COMMONWEALTH of VIRGINIA

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TO: The Honorable Glenn Youngkin
Governor of Virginia

The Honorable Robert D. Orrock
Chairman, House Committee on Health, Welfare, and Institutions

The Honorable Louise L. Lucas
Chairman, Senate Committee on Education and Health

FROM: Caroline D. Juran, RPh
Executive Director, Virginia Board of Pharmacy

DATE: December 7, 2023

RE: Report Regarding the Provision of Translated Directions for Use of Prescriptions pursuant to Ch. 630 of the 2023 General Assembly

This report is submitted by the Virginia Board of Pharmacy in compliance with Chapter 630 of the 2023 Acts of Assembly, which states:

> That the Board of Pharmacy (the Board) shall convene a work group of interested stakeholders to evaluate challenges and barriers to requiring or providing translated directions for the use of prescriptions, including the possibility of model directions and necessary changes within pharmacies to ensure patients are aware of the language services available at the pharmacy. The Board shall report the findings of the work group to the Governor and the Chairmen of the House Committee on Health, Welfare, and Institutions and the Senate Committee on Education and Health by December 1, 2023.

Should you have questions about this report, please feel free to contact me at (804) 367-4578 or caroline.juran@dhp.virginia.gov.

Enclosure
CC: The Honorable John Littel, Secretary of Health and Human Resources

Preface

This report is submitted in compliance with Chapter 630 of the 2023 Acts of Assembly which required:

> That the Board of Pharmacy (the Board) shall convene a work group of interested stakeholders to evaluate challenges and barriers to requiring or providing translated directions for the use of prescriptions, including the possibility of model directions and necessary changes within pharmacies to ensure patients are aware of the language services available at the pharmacy. The Board shall report the findings of the work group to the Governor and the Chairmen of the House Committee on Health, Welfare, and Institutions and the Senate Committee on Education and Health by December 1, 2023.

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I. Executive Summary

Pursuant to House Bill 2147, passed during the 2023 General Assembly Session, the Board of Pharmacy convened a work group on September 28, 2023, to evaluate challenges and barriers to requiring or providing translated directions for the use of prescriptions, including the possibility of model directions and necessary changes within pharmacies to ensure patients are aware of the language services available at the pharmacy. Related laws and information from Nevada, Washington, California, Oregon, and New York, including references to certain federal laws, were provided in the agenda packet to aid the discussion.

While the work group fully appreciated the need for patients to understand proper administration and possible side effects of medications, it identified fiscal and operational challenges and barriers involving associated costs, model language, software limitations, labeling, accuracy and method of translation, identifying languages, patient access, signs, and liability protection. Additionally, the work group acknowledged that federal laws already require minimum standards in certain situations and that educating pharmacies may be beneficial in encouraging more pharmacies to provide translation services without creating additional mandates.

Workgroup Members

Dale St. Clair, PharmD
Board of Pharmacy, Chairman

Cheri Garvin, RPh
Board of Pharmacy, Member

Kris Ratliff, DPh
Board of Pharmacy, Member

Patricia Richards-Spruill, RPh
Board of Pharmacy, Member

Joanne Dial, PharmD
Kaiser Permanente Mid-Atlantic States

Lauren Linkenauger, PharmD
Virginia Association of Chain Drug Stores

Tana Kaefer, PharmD
Virginia Pharmacy Association

Cinthia Coffey, PharmD
Virginia Society of Health-System Pharmacists

II. Possible Challenges and Barriers

The workgroup identified several fiscal and operational challenges and barriers which would impact pharmacies and the Board should the provision of translated directions or creation of model directions be required by the General Assembly. These challenges and barriers range from changes within pharmacies to impacts on increase in licensing fees to cover costs to the Board.

A. Fiscal Impact

To provide translated services, permitted pharmacies would be required to obtain and maintain equipment or resources to provide those translation services. Those permitted pharmacies include the small businesses that make up independent pharmacies, which often serve rural communities. The associated costs for translation services may be overly burdensome for those pharmacies that are already struggling financially due to low healthcare reimbursement rates.[1] The additional workload associated with providing translation services without associated revenue to offset the expenses would further increase the fiscal impact on pharmacies. Many chain pharmacies and independently owned pharmacies are currently facing closures for financial reasons. This fiscal challenge to implement translation services was highlighted by the Governor of Nevada in his recent veto of bill number AB 251. Finally, placing translation service requirements on in-state pharmacies without requiring the same of nonresident pharmacies creates a fundamental unfairness in impact. Nonresident pharmacies include mail order pharmacies, specialty pharmacies, or physicians who are licensed to dispense drugs. These nonresident pharmacy categories would gain a significant business advantage over in-state pharmacies.

A requirement on the Board to develop and maintain model language, such as in California, would create a fiscal impact on the Board. California received a grant and contracted with an outside entity to develop the language its pharmacies use. The Board would also have to contract with an outside entity to develop and maintain translations. The Board, however, is a special fund agency supported solely by its licensing fees.[2] The cost of such a service would ultimately be passed on to the Board's licensees in the form of increased fees. Thus, the cost for any model services required by the Board to maintain and develop would ultimately be paid for by pharmacists, pharmacy technicians, permitted pharmacies, and other regulated entities of the Board.

B. Operational

Operational concerns exist with the creation of providing translation services and providing model language for translation services, both for pharmacies and the Board. Those discussed by the workgroup are summarized in this section of the report.

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[1] *See* Alyaseen, Leen, *Challenges in Reimbursement for Pharmacy Services, DIR Fees, and the Evolving PBM Model*, PHARMACY TIMES, May 19, 2023, available at https://www.pharmacytimes.com/view/challenges-in-reimbursement-for-pharmacy-services-dir-fees-and-the-evolving-pbm-model. *See also* Gregg, A. and Peiser, J., *Drugstore Closures Leaving Millions Without Easy Access to a Pharmacy*, WASHINGTON POST, Oct. 22, 2023.

[2] Va. Code § 54.1-2400(5).

As a practical matter, model language for prescriptions cannot reasonably be developed for all directions of use for all types of drug formulations. This may restrict model language to only certain formulations, such as in California, which restricted model language to oral tablets or capsules. This limitation decreases the benefit of translations significantly while still creating fiscal impacts noted above. The workgroup also noted challenges with identifying languages that would be provided as translations.

Several software limitations were noted and discussed by the workgroup. Interoperability between dispensing software and translation software could be a challenge in smaller, independent pharmacies. Those pharmacies would be required to change dispensing software in some cases, or pay for additional services to ensure operability, creating a greater fiscal impact on these already struggling pharmacies. Of those translation software systems, not all provide dual languages on a single label, which presents a challenge for the dispensing pharmacist and the patient. Many translation software systems additionally are unable to accommodate certain directions for use, special characters, and lengthy directions often used for tapering medications or administering insulin. Dispensing pharmacists face possible risks of error and the burden associated with having to retype prescription information into a second software system for translation and associated with attempting to adhere a separate label to a medication container.

Labeling challenges generated significant discussion among the workgroup. Workgroup members noted the limited space available on already small containers and the inability of that space to contain multiple labels. Labels containing translated information may need to be adhered as a "flagged label" with adhesive or staples, which may result in patients tearing off the flagged label if the label gets in the patient's way. Tearing off translated information results in separating the translated directions from the drug the directions were associated with, defeating the purpose of providing the translation and creating a potential confusion for patients and any caregivers. The workgroup questioned the ability of a single prescription label to include information in English and a preferred translated language.[3] The workgroup also discussed use of model language directions for labeling like that used in California, which requires pharmacists to cut out language from a list of model directions and adhere the cut portion to the dispensed container. The workgroup found this unreasonably burdensome and with the potential to result in errors.

The workgroup stated concerns with the accuracy of translation for any given language based on dialects and the method of translation used, whether written or verbal. Workgroup members noted the possible inability of pharmacy staff to verbally counsel patients receiving medication even if a label contains a written translated language. For verbal translation services that may be used by pharmacies, such as call-in translation services in which a phone would be provided to the patient to speak with a translator in their preferred language, workgroup members expressed concern that a patient may not recall all significant details of a prescription if the patient is only provided a verbal translation without a written translation.

The workgroup addressed some patient and pharmacy specific limitations to access to care and business practices. In the event a particular pharmacy is unable to comply with requirements for translation services and therefore does not offer them, patients may be forced to use a different

[3] While not directly within the charge of the workgroup, it identified font size as a possible challenge for visually impaired patients.

pharmacy. This creates an access to care barrier for any patient seeking a drug which a pharmacy benefit manager[4] deems a "specialty drug" that must be obtained from a "specialty pharmacy." The number of such specialty pharmacies is already limited. Restricting patient access further by imposing translation requirements on these pharmacies could create a drug access challenge for patients that require such specialty drugs. Any required posting to inform patients of language services provided by a pharmacy may be overlooked by patients due to the number of sign requirements currently in place for pharmacies. Finally, the workgroup acknowledged that some pharmacies currently offer translation services for patients, but that liability protections for pharmacy personnel are needed.

III. Federal Laws

While the workgroup fully appreciated the need for patients to understand proper administration and possible side effects of medications, it acknowledged that federal laws already require minimum standards in certain situations and informing pharmacies may be beneficial in encouraging more pharmacies to provide translation services without creating additional mandates. The workgroup reviewed information compiled by the Washington Board of Pharmacy that identified the following federal laws: Title VI of the Civil Rights Act 1964 (42 U.S.C. 2000d) regarding discrimination based on race, color, or national origin by any program or activity receiving federal financial assistance; Section 504 of the Rehabilitation Act (29 U.S.C. § 794) regarding discrimination based on a disability from any program or activity receiving federal financial assistance; and Title III of the American with Disabilities Act (42 U.S.C. §§ 12181 to 12189; 28 C.F.R. Pt. 36) regarding discrimination at a place of public accommodation which includes a pharmacy. The workgroup recommended that the Board of Pharmacy consider at its December full board meeting its ability to inform pharmacies and pharmacy personnel of these federal laws.

IV. Additional Considerations and Conclusion

The workgroup noted some additional considerations to assist patients and pharmacists with translation of prescriptions. Pharmacies could inform patients of translation applications for phones or hire staff with language proficiencies appropriate to the geographical setting (some pharmacies already do so). The workgroup also noted that no need would exist for translation services for prescriptions administered by regulated healthcare personnel in an institutional setting, such as a hospital or skilled nursing facility.

If the General Assembly considers requiring translation services, the workgroup suggested it be limited to Spanish and to high-population density areas to avoid unnecessary burdens on pharmacies. The workgroup also recommended that grants or funding be considered to alleviate financial burdens associated with any possible requirements.[5] Prior to any such action, however, the workgroup recommended that a survey be administered to identify which pharmacies currently offer language services to their patients. This would serve the purpose of identifying the true need

[4] The Board of Pharmacy and the Department of Health Professions have no direct jurisdiction over pharmacy benefit managers or their determinations.

[5] It is unclear how this grant would be administered or distributed, however, as altering the special fund structure of the Board, even for one subject, would create unintended consequences.

for legislation as well as ensuring that pharmacies currently providing such services would not be required to change their existing models simply to conform to new requirements. Finally, the workgroup stressed that requiring many changes in pharmacy workflow at one time may be burdensome, result in patient harm, and perpetuate professional burnout.