Virginia Regulatory Town Hall

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Final Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation	18 VAC 110-20
Regulation title	Regulations Governing the Practice of Pharmacy
Action title	Outsourcing certain aspects of prescription processing
Document preparation date	6/10/05

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

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

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 certain functions of 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.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

On June 7, 2005, the Board of Pharmacy adopted final amended regulations for 18 VAC 110-20-10 et seq., Regulations Governing the Practice of Pharmacy for outsourcing of certain prescription processing functions.

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 numbers, 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 (6), 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. 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. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The Board of Pharmacy has adopted 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 identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" 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 from a hospital 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 there are no disadvantages to the public or the Commonwealth, please 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.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.

Section number	Requirement at proposed stage	What has changed	Rationale for change
276 B	Requirement for central or remote pharmacy to comply with Va. law with respect to duties of a pharmacist and for technicians to be supervised by a pharmacist	Added requirement to comply with Va. regulation as well as law with respect to requirements for supervision & the duties restricted to a pharmacist or pharmacy technician. Added requirement for technicians to possess credentials substantially equivalent to those required in VA	1) Some requirements related to patient safety and drug security are in regulation & should also apply to aspect of processing being performed at a remote location; 2) Most states have pharmacist/technician ratios more restrictive than VA but some have no ratio, so regulation will ensure that processing is not being performed at a location with an excessive number of technicians and only one pharmacist/supervisor; 3) Change will ensure that technicians are not performing duties restricted to a pharmacist in VA; 4) Change will ensure that technicians are comparably qualified.
515 B	1) Same as section 276, plus requirement for supervising pharmacist to be licensed in VA 2) Requirement for pharmacist at either the remote or dispensing pharmacy to perform a check for accuracy.	Same as above; removed requirement for supervising pharmacist to be licensed in VA 3) Transferred requirement for supervising pharmacist to be licensed in VA to #2.	Same as above 2) Performance of a check for accuracy is required by regulation as a duty for a VA licensed pharmacist, so it's not necessary to restate.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Amended regulations were published in the Virginia Register of Regulations on January 10, 2005 with a public comment for 60 days ending March 11, 2005. A Notice of Comment was sent the interested parties providing for an additional comment period ending May 18, 2005. During the Comment Period, the following comments were received:

The National Association of Chain Drug Stores (NACDS) requested reconsideration of the proposed requirement in section 276 for the check for accuracy of a prescription processed at a remote location to be performed by a pharmacist licensed in Virginia. If both pharmacies are licensed by the Board, there is adequate protection. NACDS also requested that the Board clarify that the dispensing pharmacist does not have to recheck the work of the pharmacist at the remote pharmacy – the requested language would be: "A licensed pharmacist, whether at the Virginia-licensed remote pharmacy or dispensing pharmacy, shall perform a check for accuracy on all processing they perform."

Board response: *The Board considered the comments of NACDS and decided that it was necessary for safety and accountability to retain the proposed requirement for a check for accuracy to be performed by a pharmacist licensed in Virginia - either the pharmacist at the remote location or the pharmacist at the dispensing location. When patients take a prescription to a Virginia pharmacy, there is an expectation that a licensed Virginia pharmacist will oversee the processing and dispensing of that prescription. Without a requirement for checking by a Virginia pharmacist at some point in the process, there would be no accountability to the citizens of Virginia and the Virginia Board.*

EPIC Pharmacies requested four amendments: 1) to clarify that the remote or central pharmacy must comply with law *and regulation*; 2) to ensure that pharmacy technician duties are only performed by technicians; 3) to ensure that qualifications for out-of-state technicians are substantially equivalent to Virginia; and 4) to ensure that out-of-state technicians are supervised in accordance with Virginia law and regulation.

Board response: *The Board responded to the comments from EPIC by amending sections 276 B and 515 B accordingly – see section on changes made since the proposed stage.*

A Public Hearing before the Board was held on April 25, 2005, at which time questions about the regulation were answered but there was no public comment.

All changes made in this regulatory action

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

Proposed section number	Proposed change and rationale
276	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 shall comply with Virginia law and regulation with respect to requirements for supervision of pharmacy technicians and the duties which are restricted to pharmacists and pharmacy technicians. Pharmacy technicians at the remote pharmacy shall either be registered in Virginia or possess credentials substantially equivalent to those required for a technician registered in Virginia; 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.
515	*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 virtually 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).*

Family impact

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

In its analysis of the final regulatory action, the agency has determined that there is no potential impact on the institution of the family and family stability.