6800.3950 ELECTRONIC DATA PROCESSING; COMPUTER USAGE.

Subpart 1. **Policy and procedures.** Up-to-date written policy and procedures shall be developed and maintained that explain the operational aspects of the electronic data processing system and shall:

A. include examples of output documentation provided by the electronic data processing system that pertain to dispensing or drug control records;

B. outline steps to be followed when the electronic data processing system is not operational due to scheduled or unscheduled system interruption;

C. outline regular and routine backup file procedures and file maintenance; and

D. outline audit procedures, personnel code assignments, and personnel responsibilities.

Subp. 1a. **Entering prescription drug orders.** When electronic data processing equipment is employed by any pharmacy, input of drug information may be performed by a prescriber or a pharmacist. If prescription drug orders are entered by other personnel, the pharmacist or the prescriber must certify the accuracy of the information entered and verify the prescription drug order prior to the dispensing of the medication. The unique identifier of the person entering the prescription drug order must be retained in the computer record.

Subp. 2. **Minimum requirements.** Electronic data processing equipment, when used to store prescription information, must:

A. be structured in such a manner that all prescription drug orders, communicated to a pharmacy by way of electronic transmission, will be transmitted with no intervening person having access to the information contained in the prescription drug order;

B. not infringe on a patient's freedom of choice of pharmacy provider;

C. guarantee the confidentiality of the information contained in the system's storage devices and databases;

D. produce a hard copy daily summary of controlled substance transactions and be capable of producing a hard copy printout of legend drug transactions going back two years, except that if this information is already available in hard copy form it is not necessary to duplicate the data through a computer-generated hard copy;

E. be capable of recording and carrying in the record all dates of refills of any prescription drug order and the unique identifier of the pharmacist;

F. be capable of producing a patient profile indicating all drugs being taken and the dates and quantities of fills or refills of prescription drug orders dispensed for the patient and:

(1) in the case of hospital or long-term care inpatients, these records shall be kept in the computer system or on hard copy and be immediately retrievable for two years; and

(2) in all other cases the data shall be kept in the computer system and be immediately retrievable for at least two years;

G. be capable of being reconstructed in the event of a computer malfunction or accident resulting in destruction of the system's storage devices or databases;

H. be capable of producing a printout providing a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance. The audit trail must include the name of prescribing practitioner, the name and location of patient, the quantity dispensed on each refill, the date of dispensing of each refill, the name or unique identifier of the dispensing pharmacist, and the prescription number;

I. be capable of identifying any authorized changes in drug, quantity, or directions for use of any prescription drug order including the date of change, the identity or unique identifier of the individual making the change, and what the original information was; alternatively a new prescription drug order may be created for each authorized change; and

J. be capable of preventing unauthorized access, modification, or manipulation of patient prescription data.

Subp. 3. **Original prescription retained.** In all cases where electronic data processing equipment is used the original prescription must be retained on file according to law to assure access to the information contained thereon in the event of a computer breakdown. Original prescriptions or any other patient specific records stored outside the licensed pharmacy area must be stored in a secure area accessible only to registered or licensed pharmacy staff, or others delegated by the pharmacist-in-charge and trained on the policies and procedures relating to protected health information.

Subp. 4. **New prescriptions.**

A. A pharmacy must develop and implement a written quality assurance plan that includes a pharmacist, or a pharmacist-intern working under the immediate and direct supervision of a pharmacist, comparing the original written prescription or an image of the original written prescription, to the information entered into the computer, and documenting the completion and accuracy of this comparison with the date and unique identifier of the pharmacist or pharmacist-intern completing the task. This process must not occur prior to two hours after the prescription has been initially certified, unless it is completed by a

second individual pharmacist as soon as possible after the initial certification has occurred. The process must be completed within 72 hours.

B. As an alternative to the requirements of item A, hospitals providing inpatient pharmacy services may elect instead to develop a plan to provide safeguards against errors being made and perpetuated due to inaccurate prescription data being entered into the pharmacy's computer. This written quality assurance plan shall be made available to the board surveyors upon request.

Subp. 5. **Report to Board of Pharmacy.** If dispensing information is lost due to unscheduled system interruption, the Board of Pharmacy shall be notified within 72 hours.

Subp. 6. **Computer-generated material.** Any computer-generated material, such as labels, receipts, duplicate prescriptions, or other printed matter, that is intended to be attached to the hard copy prescription to meet legal requirements shall be affixed so that the face of the prescription is unobstructed.

Statutory Authority: *MS s 151.06; 151.102; 152.02*

History: *9 SR 1656; 18 SR 1145; 23 SR 1597; 31 SR 1673; 36 SR 237*

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