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Final Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC110-20
VAC Chapter title(s)	Regulations Governing the Practice of Pharmacy
Action title	White bagging/brown bagging
Date this document prepared	5/18/20

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 (1VAC7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

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 proposes regulations for the delivery of :

• Requiring the specialty pharmacy participating in white bagging to notify the receiving pharmacy or alternative delivery site of the shipment to ensure appropriate coordination of patient care;

• Requiring the pharmacy to provide to the receiving pharmacy an estimated arrival date, to provide the name of the patient to whom the drug has been dispensed, and to provide the exact address where the product has been shipped;

• Requiring appropriate storage and security for a shipped product; and

• Prohibiting delivery to a patient's residence of any drug that requires special storage, reconstitution or compounding prior to administration is intended and that will be subsequently transported by the patient for administration.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.

NABP = National Association of Boards of Pharmacy

Statement of Final Agency Action

Provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

On May 18, 2020, the Board of Pharmacy amended 18VAC110-20, Regulations Governing the Practice of Pharmacy.

Mandate and Impetus

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding the mandate for this regulatory change, and any other impetus that specifically prompted its initiation. If there are no changes to previously reported information, include a specific statement to that effect.

The impetus for the regulatory change came from the 2016 Pharmacy Benefit Manager Workgroup report to the Secretary of Health and Human Resources on a number of issues relating to the practice of pharmacy benefits managers. It included a discussion of some issues relating to "brown bagging and white bagging." The consensus among Workgroup members was that the Board of Pharmacy should review the practices to address issues of concern for patient safety.

There are no changes to the previously reported information.

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia and Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency'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 (§ 9-6.14:1 et seq.) which 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.) of this title. ...

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

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 address patient safety concerns relating to

brown bagging and white bagging. Specific requirements for notification and patient information to the receiving pharmacy or alternative delivery site of the shipment will better ensure appropriate coordination of patient care in white bagging. Requiring appropriate storage and security for a shipped product will protect public health and safety. The prohibition on delivering drugs to a patient's residence for administration, if the drug requires special storage, reconstitution or compounding, will protect patients and the entities responsible for the integrity of the drug administered.

Substance

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.

At the 2016 annual meeting of the NABP, the membership authorized a study of "white bagging" and "brown bagging." A copy of the report may be viewed at: https://nabp.pharmacy/wpcontent/uploads/2018/04/White-Bagging-and-Brown-Bagging-Report-2018_Final.pdf
Based on the NABP report and the expertise of pharmacist members of the Board and the pharmacy benefits manager workgroup, the Board proposes regulations:
• Requiring the specialty pharmacy participating in white bagging to notify the receiving pharmacy or alternative delivery site of the shipment to ensure appropriate coordination of patient care;
• Requiring the pharmacy to provide to the receiving pharmacy an estimated arrival date, to provide the name of the patient to whom the drug has been dispensed, and to provide the exact address where the product has been shipped;
• Requiring appropriate storage and security for a shipped product; and
• Prohibiting delivery to a patient's residence of any drug that requires special storage, reconstitution or compounding prior to administration is intended and that will be subsequently transported by the patient for administration.

Issues

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) The advantage to the public is less risk of a drug that requires special storage or has a short shelf life will be delivered to a pharmacy or other entity without preparations in place to receive that drug. There are no disadvantages.
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

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any requirement of the regulatory change which is more restrictive than applicable federal requirements. If there are no changes to previously reported information, include a specific statement to that effect.

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any other state agencies, localities, or other entities that are particularly affected by the regulatory change. If there are no changes to previously reported information, include a specific statement to that effect.

Other State Agencies Particularly Affected - None

Localities Particularly Affected - None

Other Entities Particularly Affected- None

Public Comment

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

Proposed regulations were published on November 11, 2019 with comment received until January 10, 2020. The following comments were received:

Commenter	Comment	Board response
Janice Kuhn on behalf of Virginia hemophilia treatment centers	Requested amendment to subsection G of section 275 to allow an exception for patients with inherited bleeding disorders, rather than the proposed term of "hemophilia" because the more expansive terminology captures	The Board has amended subsection G accordingly.

	other inherited factor deficiencies. Also requested deletion of the phrase who may require "emergent blood factor treatment" and inclusion of the phrase "therapy to prevent or treat bleeding episodes" in include newer hemophilia treatments that are not factor concentrates.	
Natalie Nguyen for Va. Society of Health System Pharmacists	Supports Board's action to improve integrity of the supply chain. Asks for exception in subsection F 4 for administration of drugs such as factors for treatment of hemophilia which requires the patient to bring their drugs to the clinic or ED of the hospital.	The Board did amend regulations to create an exemption for patients with bleeding disorders as specifically referenced in the comment, but did not find sufficient reason to expand the exemption to any "rare condition."
Cynthia Williams Riverside Health Systems	Agrees with proposed language but asked for allowance for health systems to practice "clear bagging" Also asked for delayed implementation *Asked for clarification about "clear bagging", the commenter sent a subsequent email noting that an exemption for health system-owned pharmacies would be inconsistent with the Code.*	The Board will allow a phased-in implementation before enforcement of a final regulation is imposed.

Detail of Changes Made Since the Previous Stage

*List all changes made to the text since the previous stage was published in the Virginia Register of Regulations and the rationale for the changes. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Put an asterisk next to any substantive changes.*

Current chapter-section number	New requirement from previous stage	Updated new requirement since previous stage	Change, intent, rationale, and likely impact of updated requirements
275	Subsection G prohibits delivery of dispensed drug to a patient's residence that is	The proposed exception to the requirement previously identified	The change was requested by the Virginia hemophilia treatment centers to capture conditions and situations related to inherited factor deficiencies.

	intended to be subsequently transported to a hospital or clinic for administration	patients with hemophilia. The updated requirement is broadened to include "inherited bleeding disorders" who may require therapy to prevent or treat bleeding disordes.	

Detail of All Changes Proposed in this Regulatory Action

*List all changes proposed in this action and the rationale for the changes. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Put an asterisk next to any substantive changes.*

Current section number	Current requirement	**Proposed change, intent, and likely impact of proposed requirements**
275	Sets out requirements for delivery of a prescription	Subsection F is added to exempt the pharmacy and alternate delivery site from compliance with subsections B through E if certain conditions are met: (1) the alternate delivery site is a pharmacy, a practitioner of healing arts licensed by the board to practice pharmacy or sell controlled substances, or other entity holding a controlled substances registration for the purpose of delivery of controlled substances; (2) the alternate delivery site does not routinely receive deliveries from the pharmacy; and (3) compliance with subsections B through E would create a delay in delivery that may result in potential patient harm. *Subsection B requires that the delivering and receiving pharmacies have the same owner or a written contract or agreement specifying the services to be provided by each in order to comply with all requirements for law and regulation. Sometimes that is impractical or would cause delay in the delivery of a medication that a patient needs. If a specialty drug is needed, the pharmacy benefits manager or insurer may require that the drug be obtained from a specialty pharmacy or the pharmacy to which the prescription is sent may not carry that drug. Subsection C specifies conditions for delivery by a pharmacy to the site of a practitioner who holds a license to practice pharmacy, which also requires a written contract or agreement between the parties. This action will allow "white bagging" or delivery from one pharmacy to another or an entity authorized to receive delivery of controlled substances on a case-by-case basis.*

		However, the pharmacy and alternate delivery site must comply with following requirements: 1. To ensure appropriate coordination of patient care, the pharmacy must notify the alternate delivery site of the anticipated arrival date of the shipment, the exact address to where the drug was shipped, the name of the patient for whom the drug was dispensed, and any special storage requirements. 2. The pharmacy must provide counseling or ensure a process is in place for the patient to receive counseling. 3. Prescriptions delivered to the alternate delivery site must be stored in a lockable room or lockable cabinet, cart, or other device which cannot be easily moved and which shall be locked at all times when not in use. Access shall be restricted to the licensed prescriber, pharmacist, or either person's designee. 4. The pharmacy must provide a procedure for the return of any prescription drugs not delivered or subsequently administered to the patient. *The purpose of these conditions is to address issues identified by pharmacies and medical practices with "white bagging" in which drugs may be delivered without any coordination for patient care, leading to waste and loss of drug integrity. Since there is no written agreement or policy and procedure manual specifying the conditions for the delivery (as set out in subsections B through E), these conditions are necessary to protect the drugs and the patients.* Subsection G is added to prohibit "brown bagging" in which a drug is delivered directly to the patient's residence, but is intended to be transported to a hospital, medical clinic or other entity, and that drug requires special storage, reconstitution, or compounding prior to administration. Brown bagging is prohibited because of significant concerns about safety and efficacy. In comment on a draft adopted in November, it was noted that the prohibition was problematic for hemophiliac patients who require blood factor treatment on an emergency basis. The Board subsequently readopted the proposed regulation to add that exception to subsection G.