Virginia Regulatory Town Hall

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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	18VAC110-20
Regulation title	Regulations Governing the Practice of Pharmacy
Action title	Signing for medications in automated dispensing devices
Date this document prepared	7/27/09

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

In response to a petition for rulemaking, the Board of Pharmacy will consider amending its regulations pertaining to automated devices in hospitals for dispensing and administration of drugs to use the activity reports rather than having a nurse or other licensed person sign for loading and delivery of the drugs to the hospital floor.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

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:

§ 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 (§ 9-6.14:1 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 specific statutory authority for the Board of Pharmacy to regulate the practice of pharmacy including regulations pertaining to the safety and integrity of drugs is found in § 54.1-3307 of the Code of Virginia.

§ 54.1-3307. Specific powers and duties of Board.

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 which do not conform to the requirements of law. In so regulating the Board shall consider any of the following criteria as they are applicable:

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.

Need

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

The petitioner noted that the requirement for nurses to sign for medications loaded into an automated dispensing devices takes them away from patient care duties, which is "clinically irresponsible" as the nursing shortage continues. Hospital pharmacies utilize activity reports to verify that medications were actually loaded into the devices, and those reports provide a reliable source of accountability. Allowing nurses to stay focused on patient care without the distraction of other duties is essential to protect the health and safety of patients in hospitals.

Substance

Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.

The proposed regulation would amend section 490 to allow a hospital to utilize the activity reports from an automated dispensing device as a check on medications loaded into the machine in lieu of requiring a nurse or other person authorized to administer drugs from that specific device to sign at the time of loading.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

Since the regulation states a specific requirement, the only alternative for changing the rule is the promulgation of an amendment through the regulatory process.

Public participation

Please indicate the agency is seeking comments on the intended regulatory action, to include 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 on this notice.

The agency is seeking comments on the intended regulatory action, including but not limited to 1) ideas to assist in the development of a proposal, 2) the costs and benefits of the alternatives

stated in this background document or other alternatives and 3) 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 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 comments may do so via the Regulatory Townhall website , www.townhall.virginia.gov, or by mail, email or fax to Elaine Yeatts at the Department of Health Professions, 9960 Mayland Drive, Richmond, VA 23233 or **elaine.yeatts@dhp.virginia.gov** or by fax at (804) 527-4434. Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last day of the public comment period.

After the adoption and publication of a proposed regulation, a public hearing will be held and notice of the hearing may be found on the Virginia Regulatory Town Hall website (**www.townhall.virginia.gov**) and can be found in the Calendar of Events section of the Virginia Register of Regulations. Both oral and written comments may be submitted at that time.

Participatory approach

This proposal came to the Board of Pharmacy through a petition for rulemaking which was accepted at the June 2009 meeting. There were 31comments on the petition, primarily from pharmacists, pharmacy technicians and nurses who work in hospitals in Virginia; all commenters favored the petition. The promulgation of the amendment will be accomplished in open meetings of the Board, at which the public is invited to attend and encouraged to participate.

Family impact

Assess the potential impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

There is no impact on the family.