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## Notice of Intended Regulatory Action (NOIRA) Agency Background Document

<b>Agency name</b>	Board of Pharmacy, Department of Health Professions
<b>Virginia Administrative Code (VAC) citation(s)</b>	18VAC110-20
<b>Regulation title(s)</b>	Regulations Governing the Practice of Pharmacy
<b>Action title</b>	White bagging/brown bagging
<b>Date this document prepared</b>	12/11/17

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Subject matter and intent

*Please describe briefly the subject matter, intent, and goals of the planned regulatory action.*

The Board intends to consider adopting a regulation to regulate brown bagging of drugs requiring reconstitution or compounding prior to administration and to set specific requirements for specialty pharmacies participating in white bagging. The intent of the regulatory action is public protection to ensure drugs are appropriately dispensed and administered.

### Legal basis

*Please identify the (1) the agency (includes any type of promulgating entity) and (2) the state and/or federal legal authority for the proposed regulatory action, including the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable. Your citation should 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'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 describe the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, please explain any potential issues that may need to be addressed as the regulation is developed.*

The purpose of the proposed regulatory action is to address patient safety concerns relating to brown bagging and white bagging. Information available to the Board will enhance its ability to protect the public health and safety.

### Substance

*Please briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.*

In the amended regulation, the Board will need to define “brown-bagging and white-bagging.” At the 2016 annual meeting of the National Association of Boards of Pharmacy, a study resolution included these definitions: “white bagging” generally refers to a patient-specific medication that is distributed by a pharmacy to a hospital, clinic, physician’s office, or pharmacy for later preparation and administration to a patient where allowed by law and “brown bagging” generally refers to a patient-specific medication that is dispensed by a pharmacy to the patient and then brought by the patient to the hospital, clinic, or physician’s office for administration.”

In the addition to new definitions in the proposed regulations, the Board will consider regulations for:

- Brown bagging of drugs requiring special storage, reconstitution or compounding prior to administration;
- Requiring the specialty pharmacy participating in white bagging to notify the receiving pharmacy 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.

## Alternatives

*Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. 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 regulation.*

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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 PBMs. 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 will review 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.

## Public participation

*Please indicate whether the agency is seeking comments on the intended regulatory action, including ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments. Please include one of the following choices: 1) a panel will be appointed and the agency’s contact if you’re interested in serving on the panel is \_\_\_\_\_; 2) a panel will not be used; or 3) public comment is invited as to whether to use a panel to assist in the development of this regulatory proposal.*

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The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (<http://www.townhall.virginia.gov>) or by mail to Elaine Yeatts, 9960 Mayland Drive, Suite 300, Henrico, VA 23233; by email to [elaine.yeatts@dhp.virginia.gov](mailto:elaine.yeatts@dhp.virginia.gov); by fax to (804) 527-4434. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

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

(<http://www.townhall.virginia.gov>) and on the Commonwealth Calendar website (<https://www.virginia.gov/connect/commonwealth-calendar>). Both oral and written comments may be submitted at that time.

A Regulatory Advisory Panel will not be used for development of regulatory changes; the amendments will be drafted by the Regulation Committee.