, according to their experience. In stakeholder interviews, a small pharmacy shared that they had recently been quoted $20,000 to set up audible label services. The table below contains approximate costs according to survey respondents who currently provide audible labels, as well as estimated costs from En-Vision America. Notably, En-Vision America was the vendor for most survey respondents (aside from those that developed proprietary technology such as CVS).

Table 1: Approximate costs of audible labels[26]

Cost type	Data source: survey respondents		Data source: En-Vision America
	Approximate average	Approximate range	Approximate costs
Start-up cost	$4,000	$1,000 - $10,000	$2,000
Annual cost	$2,500	$500 - $5,000	$300
Cost per label	$3.00	$0.25 – $10.00	$2.20

Source: MDH, Health Economics Program analysis of 2024 pharmacy survey data reported to MDH.

Timeliness of providing audible labels

Timeliness is an important consideration outlined by the US Access Board best practices, which advise pharmacies to: "Provide prescription medication with an accessible prescription drug label within the time frame the same prescription would be provided to patients without visual impairments."[27]

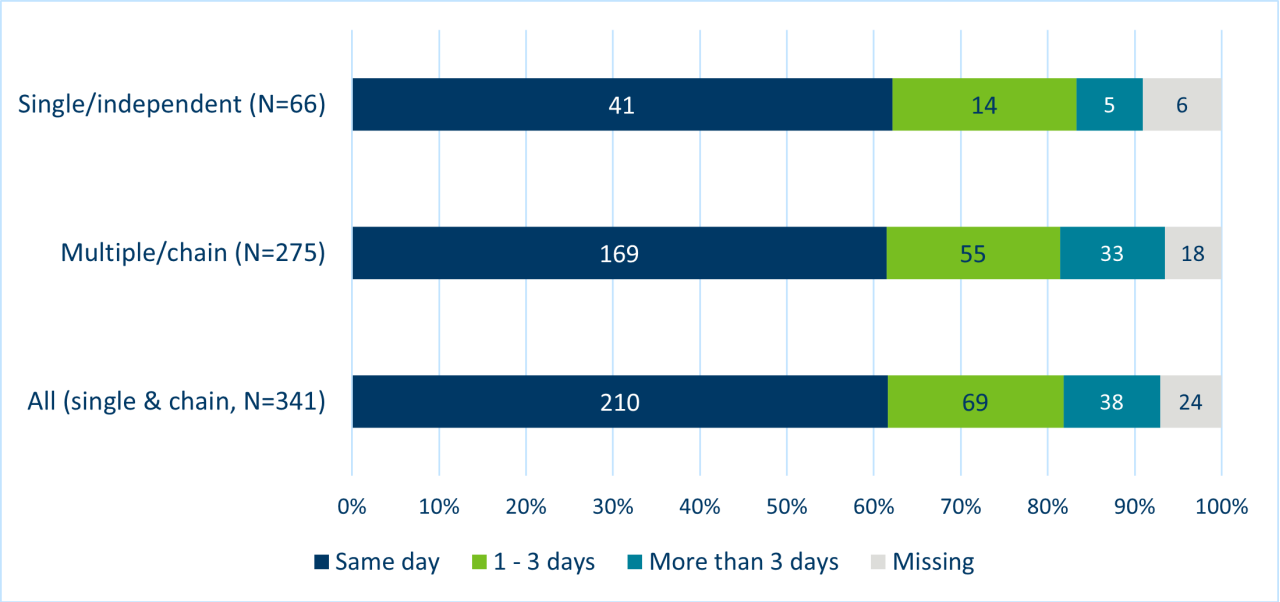
- Of all survey respondents currently providing audible labels:
  - Approximately 60% reported that the label is provided the **same day** as the patient's request.
  - Most can provide the label within **one to three days** of the patient's request.
- Factors that impact timeliness include:
  - **Mail order** prescriptions may take longer due to the time it takes to ship the medication.
  - A patient's **first audible label fill will take longer** if the patient does not yet have a reader device or reader app downloaded on their phone. Subsequent prescription medications can be filled on a shorter timeline once the patient is set up with the requisite supplies and technology.

Figure 5 further illustrates these results. It shows the percent distribution for distribution timeframes for both independent pharmacies (single/independent) and chain pharmacies (multiple/chain).

[26] The approximate costs in Table 1 were calculated based on survey responses to the question, "What is the approximate cost to your pharmacy to provide an accessible audible drug container label upon request from a customer? Please distinguish between start-up costs and ongoing costs." The average cost was calculated after removing outliers.

[27] U.S. Access Board. (2013, July). Prescription Drug Container Labels. (https://www.access-board.gov/rx.html#working-group-recommendations)

Figure 5: Timeframe for outpatient pharmacies to provide audible container labels

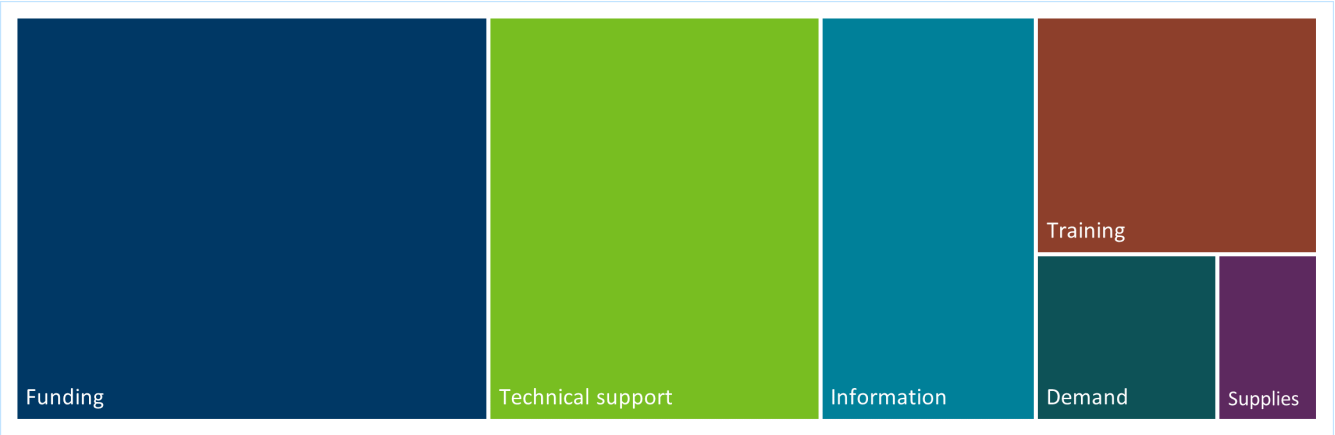


Source: MDH, Health Economics Program analysis of 2024 pharmacy survey data reported to MDH.

Implementation Challenges

In both the survey and interviews, MDH asked pharmacies that do not currently provide audible labels about what implementation challenges they perceive to provide audible labels. As shown in Figure 6, funding was the biggest area, but other supports included technical support, information, training, customer demand, and supplies.

Figure 6: Supports needed for pharmacies to provide audible container labels



Source: MDH, Health Economics Program analysis of 2024 pharmacy survey data reported to MDH.

Funding

The greatest concern among pharmacies that do not currently provide audible labels, particularly among small chain and independent pharmacies, is the need for funding. Pharmacies expressed experiencing financial

hardships because of low pharmacy benefit manager (PBM) reimbursement rates, and many fear going out of business. Financial support would help pharmacies cover the costs listed in the section above, including the costs of equipment and supplies, software, licensing fees, training, and labor costs.

> *"**Funding** would be needed. Since I am often paid below my cost of goods on prescriptions, I **can't afford** to invest a lot in new equipment (printer or software that allows these types of labels and/or a change in vial size to accommodate the new labels would be an added cost)."*

> *"**Funding**. PBMs are putting MANY MN pharmacies out of business due to LOW reimbursements on Prescriptions. Community pharmacies are teetering on extinction. WE **CANNOT AFFORD** ANOTHER UNFUNDED MANDATE!*

Other costs are staff labor, including training and the time it takes to create the label. Pharmacies also considered the need to develop processes, pay shipping fees, and have the space to accommodate the necessary equipment and supplies.

Patient utilization of services

Both chain and independent pharmacies expressed concerns about the costs of providing labels being significant in relation to the low utilization of services.[28] For example, a survey respondent reported:

> *"We have had **very little use** since implementing the ScripTalk® audible label program about 1 year ago, only about 5 patients enrolled."*

Another survey respondent representing a small, independent pharmacy shared:

> *"We are a very small independent pharmacy and I have **never had a patient ask for an audible label**. Financially this would be difficult, especially for something we would more than likely not ever use."*

Vendors and distribution

Along with low demand from customers, another concern is the limited number of vendors who provide audible labels. While a large pharmacy such as CVS has the financial capacity to invest in their own technology and processes for providing audible labels, most pharmacies will need to contract with a third-party vendor. En-Vision America is the primary vendor of this technology, leaving pharmacies with no other options. Pharmacies expressed concern about the cost of adopting audible container label technology in the face of pricing power by a single supplier in the market. An audible label mandate may affect demand for supplies, which could lead to increase in prices. Small chain and independent pharmacies already experiencing financial hardships voiced fears about high prices due to lack of competition.

Technical support

Pharmacies need the appropriate software and IT support to create and manage audible labels. Walmart, for example, is a large chain pharmacy that already has the technological capacity to provide audible labels. Pharmacists are trained to program notifications in their online system so that when they fill a prescription for a

[28] An employee of En-Vision America, a vendor of audible label technology estimated that a pharmacy (size not specified) can expect about five patients requesting audible labels with approximately five refills each per year.

patient who has requested an audible label, a reminder flashes on the computer screen to prompt them to create the label. Other pharmacies that do not currently have this type of technological capacity would require support in developing a similar system.

> *"**Modernized pharmacy software** is the biggest piece. We are in the process of developing and implementing new software that will provide us with substantially more flexibility in the labels we can provide. Audible labels in particular are a **challenge from a technical standpoint**, so flexibility in how this requirement could be met would be very helpful."*

> *"**Technical Support**: Assistance with the installation, maintenance, and troubleshooting of the technology used to produce audible labels. This could involve **support from the technology providers or third-party IT services**."*

Information

Broadly, information must be provided to pharmacies to explain what types of labels are available, the processes for providing the labels, identify vendors, and to provide guidance on the pharmacies' requirements under new mandate. Some survey respondents were unaware of how audible labels work, and others asked for guidance from other pharmacies that have implemented this to learn from their experiences.

Training

Staff training is a significant support needed to provide audible labels. A pharmacy that has the technological capacity to provide audible labels cannot do so if the staff does not know how to encode an RFID sticker. A representative from CVS, another large chain pharmacy, shared that while all their stores in Minnesota have the equipment to provide audible labels, staff training varies from site to site. A pharmacist at one store might not know where the supplies are kept, or a new pharmacist might not have received the same training as the previous staff member.

> *"**Staff training** on how to use the technology effectively, as well as how to assist customers in using audible labels. This training should cover both the technical aspects and the importance of accessibility in healthcare."*

Recommendations

Based on findings from this assessment of community/outpatient pharmacies, MDH recommends the following:

Recommendation 1: All Minnesotans should have access to prescription drug container labels that meet their needs and are available in their preferred format, including audible labels. All patients and caregivers—including those who are blind, DeafBlind, and visually impaired, need to access safe and reliable information about prescribed medications. Because visual impairments vary, so do the needs and preferences of patients. While audible labels do not meet the needs of all, they serve the needs of many Minnesotans and need to be available.

Recommendation 2: Any audible label requirement should not add to the financial challenges already faced by small chain and independent pharmacies. Pharmacies, particularly small chain and independent pharmacies, likely need financial and technical support to enable them to implement a requirement to provide audible container label. Pharmacies already facing financial hardships likely do not have the resources (i.e., funds, equipment, software, information, and training) to provide audible container labels and would need assistance. Moreover, an audible label mandate may affect demand for labels, which could influence prices. A possible solution could be a grant program for independent pharmacies like the one enacted in Colorado (HB24-1115). Alternatively, these pharmacies could be carved out of a requirement, a pharmacy partnering program could be piloted, or a centralized state-run program could be established.

Recommendation 3: Minnesota should explore audible label technologies that are less expensive and easier for pharmacies to implement. If this creates delays, pharmacies should be required to provide patients information on where they can obtain an audible container label. Given the relatively high cost of adoption, the financial impact to pharmacies, the relative lack of technological advancement in providing audible labels, and the lack of competition in the market for audible container labels, Minnesota should explore technology or solutions that are lower cost, modern, and more universally accessible. In the meantime, pharmacies should make reasonable efforts to inform patients on where they can obtain audible container labels.

Recommendation 4: The Legislature should develop estimates for audible container label demand. To ensure future requirements are targeted and well-suited to the need—such as patients who are not well served by large print and Braille prescription drug labels—the Legislature should seek to better understand how many patients require different solutions and their specific requirements.

Recommendation 5: Any audible label requirement should include clear requirements, including specifications about which types of medications, which modes of administering medications, which settings, what information must be included with the audible label, and timeliness. There are many pharmacy types, care settings, and patient needs that all may have their own requirements. One facility may provide multiple types of care and multiple methods of administering medications. Thus, audible label requirements or exemptions should not be universally applied by pharmacy type. The Legislature should clarify whether medications directly administered to patients by health care professionals are exempt from audible label requirements. This includes but may not be limited to prescriptions or orders prepared by hospital inpatient pharmacies, long-term care pharmacies, and outpatient infusion pharmacies. The Legislature should also specify whether audible labels must duplicate printed labels, or only contain a portion of the information.

Considerations

In weighing potential policy development, legislators should consider the following additional questions:

1. Should certain small and medium-sized pharmacies be granted a longer adoption window to implement technology, training, and other resources needed to provide audible labels?
2. Should there be a requirement for a dual-language option to expand accessibility to those who are not English proficient?
3. Are there opportunities for developing alternative approaches, including developing a centralized program for distributing audible label readers?
4. Are there other gaps in service—either related to the patients' ability to effectively use a prescription drug label or for the blind, Deafblind, and hard of hearing community—that could be simultaneously addressed, thus creating opportunities for efficiency?
5. What are the risks for errors in audible labeling, and how can they be addressed to reduce potential patient harm?