6800.7520 PHARMACEUTICAL SERVICE POLICIES.

Subpart 1. **Dispensing drugs.** Pharmaceutical service policies shall cover at least the following measures related to the control, accessibility, dispensing, and administration of drugs:

A. developing, implementing, and maintaining a system assuring the availability of prescribed drugs at all times;

B. dispensing of legend drugs;

C. changing of labels or the transfer of drugs from one container to another;

D. maintaining security and emergency access in accordance with part 6800.7530;

E. supplying of prepackaged legend drugs which are accessible for use without entering either the pharmacy or drug room maintained for use when a pharmacist is not available. Such supply may be located in nursing units, with access limited to designated registered nurses. No hospital pharmacy shall utilize a floor stock drug distribution system of this or any other type as its primary system of drug delivery;

F. maintaining a supply of drugs for use in medical emergencies;

G. specifying the maintenance of permissible supplies of nonprescription drugs in nursing service units;

H. assuring that unused patient drugs, discontinued and outdated drugs, and containers with worn, illegible, or missing labels be returned to a pharmacist for disposition;

I. maintaining a drug recall procedure which can be implemented no more than 24 hours after recall notification by the manufacturer;

J. permitting the dispensing of drugs only pursuant to orders initiated by a licensed practitioner;

K. assuring that orders for drugs are transmitted to the pharmacy by the prescriber or by an order format which produces a direct copy of the order as it is documented in the patient chart;

L. providing for a system of accountability for inpatient dispensing meeting the intent of the certification requirement of part 6800.3100;

M. establish a pharmacist monitoring system that reconciles a nurse prepared medication administration record (MAR) to the pharmacy profile;

N. requiring authorization for a standing order to be noted on the patient's medical record. Standing orders shall specify the circumstances under which the drug is to be administered, the drug, dosage, route, frequency of administration, and duration;

O. assuring that when drug therapy is not renewed on an established regular basis the therapy is limited either by the prescriber's specific indication or by automatic stop orders;

P. assuring that precautionary measures, including quality control documentation, for the safe admixture of parenteral products are developed in writing. Admixture preparation shall be limited to pharmacists, pharmacist-interns, supportive personnel under the supervision of a pharmacist, licensed practitioners, and licensed nurses. Furthermore, sterile admixtures shall be labeled as required in part 6800.7900 and must be prepared as required in part 6800.3300, subpart 2;

Q. assuring that investigational drug use is in accordance with state and federal law: basic information concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions, and symptoms of toxicity of such drugs shall be available in the pharmacy (investigational drugs shall be distributed only from the pharmacy);

R. assuring that the practice of drug reconstitution is performed only by pharmacists, licensed practitioners, licensed nurses, or hospital-authorized personnel under the supervision of licensed pharmacists, licensed practitioners, or licensed nurses;

S. developing, implementing, and maintaining a system of controlled substance and narcotic control in accordance with subitems (1) to (7);

(1) controlled substances must be accounted for by either:

(a) a "proof-of-use" sign-out sheet where each dose given is accounted for by the licensed health care professional who procures the drug. No controlled substance may be kept on floor stock unless it is accompanied by the sign-out sheet and each dose is documented by the licensed health care professional at the time the drug is procured from the stock. The proof-of-use sheets must include at least the date and time, the patient's name, the dose administered, and the licensed health care professional's signature;

(b) the dispensing of the drug to a specific patient after the pharmacy receives an individual drug order; or

(c) a computer system which utilizes electronic distribution records of controlled substance transactions as long as the system complies with the following requirements:

i. allows for retrieval of all information required by this regulation for all distribution and dispensing transactions for two years;

ii. provides for at least weekly transaction printouts, except that this requirement does not have to be met if a secure daily 24-hour backup is performed which allows for restoration of required information in case of a system failure;

iii. maintains a complete online transaction file that is printable on request, or have a "lock-out" feature that prevents editing of distribution or dispensing information; and

iv. allows for the printing of a report of all distribution and dispensing transactions for a minimum of two years. The system must be capable of retrieving and printing a report listing variables which include, but are not limited to: the identity of a user accessing the system; the date and time controlled substances are distributed to or removed from the automated distribution machine; the quantity of a controlled substance distributed to or removed from the automated distribution machine; drug name, strength, and dosage form; patient name; and practitioner name;

(2) wasting of doses must be carried out by two licensed individuals who are authorized to have access to controlled substances. The wasting of doses must be documented, with the accuracy of the documentation being certified by the licensed individuals who carried out the wasting. Certification must include the signature or other unique identifier of the licensed individuals who carried out the wasting;

(3) there must be a system for reconciling the proof-of-use sheets in the pharmacy to assure accountability of all sheets sent to the various nursing stations;

(4) controlled substances must be stored under lock on the nursing stations or other patient care area;

(5) access to the main supply of Schedule II controlled substances in the pharmacy must be restricted to a limited number of persons in the pharmacy. The main supply of Schedule II controlled substances in the pharmacy must be kept locked when not being used;

(6) single unit-of-use dosage forms should be used when possible; and

(7) a perpetual inventory of Class II controlled substances must be accurately maintained; and

T. developing policies for the issuance of medications to patients who are going on leave from the facility. These policies may allow the preparation, by the facility's registered nurses responsible for overseeing medication administration, of a supply of medications, not to exceed a 72-hour supply, in paper envelopes or other more suitable containers for use by a patient temporarily leaving the facility at times when the facility's pharmacy is closed or cannot supply the needed medication in a timely manner. A container may hold only one medication. A label on the container shall include the date,

the patient's name, the facility, the name of the medication, its strength, dose, and time of administration, and the initials of the person preparing the medication and label.

Subp. 2. **Maintenance of documents.** Pharmaceutical service policies shall cover at least the following measures related to the maintenance of documents.

A. The pharmacist-in-charge shall maintain at least the following written documents:

(1) a statement of service philosophy and objectives;

(2) a job description for each classification of personnel;

(3) a list of pharmaceutical service committees, and other hospital committees on which the pharmaceutical service is represented, with minutes of proceedings and attendance records;

(4) procurement records for controlled substances for two years or as required by law;

(5) prescriptions or other forms initiated by the prescriber, for two years or as required by law;

(6) records of packaging, bulk compounding, or manufacturing for two years or as required by law;

(7) records of action taken pursuant to drug recalls for two years or as required by law;

(8) special reports concerning narcotics and other drugs for two years or as required by law;

(9) records of pharmacist's inspections of drug supplies maintained outside the pharmacy or drug room, as permitted under subpart 1, items E and F, for two years; and

(10) records of withdrawals by nonpharmacists of prepackaged drugs from the pharmacy or drug room, as permitted under subpart 1, item D and part 6800.7530, for two years.

B. The following documents relative to pharmaceutical services shall also be maintained:

(1) a current organization chart delineating intraservice structure and lines of authority, and describing the pharmaceutical service's relationship to the administration, organized medical staff, and other relevant hospital services;

(2) a list of all licensed and/or credentialed personnel, with verification of the present validity of those licenses or credentials;

(3) a record of the number of persons, by job description, employed full-time and part-time in the pharmaceutical services;

(4) copies of current staffing patterns and weekly work schedules for two years;

(5) receipted invoices for drugs, chemicals, and pharmaceutical service supplies purchased and received over the immediately preceding two years; and

(6) any agreement or contract between an off-premises pharmacy and the hospital.

Statutory Authority: *MS s 151.06; 152.02*

History: *18 SR 1145; 27 SR 260; 31 SR 1673; 36 SR 237*

Published Electronically: *October 11, 2013*