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TITLE 856 INDIANA BOARD OF PHARMACY

LSA Document #00-323

DIGEST

Under IC 4-22-2.5-3, the Indiana Board of Pharmacy intends to readopt, repeal, and adopt rules in anticipation of IC 4-22-2.5, providing that all rules of the Indiana administrative agencies in force on December 31, 1995, expire on January 1, 2002. 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 UNDER IC 4-22-2.5-3, THE FOLLOWING ARE REPEALED: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 25-26-13-17

Sec. 1. In addition to the definitions in IC 25-26-13-2, the following definitions apply throughout this rule:
(1) "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.
(2) "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.
(3) "Institutional pharmacy" means that portion of an institutional facility where pharmacy is:
(A) practiced;
(B) 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

(C) licensed with the board pursuant to IC 25-26-13-17.

(4) "Performance improvement program" means a system of standards and procedures to identify and evaluate quality-related events and improve patient care.

(5) "Pharmacist in charge" means the pharmacist who is directing the activities of the institutional pharmacy and who is then responsible for:

(A) all activities of the institutional pharmacy; and

(B) meeting the requirements of IC 25-26-13, the rules of the board, and 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 does not have to be the qualifying pharmacist.

(6) "Policy and procedure manual" means a written document containing the following:

(A) The agreed-to institutional rules of operation and methodology for the effective delivery of pharmacy services.

(B) Provisions for the formation and constitution of a performance improvement committee.

(C) Provisions for the qualifying pharmacist or the pharmacist in charge or a designee of either to assure that the performance improvement committee conducts a review of quality-related or sentinel events.

(D) A process to record, measure, assess, and improve quality of patient care.

(E) A procedure for reviewing quality-related or sentinel events.

(7) "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 listed on the pharmacy permit granted under IC 25-26-13-17.

(8) "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 any of the following:

(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.

(vii) Clinical abuse and/or misuse.

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

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

(11) "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 practicing in a pharmacy located within an institutional facility as defined in section 1 of this rule. *(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 applies to pharmacies located within institutional facilities as defined in section 1 of this rule. *(Indiana*

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

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

Sec. 4. 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 1-28.1-4)*

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

Sec. 5. The pharmacist in charge shall develop or be responsible for the development of a policies and procedures manual which shall be of sufficient scope and detail that pharmacists practicing in the institutional pharmacy will be able to practice effectively and safely. The manual required in this section shall be available for inspection by a member of the board or its representative. 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, pharmacists, pharmacist interns or externs, pharmacy technicians, clerical or support staff, and 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 Pharmacist's duties
Authority: IC 26-26-13-4
Affected: IC 25-26-13-17; IC 25-26-13-31; IC 25-26-16; IC 15-42-19-3

Sec. 6. Pursuant to authority granted in IC 25-26-13-31, the duties of the pharmacists practicing in the institutional pharmacy may include 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) Responsibility for drug product selection of the item that will be used to fill the drug order. Drug product selection may be established either by policy or formulary pursuant to the institution's pharmacy and therapeutics committee or related committee.
(5) Responsibility for determining the legality, completeness, and appropriateness of the drug order and product pursuant to IC 16-42-19-3.
(6) Participate in drug or drug-related research.
(7) Provide counseling, advising, and education of patients, patients' care givers, and health care providers and professionals on issues regarding drugs or drug therapy.
(8) Compound, label, administer, and dispense drugs or devices.
(9) Assess, record, and report quality-related events as defined in this rule.
(10) Responsibility for storage and distribution of drugs and devices.
(11) Any other duties that shall from time to time be necessary for the proper operation of the Institutional pharmacy.
(12) Provide documentation in the medical record of the recommendations made related to the patient's therapeutic response to medication.
(Indiana Board of Pharmacy; 856 IAC 1-28.1-6)

856 IAC 1-28.1-7 Absence of pharmacist

Authority: IC 26-26-13-4
Affected: IC 25-26-13-17

Sec. 7. 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 subsections (b) and (c).

(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 pharmacy manager 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. *(Indiana Board of Pharmacy; 856 IAC 1-28.1-7)*

856 IAC 1-28.1-8 Security
Authority: IC 26-26-13-4
Affected: IC 25-26-13-17

Sec. 8. 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 1-28.1-8)*

856 IAC 1-28.1-9 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. 9. (a) The pharmacist in charge shall, as a part of the pharmacy's performance improvement program:

(1) assure or be responsible for assuring that data are collected to monitor the effectiveness of existing medication use processes;

(2) monitor for sentinel and quality-related events; and

(3) identify opportunities for improvement, 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 an intensive analysis of causal factors involved in the event and plans for corrective actions. 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.

(c) The committee created under section 5(a) of this rule shall, at a minimum, consider the effects on quality of the pharmacy system due to staffing levels of both professional and technical personnel, workflow, and use of technology.

(d) 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. The quality-related or sentinel event shall be initially documented by the pharmacist to whom it is first described, and shall be recorded on the same day of its having been so described to the pharmacist. Documentation shall include a description of the event that is of sufficient detail to permit analysis of the event. Pharmacists shall summarize efforts to improve the medication use process on a semiannual basis. No patient names or employee names shall be included in this summary report. This report shall be maintained for a period of not less than two (2) years. 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 (d). *(Indiana Board of Pharmacy; 856 IAC 1-28.1-9)*

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

Sec. 10. (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 pharmacist in charge, and the medical staff, and deal with the selection, distribution, storage, and safe and effective use of drugs, new drugs, investigational new drugs, and 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.
(C) Strength.
(D) Location.
(2) Unit-of-use packages shall contain information to adequately label them, at a minimum, the drug:
(A) name (brand or generic);
(B) strength;
(C) control number; and
(D) expiration date.
(3) All drugs dispensed from an institutional pharmacy to patients about to be discharged, or temporarily discharged, from institutions, shall be labeled with the following minimum information:
(A) Name, address, and telephone number of the institutional pharmacy.
(B) Date.
(C) Name of patient or patient identifier.
(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.

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

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

(f) The pharmacist in charge of an institutional pharmacy shall ensure that policies and procedures documenting the trail of controlled substances, and 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. The pharmacist in charge 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 shall be able to identify the following:

(1) The name of 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 witness.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-10)

856 IAC 1-28.1-11 Drug self-administration
Authority: IC 26-26-13-4
Affected: IC 25-26-13-17

Sec. 11. Self-administration of drugs by patients of an institutional facility shall be permitted only when specifically authorized by the treating or ordering physician, provided, however, the patient's knowledge of self-administration has been evaluated or patient has received training in the proper manner of self-administration by a pharmacist, or according to hospital policy, and there is no risk of harm to the patient. *(Indiana Board of Pharmacy; 856 IAC 1-28.1-11)*

856 IAC 1-28.1-12 Hospital emergency drug kits
Authority: IC 26-26-13-4
Affected: IC 25-26-13-17

Sec. 12. Pharmacy policy and procedures shall assure the availability, control, and security of emergency drug carts, drug kits, or drug boxes in the pharmacy and patient care areas. Procedures shall include the following:

(1) Determination of drugs and quantities of drugs to be included.
(2) Labeling for expiration date.
(3) Process for restocking the cart, kit, or box.
(4) Security measures to prevent unauthorized access.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-12)

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

Sec. 13. 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, the patient or the patient's representative may maintain the patient's own medication at the bedside for appropriate administration to that patient only. The nurses in charge of that patient's care shall witness the administration and maintain records of such use. 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. At time of discharge, patients shall take with them their own medications brought to the institution under the terms of this section. *(Indiana Board of Pharmacy; 856 IAC 1-28.1-13)*

856 IAC 1-28.1-14 Inspections

Authority: IC 26-26-13-4
Affected: IC 25-26-13-17

Sec. 14. The 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 that the drugs are not adulterated.

(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 appropriately disposed of.

(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 1-28.1-14)

Notice of Public Hearing

Under IC 4-22-2-24 and IC 4-22-2.5-4, notice is hereby given that on April 9, 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 on 856 IAC 1-28.1.

Requests for any part of rule readoptions of 856 IAC 1-7-1, 856 IAC 1-7-2, 856 IAC 1-7-3, and 856 IAC 1-7-4 to be separate from this action must be made in writing within 30 days of this publication. Send written comments to:

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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
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