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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) Chapter citation(s)	18VAC110-20
VAC Chapter title(s)	Regulations Governing the Practice of Pharmacy
Action title	Exemption of automated dispensing devices stocked solely with emergency or stat use medications from certain requirements of 18VAC110-20-555
Date this document prepared	June 6, 2022

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 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).

In response to a petition for rulemaking, the Board is issuing a Notice of Intended Regulatory Action to consider an amendment to section 555 to exempt an automated dispensing device ("ADD") from the requirements of 18VAC110-20-555 when that ADD is exclusively stocked with certain drugs that may be kept in a stat-drug box pursuant to 18VAC110-20-550 or an emergency drug kit pursuant to 18VAC110-20-540 and are solely administered for stat or emergency use.

Acronyms and Definitions

Define all acronyms or technical definitions used in this form.

ADD = automated dispensing device

Mandate and Impetus

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, or board decision). 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the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part.”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 change is a petition for rulemaking requesting an amendment to regulations for ADDs stocked solely with stat or emergency use drugs. As presented by the petitioner, it would be more secure for such drugs to be stored in an ADD than a “tackle-box” style mechanism which is currently used.

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 of the Board of Pharmacy are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Virginia Code § 54.1-2400(6) specifically states that the general powers and duties of health regulatory boards shall be “[t]o 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.”

Purpose

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, explain any potential issues that may need to be addressed as the regulation is developed.

The Board determined that the petitioner correctly identified a potential hazard in storage of stat or emergency use only medications under 18VAC110-20-540 or 18VAC110-20-550. Stat or emergency use drugs stored in an ADD would contain an electronic record of access to those drugs, while the current tackle-box style storage systems do not. For some facilities, such as nursing homes, ADDs are not used because the only drugs stored on the premises are stat or emergency use medication. Patient and drug security may be increased through utilization of ADDs when exempted from certain requirements that would unacceptably delay the administration of life-saving drugs for patients.

Substance

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

An amendment to 18VAC110-20-555 would exempt ADDs exclusively stocked with drugs that would be kept in an emergency drug kit pursuant to 18VAC110-20-540 or a stat-drug box pursuant to 18VAC110-20-550 and are solely administered for stat or emergency use from the requirements of 18VAC110-20-555(1), (4)(a), and (4)(b).

Alternatives to Regulation

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 of Pharmacy regulates both the use of ADDs and the use of emergency or stat drugs. There is no alternative to regulation to create this exemption.

Periodic Review and Small Business Impact Review Announcement

This NOIRA is not being used to announce a periodic review or a small business impact review.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below. In addition, as required by § 2.2-4007.02 of the Code of Virginia describe any other means that will be used to identify and notify interested parties and seek their input, such as regulatory advisory panels or general notices.

The Board of Pharmacy is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal, (ii) any alternative approaches, and (iii) the potential impacts of the regulation.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: <https://townhall.virginia.gov>. Comments may also be submitted by mail, email or fax to Erin Barrett, 9960 Mayland Drive, Suite 300, Henrico, Virginia 23233, erin.barrett@dhp.virginia.gov, or by fax at (804) 915-0382. 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 not be held following the publication of the proposed stage of this regulatory action.