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	18VAC110-20-10 et seq.
Regulation title	Regulations Governing the Practice of Pharmacy
Action title	Outsourcing of data entry and DUR by hospitals and other pharmacies
Document preparation date	

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) 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.

The Board of Pharmacy intends to consider amendments to regulation to allow pharmacies in hospital or retail settings to possibly outsource data entry, the drug utilization review (DUR) and other aspects of dispensing prescription drugs. The Board has already approved a pilot program for a large retail chain to centralize data processing and verification of refill orders at a central location apart from the individual pharmacy. A pilot program application has been filed by a hospital and another is pending to outsource data entry and DUR. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is beginning to strictly enforce the requirement for drug review by a pharmacist prior to administration, which is difficult for smaller hospitals or those in rural areas that do not operate a 24-hour pharmacy. The goal of the amended regulation would be to make outsourcing permissible, provided important safeguards are in place that ensure accountability, confidentiality and security.

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.

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18 VAC 110-20-10 et seq. Regulations Governing the Practice of Pharmacy are promulgated under the general authority of Title 54.1, Chapter 24 of the Code of Virginia. Chapter 24 establishes the general powers and duties of health regulatory boards including the responsibility to promulgate regulations in accordance with the Administrative Process Act.

> ***§ 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 to regulate the practice of pharmacy including the dispensing of controlled substances 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.

The Board may collect and examine specimens of drugs, devices and cosmetics which are manufactured, stored or dispensed in this Commonwealth.

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. Include the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. Delineate any potential issues that may need to be addressed as the regulation is developed.

Amendments to regulations will likely address the use of new technology and methods in a manner that will ensure the *"quality, quantity, integrity, safety and efficacy of drugs or devices distributed and dispensed in the Commonwealth."* Regulations for oversight and supervision of pharmacy technicians, maintenance of records, drug utilization review, refilling of prescriptions and others will have to be reviewed to determine whether changes can be made that will accommodate the potential use of outsourcing or off-site entry by pharmacies in Virginia. Since the needs and issues relating to retail differ from those in hospital pharmacies, the amendments will have to specifically address practice in a variety of settings.

In consideration of amending regulations, the Board will weigh the need for efficiency and effective utilization of new technology with issues relating to drug security and accountability. For example, if the DUR is to be out-sourced to someone other than the dispensing pharmacist, responsibility and accountability will have to be clearly set out, particularly if the out-sourcing is to a facility in another state where that reviewing pharmacist may not currently hold a Virginia license.

The Board will have to carefully review each aspect of the process to determine what safeguards and accountability must be built into the system and then write regulations that ensure that they are. While the Board is proactively seeking to make dispensing of prescription drugs more accessible and economically feasible, its first obligation is to the safety and health of the public and will be so directed in the consideration of amending regulations.

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.

The alternative for approval of innovative programs in the practice of pharmacy has been through approval of a pilot program. In July of 2003, the Board approved a pilot program for Giant Foods to allow for centralized processing for refill prescriptions and electronic

prescriptions for all of their pharmacies in Northern Virginia. Central processing included computer entry of the refill request, review for refill authority, third-party billing and any other computer functions required to process the prescriptions. In approving the pilot, the Board waived certain portions of regulation to allow technicians to perform the data entry of refill information and label preparation without direct supervision by the dispensing pharmacist. The actual dispensing is then done at the originating pharmacy by the pharmacist. Giant has been filing quarterly reports as required by the Board Order and is due for a random, unannounced inspection in the next few months.

Related to the issue of centralized processing of refill prescription but different in its purpose and utilization is the need for outsourcing or centralizing of order entry and review in hospitals. An application for a pilot program from Retreat Hospital is pending which requests permission to use a central service location to review orders that have been scanned or faxed to a central location. Waivers are requested to allow storage of digital images as opposed to hard copy of a chart order and to allow the chart order to be sent to a location other than the dispensing pharmacy.

While the Board can continue to consider applications for pilot programs, it has determined that there is a growing demand for utilization of more efficient technology and a need to address the issues related to outsourcing and off-site data entry in a broader way. Following receipt of comment on the Notice of Intended Regulatory Action, the Board will review Model Regulations of the National Association of Boards of Pharmacy and also utilize expertise among its members and other persons who have familiarity with the issues and available technology.

Family impact

Assess the potential impact of the proposed regulatory action on the institution of the family and family stability.

There is no potential impact on the family and family stability.