Document: Readopted Rules
Source: May 1, 2001, Indiana Register, Volume 24, Number 8
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TITLE 856 INDIANA BOARD OF PHARMACY

LSA Document #00-323

DIGEST

Readopts, repeals, and adopts rules in anticipation of IC 4-22-2.5-2, providing that all rules of Indiana administrative agencies in force on December 31, 1995, expire on January 1, 2002. *NOTE: Under IC 4-22-2-40, this document, originally printed at 24 IR 1965, was revised and readopted.* Effective 30 days after filing with the secretary of state.

856 IAC 1-7-1
856 IAC 1-7-2
856 IAC 1-7-3
856 IAC 1-7-4
856 IAC 1-7-5
856 IAC 1-7-6
856 IAC 1-7-7
856 IAC 1-28
856 IAC 1-28.1

SECTION 1: UNDER IC 4-22-2.5-3, THE FOLLOWING ARE READOPTED:

856 IAC 1-7-1 Change of pharmacy ownership
856 IAC 1-7-2 Application for permit to conduct pharmacy
856 IAC 1-7-3 Relocation of pharmacy
856 IAC 1-7-4 Licensed permit required for each pharmacy

SECTION 2: UNDER IC 4-22-2.5-3, THE FOLLOWING ARE REPEALED:

856 IAC 1-7-5 Pharmaceutical consultation service for extended care facilities
856 IAC 1-7-6 Consulting pharmacist and dispensing pharmacist; definitions
856 IAC 1-7-7 Duties of consulting pharmacist
856 IAC 1-28 Institutional Pharmacies

SECTION 3. UNDER IC 4-22-2.5-3, 856 IAC 1-28.1 IS ADDED TO READ AS FOLLOWS:

Rule 28.1. Institutional Pharmacies and Pharmacy Services

856 IAC 1-28.1-1 Definitions
Authority: IC 26-26-13-4
Affected: IC 16-42-19-5; IC 25-6-3-7; IC 25-26-13

Sec. 1. In addition to the definitions in IC 25-26-13-2 and for purposes of this rule, the following definitions apply throughout this rule:
(1) "Cabinet" includes a mechanical storage device for dispensing drugs. The term means a locked or secured enclosure located outside the pharmacy licensed area:
(A) to which only specifically authorized personnel may obtain access by key or combination available only to those authorized persons by:
(i) security code;
(ii) password; or
(iii) other method of positively identifying an individual; and
(B) that is sufficiently secure to deny access to unauthorized persons.
(2) "Cognitive services" means those acts and operations related to a patient's drug therapy that are judgmental in nature, based on knowledge, and derived from empirical factual information.

(3) "Consultant pharmacist" means a pharmacist licensed pursuant to IC 25-26-13-11 and who engages in the practice of pharmacy in or for long term care facility or other residential patients, other than as a supplying pharmacist.

(4) "Consulting" means the provision of nonsupply related cognitive services that include, but are not necessarily limited to, the following:

(A) Drug regimen review as defined in IC 25-26-13-2.

(B) Provision of advice and counsel on drugs, the selection and use thereof to the facility, the patients therein, the health care providers of the facility regarding the appropriateness, use, storage, handling, administration, and disposal of drugs within the facility.

(C) Participation in the development of policies and procedures for drug therapy within the institution, including storage, handling, administration, and disposing of drugs and devices.

(D) Assuring the compliance with all applicable laws, rules, and regulations.

(E) Provision of educational and drug information sources for the education and training of the facility health care professionals.

(F) Accepting responsibility for the implementation and performance of review of quality-related or sentinel events as defined in this rule.

(5) "Emergency drugs" means those drugs that:

(A) may be required to meet the immediate therapeutic needs of patients; and

(B) are not available from any other authorized source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining such drugs from other sources.

(6) "Institutional facility" means any health care facility whose primary purpose is to provide a physical environment for patients to obtain health care services, except those places where practitioners, as defined by IC 16-42-19-5, who are duly licensed, engage in private practice and pharmacies licensed under IC 25-26-13-17.

(7) "Institutional pharmacy" means that portion of an institutional facility where pharmacy is practiced and is:

(A) the location of the selection, compounding, production, sale, storage, and distribution of drugs, devices, and investigational or new drugs used in the diagnosis and treatment of injury, illness, and disease pursuant to drug orders and prescriptions by practitioners; and

(B) licensed with the board under IC 25-6-3-7.

(8) "Performance improvement program" means a continuous, systematic review of key medication use processes to identify, evaluate, and improve medication use and patient care.

(9) "Pharmacist in charge" (by whatever title, for example, "pharmacy manager","pharmacy director", or "director of pharmacy") means the pharmacist who directs the activities of the institutional pharmacy and who is, as such, responsible for:

(A) all activities of the institutional pharmacy; and

(B) meeting the requirements of:

(i) IC 25-26-13;

(ii) the rules of the board; and

(iii) any federal requirements pertaining to institutional pharmacies.

The qualifying pharmacist may, depending on the circumstances, also be the pharmacist in charge, though the pharmacist in charge is not required to be the qualifying pharmacist.

(10) "Policy and procedure manual" means a written document containing the agreed-to institutional rules of operation and methodology for the effective delivery of pharmacy services.

(11) "Qualifying pharmacist" means the pharmacist who accepts responsibility for the operation of a pharmacy as defined in IC 25-26-13-2 and whose name is listed on the pharmacy permit granted under IC 25-26-13-17.

(12) "Quality-related event" means the inappropriate provision of pharmaceutical services whether or not resulting in an adverse health incident, including the following:

(A) A variation from the practitioner's order, including, but not limited to, the following:

(i) Dispensing an incorrect drug.

(ii) Dispensing an incorrect drug strength.

(iii) Dispensing an incorrect dosage form.

(iv) Dispensing a drug to a wrong patient.

(v) Providing inadequate or incorrect packaging, labeling, or directions.

(vi) Failing to provide an ordered drug.

(B) A failure to identify and manage:

(i) over-utilization or under-utilization;

(ii) therapeutic duplication;

(iii) drug-disease contraindications;
(iv) drug-drug interactions;
(v) incorrect drug dosage or duration of therapy;
(vi) drug-allergy interactions; or
(vii) clinical abuse and/or misuse.

(13) "Reversible condition" means a condition that requires intervention to resolve in a reasonable time.

(14) "Sentinel event" means an unexpected occurrence involving serious adverse effect, such as disability, life threatening condition, prolonged hospitalization, or death in a patient resulting from medication use.

(15) "Supplying pharmacist" means that pharmacist licensed in the state where the pharmacist is practicing and who is practicing in a supplying pharmacy (as defined in this rule) and who accepts responsibility for all aspects the drugs and devices sold (as defined in IC 25-26-13-2) or dispensed to a facility.

(16) "Supplying pharmacy" means a pharmacy licensed in the state where the pharmacy is located, and which provides drugs and devices to patients in long term care or other facilities where patients reside.

(17) "Temporary condition" means a condition that resolves in a reasonable time without intervention.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-1)

856 IAC 1-28.1-2 Purpose
Authority: IC 26-26-13-4
Affected: IC 25-26-13-17

Sec. 2. The purpose of this rule is to set forth the responsibilities of pharmacists and pharmacies serving institutional and home health care patients. *(Indiana Board of Pharmacy; 856 IAC 1-28.1-2)*

856 IAC 1-28.1-3 Applicability
Authority: IC 26-26-13-4
Affected: IC 25-26-13-17

Sec. 3. This rule is applicable to pharmacies located:

(1) within institutional facilities as defined in section 1 of this rule and classified as Type II pharmacies in IC 25-26-13-17; and

(2) outside institutional facilities that serve institutionalized patients who are classified as Type III and Type VI pharmacies as in IC 25-26-13-17.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-3)

856 IAC 1-28.1-4 Pharmacist in charge; responsibilities
Authority: IC 26-26-13-4
Affected: IC 25-26-13-17

Sec. 4. The pharmacist in charge or an appropriate designee shall:

(1) be responsible for establishing and carrying out a performance improvement program as defined in section 1 of this rule; and

(2) develop or be responsible for development of a policies and procedures manual that shall be of sufficient scope and detail that pharmacists practicing in the institutional pharmacy will be able to practice effectively and safely.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-4)

856 IAC 1-28.1-5 Policies and procedures manual
Authority: IC 26-26-13-4
Affected: IC 25-26-13-17

Sec. 5. (a) The pharmacist in charge shall develop or be responsible for the development of a policies and procedures manual that shall be of sufficient scope and detail that pharmacists practicing in the institutional pharmacy will be able to practice effectively and safely.

(b) The manual required in this section shall be available for inspection by a member of the board or its representative.

(c) The policies and procedures manual shall contain, at a minimum, the following:
(1) Provisions for a continuous quality improvement committee that shall be comprised of staff members of the pharmacy, including, but not necessarily limited to, the following:
(A) Pharmacists.
(B) Pharmacist interns or externs.
(C) Pharmacy technicians.
(D) Clerical or support staff.
(E) Other persons deemed necessary by the qualifying pharmacist.
(2) Provisions for the pharmacist in charge or designee to ensure that the committee conducts a review of quality related events at least every three (3) months.
(3) A process to record, measure, assess, and improve quality of patient care.
(4) The procedure for reviewing quality related or sentinel events.
(Indiana Board of Pharmacy; 856 IAC 1-28.1-5)

856 IAC 1-28.1-6 Personnel
Authority: IC 26-26-13-4
Affected: IC 25-26-13-17

Sec. 6. The qualifying pharmacist and/or the pharmacist in charge shall develop and implement, or cause to be developed and implemented, policies and procedures that specify duties to be performed by pharmacy technicians and other ancillary personnel. *(Indiana Board of Pharmacy; 856 IAC 1-28.1-6)*

856 IAC 1-28.1-7 Pharmacist's duties
Authority: IC 26-26-13-4
Affected: IC 16-42-19-3; IC 25-26-13; IC 25-26-16

Sec. 7. (a) Pursuant to authority granted in IC 25-26-13-2 and IC 25-26-13-31, the duties of the pharmacists practicing in the institutional pharmacy include, but are not limited to, the requirements in this section.

(b) The pharmacist practicing in an institutional pharmacy shall, at a minimum, do the following:
(1) Obtain and maintain patient drug histories and drug profiles.
(2) Perform drug evaluations, drug utilization review, drug regimen review, and drug therapy management under protocol approved by the medical staff of the institution and authorized by IC 25-26-16.
(3) Interpret the drug order written by a practitioner in or transmitted to an institutional facility and either received in or subsequently transmitted to the pharmacy.
(4) Be responsible for checking all drug orders within a maximum of twenty-four (24) hours, including those written during periods when the pharmacy is closed and orders are filled from sources, including emergency kits, drug cabinets, or the pharmacy as authorized under section 8(c) of this rule.
(5) Be responsible for drug product selection of the item that will be used to fill the drug order that may be established either by policy or formulary pursuant to the institution's pharmacy and therapeutics committee or related committee.
(6) Be responsible for determining the legality, completeness, and appropriateness of the drug order and product pursuant to IC 16-42-19-3.
(7) Participate in drug or drug-related research.
(8) Provide counseling, advising, and education of patients, patients' care givers, and health care providers and professionals on issues regarding drugs or drug therapy.
(9) Compound, label, administer, and dispense drugs or devices.
(10) Assess, record, and report quality related events as defined in this rule.
(11) Be responsible for storage and distribution of drugs and devices.
(12) Provide documentation in the medical record of the recommendations made related to the patient's therapeutic response to medication.
(13) Any other duties that shall from time to time be necessary for the proper operation of the institutional pharmacy.

(c) The consultant pharmacist shall, in addition to the duties in subsection (b), provide cognitive services as defined in this rule, including, at a minimum, the following:
(1) Drug regimen reviews as defined in IC 25-26-13-2.

(2) Offer advice and counsel to other health care providers as deemed appropriate regarding the pharmaceutical care of the patient.

(3) Develop or assist in the development of policies and procedures for the legal, safe, and effective means of handling, storing, and disposing of drugs and devices.

(4) Be responsible for assuring the safe and appropriate receipt, labeling, storage, and disposal of all drugs placed outside the pharmacy licensed area in emergency drug kits or other storage devices as authorized by law or rule.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-7)

856 IAC 1-28.1-8 Absence of pharmacist

Authority: IC 26-26-13-4

Affected: IC 25-26-13-17

Sec. 8. (a) During such times as an institutional pharmacy is closed and unattended by a pharmacist, the drugs may be obtained for patient use as outlined in this section.

(b) Cabinets, including mechanical storage devices for dispensing drugs, are locked or secured enclosures located outside the pharmacy licensed area, to which only specifically authorized personnel may obtain access by key, combination, or security code, password, or other method of positively identifying an individual, and are sufficiently secure to deny access to unauthorized persons. The qualifying pharmacist and/or pharmacist in charge shall, in conjunction with the appropriate committee of the institutional facility, develop inventory listings of the drugs to be included in such cabinets and shall ensure the following:

(1) Such listed drugs, properly labeled, are available therein.

(2) Only prepackaged drugs (meaning that no repackaging is required at the time of removal for an individual patient's use) are available therein, in amounts sufficient for immediate therapeutic requirements for a period not to exceed twenty-four (24) hours.

(3) When drugs are used, a record is made to include a written physician's order or accountability record.

(4) All drugs therein are reviewed by a pharmacist upon return to duty, not to exceed twenty-four (24) hours.

(5) There are written policies, procedures, and forms established to implement the requirements of this subsection.

(c) Whenever any drug is not available from floor supplies or cabinets, as defined in this section, and such drug is required to treat the immediate needs of a patient, such drug may be obtained from the pharmacy in accordance with the requirements of this subsection. One (1) supervisory licensed nurse in any given shift may have access to the pharmacy and may remove drugs therefrom. The qualifying pharmacist shall require that the removal of any drug from the pharmacy by an authorized nurse be recorded on a suitable form, which includes the name of the drug, strength, amount, date, time, and signature of nurse, and that a copy of the order shall be left with the form.

(d) Requirements for hospital emergency drug boxes, drug carts, emergency kits, emergency drug kits, crash carts, drug kits, or other storage method for emergency drugs are as follows:

(1) Pharmacy policy and procedures shall assure the:

(A) availability;

(B) control; and

(C) security;

of emergency drug carts, drug kits, or drug boxes in the pharmacy and patient care areas.

(2) Procedures shall include the following:

(A) Determination of drugs and quantities of drugs to be included.

(B) Labeling for expiration date.

(C) Process for restocking the cart, kit, or box.

(D) Security measures to prevent unauthorized access.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-8)

856 IAC 1-28.1-9 Emergency drug kits from Type III and Type VI pharmacies

Authority: IC 26-26-13-4

Affected: IC 25-26-13-17; IC 35-38

Sec. 9. (a) Emergency drug kits supplied by pharmacies with a Type III or Type VI permit shall be in compliance with this

section.

(b) All drugs in the emergency kit shall be provided and owned by a single supplying pharmacy.

(c) All drugs in the emergency drug kit shall be selected and approved by a committee whose membership includes, at a minimum, the following:
(1) The facility's consultant pharmacist.
(2) A licensed nurse.
(3) A physician (medical doctor or doctor of osteopathy).
(4) The facility administrator.

(d) The selection process must identify drugs and quantities thereof in the emergency drug kit.

(e) The lists of drugs and quantities included in the emergency drug kit shall be reviewed as required periodically, but no less often than yearly.

(f) Labeling as follows:
(1) The exterior labeling of the emergency drug kit as described in this subsection shall contain, at a minimum, the following:
(A) Drug name (trade name, generic name, or active ingredients).
(B) Drug strength or size, if any.
(C) Quantity included therein.
(D) Expiration date of the kit as defined in this section.
(2) All drugs contained in the emergency drug kit as described in this section shall be labeled, at a minimum, with the following:
(A) Drug name (trade name, generic name, or active ingredients).
(B) Drug strength or size, if applicable.
(C) Name of the manufacturer, packer, or distributor.
(D) Lot number.
(E) Expiration date.

(g) The expiration date of the emergency drug kit, as required in subsection (f)(1)(D) shall be the earliest date of expiration of any of the drugs included in the kit at any time.

(h) All emergency kits subject to this subsection:
(1) shall be stored in a secure area, suitable for the prevention of unauthorized access to or diversion of the drugs therein;
(2) if controlled substances, as defined in IC 35-38, are stored in such a manner as to facilitate periodic reconciliation by the facility nursing staff, that reconciliation shall be recorded in an appropriate manner as determined by the committee described under this section; and
(3) all controlled substances contained in emergency drug kits shall remain the property of the supplying pharmacy and as such shall be included in the pharmacy's biennial inventory as required by 21 CFR 1303.04 and 21 CFR 1301.11.

(i) The nurse responsible for removing drugs from an emergency drug kit shall record or cause to be recorded, in a manner designated under subsection (h)(2), the following minimum information:
(1) Name of the patient.
(2) Name of the drug.
(3) Strength of the drug.
(4) Quantity removed.
(5) Date of removal.
(6) Time of removal.

(j) Removal of a controlled substance in Schedule II pursuant to an oral authorization from a practitioner shall be documented and the nurse accepting such authorization is responsible for compliance with 856 IAC 2-6-7 regarding prescription requirements for controlled substances in Schedule II.

(k) Removal of a controlled substance in Schedule III, IV, or V, pursuant to an oral authorization from a practitioner shall be documented and the nurse accepting such authorization is responsible for compliance with 856 IAC 2-6-12.

(l) Whenever an emergency kit is opened, for any reason, the supplying pharmacy shall be notified in a timely manner and the pharmacy shall restock if necessary, and reseal the kit promptly so as to prevent risk of harm to patients of the facility. *(Indiana Board of Pharmacy; 856 IAC 1-28.1-9)*

856 IAC 1-28.1-10 Security
Authority: IC 26-26-13-4
Affected: IC 25-26-13-17

Sec. 10. The pharmacy shall be capable of being secured against entry by key, combination, code, password, or other method developed that can positively identify an individual so as to prevent access by unauthorized personnel. *(Indiana Board of Pharmacy; 856 IAC 1-28.1-10)*

856 IAC 1-28.1-11 Performance improvement events, sentinel events, corrective and avoidance measures, review, records, and documentation
Authority: IC 26-26-13-4
Affected: IC 25-26-13-17

Sec. 11. (a) The pharmacist in charge shall, as a part of the pharmacy's performance improvement program, assure or be responsible for assuring that data are collected to:
(1) monitor the stability of existing medication use processes;
(2) identify opportunities for improvement; and
(3) identify changes that will lead to and sustain improvement.

(b) Identification of quality related or sentinel event as defined in section 1 of this rule shall be cause for:
(1) an intensive analysis of causal factors involved in the event; and
(2) plans for corrective actions.

(c) Records of all processes, analysis, and corrective measures instituted involving such pharmacy quality related or sentinel event shall be maintained for a period of not less than two (2) years.

(d) The committee created under section 5(c)(1) of this rule shall, at a minimum, consider the effects on quality of the pharmacy system due to the following:
(1) Staffing levels of both professional and technical personnel.
(2) Workflow.
(3) Use of technology.

(e) Requirements for documentation of performance improvement monitoring of medication use processes, confidentiality of records, summarization, and examination by the board shall be as follows:
(1) Each quality related or sentinel event that occurs, or is alleged to have occurred, as the result of activities involving pharmacy operations, shall be documented in a written or electronic storage record created solely for that purpose.
(2) The quality related or sentinel event shall be:
(A) initially documented by the pharmacist to whom it is first described; and
(B) recorded on the same day of its having been so described to the pharmacist.
(3) Documentation shall include a description of the event that is of sufficient detail to permit analysis of the event.
(4) The pharmacist in charge shall summarize, or cause to be summarized, efforts to improve the medication use process on a semiannual basis.
(5) No patient names or employee names shall be included in this summary report.
(6) This report shall be maintained for a period of not less than two (2) years.
(7) The records created and maintained as a component of a pharmacy performance improvement program are confidential to the extent law permits. However, to assure compliance, the board or its representative may review the policies and procedures manual and a summarization of events described in subsection (b).
(Indiana Board of Pharmacy; 856 IAC 1-28.1-11)

856 IAC 1-28.1-12 Drug distribution, storage, and accountability

Authority: IC 26-26-13-4

Affected: IC 25-26-13-17

Sec. 12. (a) All drugs and devices in pharmacies located within institutions shall be obtained and used in accordance with written policies and procedures that have been prepared or approved by the qualifying pharmacist or pharmacist in charge, and the medical staff who explain the:

(1) selection;

(2) distribution;

(3) storage; and

(4) safe and effective use of:

(A) drugs;

(B) new drugs;

(C) investigational new drugs; and

(D) devices;

in the facility.

(b) The pharmacist in charge of the pharmacy located within an institution shall be responsible for the following:

(1) The safe and efficient:

(A) distribution;

(B) control;

(C) storage; and

(D) accountability;

for all drugs and devices.

(2) The compliance with all applicable Indiana and federal laws and rules.

(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, or both.

(C) Strength if applicable.

(D) Route of administration.

(E) Quantity.

(F) Pharmacist's initials.

(G) Location of the patient within the institution.

(2) Unit-of-use packages shall contain information to adequately label them, at a minimum, as follows:

(A) Drug name (brand or generic, or both).

(B) Strength, if applicable.

(C) Control number and/or expiration date.

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

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

(B) Date and identifying serial number.

(C) Name of patient.

(D) Name of drug and strength (if applicable).

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

(F) Name of prescribing practitioner.

(G) Precautionary information if any contained in the prescription.

(d) Requirements for the disposition of discontinued or recalled drugs are as follows:

(1) The qualifying pharmacist or pharmacist in charge shall be responsible for the development and implementation of policies and procedures for the return to the pharmacy of drugs and containers that are:

(A) discontinued, outdated, or recalled; or

(B) in containers with worn, illegible, or missing labels;

for proper disposition.
(2) The qualifying pharmacist or pharmacist in charge or his or her designee shall make proper disposition of such drugs at the storage site.

(e) The qualifying pharmacist or pharmacist in charge shall ensure that drugs are dispensed from the institutional pharmacy only upon authorized practitioner's:
(1) written orders;
(2) direct copies;
(3) facsimiles thereof; or
(4) electronically transmitted by other means and printed or displayed appropriately.

(f) Accountability requirements are as follows:
(1) The qualifying pharmacist or pharmacist in charge of an institutional pharmacy shall ensure that policies and procedures documenting the trail of:
(A) controlled substances; and
(B) such other drugs as may be specified by the appropriate committee of the institutional facility, from ordering and receiving by the pharmacy through administration or wastage of drug at the patient level.
(2) The qualifying pharmacist or pharmacist in charge shall be responsible for review of this process on a continual basis by review of:
(A) proofs-of-use documentation; or
(B) other electronic documentation methodology.
(3) At a minimum, the documentation process shall be able to identify the following:
(A) The name of the drug.
(B) The dose.
(C) The patient's name.
(D) The date and time of administration to the patient.
(E) The identification of the individual administering.
(F) The record of aliquot portion destroyed, if any, and identification of witness.

(g) All records and reports that are required for pharmacy functions shall be maintained according to policies and procedures developed within the institution with the approval of the pharmacist in charge, for a period of not less than two (2) years. *(Indiana Board of Pharmacy; 856 IAC 1-28.1-12)*

856 IAC 1-28.1-13 Drug self-administration
Authority: IC 26-26-13-4
Affected: IC 25-26-13-17

Sec. 13. Self-administration of drugs by patients of an institutional facility shall be permitted only if such use is specifically authorized by the treating or ordering physician and:
(1) the patient's knowledge of self-administration has been evaluated; or
(2) the patient has received training in the proper manner of self-administration:
(A) by a pharmacist; or
(B) according to hospital policy; and
(3) there is no risk of harm to the patient.
(Indiana Board of Pharmacy; 856 IAC 1-28.1-13)

856 IAC 1-28.1-14 Patient's own medication
Authority: IC 26-26-13-4
Affected: IC 25-26-13-17

Sec. 14. (a) An institutional pharmacy is prohibited from accepting and dispensing drugs that are brought into the institution by the patient, even if intended for use by that same patient. However, use of the patient's own medication may be permitted if:
(1) the patient or the patient's representative may maintain the patient's own medication:
(A) at the bedside; or

(B) for drugs with special storage requirements, including, but not limited to, refrigeration in an appropriate storage area in the patient care area under control of nursing personnel for appropriate administration to that patient only; and

(2) the nurses in charge of that patient's care shall witness the administration and maintain records of such use.

(b) If the patient or the patient's representative brings in medication part or all of which is still present at such time a patient expires, those drugs shall be delivered to the institutional pharmacy for appropriate destruction. Such drugs may not be turned over to the patient's representatives. This rule shall be made clear to the parties involved prior to the permission to use such medication. Patients who are discharged shall take with them their own medications brought to the institution under the terms of this section.

(c) In the event the patient is discharged and leaves drugs brought in under this section, either deliberately or inadvertently, such drugs shall be documented and stored at the appropriate nursing location for a maximum of seven (7) calendar days. If not claimed by the patient or the patient's agent within those seven (7) calendar days, the drugs so stored shall be destroyed as described in subsection (b). *(Indiana Board of Pharmacy; 856 IAC 1-28.1-14)*

856 IAC 1-28.1-15 Inspections

Authority: IC 26-26-13-4

Affected: IC 16-42-3-3; IC 25-26-13-17

Sec. 15. The qualifying pharmacist or pharmacist in charge shall be responsible for the timely inspection of all areas where drugs are stored, used, or administered. The inspection can be carried out by qualified designee and appropriate records kept. The inspection shall verify, at a minimum, the following:

(1) Disinfectants and drugs solely for nontherapeutic external use are stored separately and apart from drugs for internal use or injection.

(2) Drugs requiring special storage conditions are appropriately stored to assure the drugs are not adulterated as described in IC 16-42-3-3.

(3) Drugs subject to deterioration are removed from any accessible location prior to the expiration date (manufacturer's or other such as required under 856 IAC 1-21) and disposed of appropriately.

(4) Emergency drugs designated by the institution are in adequate supply and are properly stored in the institution.

(5) All necessary and required security and storage standards are met.

(6) All pharmacy-related policies and procedures of the institution are complied with.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-15)

Questions or comments on the readoption may be directed by mail to the Indiana Board of Pharmacy, 402 West Washington Street, Room W041, Indianapolis, Indiana 46204 or by electronic mail to mbina@hpb.state.in.us. Statutory authority: IC 25-26-15-13.

Notice of Public Hearing

Under IC 4-22-2-24 and IC 4-22-2.5-3, notice is hereby given that on June 11, 2001 at 10:00 a.m., at the Indiana Government Center-South, 402 West Washington Street, Conference Center Room C, Indianapolis, Indiana the Indiana Board of Pharmacy will hold a public hearing to readopt rules.

Requests for any part of this readoption to be separate from this action must be made in writing within 30 days of this publication. Send written comments to:

Mark Bina, Director
Health Professions Bureau
402 West Washington Street, Room W041
Indianapolis, Indiana 46204
Mbina@hpb.state.in.us

Copies of these rules are now on file at the Indiana Government Center-South, 402 West Washington Street, Room W041 and Legislative Services Agency, One North Capitol, Suite 325, Indianapolis, Indiana and are open for public inspection.

Beth Anne Compton
Executive Director
Health Professions Bureau