townhall.virginia.gov

Proposed Regulation
Agency Background Document

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	White bagging/brown bagging
Date this document prepared	3/22/19

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 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

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.

NABP = National Association of Boards of Pharmacy

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 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.

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 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

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.

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/wp-content/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

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) 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

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

For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and	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

c) whether any costs or revenue loss can be absorbed within existing resources	mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities.
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	There are no costs for other state agencies.
For all agencies: Benefits the regulatory change is designed to produce.	There are no benefits.

Impact on Localities

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

Impact on Other Entities

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.	The entities likely to be affected are specialty pharmacies that ship drugs to other pharmacies or entities that possess such drugs for administration to a patient.
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.	The agency has no estimate of the number of such entities. Resident and non-resident pharmacies are permitted to conduct the practice of pharmacy and are not identified by category – retail, specialty, mail order, etc.
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.	There should not be additional costs. The regulation only affects situations in which the delivery site does not routinely receive deliveries from the pharmacy; and compliance with current rules for the practice of pharmacy would create a delay in delivery that may result in potential patient harm. There are current regulations for patient counseling, proper security, and storage; this action allows an exemption from certain requirements of section 275, such as those relating to contracts and written agreements.
Benefits the regulatory change is designed to produce.	The regulation will benefit the patient by assuring that white bagging of a drug has necessary controls of storage, notification, and communication for efficacy and security and to ensure coordination of care for the patient.

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.

On March 4, 2016, a Pharmacy Benefit Manager Workgroup issued its 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 viable alternatives to achieve the essential purpose of safety and efficacy of prescription drugs.

The Board reviewed regulations adopted in other states, such as provisions from Oregon, which allow for "white bagging" with certain safeguards in place for reconstitution, labeling and accountability.

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.

The Board has analyzed the issues associated with white bagging and brown bagging and concluded that current regulations are not sufficient to address the problems identified. For patient safety, rules need to be in place to assure the integrity and efficacy of specialty drugs.

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.

Commenter	Comment	Agency response
John Lubkowski	Supports regulation of practice of white bagging and brown bagging because of potential negative	The Board concurs with the comments. Regarding the application of "any willing provider," the Board does not regulate the

	implications of the practices. Supports definitions as presented. Agrees with restriction on brown bagging of drugs requiring reconstitution or compounding prior to administration with exception for drugs emergently needed in life threatening situations. Supports the specific requirements for specialty pharmacies that participate in white bagging. Suggests application of "any willing provider" regulations to allow health systems that have retail pharmacy capability to provide needed medication at health system owned locations.	insurance companies or pharmacy benefits managers. The commenter may wish to refer that issue to a legislator or the Bureau of Insurance.
Laura Joyner, on behalf of Premier Health Care Associates	Strongly opposed to "brown bagging" as a means of delivering injectable rheumatology drugs to patients to take to physician for administration. Patient health at risk due to improper handling, storage and transport of drug. Strongly opposed to "white bagging" Patient's dose and strength may change at administration, which is not possible when drug is shipped ahead of time prior to patient visit. Rheumatology drugs for administration by injection should be procured and stored by physician practice for optimal treatment.	Regulations being promulgated do not prohibit their "preferred method" of physician practices procuring the drugs and inventories at the site of care. It is possible that the patient's health insurance company or the associated pharmacy benefit manager is in essence prohibiting this model when requiring the patient to obtain the drug from a specialty pharmacy via white bagging or brown bagging. While the board does not regulate health insurance companies or pharmacy benefit managers, it does regulate pharmacies. Thus, the board cannot prevent insurance companies or pharmacy benefit managers from requiring a patient to obtain the drug from a specialty pharmacy, but it can place requirements on the pharmacy for how those drugs must be delivered to the patient. While the board agrees that brown bagging poses potential patient risk and should be prohibited, the board recognizes that white bagging may assist patient access to medication when delivered in a restricted manner. The board's proposed regulations intend to place restrictions on white bagging to mitigate patient harm.
Lauren Paul, PharmD. on behalf of CVS Health	Commented that white bagging and brown bagging are already sufficiently regulated under the practice of pharmacy and that the Board should table this issue and not pursue further adoption of regulations.	The Board does not believe 18VAC110-20-275 adequately addresses white bagging. It is unrealistic for a contract to be in place in regard to specialty drugs, as specified in current regulation, so compliance may be difficult and may restrict patient access to these drugs. Additionally, that section does not address the risks associated with white bagging. While "brown bagging" may be included in the "practice of pharmacy," the definition does not address risks.

Ricky Newton on behalf of Community Oncology Alliance	Recognizes definitions from NABP. Strongly opposed to brown bagging due to concerns for patient safety; oncology drugs are highly sensitive and toxic; brown bagging risks compromising the integrity of the drugs. Strongly opposed to white bagging; can also put patient safety and health at risk. Drug may not arrive at the physician's office in a timeframe that meets the patient's treatment plan – deviation from the therapy schedule may result in decreased efficacy for the patient. White bagging may also result in waste if a physician decides to change the drug, dosage or adjust the treatment plan.	See response to Joyner comment.
Richard Ingram on behalf of Va. Assn. of Hematologists and Oncologists	Same comments as above	See response to Joyner comment.
Cynthia Williams Riverside Health System	Overall support of regulations. Brown bagging puts both the patient and the organization administering the medication at risk; practice is for benefit of insurers not patients. Similar concerns for storage of white bagging; even with special packaging, no assurance of maintenance of temperature. Coordination of care is challenging with a white bag process, often resulting in delays in care; burden should be on dispensing pharmacy to take ownership of coordination of shipping and receipt of medication.	See response to Joyner comment.
Jamin Engel	Supports regulations of white and brown bagging – through the utilization of specialty pharmacies, significant burden on sites of care and patients. Sites where patients receive treatment are forced to accept the burden of risk for a medication procured outside traditional channels and are spending significant resources in coordination of care. Brown bagging should not be allowed.	See response to Joyner comment.

	Should improve communication and chain of custody with white bagging	
Elizabeth Early	Brown bagging should not be allowed; cannot ensure the storage and integrity of the medication. White bagging should not be allowed for a facility that is capable of providing the medication for their patients because of financial concerns and delays in continuity and coordination of care.	See response to Joyner comment.
Tracie Chambers Community Health Centers	Notes the difficulty with the current regulation requiring a contract with a specialty pharmacy to do business. Also, commented on problems associated with communication and storage.	Regulations proposed by the Board are intended to address problems pharmacies and health systems currently have with white bagging and brown bagging.
Natalie Nguyen Va. Society of Health Systems Pharmacists	Overall support of regulation for brown bagging of drugs requiring reconstitution or compounding prior to administration & establishment of requirements for specialty pharmacies in white bagging. Create exception for emergent situations for patients who require blood factor products.	See response to Lubkowski comment

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	Current requirement	Change, intent, rationale, and likely impact of new 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.