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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	Petition requests
Date this document prepared	10/11/16

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 acted on a petition for rulemaking to permit a pharmacist to dispense a quantity of a Schedule VI drug greater than the face amount prescribed, up to the total amount authorized in refills. During the comment period which ended June 29, 2016, the board received one comment which supported the request. Currently a pharmacist may not dispense more than the specific quantity prescribed at each dispensing and may not exceed that quantity by taking authorized refills into consideration. The Board voted unanimously to accept the petition for rulemaking authorizing a pharmacist, when deemed appropriate in his professional judgement and upon request by the patient, to dispense a quantity of a Schedule VI drug, excluding psychotherapeutic drugs, in excess of the specific quantity prescribed for a dispensing, not to exceed the total amount authorized in refills.

The Board acted on another petition for rulemaking to amend 18VAC110-20-540, 18VAC110-20-550

and 18VAC110-20-555 to authorize the use of electronic devices in lieu of manual emergency drug kits and stat-drug boxes. The petition states that current regulation does not distinguish between automated dispensing devices being utilized for first dose non-routine administration vs routine drug administration. During the comment period which ended August 31, 2016, the Board received one comment in support of the petition.
The Board voted unanimously to accept the petition for rulemaking by amending Regulation 18VAC110-20-555 to specifically authorize the use of an automated dispensing device in a nursing home for obtaining drugs that would be stocked in a stat-drug box and to clarify the quantity of drugs in Schedules II-V that may be stocked in the device for this purpose, and to consider the appropriateness of requiring a provider pharmacy to the nursing home to obtain a controlled substances registration at the location of the facility for the purpose of placing an automated dispensing device in the facility. It was determined it was unnecessary to amend other sections of regulations to achieve the petitioner's request.

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. (Effective until January 1, 2017) To promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 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 statutory authority for the Board to promulgate regulations for the practice of pharmacy is found in the following sections:

§ 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.

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.

Granting the pharmacist authority to dispense a quantity of a Schedule VI substance greater than the amount initially noted on the prescription would benefit patients and prescribers with greater flexibility and improved medication adherence. A pharmacist would be able to use his/her professional judgment about whether to dispense in conformity with the prescribed amount and dosage.

Allowing the use of electronic devices for emergency and stat boxes is becoming a standard for acute long-term care facilities, as such devices can minimize diversion and limit access for staff to the correct location for first dose administration.

Both changes are reasonable accommodations in the practice of pharmacy that will benefit the health and safety of patients without jeopardizing the integrity and efficacy of the drug supply in the Commonwealth.

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.

The Board voted unanimously to accept petitions for rulemaking to:

1) Amend 18VAC110-20-320 to authorize a pharmacist, when deemed appropriate in his professional judgement and upon request by the patient, to dispense a quantity of a Schedule VI drug, excluding psychotherapeutic drugs, in excess of the specific quantity prescribed for a dispensing, not to exceed the total amount authorized in refills; and
2) Amend 18VAC110-20-555 to specifically authorize the use of an automated dispensing device in a nursing home for obtaining drugs that would be stocked in a stat-drug box and to clarify the quantity of drugs in Schedules II-V that may be stocked in the device for this purpose, and to consider the appropriateness of requiring a provider pharmacy to the nursing home to obtain a controlled substances registration at the location of the facility for the purpose of placing an automated dispensing device in the facility.

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.

The petitions requested less burdensome and intrusive alternatives to current regulations, so changes to achieve that purpose must be accomplished by amendments to Chapter 20.

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.

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.