

1 BOARDS AND COMMISSIONS

2 Board of Pharmacy

3 (Amendment)

4 201 KAR 2:074. Pharmacy services in hospitals.

5 RELATES TO: KRS 315.010, 315.020, 315.030, 315.121

6 STATUTORY AUTHORITY: KRS 315.002, KRS 315.005, KRS 315.191(1)

7 CERTIFICATION STATEMENT: This is to certify that this administrative regulation complies
8 with 2025 RS HB 6, Section 8.

9 NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1) authorizes the Kentucky Board
10 of Pharmacy to establish requirements to regulate and control pharmacies. KRS 315.002
11 and 315.005 require standards of practice in all settings where drugs are handled and
12 requires the board to ensure the safety of all drug products provided to the citizens of
13 Kentucky. This administrative regulation establishes requirements for pharmacy services in
14 hospitals.

15 Section 1. Definitions.

16 1) "Automated pharmacy system" means a mechanical system that performs operations or
17 activities, other than compounding or administration, relative to the storage, packaging,
18 counting, labeling, and dispensing of medications, and which collects, controls, and
19 maintains all transaction information and shall be either:

(1) "Automated pharmacy system" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications, and which collects, controls, and maintains all transaction information and shall be either:

(a) A decentralized automated pharmacy system that is located outside the pharmacy department, but within the same institution, and under the supervision of a pharmacist; or

(b) A centralized automated pharmacy system from which medications are prepared for final distribution that require the approval of a pharmacist.

(2) "Institutional pharmacy" means:

(a) A pharmacy in an acute care hospital licensed pursuant to 902 KAR 20:016; or

(b) An onsite pharmacy serving an infusion center where medication is administered.

(3) "Investigational drug" means a drug that has not been approved for use in the United States, but for which an investigational drug application has been approved by the FDA.

(4) "Unit dose distribution" means a system in which drug therapy profiles are maintained in the pharmacy and doses are scheduled, prepared, and delivered in a ready-to-administer form to the patient care area as the doses are needed.

(5) "Within the same institution" means a location that is not separated from the primary hospital facility by other commercial or residential property.

Section 2. Pharmacy Administration.

(1) General.

1 (a) The pharmacy, organized as a separate department or service, shall be directed by a
2 pharmacist, who shall be thoroughly knowledgeable about institutional pharmacy
3 practice and management.

4 (b) The director of pharmacy services shall be responsible for departmental management
5 and the development and implementation of goals and objectives to meet the needs of
6 the institution and shall be responsible to the chief executive officer of the institution or
7 the chief executive officer's designee.

8 (c) If the director of pharmacy services is not employed full time, the institution shall
9 establish an ongoing arrangement in writing with a pharmacist to provide services
10 required by this administrative regulation and KRS 315.020(1).

11 (d) If a hospital pharmacy is decentralized, each decentralized section or separate
12 organizational element shall be under the immediate supervision of a pharmacist
13 responsible to the director of pharmacy services.

14 (2) Pharmacy personnel.

15 (a) The institutional pharmacy shall maintain additional pharmacists in cooperation with
16 the institution's administration, either full time or part time, as required to operate safely
17 and effectively to meet the needs of the patients.

18 (b) If nonpharmacist personnel are employed, nonpharmacist personnel shall perform all
19 duties under the supervision of a pharmacist and shall not be assigned and shall not
20 perform duties that are to be performed only by a pharmacist.

21 (3) Responsibilities.

22 (a)

1 1. Lines of authority and areas of responsibility within the pharmacy shall be clearly
2 defined.

3 2. Written job descriptions for all categories of pharmacy personnel shall be prepared
4 and revised as necessary.

5 (b)

6 1. There shall be policies and procedures to provide for selection of drugs as well as a
7 distribution system to serve the needs of the patient.

8 2. Provision for procurement of drugs in an emergency situation shall be provided for.

9 (4) Supportive personnel.

10 (a) Sufficient supportive personnel (technical, clerical, and other) shall be available in
11 order to optimize the participation of pharmacists in activities requiring professional
12 judgment.

13 (b) The training and supervision of supportive personnel shall be the responsibility of the
14 pharmacist.

15 (5) Availability.

16 (a) The services of a pharmacist shall be available continuously. If around-the-clock
17 operation of the pharmacy is not feasible, the pharmacist shall be available on an on-call
18 basis, and an adequate night drug cabinet shall be established. The pharmacy itself shall
19 not be designated as the night drug cabinet.

20 (b) A hospital not having a full-time pharmacist, but in which drugs are prepackaged or
21 relabeled or transferred from one (1) container to another, shall obtain a pharmacy permit

and have at least a part-time pharmacist designated to perform those functions or to provide personal supervision of those functions.

Section 3. Physical Facility.

(1) The institutional pharmacy shall have adequate space, equipment, and supplies sufficient to provide for safe and efficient drug storage, preparation, and distribution, patient education and consultation, drug information services, and proper management of the department.

(2) Legal requirements. The physical facility shall meet state and federal regulations and shall be accessible by authorized pharmacy personnel only.

(3)

(a) A currently licensed hospital shall be exempt from the provisions of subsection (2) of this section if it:

1. Is authorized by the Department for Health and Human Services to provide pharmacy services; and

2. Does not currently possess a pharmacy permit.

(b) A currently licensed hospital exempt from the provisions of subsection (2) of this section shall permit access by authorized personnel only.

(4) Location. Locked storage or locked medication carts shall be provided for use in each nursing unit or service area.

(5) Reference materials. The pharmacy shall have current pharmaceutical reference materials in accordance with 201 KAR 2:090. References related to the following subjects shall also be available:

- (a) Drug identification;
- (b) Toxicology;
- (c) Drug interactions;
- (d) Parenteral drug compatibility; and
- (e) Microbiology.

Section 4. Drug Distribution and Control.

(1) General. The institutional pharmacy shall be responsible for the procurement, distribution, and control of all drugs and parenteral solutions used within the institution. Policies and procedures governing these functions shall be developed by the pharmacist with input from other involved hospital, or infusion center, staff (for example, nurses) and committees (for example, pharmacy and therapeutics committee and patient care committee).

(2) Dispensing. The pharmacist shall dispense medications only on the order of a licensed medical practitioner.

(3) Prescriber's order. The pharmacist shall review the medication order.

(4) Recordkeeping. The pharmacist shall maintain appropriate records of each medication order. The records shall be retained for the time and in the manner prescribed by state and federal law.

(5) Patient medication profile. A medication profile shall be maintained for all inpatients and for those ambulatory patients routinely receiving care at the institution. The pharmacist shall utilize this profile to properly review, schedule, prepare, and distribute medications except in an emergency situation.

1 (6) Labeling and packaging.

2 (a) Each licensee shall comply with U.S.P. Standards established pursuant to federal law
3 and all state and federal laws and regulations regarding labeling and packaging.

4 (b) Labeling and packaging of medications used for outpatients shall meet the
5 requirements of state and federal law.

6 (7) Dispensing. The pharmacist shall dispense medications by the unit dose distribution
7 system if feasible. If the unit dose distribution system is not utilized, adequate safeguards
8 shall be in place to protect patients.

9 (8) Stop orders. There shall be established written stop order policies or other methods of
10 assuring that drug orders are not continued inappropriately in accordance with the status
11 of the patient.

12 (9) Administration.

13 (a) Drugs shall be administered only upon order of a licensed medical practitioner.

14 (b) The institutional pharmacy shall participate in the establishment of policies and
15 procedures regarding the administration of medications. Specific procedures shall be
16 developed in cooperation with appropriate hospital, infusion center, or other health care
17 facility personnel and shall include personnel authorized to schedule, prepare, and
18 administer medications.

19 (10)

20 (a) Unused medication. The institutional pharmacy shall establish policies and
21 procedures for the disposition of patients' unused medications.

(b) Medication in unit dose form may be reissued if package integrity has been maintained and the product has not expired.

(11) Hospital floor stocks.

(a) Floor stocks of drugs shall be kept as small as possible. The pharmacist in charge shall be responsible for authenticating the need for floor stock.

(b) A pharmacist shall review all orders distributed through floor stock.

(c) The pharmacist in charge shall be responsible for defining those areas of the hospital requiring floor stock (for example, emergency room, surgery, critical care, or medical or surgical wards).

(d) All drug storage areas within the hospital shall be routinely inspected by pharmacy personnel at least monthly, and documentation shall be maintained to ensure that:

1. Unusable items shall not be present; and

2. All stock items shall be properly labeled and stored.

(e) This subsection shall apply to infusion centers where medications are administered with an onsite pharmacy.

(12) Drug recall. There shall be a system for removing from use a drug that has been recalled.

(13) Sample medications. The institutional pharmacy shall establish policies and procedures regarding medical representatives and the obtaining, storage, and dispensing of complimentary packages of medications.

(14) Emergency drugs.

(a) The institutional pharmacy shall establish policies and procedures for supplying emergency drugs.

(b) For expediency and efficiency, emergency drugs shall be limited in number to include only those whose prompt use and immediate availability are generally regarded by physicians as essential in the proper treatment of sudden and unforeseen patient emergencies.

(c) Emergency stocks shall be routinely inspected by pharmacy personnel on a monthly basis and documentation maintained to determine if contents have become outdated and if the stocks are being maintained at adequate levels.

(15) Investigational drugs.

(a) Policies and procedures controlling the use of investigational drugs (if used in the institution) shall be developed and followed.

(b) The pharmacy shall be responsible for storing, packaging, labeling, distributing, maintaining inventory records (including lot numbers and expiration date), and providing information about investigational drugs (including proper disposal).

(16) Controlled substances. All permit holders shall comply with state and federal laws regarding controlled substances.

(17) Compounding. Compounding at a location that is not within the same institution shall require a separate pharmacy permit.

Section 5. Assuring Rational Drug Therapy.

(1) Appropriate clinical information about patients shall be available and accessible to the pharmacist for use in daily practice activities.

(2) The pharmacist shall be a member of the pharmacy and therapeutics committee and any other committees where input concerning the use of drugs is required.

(3) The pharmacist shall provide a means to ensure that patients receive adequate information about the drugs they receive. Patient education activities shall be in coordination with the nursing and medical staffs and patient education department, if any.

Section 6. Responsibility. The pharmacist-in-charge of a pharmacy utilizing an automated pharmacy system shall be responsible for:

(1) An initial validation of system accuracy prior to use for distribution to patients;

(2) Ensuring the system:

(a) Is properly maintained;

(b) Is in good working order;

(c) Accurately dispenses the correct strength, dosage form, and quantity of drug prescribed; and

(d) Complies with the recordkeeping, access, and security safeguards pursuant to all applicable state and federal laws;

(3) Assuring medications are reviewed prior to loading into an automated pharmacy system and distribution;

(4) Implementing an ongoing quality assurance program that monitors performance of the pharmacy compounding robotics, which is evidenced by written policies and procedures and requires a continued documented validation of doses distributed on a routine basis and annual review of the quality assurance program;

(5) Establishing policies and procedures if there is a system failure of an automated pharmacy system;

(6) Providing the board with prior written notice of installation or removal of an automated pharmacy system. This notification shall include the:

(a) Name and address of the pharmacy; and

(b) Initial location of the automated pharmacy system;

(7) Oversight for assigning, discontinuing, or changing personnel access to the system, including establishment of written policies and procedures for security and control;

(8) Reviewing personnel access on at least an annual basis;

(9) Assuring that the decentralized automated pharmacy system stock is checked at least monthly in accordance with established policies and procedures, including checking for:

(a) Accuracy;

(b) Integrity of packaging; and

(c) Expiration dates;

(10) Maintaining in the pharmacy the following documentation relating to an automated pharmacy system:

(a) The name and address of the pharmacy or inpatient health care facility where the system is being used;

(b) The automated pharmacy system manufacturer's name, model, serial number, and software version;

(c) A description of how the system is used;

(d) Written quality assurance procedures and accompanying documentation of use to determine continued appropriate use of the system as established in subsections (7) and (8) of this section; and

(e) Written policies and procedures for system operation, safety, security, accuracy, emergency medication access, access, and malfunction which includes clearly defined down time and procedures;

(11) Maintaining adequate security systems and procedures, evidenced by written policies and procedures to:

(a) Prevent unauthorized access;

(b) Maintain patient confidentiality;

(c) Allow user access modification; and

(d) Comply with federal and state laws; and

(12) Maintaining in the pharmacy a current list of all locations where automated pharmacy systems are located and providing the list to the board upon request.

Section 7. Standards.

(1)

(a) All events involving the contents of the automated pharmacy system shall be recorded electronically.

(b) Records shall be maintained by the pharmacy and be available to the board and shall include the following:

1. The date, time, and location of the system accessed;

2. Identification of the individual accessing the system;

3. Type of transaction;

4. Name, strength, dosage form, and quantity of drug accessed; and

5. Name of the patient for whom the drug was ordered, if applicable.

(2)

(a) All medications to be stocked into the centralized automated pharmacy system shall:

1. Have been previously validated by a machine readable identifier that meets established industry standards as approved by the board to ensure quality, performance, and safety; and

2. Be utilized by a pharmacist, pharmacist intern, or certified pharmacy technician.

(b) Integrity and accuracy shall be validated by a pharmacist.

(3) The stocking of medications in a decentralized automated pharmacy system utilizing a machine readable identifier that meets established industry standards as approved by the board to ensure quality, performance, and safety shall be done by a pharmacist, pharmacist intern, or a [certified] pharmacy technician.

(4) The stocking of medications in a decentralized automated pharmacy system without a machine readable identifier that meets established industry standards as approved by the board to ensure quality, performance, and safety shall be done by a pharmacist, pharmacist intern, or a certified pharmacy technician. Integrity and accuracy shall be validated by a pharmacist.

(5) If a hospital licensed pursuant to 902 KAR 20:016 utilizes technology that validates appropriate drug, dose, dosage form, route of administration, time of administration, and patient at the exact time of medication administration, the stocking of the decentralized

1 automated pharmacy system shall be done by a pharmacist, pharmacist intern, or
2 [~~certified~~] pharmacy technician.

3 (6) A record of medications stocked in an automated pharmacy system shall be maintained
4 for at least five (5) years and shall include:

5 (a) The name of the person repacking the medications; and

6 (b) Documentation of the pharmacist checking the medications.

7 (7) All containers of medications stored in the automated pharmacy system shall be
8 packaged and labeled in accordance with federal and state laws.

9 (8) The automated pharmacy system shall provide a mechanism for securing and
10 accounting for medications removed from and subsequently returned to the automated
11 pharmacy system, in accordance with federal and state laws.

12 (9) All medications initially received in the pharmacy for use in an automated pharmacy
13 system shall be quarantined until validation by a machine readable identifier that meets
14 established industry standards as approved by the board to ensure quality, performance,
15 safety, accuracy, and existence of the item in the database powering automated pharmacy
16 system by a certified pharmacy technician, pharmacist intern, or pharmacist.

17 (10) If a medication needs to be repackaged:

18 (a) A pharmacist, pharmacist intern, or certified pharmacy technician shall:

19 1. Perform the repackaging and validate the presence of an accurate machine readable
20 identifier that meets established industry standards as approved by the board to ensure
21 quality, performance, and safety on the unit dose packaging; and

22 2. Document the repackaging process including:

- a. Manufacturer;
- b. Date and time of repackaging;
- c. The person repackaging;
- d. The lot number or batch number;
- e. The expiration date; and
- f. The quantity repackaged; and

(b) A pharmacist shall:

1. Validate for accuracy and integrity prior to the addition to the automated pharmacy system; and
2. Document the validation including:
 - a. The date and time of the validation;
 - b. The name of the pharmacist validating;
 - c. The lot number or batch number;
 - d. The expiration date; and
 - e. The quantity validated.

(11) A medication returned to the pharmacy from a patient care area shall follow the processes established pursuant to Section 4(10) of this administrative regulation.

(12) A medication distributed by the centralized automated pharmacy system shall be distributed in the delivery device utilized by that system.

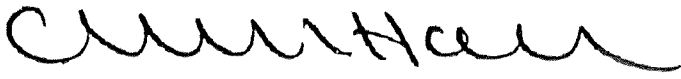
(13) A medication distributed by an automated pharmacy system shall be accessed and administered by a professional licensed to administer medications.

(14) A medication distributed by an automated pharmacy system shall not be dispensed.

1 (15) Board inspectors may inspect and investigate complaints regarding an automated
2 pharmacy system on all premises owned by the hospital where an automated pharmacy
3 system is located and supplied with medications purchased under the hospital's pharmacy
4 permit.

5 (16) All transfers of medications to automated pharmacy systems shall be in accordance
6 with federal and state laws.

APPROVED BY AGENCY:

A handwritten signature in black ink, appearing to read "Chris Harlow", written over a horizontal line.

Christopher Harlow, Executive Director

9/10/2026

Date

PUBLIC HEARING AND PUBLIC COMMENT PERIOD

A public hearing on this administrative regulation shall be held on November 30, 2026, at 10:00 a.m. EST via Zoom Meetings. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be cancelled. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through November 30, 2026. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

CONTACT PERSON: Christopher Harlow, Executive Director, Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, Frankfort, Kentucky 40601, phone (502) 564-7910, fax (502) 696-3806, email Christopher.harlow@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

201 KAR 2:074, Pharmacy Services in Hospitals

Contact person: Christopher Harlow

Contact Phone No.: 502-564-7910

Contact email: Christopher.harlow@ky.gov

Subject Headings: Pharmacy, Hospitals and Workforce Development

(1) Provide a brief summary of:

- (a) What this administrative regulation does: This administrative regulation establishes the standards for hospital pharmacies.
- (b) The necessity of this administrative regulation: KRS 315.191(1)(a) authorizes the Board of Pharmacy to promulgate administrative regulations.
- (c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation provides the criteria that the statute requests be provided in regulation.
- (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation provides the criteria that the statute requests be provided in regulation.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

- (a) How the amendment will change this existing administrative regulation: The amendment aligns this regulation with the proposed amendment for 201 KAR 2:045 which permits registered pharmacy technicians to stock or load an automated pharmacy system under the general supervision of a pharmacist, provided the system utilizes machine readable coding technology and so long as the activity occurs under the general supervision of a pharmacist.
- (b) The necessity of the amendment to this administrative regulation: This amendment is necessary to clarify the circumstances under which a registered pharmacy technician may perform specified inventory-related activities in an automated pharmacy system that uses machine readable coding within a hospital.
- (c) How the amendment conforms to the content of the authorizing statutes: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations pertaining to pharmacists and pharmacies.
- (d) How the amendment will assist in the effective administration of the statutes: The amendment provides further clarity on what registered pharmacy technicians can and cannot do within a hospital setting.

(3) Does this administrative regulation or amendment implement legislation from the previous five years? No.

(4) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The board anticipates hospital pharmacies and pharmacists will be minimally impacted by the amendments proposed here.

(5) Provide an analysis of how the entities identified in question (4) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (4) will have to take to comply with this administrative regulation or amendment:

Pharmacies and pharmacists will have to familiarize themselves with amended language. The board will help to educate pharmacists, pharmacy technicians and hospital pharmacies of these changes.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (4): There are no expected costs for the entities identified to comply with the amendment.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (4): This amendment assists hospital systems by allowing registered pharmacy technicians to participate in the stocking and loading of an automated pharmacy system under the general supervision of a pharmacist so long as the system includes machine-readable coding technology safeguards.

(6) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: No costs will be incurred.

(b) On a continuing basis: No costs will be incurred.

(7) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation or this amendment: Board revenues from pre-existing fees provide the funding for the implementation of the regulation.

(8) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding will be required because of this amendment.

(9) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation does not establish fees or directly or indirectly increase any fees.

(10) TIERING: Is tiering applied? Tiering is not applied because the regulation is applicable to all hospital pharmacies and registered pharmacy technicians that desire license transfer into the Commonwealth of Kentucky.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

201 KAR 2:074, Pharmacy Services in Hospitals

Contact person: Christopher Harlow

Contact Phone No.: 502-564-7910

Contact email: Christopher.harlow@ky.gov

(1) Identify each state statute, federal statute, or federal regulation that requires or authorizes the action taken by the administrative regulation: KRS 315.002, KRS 315.005, KRS 315.191(1)\

(2) State whether this administrative regulation is by an act of the General Assembly, and if so, identify the act: No.

(3)(a) Identify the promulgating agency and any other affected state units, parts or divisions: The promulgating agency is the Kentucky Board of Pharmacy.

(b) Estimate the following for each affected state unit, part or division identified in (3)(a): We do not anticipate any other state units to be impacted by this regulation.

1. Expenditures: N/A

For the first year: N/A

For subsequent years: N/A

2. Revenues

For the first year: N/A

For subsequent years: N/A

3. Cost Savings:

For the first year: N/A

For subsequent years: N/A

(4)(a) Identify any affected local entities (for example: cities, counties, fire departments, school districts): We do not anticipate any local entities to be impacted by this regulation.

(b) Estimate the following for each affected local entity identified in (4)(a):

1. Expenditures: N/A

For the first year: N/A

For subsequent years: N/A

2. Revenues

For the first year: N/A

For subsequent years: N/A

3. Cost Savings:

For the first year: N/A

For subsequent years: N/A

(5)(a) Identify any affected regulated entities not listed in (3)(a) or (4)(a): We do not anticipate any other affected regulated entities.

(b) Estimate the following for each regulated entity identified in (5)(a):

1. Expenditures: N/A

For the first year: N/A

For subsequent years: N/A

2. Revenues

For the first year: N/A

For subsequent years: N/A

3. Cost Savings:

For the first year: N/A

For subsequent years: N/A

(6) Provide a narrative to explain the following for each entity identified in (3)(a), (4)(a) and (5)(a):

(a) Fiscal impact of this administrative regulation: The amendment is not anticipated to result in additional costs to the Kentucky Board of Pharmacy, other state or local government entities, or regulated entities. The amendment permits, but does not require, registered pharmacy technicians to perform specified inventory-related activities under the general supervision of a pharmacist when machine-readable coding technology is utilized. Regulated entities may choose whether to utilize the additional flexibility provided by the amendment based upon their existing staffing, technology, and operational needs. To the extent regulated entities elect to utilize the provisions of the amendment, they may experience operational efficiencies or cost savings associated with the allocation of pharmacist and pharmacy technician personnel; however, any such savings vary by entity and cannot be reliably quantified.

(b) Methodology and resources used to reach this conclusion: The Board reviewed the nature and scope of the amendment, the existing requirements of 201 KAR 2:074, and the anticipated operational effect on hospital pharmacies and pharmacy personnel. Because the amendment authorizes additional flexibility in the supervision and utilization of registered pharmacy technicians but does not require regulated entities to purchase new equipment, employ additional personnel, modify existing automated pharmacy systems, or otherwise incur new expenditures, the Board does not anticipate an adverse fiscal impact. Any potential cost savings will depend upon the staffing structure, technology, and operational practices of individual regulated entities and therefore cannot be reasonably quantified.

(7) Explain, as it relates to the entities identified in (3)(a), (4)(a) and (5)(a):

(a) Whether this administrative regulation will have a “major economic impact” as defined in KRS 13A.010(13): No. The amendment is not anticipated to have a “major economic impact” as defined by KRS 13A.010(13). The amendment does not impose additional mandatory expenditures on state or local government or regulated entities and is not anticipated to result in an aggregate negative or adverse economic impact of \$500,000 or more.

(b) The methodology and resources used to reach this conclusion. The Board considered the scope of the amendment, the existing regulatory requirements applicable to hospital pharmacies, and the nature of the activities authorized by the amendment. The amendment is permissive and provides regulated entities with additional staffing and operational flexibility; it does not mandate the purchase or implementation of machine-

readable coding technology or require additional personnel, equipment, or expenditures. Because regulated entities may elect whether to utilize the additional flexibility provided by the amendment and no new mandatory costs are imposed, the Board determined that the amendment will not result in an aggregate negative or adverse economic impact meeting the threshold established in KRS 13A.010(13).