

## **Virginia Board of Pharmacy**

### **Use of Dispensing Records to Identify Pharmacist Responsible for Dispensing Error**

At its June 12, 2012 meeting, the Board of Pharmacy discussed a possible conflict between Regulations 18VAC 110-20-270 and 18VAC 110-20-276. Regulation 18VAC110-20-270 C suggests that one pharmacist shall verify the accuracy of the prescription product in all respects and assume responsibility for the entire transaction. However, Regulation 18VAC110-20-276 requires the identification of individual pharmacists involved in central or remote dispensing and thus, suggests that multiple pharmacists may assume responsibility for individual dispensing functions associated with dispensing one prescription product. Furthermore, the Board discussed current dispensing practices and the required recordkeeping when more than one pharmacist at the same location assumes responsibility for individual dispensing functions associated with dispensing one prescription product. To improve compliance with regulations and assist in determining which pharmacist to hold responsible for a dispensing error, the Board offers the following guidance.

#### **Dispensing Scenario #1**

One pharmacist verifies the accuracy of the prescription product in all respects and assumes responsibility for the entire transaction. Per Regulation 18VAC110-20-270 C, he shall place his initials on the record of dispensing as a certification of the accuracy of, and the responsibility for, the entire transaction. Such record showing verification of accuracy shall be maintained for the required time period of two years. Additionally, if the pharmacist makes use of an automated data processing system, he shall document the fact that the information entered into the computer is correct in compliance with Regulation 18VAC110-20-250.

#### **Dispensing Scenario #2**

More than one pharmacist at the same pharmacy location verifies the accuracy of individual tasks associated with the dispensing of a prescription product and assumes responsibility for these individual tasks, i.e., one pharmacist may verify accuracy of the data entry while another may verify accuracy of product selection. If the pharmacy's record of dispensing only captures one set of pharmacist initials on the record and this is the only record of dispensing maintained, then that pharmacist shall be responsible for the entire transaction and any resulting dispensing errors.

To identify more than one pharmacist responsible for individual tasks when the pharmacy's record of dispensing is incapable of capturing more than one set of pharmacist initials, an alternative record shall be used in compliance with Regulation 18VAC110-20-255. The alternative record shall indicate the date of dispensing and the identity of the other pharmacist(s) involved in the dispensing. An example of an alternative record could be a manual log. Such alternative record shall be maintained for a period of two years on premises. A pharmacy using such alternative record shall maintain a current policy and procedure manual documenting the procedures for using the record, how the record is integrated into the total dispensing record system, and how the data included in the record shall be interpreted, i.e., which set of pharmacist initials is associated with verifying the accuracy of which dispensing function. For example, the policy and procedure manual could indicate that the pharmacist whose initials are on the record of dispensing maintained in the computer is responsible for verifying the validity of the prescription, drug-therapy appropriateness, including, but not limited to, interactions, contraindications, adverse effects, incorrect dosage or duration of treatment, clinical

misuse or abuse, noncompliance and duplication of therapy, and prospective drug review. Additionally, the manual could indicate that the pharmacist whose initials are captured on the manual log is responsible for product verification and ensuring that the correct quantity of the correct drug and strength have been placed in the properly labeled container.

### **Dispensing Scenario #3**

More than one pharmacist at different pharmacy locations participate in central or remote processing pursuant to Regulation 18VAC110-20-276 or 18VAC110-20-515. The pharmacist and/or pharmacies must be properly licensed in compliance with regulations. Retrievable records shall be maintained at the participating pharmacies which show, for each prescription processed, each individual processing function and identity of the pharmacist or pharmacy technician who performed a processing function and the pharmacist who checked the processing function, if applicable. 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. The Virginia-licensed pharmacist identified on these records who assumed responsibility for checking an individual function which resulted in a dispensing error shall be held responsible for that dispensing error, i.e., if the dispensing error resulted from incorrect data entry, then the pharmacist identified on the record for checking the data entry shall be responsible for the error and if the dispensing error resulted from incorrect product selection, then the pharmacist identified on the record for checking the product selection shall be responsible for the error.

**\*\*\*Note Regarding Partial Filling of a Prescription:** When a prescription is partially-filled, a record of each dispensing shall be maintained. The records shall indicate the date a partial quantity was dispensed, the quantity dispensed, and the initials of the pharmacist verifying the accuracy of the dispensing. If the pharmacy's record of dispensing is maintained in an automated dispensing system capable of capturing only the total quantity dispensed and not each partial dispensing, then the pharmacy's records are out of compliance. To improve compliance with recordkeeping requirements, the pharmacy shall maintain another record that is accurate from which dispensing information is retrievable and in which the original prescription and any information maintained in the data processing system concerning such prescription can be found. An example of an alternative record could be a manual log that indicates the date of dispensing for each partial quantity, the quantity dispensed, and the initials of the pharmacist verifying the accuracy of each dispensing. Pursuant to Regulation 18VAC110-20-255, a pharmacy using such alternative record shall maintain a current policy and procedure manual documenting the procedures for using the record, how the record is integrated into the total dispensing record system, and how the data included in the record shall be interpreted.\*\*\*

***Relevant sections of law and regulation:*****§ 54.1-3412. Date of dispensing; initials of pharmacist; automated data processing system.**

Pursuant to regulations promulgated by the Board, the pharmacist dispensing any prescription shall record the date of dispensing and his initials on the prescription in (i) an automated data processing system used for the storage and retrieval of dispensing information for prescriptions or (ii) on another record that is accurate from which dispensing information is retrievable and in which the original prescription and any information maintained in such data processing system concerning such prescription can be found.

**18VAC110-20-250. Automated data processing records of prescriptions.**

- A. An automated data processing system may be used for the storage and retrieval of original and refill dispensing information for prescriptions instead of manual record keeping requirements, subject to the following conditions:
1. A prescription shall be placed on file as set forth in 18VAC110-20-240 B with the following provisions:
    - a. In lieu of a hard copy file for Schedule VI prescriptions, an electronic image of a prescription may be maintained in an electronic database provided it preserves and provides an exact image of the prescription that is clearly legible and made available within 48 hours of a request by a person authorized by law to have access to prescription information. Storing electronic images of prescriptions for Schedule II-V controlled substances instead of the hard copy shall only be authorized if such storage is allowed by federal law.
    - b. If the pharmacy system's automated data processing system fields are automatically populated by an electronic prescription, the automated record shall constitute the prescription and a hard copy or electronic image is not required.
    - c. For Schedule II-V controlled substances, electronic prescriptions shall be maintained in accordance with federal law and regulation.
  2. Any computerized system shall provide retrieval (via computer monitor display or printout) of original prescription information for those prescriptions which are currently authorized for dispensing.
  3. Any computerized system shall also provide retrieval via computer monitor display or printout of the dispensing history for prescriptions dispensed during the past two years.
  4. Documentation of the fact that the information entered into the computer each time a pharmacist fills a prescription for a drug is correct shall be provided by the individual pharmacist who makes use of such system. If a printout is maintained of each day's prescription dispensing data, the printout shall be verified, dated and signed by the individual pharmacist who dispensed the prescription. The individual pharmacist shall verify that the data indicated is correct and then sign the document in the same manner as his name appears on his pharmacist license (e.g., J. H. Smith or John H. Smith).
- If a bound log book, or separate file is maintained rather than a printout, each individual pharmacist involved in dispensing shall sign a statement each day in the log, in the manner previously described, attesting to the fact that the dispensing information entered into the computer that day has been reviewed by him and is correct as shown.
- B. Printout of dispensing data requirements. Any computerized system shall have the capability of producing a printout of any dispensing data which the user pharmacy is responsible for maintaining under the Drug Control Act (§54.1-3400 et seq. of the Code of Virginia) and such printout shall be provided within 48 hours of a request of an authorized agent.

**18VAC110-20-255. Other dispensing records.**

Pursuant to §54.1-3412 of the Code of Virginia, any other record used to record the date of dispensing or the identity of the pharmacist dispensing shall be maintained for a period of two years on premises. A pharmacy using such an alternative record shall maintain a current policy and procedure manual documenting the procedures for using the record, how the record is integrated into the total dispensing record system, and how the data included in the record shall be interpreted.

**18VAC110-20-270. Dispensing of prescriptions; certification of completed prescriptions; supervision of pharmacy technicians.**

- C. After the prescription has been prepared and prior to the delivery of the order, the pharmacist shall inspect the prescription product to verify its accuracy in all respects, and place his initials on the record of dispensing as a certification of the accuracy of, and the responsibility for, the entire transaction. Such record showing verification of accuracy shall be maintained on a pharmacy record for the required time period of two years, unless otherwise specified in regulation

**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 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.

- 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:

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 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 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. Any pharmacist participating in remote prescription order processing shall be a Virginia licensed pharmacist; 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;
  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.