Virginia Regulatory Town Hall

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Proposed Regulation
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	9/29/04

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.*

Brief summary

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

Two new sections are being added to Chapter 20; both will set out the requirements and conditions that must be met for a dispensing pharmacy (a retail pharmacy or within a hospital or long-term care facility) to outsource prescription order processing to a remote or centralized location. Regulations establish the aspects of the dispensing process that may be performed at the remote pharmacy, requirements for accountability and adherence to Virginia law and regulation, required content of a policy and procedure manual for outsourcing, requirements for record-keeping and confidentiality. The rules for retail pharmacies also include requirements for disclosure of the outsourcing arrangement to the public.

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., the agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

18 VAC 110-20-10 et seq. Regulations Governing the Practice of Pharmacy are promulgated by the Board of Pharmacy 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 of Pharmacy 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.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal and the problems the proposal is intended to solve.

The Board of Pharmacy has proposed amendments to regulation to allow pharmacies in hospital or retail settings to 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 others are 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 is to make outsourcing permissible, provided important safeguards are in place to ensure accountability, confidentiality and security.

The Board has considered each aspect of the dispensing process to determine what safeguards and accountability must be built into the system. 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 was so directed in the consideration of amending regulations.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)

Amendments to regulations 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 and others are adopted to allow for outsourcing or off-site entry by pharmacies in Virginia. Since the needs and issues relating to retail differ from those in hospital pharmacies, amendments specifically address practice in a variety of settings.

In consideration of amending regulations, the Board has weighed 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 is clearly set out both in regulation and in a policy and procedure manual that is available for inspection. If the out-sourcing is to a facility in another state, accountability is required by having the pharmacy licensed as a non-resident pharmacy and the supervising pharmacist licensed in Virginia.

Issues

Please identify the issues associated with the proposed regulatory action, including:
1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;
2) the primary advantages and disadvantages to the agency or the Commonwealth; and
3) other pertinent matters of interest to the regulated community, government officials, and the public.

If the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.

1) There may be several advantages to the public. In a retail pharmacy, there are often distractions for the pharmacist and technicians related to dealing with consumers. If data entry, utilization review, authorizations for refills and other tasks are performed in an environment dedicated to such tasks, there is not only an economy of scale but a focus on the core processes without interruption and distraction. If facilities are able to operate more efficiently, the net result should have a positive effect on consumers. If all regulations for accountability and confidentiality are followed, there should be no increase in errors, and patient safety may actually be enhanced. In hospital settings, where dispensing often occurs throughout a 24-hour period, the availability of off-site utilization review should improve patient safety and reduce the risk of drug interactions. Proposed rules for out-sourcing provide sufficient controls on the process that there should be no disadvantages to the public.

2) There are no disadvantages to the agency. There should be fewer applications for pilot projects to process, review and approve, but there may be a slight increase in the number of non-resident and out-of-state pharmacists licensed to practice in Virginia.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners or entities for necessary functions of regulation. There would be a one-time expense of approximately $2,000 for promulgation of the amended rule. A public hearing would be heard in conjunction with a regularly scheduled board meeting, and to the extent possible, all notifications would be done electronically to minimize the cost. There would be no on-going

	expenditures.
Projected cost of the regulation on localities	None
Description of the individuals, businesses or other entities likely to be affected by the regulation	The individuals who may be affected by the amended regulation would be pharmacies and pharmacists.
Agency's best estimate of the number of such entities that will be affected	There are 8029 pharmacists with active Virginia licenses, 2155 of whom list out-of-state addresses. There are 1554 permitted pharmacies in Virginia and 491 non-resident pharmacies currently licensed to do business in Virginia.
Projected cost of the regulation for affected individuals, businesses, or other entities	There are no cost estimates for out-sourcing aspects of the dispensing process, but it is voluntary for pharmacies and not required in order to conduct business. Evidently there are cost-savings related to facility cost and personnel for out-sourcing that could be realized by pharmacies and hospitals who are able to take advantage of these provisions.

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.

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. Applications for pilot programs from Retreat Hospital and Sentara Hospitals have been approved; and an application from Bon Secours-Memorial is pending. All have requested 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 review Model Regulations of the National Association of Boards of Pharmacy and regulations from other states, including Texas, Nevada, and Florida. It also utilized expertise among its members and other persons who have familiarity with the issues and available technology.

Public comment

Please summarize all comments received during public comment period following the publication of the NOIRA, and provide the agency response.

The Notice of Intended Regulatory Action was published on August 9, 2004 with public comment received through September 8, 2004. There was no comment received. However, representatives of chain drug stores and hospital pharmacies were represented at committee meetings at which these regulations were discussed and had opportunity for input at that time.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability.

There is no impact of the proposed regulatory action on the institution of the family and family stability.

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
n/a	276	n/a	Subsection A sets out the activities related to the dispensing process that may be performed by a remote or centralized pharmacy on behalf of the dispensing pharmacy. Those include: 1. Receiving, interpreting, analyzing, or clarifying prescriptions; 2. Entering prescription and patient data into a data processing system;

			3. Transferring prescription information; 4. Performing a prospective drug review as set forth in § 54.1-3319 of the Code of Virginia; 5. Obtaining refill or substitution authorizations, or otherwise communicating with the prescriber concerning a patient's prescription; 6. Interpreting clinical data for prior authorization for dispensing; 7. Performing therapeutic interventions; and 8. Providing drug information or counseling concerning a patient's prescription to the patient or patient's agent. *The activities that may be outsourced or performed at a centralized location would include gathering and entering pertinent information into a data system, obtaining appropriate authorizations, performing the utilization review, and providing counseling on the prescription. These activities may be more safely performed in a remote pharmacy where there are fewer interruptions and distractions from interacting with the public. Once the remote or centralized pharmacy has processed the prescription, the actual dispensing takes place at the patient's pharmacy and is overseen by the pharmacist.* Subsection B states the conditions that must be met in order for a pharmacy to outsource certain prescription processing functions as described in subsection A to another pharmacy in Virginia or to a registered non-resident pharmacy. Those include: 1. The pharmacies must either have the same owner or have a written contract describing the scope of services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with all federal and state laws and regulations related to the practice of pharmacy; 2. Any central or remote pharmacy must comply with Virginia law with respect to duties which are restricted to pharmacists and pharmacy technicians must be directly supervised by a pharmacist; 3. A pharmacist licensed in Virginia, whether at the remote pharmacy or the dispensing pharmacy, shall perform a check for accuracy on all processing done by the remote processor; and 4. The pharmacies shall share a common electronic file or have technology which allows sufficient information necessary to process a non-dispensing function. *The conditions for outsourcing are intended to ensure that Virginia law and regulation is followed in the dispensing process, whether the remote pharmacy holds a resident or non-resident license. In addition, the pharmacist responsible*

			for checking for accuracy and for supervising the activities of pharmacy technicians must be licensed by Virginia, so that both the pharmacy and the pharmacist are accountable to the Virginia board should there be an error made in the process. The rules also require 1) common ownership or a written contract that specifies the responsibility and accountability of the pharmacies; and 2) common electronic files or technology that will ensure ready transfer of sufficient data to complete the tasks of each pharmacy. For example, the remote pharmacy must have access to the patient's drug profile in order to perform the DUR or prospective drug review. Subsection C requires that any pharmacy that outsources prescription processing to another pharmacy to provide notification of such to patients in the form of a one-time written notification or a sign posted in the pharmacy in a location that is readily visible to the public will satisfy this notification requirement. The notice must state the name of any contract pharmacy providing central or remote prescription processing. If the pharmacy uses a network of pharmacies under common ownership, this fact must be disclosed in the notice. *A requirement for public notification is intended to give patients adequate information about the processing of their prescriptions, so they understand that much of the dispensing process is not being performed at the dispensing pharmacy. Consumer information is necessary to give consumers the opportunity to make choices about where they go to have prescriptions filled or refilled.* Subsection D requires a policy and procedure manual relating to central or remote processing to be maintained at each pharmacy involved in the processing of a prescription and available for inspection. The manual shall at a minimum include the following: 1. The responsibilities of each pharmacy; 2. A list of the name, address, telephone numbers, and permit/registration numbers of all pharmacies involved in central or remote processing; 3. Procedures for protecting the confidentiality and integrity of patient information; 4. Procedures for ensuring that pharmacists performing prospective drug reviews have access to appropriate drug information resources; 5. Procedures for maintaining required records; 6. Procedures for complying with all applicable laws and regulations to include counseling; 7. Procedures for objectively and systematically monitoring

			and evaluating the quality of the program to resolve problems and improve services; and 8. Procedures for annually reviewing the written policies and procedures for needed modifications and documenting such review. *Policies for quality control and improvement, compliance with law and regulation, maintenance of records and confidentiality, and the individual responsibilities of the participating pharmacies must be agreed upon, put in writing and available for inspection. Rather than prescribing all such policies in regulation, the Board has established standards for dispensing prescription drugs and requires adherence to such standards by whatever procedures are appropriate to each practice setting.* Subsection E provides that, in addition to any other required records, pharmacies engaged in central or remote processing must maintain retrievable records which show, for each prescription processed, each individual processing function and identity of the pharmacist or pharmacy technician who performs a processing function and the pharmacist who checked the processing function, if applicable. 1. The records may be maintained separately by each pharmacy, or in a common electronic file shared by both pharmacies provided the system can produce a record showing each processing task, the identity of the person performing each task, and the location where each task was performed. 2. The record shall be readily retrievable for at least the past two years through the primary dispensing pharmacy, and shall be available for inspection by the board. *Prescription records must be both accurate and retrievable to prevent drug interactions and to provide accountability in the dispensing process. Rules for record-keeping ensure that the responsible parties are identifiable throughout the process and that records are maintained in such a manner as to be easily accessible to the participating pharmacies.* F. Nothing in this section shall prohibit an individual employee licensed as a pharmacist in Virginia from accessing the employer pharmacy's database from a remote location for the purpose of performing certain prescription processing functions as described in subsection A provided the pharmacy establishes controls to protect the privacy and security of confidential records. *Subsection F is added to ensure that the rule cannot be interpreted in a manner that denies access to prescription records by a licensed pharmacist in a remote location,*

			provided there are appropriate controls on that access to ensure patient privacy and confidentiality. **18VAC110-20-515. Remote prescription order processing for hospitals and long term care facilities.** *Section 515 is very similar to 276, but it applies to pharmacies located in hospitals and long-term care facilities.* Subsection A provides that remote processing of a prescription does not include the dispensing of a drug, but does include any of the following activities related to the dispensing process: 1. Receiving, interpreting, analyzing, or clarifying prescriptions; 2. Entering prescription and patient data into a data processing system; 3. Transferring prescription information; 4. Performing a prospective drug review to include an evaluation of a prescription order and patient records for over- or under-utilization of medication, therapeutic duplication of medication, drug-disease contraindications, drug interactions, incorrect drug dosage or duration of drug treatment, or clinical abuse or misuse of medication; 5. Obtaining substitution authorizations, or otherwise communicating with the prescriber concerning a patient's order; 6. Interpreting or acting on clinical data; 7. Performing therapeutic interventions; 8. Providing drug information to the medical or nursing staff of the hospital or long term care facility; and 9. Authorizing the administration of the drug to the patient by appropriate hospital or long term care facility staff. *Subsection A of 515 is similar to subsection A of 276 except the functions are specific to those facilities in which the drug is not only dispensed but also administered. Therefore, the pharmacy would not be providing drug information directly to the patient but instead to the medical or nursing staff and would not be authorizing refills but would be authorizing administration by appropriate staff. Remote processing of a prescription does not include the dispensing of a drug, but does include any of the following activities related to the dispensing process.* Subsection B provides the conditions that must be met in order for the primary pharmacy providing pharmacy services to a hospital or long term care facility to outsource certain order processing functions to another pharmacy in Virginia or a registered non-resident pharmacy. *With some*

			differences in wording unique to hospitals and long-term care, the requirements are identical to subsection B of section 276 (see above). *Subsection C is identical to subsection D in section 276 (see above).* Subsection D provides requirements for record-keeping that identifies each person who performed a processing function for every order. 1. The record shall be available by prescription order or by patient name. 2. The record may be maintained in a common electronic file if the record is maintained in such a manner that the data processing system can produce a printout which identifies every person who performed a task involved in processing a prescription order and the location where the task was processed. 3. The record shall be readily retrievable for at least the past two years through the primary dispensing pharmacy, and shall be available for inspection by the board. *With some differences in wording unique to hospitals and long-term care, the requirements in subsection D are identical to subsection E of section 276 (see above).* *Subsection E is identical to subsection F in section 276 (see above).*