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TITLE 856 INDIANA BOARD OF PHARMACY

LSA Document #00-85(F)

DIGEST

Amends 856 IAC 1-28-9 to establish policies and procedures for documenting the trail of controlled substances in institutional pharmacies. Effective 30 days after filing with the secretary of state.

856 IAC 1-28-9

SECTION 1. 856 IAC 1-28-9 IS AMENDED TO READ AS FOLLOWS:

856 IAC 1-28-9 Drug distribution and control
Authority: IC 25-26-13-4
Affected: IC 25-26-13-17

Sec. 9. ~~Drug Distribution and Control.~~ (a) All institutional pharmacy drugs should be obtained and used in accordance with written policies and procedures that have been approved by the pharmacy manager and the medical staff, and deal with the selection, distribution, and the safe and effective use of drugs, new drugs and investigational drugs, in the facility.

(b) ~~Responsibility.~~ The pharmacy manager of the institutional pharmacy is responsible for the safe and efficient distribution of, control of, and accountability for drugs as well as meeting all the inspection and other requirements of the Pharmacy Practice Act, the federal and the Indiana Controlled Substances Act, and all regulations promulgated under these acts, including this rule. All drugs, chemicals, and biologicals shall meet national standards of quality, and shall be clearly and accurately labeled as to contents, and such information disclosed to the medical staff. It is suggested that such written policies and procedures be developed, in accordance with hospital policy, with the coordinated effort of the pharmacy manager, the medical staff, the nursing service, and the administration. Within this framework, the pharmacy ought to be responsible for at least the following:

(1) Maintaining an adequate drug supply.

(2) Establishing specifications for the procurement of all approved drugs, and those chemicals and biologicals related to the practice of pharmacy.

(3) Preparing and dispensing drugs and chemicals.

(4) Preparing, sterilizing, and labeling parenteral medications and solutions that are manufactured in the institutional facility. When any part of this function is performed within the institutional facility but not under direct pharmacy supervision, the pharmacy manager shall be responsible for providing written guidelines and approving the procedure to be sure that all pharmaceutical requirements are met. The compounding of large volume parenterals should ordinarily be the responsibility of a qualified pharmacist. Individuals who prepare or administer large volume parenterals shall have special training to do so. There shall be an associated quality control program to monitor personnel qualifications, training and performance, and equipment and facilities. The end product should be examined on a sampling basis as determined by the pharmacy manager, to assure that it meets the required specifications. Appropriate records shall be maintained. In the interest of safety of preparation and administration, and effective nutritional content, overall direction shall be provided by a qualified physician when total parenteral nutrition products (hyperalimentation) are required.

(5) Participating in the initial orientation and subsequent in-service education, including the provision of appropriate incompatibility information, of all personnel involved in the preparation or administration of sterile parenteral medications and solutions.

(6) Any manufacturing of pharmaceuticals within the institutional facility, with proper control procedures.

(7) Maintaining and keeping available the medical staff approved stock of antidotes and other emergency drugs, both in the pharmacy and in **the** patient care areas. Authoritative current antidote information, as well as the phone number of the regional poison control center, should also be readily available in areas outside the pharmacy where these drugs are stored.

(8) Filling and labeling all drug containers issued on the department/service from which medications are to be administered.

(9) Maintaining records of the transactions of the pharmacy as required by federal, state, and local laws, and as necessary to maintain adequate control and accountability of all drugs, ~~This should include~~ **including** a system of controls and records for the requisitioning and dispensing of pharmaceutical supplies to nursing care units and to other departments/services of the hospital.
(10) Participating in the development and subsequent updating of an institutional formulary or drug list. The medical staff, through its pharmacy and therapeutics function, shall determine the institutional formulary system to be used. When properly annotated, a formulary developed outside the institutional facility will suffice if maintained as a current document and if it has been approved by the medical staff. Any institutional formulary or drug list should be readily available to the professional staff who use it, and the staff should be kept informed of any changes. The medical staff should be kept informed of any changes. The formulary or drug list should also include the availability of nonlegend medications. The existence of a formulary does not preclude the use of unlisted drugs, and there should be a written policy and procedure for their procurement.
(11) Requiring and documenting the participation of pharmacy personnel in relevant continuing education programs to include orientation of new employees, as well as in-service and outside educational programs. Frequency shall be related to the scope of the pharmaceutical services offered and shall be established with approval of the chief executive officer.
(12) Participating in those aspects of the institution's patient care evaluation program that relate to drug utilization and effectiveness. This may include the determination of usage patterns for each drug according to clinical department/service or individual prescribers, and assisting in the setting of drug use criteria.
(13) Participating in all meetings of the pharmacy and therapeutics committee and implementing the decisions of that committee throughout the institutional facility.
(14) Communicating new product information to nursing service and other institutional personnel as required.
(15) Performing an annual review of all pharmaceutical policies and procedures for the purpose of establishing their consistency with current practices within the institutional facility.
(16) Maintaining confidentiality of patient/medical staff information.
(17) Maintaining a means of identifying the signature of all practitioners authorized to use the pharmaceutical services for prescriptions and drug orders, as well as a listing of their Drug Enforcement Administration numbers.
(18) Cooperating in the teaching and research programs of the institution.
(19) Effective and efficient messenger and delivery service to connect the pharmacy with appropriate parts of the facility on a regular basis throughout the normal workday of the facility.
(20) Within the limit of resources available, the pharmaceutical services should provide drug monitoring services in keeping with each patient's needs. These may include, but are not necessarily limited to, **the following:**

(A) The maintenance of a medication record or drug profile for each patient which is based on available drug history and current therapy and includes the **following:**

(i) The name, age, and weight of the patient.

(ii) The current diagnoses.

(iii) The current drug therapy.

(iv) Any drug allergies or sensitivities. ~~and~~

(v) Other pertinent information relating to the patient's drug regimen.

This information should be available to the responsible practitioners at all times.

(B) A review of the patient's drug regimen for any potential interactions, interferences, or incompatibilities prior to dispensing drugs to the patient. Such irregularities must be resolved promptly with the prescribing practitioner, and, where appropriate, with notification of the nursing service and administration.

(C) The instruction of the patient or of the appropriate nursing service personnel who advise the patient, verbally or in writing, on the importance and correct use of medication to be taken following discharge, in the interest of assuring safe and correct self-administration, when such instruction is requested by the responsible practitioner or as provided by written medical staff policy.

(c) Labeling **requirements are as follows:**
(1) All drugs, other than unit-of-use packages, dispensed by an institutional pharmacy, intended for use within the facility, shall be distributed in appropriate containers and adequately labeled so as to identify, at a minimum, **the following:**

(A) Patient identification.

(B) Brand name or generic name.

(C) Strength.

(D) Route of administration.

(E) Quantity.

(F) Pharmacist's initials. ~~and~~

(G) Room number.

Unit-of-use packages shall contain information to adequately label them, at a minimum, the drug name (brand or generic), strength,

control number, and/or expiration date.

(2) All drugs dispensed by an institutional pharmacy having a Type II pharmacy permit, or to patients about to be discharged, or temporarily discharged, from institutions with Type III or IV permits, shall be labeled with the following information:

(A) Name, address, and telephone number of the institutional pharmacy.

(B) Date and identifying serial number.

(C) Full name of patient.

(D) Name of drug and strength.

(E) Directions for use to the patient and route of administration.

(F) Name of prescribing physician.

(G) Required precautionary information regarding controlled substances.

(3) Precautionary measures for the safe admixture of parenteral products shall be developed by institutional pharmacies so that whenever drugs are added to intravenous solutions, a distinctive supplementary label shall be affixed to the container. The label shall indicate the **following:**

(A) The patient's name and location.

(B) The name and amount of the drugs added.

(C) The name of the basic parenteral solution.

(D) The date and time of the addition.

(E) The date, time, and rate of administration.

(F) The name or identifying code of the individual who prepared the admixture.

(G) Supplemental instructions. ~~and~~

(H) The expiration date of the compounded solution.

(d) ~~Discontinued or Recalled Drugs.~~ The pharmacy manager of institutional facilities shall be responsible for the development and implementation of policies and procedures for the return to the pharmacy of discontinued, outdated, and recalled drugs, and containers with worn, illegible, or missing labels for proper disposition. The pharmacy manager or ~~his~~ **the pharmacy manager's** designee shall make proper disposition of such drugs at the storage site.

(e) ~~Physician's Orders.~~ The pharmacy manager of an institutional pharmacy shall ~~insure~~ **ensure** that drugs ~~be~~ **are** dispensed from the institutional pharmacy only upon authorized physician's written orders, direct copies, facsimiles thereof, or computer-generated printouts. **The pharmacy manager shall do the following:**

(1) ~~Authorization. The pharmacy manager shall~~ Determine that an appropriate committee of the institutional facility shall, from time to time as appropriate, designate those physicians who are authorized to issue orders to the pharmacy.

(2) ~~Abbreviations. The pharmacy manager shall insure~~ **Ensure** that abbreviations are discouraged, but orders employing abbreviations and chemical symbols shall be utilized and filled only if such abbreviations and symbols appear on a published list of accepted abbreviations developed by the appropriate committee of the institutional facility.

(3) ~~Requirements – Orders for drugs for use by inpatients in an institutional facility with a Type III or IV pharmacy permit. The pharmacy manager shall~~ Determine that orders for drugs for use by inpatients **in an institutional facility with a Type III or IV pharmacy permit** shall, at a minimum, contain **the following:**

(A) Patient name and room number.

(B) Drug name.

(C) Strength.

(D) Directions for use.

(E) Date and physician's signature or that of ~~his~~ **the physician's** authorized representative.

(4) ~~Requirements – Orders for drugs for use by outpatients in an institutional facility with a Type II pharmacy permit. The pharmacy manager shall~~ Determine that orders for drugs for use by outpatients **in an institutional facility with a Type II pharmacy permit** shall, at a minimum, contain all of the items required by ~~Subsection 9(E)(3),~~ **subdivision (3)** and ~~in addition:~~ the **following:**

(A) The quantity to be dispensed.

(B) The physician's address. ~~and~~

(C) The Drug Enforcement Administration identification number. ~~and~~

(D) The patient's address.

(f) ~~Proofs of Use.~~ The pharmacy manager of an institutional pharmacy shall ~~insure~~ **ensure** that ~~proofs of use~~ **policies and procedures are in place for documenting the trail** of controlled substances, and such other drugs as may be specified by the appropriate committee of the institutional facility, ~~shall be submitted to the pharmacy manager, on forms provided by the pharmacy~~

~~manager, together with any and all unused portions of such drugs. Proof-of-use forms shall specify, at a minimum, name of drug, dose, name of ordering physician, name of patient, date and time of administration to patient, signature of individual administering, record of aliquot portion destroyed, if any, and signature of witness.~~ **from ordering and receiving by the pharmacy through administration or wastage of drug at the patient level. The pharmacy manager shall be responsible for review of this process on a continual basis by review of proof's-of-use documentation or other electronic documentation methodology. At a minimum, the documentation process must be able to identify the following:**

(1) The name of the drug.
(2) The dose.
(3) The name of the patient.
(4) The date and time of administration to the patient.
(5) The identification of the individual administering.
(6) The record of aliquot portion destroyed, if any.
(7) The identification of the witness.

(g) ~~Suspected Adverse Drug Reactions.~~ The pharmacy manager of an institutional pharmacy shall ~~insure~~ **ensure** that all suspected adverse drug reactions shall be reported orally immediately to the ordering physician, in writing to the pharmacy, and to the appropriate committee of the institutional facility. The pharmacy manager may, at his **or her** discretion, make further reports of such suspected reactions to the Hospital Reporting Program of the ~~U.S.~~ **United States** Food and Drug Administration, to the manufacturer, and to the United States Pharmacopoeia.

(h) ~~Records and Reports.~~ The pharmacy manager of an institutional pharmacy shall maintain and submit, as appropriate, such records and reports as are required to ~~insure~~ **ensure** patient health, safety, and welfare, and, at a minimum, the following:

(1) Physician's orders, direct copies, facsimiles thereof, or pharmacy patient profiles to be retained, filed chronologically, readily retrievable, in **the** pharmacy or in a room under control of **a** pharmacist **for five** (5) years.
(2) Proofs of use **for five** (5) years.
(3) Reports of suspected adverse drug reactions **for two** (2) years.
(4) Inventories of night cabinets and emergency kits **for two** (2) years.
(5) Inventories of the pharmacy **for two** (2) years.
(6) Biennial controlled substances inventories **for two** (2) years.
(7) Alcohol and flammables reports **for two** (2) years.
(8) Such other and further records and reports as may be required by law and this rule.

(Indiana Board of Pharmacy; 856 IAC 1-28-9; filed Jun 8, 1982, 10:04 a.m.: 5 IR 1416; filed Sep 26, 2000, 4:15 p.m.: 24 IR 378)

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