

PROPOSED REGULATIONS ON OUTSOURCING PRESCRIPTION PROCESSING

18VAC110-20-276. Central or remote processing.

A. Centralized or 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 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; or
8. Providing drug information or counseling concerning a patient's prescription to the patient or patient's agent.

B. A pharmacy may outsource certain prescription processing functions as described in subsection A to another pharmacy in Virginia or a registered non-resident pharmacy under the following conditions:

1. The pharmacies shall 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 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.

C. Any pharmacy that outsources prescription processing to another pharmacy shall provide notification of such to patients. 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 shall 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 shall be disclosed in the notice.

D. A policy and procedure manual that relates to central or remote processing shall 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:

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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.

E. In addition to any other required records, pharmacies engaged in central or remote processing shall 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.

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.

18VAC110-20-515. Remote prescription order processing for hospitals and long term care facilities.

A. 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

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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; or

9. Authorizing the administration of the drug to the patient by appropriate hospital or long term care facility staff.

B. The primary pharmacy providing pharmacy services to a hospital or long term care facility may outsource certain order processing functions as described in subsection A to another pharmacy in Virginia or a registered non-resident pharmacy under the following conditions:

1. The pharmacies shall 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 pharmacist participating in remote prescription order processing shall be a Virginia licensed pharmacist and the remote pharmacy shall comply with Virginia law with respect to duties which are restricted to pharmacists and supervision requirements for pharmacy technicians;

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 prescription order.

C. A policy and procedure manual that relates to remote processing shall 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 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;

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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.

D. A pharmacy involved in remote prescription order processing shall maintain a record 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.

E. 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.