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Notice of Intended Regulatory Action (NOIRA) 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	Incorporation of allowances from pilot programs
Date this document prepared	1/28/19

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 VAC 7-10), 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 the subject matter, intent, and goals of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation).

The Board intends to incorporate into regulations certain allowances that have been approved for implementation by pilot programs in several hospital systems. Amendments will be proposed for section 425 on robotic pharmacy systems to allow for medication carousels used in a hospital to store and guide the selection of drugs to be dispensed or removed from the pharmacy. Certain safeguards will be adopted to include a verification check by a pharmacist for the accuracy of the barcode assignment to an individual drug. Under specified conditions, a pharmacist will not be required to check the accuracy of a patient-specific drug removed from a carousel or the accuracy of a drug removed by a pharmacy technician to be placed into an automated drug dispensing system.

A new section (505) will be added to incorporate another technology already approved for innovative pilot programs – the use of radio-frequency identification to verify the accuracy of

drugs placed into a kit for licensed emergency medical services personnel or other kits used as floor stock throughout a hospital. The regulations will specify the responsibilities of a pharmacist and the duties of a pharmacy technician in the use of RFID technology.

The intent is utilization of newer technologies that facilitate the ability of pharmacists to focus on patient-centered care and reduce the possibility of medication errors.

Acronyms and Definitions

Please define all acronyms or technical definitions used in the Agency Background Document. .

RFID = radio-frequency identification

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 change is updating of regulations to facilitate new technologies in the practice of pharmacy. Since the technologies have already been approved for pilot programs in several hospital systems and have shown to be safe and effective, the Board's decision was to incorporate the allowances into regulation.

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 describe the specific reasons why the agency has determined that this regulation 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 this regulatory action is to update regulations for utilization of newer technologies in the practice of pharmacy in a hospital system and for facilitating time for pharmacists to be more involved in direct patient care. Technologies such as medication carousels for placement of drugs in kits used by EMS personnel or as floor stock and RFID components of a robotic pharmacy system have already been approved for use as pilot programs and have been shown to protect the health and safety of the drug supply and patients in hospitals.

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.

Amendments will be proposed for section 425 on robotic pharmacy systems to allow for medication carousels used in a hospital to store and guide the selection of drugs to be dispensed or removed from the pharmacy. Certain safeguards will be adopted to include a verification check by a pharmacist for the accuracy of the barcode assignment to an individual drug. Under specified conditions, a pharmacist will not be required to check the accuracy of a patient-specific drug removed from a carousel or the accuracy of a drug removed by a pharmacy technician to be placed into an automated drug dispensing system.

A new section (505) will be added to incorporate another technology already approved for innovative pilot programs – the use of radio-frequency identification to verify the accuracy of drugs placed into a kit for licensed emergency medical services personnel or other kits used as floor stock throughout a hospital. The regulations will specify the responsibilities of a pharmacist and the duties of a pharmacy technician in the use of RFID technology.

Section 500 is amended to reference the exception allowed in new section 505.

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.

The Board has provided a draft of regulations in the publication of the Notice of Intended Regulatory Action, so affected parties will have an opportunity to recommend any less burdensome or intrusive alternatives that would be consistent with the Board’s statutory responsibility to protect the safety and integrity of drugs in the Commonwealth.

Public Participation

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; 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.