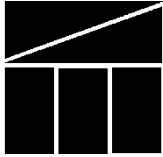


Adverse impact notification sent to Joint Commission on Administrative Rules, House Committee on Appropriations, and Senate Committee on Finance (COV § 2.2-4007.04.C): Yes¹ Not Needed

If/when this economic impact analysis (EIA) is published in the *Virginia Register of Regulations*, notification will be sent to each member of the General Assembly (COV § 2.2-4007.04.B).



Virginia Department of Planning and Budget Economic Impact Analysis

18 VAC 110-20 Regulations Governing the Practice of Pharmacy
Virginia Department of Health Professions
Town Hall Action/Stage: 5093/8779
November 20, 2019

Summary of the Proposed Amendments to Regulation

The Board of Pharmacy (Board) proposes to amend 18 VAC 110-20 *Regulations Governing the Practice of Pharmacy* (regulation) in order to clarify the Board's interpretation of the labeling requirements in response to a petition for rulemaking filed by Joseph Lavino, Legal Counsel of Pharmacy Regulatory Affairs for CVS Health in September 2017.² Specifically, the Board seeks to amend 18 VAC 110-20-275 by adding that, "A unique identifier on the prescription label is not required to identify a pharmacy solely involved in the holding of a prescription for pick-up or further delivery when that pharmacy has not shared in other filling or dispensing functions."³ The proposed addition would reduce the amount of detailed information that pharmacies are currently expected to include on limited prescription label space, making it easier for pharmacies to comply with the labeling requirements.

Background

In response to the petition for rulemaking, the Board seeks to clarify that a unique identifier on the prescription label is not required to identify a pharmacy solely involved in holding a prescription for pick-up or further delivery when that pharmacy does not share in other

¹ Adverse impact is indicated if there is any increase in net cost or reduction in net revenue for any entity, even if the benefits exceed the costs for all entities combined.

² See <https://townhall.virginia.gov/L/viewpetition.cfm?petitionid=262>

³ See <https://law.lis.virginia.gov/admincode/title18/agency110/chapter20/section275/>

filling or dispensing functions. As per current regulation, pharmacies are required to (i) formulate their own policy regarding their prescription labels, including a procedure to identify “all pharmacies involved in filling and dispensing the prescription,” (ii) administer the policy via a current “policy and procedure manual” and (iii) maintain adherence to their own policies and procedures as laid out in their manual.⁴

According to the Department of Health Professions (DHP), the Board heretofore interpreted 18 VAC 110-20-275 as applying to every pharmacy involved in “drug delivery.” As a result, the Board expected that pharmacies that only receive and hold a prescription for the consumer to pick up would be identified, not just pharmacies that fill and dispense the prescription.⁵ However, the petitioner noted that identification of multiple pharmacies is confusing and that the dispensing pharmacy is best able to answer questions and respond to patients’ questions or concerns.⁶

Estimated Benefits and Costs

As of this writing, CVS Health operates 344 pharmacy locations in Virginia and relies on the size of their network to optimize inventory management: some prescriptions are filled by CVS’ specialty pharmacies and then sent to local CVS pharmacies. This allows customers to pick up their medications at a store location that suits their convenience, while also having the address and phone number of the dispensing pharmacy should they have any questions or concerns.⁷ The proposed amendment would allow CVS to continue filling and delivering prescriptions without having to change their labeling procedures. They would also not risk being cited during routine pharmacy inspections for not meeting the Board’s labeling requirements. Thus CVS and their customers would benefit from maintaining the status quo without having to incur any additional costs. Further, other pharmacy chains that may have been found to be in violation of the labeling requirements for not identifying the delivering pharmacy on their labels would also benefit from not having to make changes. Independent pharmacies, or pharmacies

⁴ 18VAC110-20-275(B)(2) currently states that “Each pharmacy using such a drug delivery system shall maintain and comply with all procedures in a current policy and procedure manual that includes the following information” with sub-part (d) requiring “The procedure for identifying on the prescription label all pharmacies involved in filling and dispensing the prescription.” (<https://law.lis.virginia.gov/admincode/title18/agency110/chapter20/section275/>)

⁵ DHP provided this explanation regarding “the Board’s interpretation” via phone communication.

⁶ See p. 3 https://townhall.virginia.gov/l/GetFile.cfm?File=30\5093\8779\AgencyStatement_DHP_8779_v2.pdf

⁷ DHP also helpfully pointed out that customers do not need the location of the pharmacy where they picked up the prescription to be on the label, because they just went there to pick it up.

belonging to local chains may not be affected by the proposed amendment if they fill prescriptions which are picked up at the same location.⁸

Pharmacies that have currently been including information to identify both the dispensing as well as the delivering pharmacy on their labels would not be affected, as the proposed amendment would not require them to change their labeling procedures. However, they may choose to discontinue including identifying information about the delivering pharmacy, which could benefit their customers if it makes the label easier to read and less confusing.

Comments received at the NOIRA stage pointed out the potential benefits of dispensing with the requirement to identify pharmacies that are merely holding a prescription for pick-up. A comment made on behalf of CVS Health noted that the Institute for Safe Medication Practices, which has published guidelines for medication labels, suggests that “maximizing the use of white space on a label would improve medication adherence and reduce inadvertent medication errors.”⁹ Older adults and adults with visual impairments have reported a strong subjective preference for larger print size and the use of uppercase letters to denote numeric information on prescription labels.¹⁰ This is especially relevant given that 80 percent of older adults in the U.S. (and 90 percent of Medicare beneficiaries) take at least one daily prescription.¹¹ Hence, the proposed amendment could benefit older adults and adults with visual impairments to the extent that a reduction in the amount of information required on the label leads pharmacies to design labels that are easier to read.

Another commenter in support of the Board’s action pointed out that mail order pharmacies sometimes put a customer service number on the label, rather than the number of the pharmacy. While it can be confusing to the consumer to have multiple phone numbers on the prescription label, the commenter recommended prioritizing information regarding where the prescription was filled and how to contact the pharmacist directly.¹² Rx Partnership (a nonprofit

⁸ However, if they participate in any prescription networks or have any reciprocal contracts with other pharmacies and have only been identifying the pharmacy that fills the prescription, they too would benefit in the same way as CVS and other pharmacy chains.

⁹ The commenter also noted that there would still be an audit trail to track the prescription, and information provided to the patient to answer any questions or provide any counseling. See p.7 of the ABD, https://townhall.virginia.gov/l/GetFile.cfm?File=30\5093\8779\AgencyStatement_DHP_8779_v2.pdf.

¹⁰ See <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4860753/>.

¹¹ See <https://bemedwise.org/health-education-resources/older-adults> and https://bemedwise.org/documents/must_factsheet.pdf.

¹² See <https://townhall.virginia.gov/l/viewcomments.cfm?commentid=68800>.

working to increase medication access) commented in support of the initial petition saying it would increase efficiency and make it easier to provide prescriptions for individuals who need a convenient location for pick-up that may not be where the prescription was filled.¹³ Hence, consumers of prescription medications stand to benefit as long as the proposed amendment would at least preserve, if not increase, the clarity of information regarding whom to contact with questions, while also enabling more efficient delivery systems and convenient pick-up locations.

Businesses and Other Entities Affected

The proposed amendment would affect pharmacies that are either operated as part of larger chains or belong to pharmacy networks, to the extent that prescriptions filled at one pharmacy are delivered to the customer at a different pharmacy. The proposal would not increase costs for any entities.

Localities¹⁴ Affected¹⁵

The proposed amendments do not introduce new costs for local governments and are unlikely to affect any locality in particular.

Projected Impact on Employment

The proposed amendments are unlikely to have any impact on employment.

Effects on the Use and Value of Private Property

The proposed amendments are unlikely to affect the use and value of private property. Real estate development costs are not affected.

Adverse Effect on Small Businesses¹⁶:

The proposed amendments are unlikely to have an adverse impact on any small business. As mentioned previously, independent pharmacies are unlikely to be affected at all, unless they participate in contractual arrangements with other pharmacies to fill and deliver prescriptions across multiple locations, in which case they would benefit from the greater flexibility allowed by the proposed amendment.

¹³ See <https://townhall.virginia.gov/viewcomments.cfm?commentid=63283>.

¹⁴ “Locality” can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulatory change are most likely to occur.

¹⁵ § 2.2-4007.04 defines “particularly affected” as bearing disproportionate material impact.

¹⁶ Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as “a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.”

Legal Mandates

General: The Department of Planning and Budget has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Code of Virginia (Code) and Executive Order 14 (as amended, July 16, 2018). Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the report should include but not be limited to: (1) the projected number of businesses or other entities to whom the proposed regulatory action would apply, (2) the identity of any localities and types of businesses or other entities particularly affected, (3) the projected number of persons and employment positions to be affected, (4) the projected costs to affected businesses or entities to implement or comply with the regulation, and (5) the impact on the use and value of private property.

Adverse impacts: Pursuant to Code § 2.2-4007.04(D): In the event this economic impact analysis reveals that the proposed regulation would have an adverse economic impact on businesses or would impose a significant adverse economic impact on a locality, business, or entity particularly affected, the Department of Planning and Budget shall advise the Joint Commission on Administrative Rules, the House Committee on Appropriations, and the Senate Committee on Finance within the 45-day period.

If the proposed regulatory action may have an adverse effect on small businesses, Code § 2.2-4007.04 requires that such economic impact analyses include: (1) an identification and estimate of the number of small businesses subject to the proposed regulation, (2) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the proposed regulation, including the type of professional skills necessary for preparing required reports and other documents, (3) a statement of the probable effect of the proposed regulation on affected small businesses, and (4) a description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation. Additionally, pursuant to Code § 2.2-4007.1, if there is a finding that a proposed regulation may have an adverse impact on small business, the Joint Commission on Administrative Rules shall be notified.