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Proposed Regulation Agency Background Document

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| Agency name | Board of Pharmacy, Department of Health Professions |
| Virginia Administrative Code (VAC) citation(s) | 18VAC110-20 |
| Regulation title(s) | Regulations Governing the Practice of Pharmacy |
| Action title | Delivery of dispensed prescriptions |
| Date this document prepared | 9/26/19 |

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations*.

Brief Summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

The Board is amending section 275 of Chapter 20 pertaining to the procedure for identifying all pharmacies involved in the filling and dispensing of a prescription. The amendment would specify 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.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

N/A

Mandate and Impetus

Please identify the mandate for this regulatory change, and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, board decision, etc.). For purposes of executive branch review, "mandate" has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

The impetus for the action is a petition for rulemaking from CVS Health. The Board responded that at its meeting on December 11, 2017 that it would move forward with rulemaking.

Legal Basis

Please identify (1) the agency or other promulgating entity, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency or promulgating entity's overall regulatory authority.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Pharmacy the authority to promulgate regulations to administer the regulatory system:

§ 54.1-2400 -General powers and duties of health regulatory boards

The general powers and duties of health regulatory boards shall be:

6. To promulgate regulations in accordance with the Administrative Process Act (§ [2.2-4000](#) et seq.) that are reasonable and necessary to administer effectively the regulatory system, which shall include provisions for the satisfaction of board-required continuing education for individuals registered, certified, licensed, or issued a multistate licensure privilege by a health regulatory board through delivery of health care services, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those health services. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ [54.1-100](#) et seq.) and Chapter 25 (§ [54.1-2500](#) et seq.).

The specific authority for the Board to regulate the dispensing of prescription drugs is found in:

§ 54.1-3307. Specific powers and duties of Board.

A. The Board shall regulate the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding, or disposal of drugs and devices. The Board shall also control the character and standard of all drugs, cosmetics and devices within the Commonwealth, investigate all complaints as to the quality and strength of all drugs, cosmetics,

and devices and take such action as may be necessary to prevent the manufacturing, dispensing, selling, distributing, processing, compounding and disposal of such drugs, cosmetics and devices that do not conform to the requirements of law.

The Board's regulations shall include criteria for:

- 1. Maintenance of the quality, quantity, integrity, safety and efficacy of drugs or devices distributed, dispensed or administered.*
- 2. Compliance with the prescriber's instructions regarding the drug, its quantity, quality and directions for use.*
- 3. Controls and safeguards against diversion of drugs or devices.*
- 4. Maintenance of the integrity of, and public confidence in, the profession and improving the delivery of quality pharmaceutical services to the citizens of Virginia.*
- 5. Maintenance of complete records of the nature, quantity or quality of drugs or substances distributed or dispensed, and of all transactions involving controlled substances or drugs or devices so as to provide adequate information to the patient, the practitioner or the Board.*
- 6. Control of factors contributing to abuse of legitimately obtained drugs, devices, or controlled substances.*
- 7. Promotion of scientific or technical advances in the practice of pharmacy and the manufacture and distribution of controlled drugs, devices or substances.*
- 8. Impact on costs to the public and within the health care industry through the modification of mandatory practices and procedures not essential to meeting the criteria set out in subdivisions 1 through 7 of this section.*
- 9. Such other factors as may be relevant to, and consistent with, the public health and safety and the cost of rendering pharmacy services.*

B. The Board may collect and examine specimens of drugs, devices and cosmetics that are manufactured, distributed, stored or dispensed in the Commonwealth.

Purpose

Please explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it's intended to solve.

The purpose of the proposed regulatory action is to respond to a petition for rulemaking from CVS Health to eliminate a requirement for a pharmacy that is only holding a prescription for pick-up or delivery to a consumer to be identified on the prescription label. The petitioner noted that identification of multiple pharmacies is confusing; the dispensing pharmacy is best able to answer questions and respond to problems or concerns by a patient about his/her medication. The Board believes an amendment to its regulation will safeguard patient health and safety by ensuring that a prescription label has pertinent information.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.

An amendment to section 275 would specify that a unique identifier on the prescription label is not required to identify a pharmacy that is 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.

Issues

Please identify the issues associated with the regulatory change, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, include a specific statement to that effect.

1) Some commenters, such as Rx Partnership, believe the amendment is advantageous to the public, especially many low income and uninsured patients who experience transportation challenges and would be able to receive medications at a preferred pharmacy rather than the pharmacy where the prescription was filled.

Others have expressed concern that patients, particularly senior citizens, might want the information about the pharmacy where the prescription was being picked up, as well as the pharmacy where it was filled. To address those concerns, letters were sent directly to consumer groups and senior advocacy groups explaining the possible amendment and requesting comment. None was received. The groups were: Virginia Citizens Consumer Council, Virginia Association of Area Agencies on Aging, Virginia Navigators, Senior Connections, and AARP Virginia.

2) There are no advantages or disadvantages to this agency or the Commonwealth.

3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. The Board is authorized under § 54.1-2400 to promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) that are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) This proposal is consistent with the agency's statutory responsibility to protect public health and safety and to protect the integrity and safety of prescription drugs in the Commonwealth.

Requirements More Restrictive than Federal

Please identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements, or no requirements that exceed applicable federal requirements, include a specific statement to that effect.

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Please identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected - None

Localities Particularly Affected - None

Other Entities Particularly Affected - None

Economic Impact

Pursuant to § 2.2-4007.04 of the Code of Virginia, please identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Please keep in mind that this is change versus the status quo.

Impact on State Agencies

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| <p><i>For your agency:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including:</p> <ul style="list-style-type: none"> a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources | <ul style="list-style-type: none"> a) As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation; b) The agency will incur no additional costs for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities. |
| <p><i>For other state agencies:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.</p> | <p>There are no costs for other state agencies.</p> |
| <p><i>For all agencies:</i> Benefits the regulatory change is designed to produce.</p> | <p>There are no benefits.</p> |

Impact on Localities

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| <p>Projected costs, savings, fees or revenues resulting from the regulatory change.</p> | <p>There are no costs or savings for localities.</p> |
| <p>Benefits the regulatory change is designed to produce.</p> | <p>There are no benefits.</p> |

Impact on Other Entities

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| <p>Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.</p> | <p>The entities likely to be affected would be retail pharmacies (including those located in free clinics, health departments, etc.)</p> |
| <p>Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p> | <p>The agency has no estimate of the number of entities that may engage in such a business arrangement. The Board does not issue pharmacy permits by category, so there is no information about how many are retail, hospital, etc. The total count of permitted pharmacies is: 1801 resident pharmacies; 778 non-resident pharmacies.</p> |
| <p>All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Please be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.</p> | <p>There will not be additional costs; the proposed regulation could result in a cost-savings.</p> |
| <p>Benefits the regulatory change is designed to produce.</p> | <p>The regulation will make labeling less complicated for pharmacies that dispense a medication in one location and send it to another pharmacy for delivery to a patient.</p> |

Alternatives

Please describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulatory change.

CVS Health petitioned the Board for an amendment that will result in a less restrictive and less costly requirement for prescription labels. There is no alternative other than amending the current rule to achieve that purpose.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) establishing less stringent compliance or

reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the regulatory change.

In order to achieve the efficiency requested, the Board must amend regulations.

Public Comment

Please summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency response. Ensure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency or board. If no comment was received, enter a specific statement to that effect.

A Notice of Intended Regulatory Action was published on October 29, 2018 with comment requested until November 28, 2019. There were two comments received:

Lauren Paul on behalf of CVS Health commented in support of the action, noting that the Institute for Safe Medication Practices published guidelines for medication labels suggests maximizing the use of white space on a label would improve medication adherence and reduce inadvertent medication errors. There would still be an audit trail for the tracking of the prescription with information provided to the patient to answer any questions or provide additional counseling.

Otto Wachsmann commented that it is time-consuming on the part of a pharmacist at the location where the prescription is being picked up to contact the pharmacy where the prescription was filled and dispensed if there are questions about the medication. His primary concern was that mail order pharmacies sometimes put a customer service number on the label rather than the number of the pharmacy. He acknowledged that having the names of both pharmacies on the label can be confusing to the patient, but the label should clearly state where the prescription was filled and how to contact the pharmacist directly.

In commenting on the petition for rulemaking, the Rx Partnership (a nonprofit organization working statewide to increase medication access) supported the amendment as it would increase efficiency and ease related to providing prescriptions for individuals who need a convenient location for pick-up that may not necessarily be where the prescription was filled.

Board response: The Board concurs with the comments and adopted amendments that are consistent with the comments.

Public Participation

Please include a statement that in addition to any other comments on the regulatory change, the agency is seeking comments on the costs and benefits of the regulatory change and the impacts of the regulated community. Also, indicate whether a public hearing will be held to receive comments.

In addition to any other comments, the Board of Pharmacy is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail to Elaine Yeatts at Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, VA 23233 or elaine.yeatts@dhp.virginia.gov or by fax to (804) 527-4434. Comments may also be submitted through the Public Forum feature of the Virginia Regulatory Town Hall web site at: <http://www.townhall.virginia.gov>. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will be held following the publication of this stage and notice of the hearing will be posted on the Virginia Regulatory Town Hall website

Detail of Changes

Please list all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation.

| Current section number | New section number | Proposed change, intent, and likely impact of proposed requirements |
|------------------------|--------------------|---|
| 275 | N/A | <p>Subsection B of section 275 is amended to provide that in the delivery of a prescription from one pharmacy to another, it is not required that the label include information identifying the pharmacy that is solely involved in holding the prescription for pick-up or further delivery if that pharmacy has not shared in the filling or dispensing functions.</p> <p><i>Information on the prescription label is necessary for the patient or consumer to know what he is taking, how to take the medication and who to contact if he has a question about his medication. The pharmacist who should answer any questions is the person at the location where the prescription was filled and the drug was dispensed. As the petitioner noted, the ability to craft a prescription label with adequate font size and critical prescription elements is an essential component in driving patient adherence to medication as prescribed. The addition of the name and address of the “depot pharmacy” has the potential of encroaching on that purpose and the risk of contributing to medication errors. The majority of Board members believe that there is greater benefit to the proposed amendment than the omission of information might cause concern.</i></p> |