

Proposed Rule
LSA Document #07-590

DIGEST

Adds [856 IAC 5](#) to establish standards applicable to all pharmacies and facilities that utilize and rely on automation technology to store, package, dispense, and distribute prescriptions or medication orders and to define "automated medication system". Effective 30 days after filing with the Publisher.

[IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses](#)

[856 IAC 5](#)

SECTION 1. [856 IAC 5](#) IS ADDED TO READ AS FOLLOWS:

[856 IAC 5-1-1 Purpose and scope](#)

Authority: [IC 25-26-13-4](#)

Affected: [IC 25-26-13](#)

Sec. 1. This article establishes standards applicable to any:

(1) pharmacy holding a permit issued by the board; and

(2) facility subject to inspection by the board;

that utilizes automation technology to store, package, dispense, and distribute prescriptions or medication orders.

(Indiana Board of Pharmacy; [856 IAC 5-1-1](#))

[856 IAC 5-1-2 "Automated medication system" defined](#)

Authority: [IC 25-26-13-4](#)

Affected: [IC 25-26-13](#)

Sec. 2. (a) As used in this article, "automated medication system" means any technology assisted operation approved by the board that:

(1) relies on bar code or other automated technology to dispense and distribute medications; and

(2) records all transactions related to its operation.

(b) The term does not include automatic counting devices or unit-based dispensing cabinets utilized by a pharmacy or facility to automatically count medication for dispensing.

(Indiana Board of Pharmacy; [856 IAC 5-1-2](#))

[856 IAC 5-1-3 "Board" defined](#)

Authority: [IC 25-26-13-4](#)

Affected: [IC 25-26-13-3](#)

Sec. 3. As used in this rule, "board" means the Indiana board of pharmacy established under [IC 25-26-13-3](#).

(Indiana Board of Pharmacy; [856 IAC 5-1-3](#))

[856 IAC 5-1-4 "Operation" defined](#)

Authority: [IC 25-26-13-4](#)

Affected: [IC 25-26-13](#)

Sec. 4. As used in this article, "operation" means the storing, assembly, packing, dispensing, and distributing of drugs including the:

- (1) operability;**
- (2) integrity;**
- (3) maintenance;**
- (4) safety;**
- (5) security;**
- (6) confidentiality; and**
- (7) accuracy;**

of the automated process.

(Indiana Board of Pharmacy; [856 IAC 5-1-4](#))

[856 IAC 5-1-5](#) Authority to use automated medication system

Authority: [IC 25-26-13-4](#)

Affected: [IC 16-42-19-5](#); [IC 25-26-13](#); [IC 35-48](#)

Sec. 5. (a) A pharmacy or facility may use an automated medication system to fill prescriptions or medication orders provided that:

- (1) the qualifying pharmacist of the pharmacy or a practitioner as defined by [IC 16-42-19-5](#) is responsible for the operation of the automated medication system;**
- (2) the board:**
 - (A) conducts an inspection of the pharmacy or facility including an inspection of the automated medication system; and**
 - (B) approves the system; and**
- (3) the automated medication system is tested by the pharmacy or facility and found to dispense accurately. The pharmacy or facility shall make the results of such testing available to the board upon request.**

(b) The qualifying pharmacist or practitioner is responsible for the following:

- (1) Reviewing and approving all policies and procedures for system operation.**
- (2) Ensuring that:**
 - (A) medications in the automated medication system are inspected for expiration or use by date, misbranding, and physical integrity; and**
 - (B) the automated medication system is inspected monthly for security and accountability.**
- (3) Managing all personnel with access to the automated medication system.**
- (4) Ensuring that the automated medication system is stocked accurately and an accountability record is maintained in accordance with the written policies and procedures of operation.**
- (5) Providing the board with copies of records associated with the operation of the automated medication system upon request by the board.**
- (6) Ensuring compliance with all applicable provisions of:**
 - (A) [IC 25-26](#);**
 - (B) [IC 16-42](#);**
 - (C) [IC 35-48](#);**
 - (D) this title; and**
 - (E) 858 IAC.**

(Indiana Board of Pharmacy; [856 IAC 5-1-5](#))

[856 IAC 5-1-6](#) Written policies and procedures of operation

Authority: [IC 25-26-13-4](#)

Affected: [IC 25-26-13](#)

Sec. 6. (a) An automated medication system used to fill prescriptions or medication orders shall be operated according to the pharmacy's or facility's written policies and procedures of operation. The policies and procedures of operation shall:

(1) include a:

(A) table of contents; and

(B) description of all procedures of operation;

(2) set forth methods that record any revision of the policies and procedures for a minimum of two (2) years from the date of the revision. Any such revision must be approved by the qualifying pharmacist or practitioner by handwritten signature and date;

(3) set forth methods that ensure that a pharmacist currently licensed in the transmitting jurisdiction reviews and approves the transmission of each original or new prescription or medication order to the automated medication system before the transmission is made;

(4) set forth methods to protect patient confidentiality as required by state and federal law;

(5) set forth methods that ensure access to the system is limited to approved personnel with accountability for all access to the system; and

(6) identify the circumstances under which medications may be removed from the automated medication system by a licensed practitioner for distribution to a patient without prior order review by a registered pharmacist.

(b) A pharmacy or facility that uses an automated medication system to fill prescriptions or medication orders shall annually review its written policies and procedures of operation and revise them if necessary.

(c) A copy of the written policies and procedures of operation adopted under this section shall be retained at the pharmacy or facility where the automated medication system is utilized. The pharmacy or facility shall provide to the board a copy of the written policies and procedures of operation for inspection and review upon request by the board.

(Indiana Board of Pharmacy; [856 IAC 5-1-6](#))

[856 IAC 5-1-7](#) Personnel training requirements

Authority: [IC 25-26-13-4](#)

Affected: [IC 25-26-13](#)

Sec. 7. The qualifying pharmacist or practitioner shall be responsible for ensuring that all personnel with access to the automated medication system are trained in the pharmacy's or facility's written policies and procedures of operation prior to performing any automated medication system operations.

(Indiana Board of Pharmacy; [856 IAC 5-1-7](#))

[856 IAC 5-1-8](#) Written program for quality assurance

Authority: [IC 25-26-13-4](#)

Affected: [IC 25-26-13](#)

Sec. 8. A pharmacy or facility that uses an automated medication system to fill prescriptions or medication orders shall operate according to a written program for quality assurance of the automated medication system that:

(1) requires continuous monitoring of the automated medication system;

(2) establishes mechanisms and procedures to test the accuracy of the automated medication system biannually and upon any modification to the system including medications used within that system;

(3) establishes a protocol for measuring the effectiveness of the automated medication system; and

(4) requires the pharmacy or facility to:

(A) report to the board each recurring error of the automated medication system; and

(B) maintain all documentation relating to the written program for quality assurance for at least two (2) years.

(Indiana Board of Pharmacy; [856 IAC 5-1-8](#))

[856 IAC 5-1-9](#) Written plan for recovery

Authority: [IC 25-26-13-4](#)

Affected: [IC 25-26-13](#)

Sec. 9. A pharmacy or facility that uses an automated medication system to fill prescriptions or medication orders shall maintain a written plan for recovery from an emergency that interrupts the ability of the pharmacy or facility to provide services. The written plan for recovery shall include the following:

- (1) Planning and preparation for an emergency.**
 - (2) Procedures for response to an emergency.**
 - (3) Procedures for the maintenance and testing of the written plan for recovery.**
 - (4) A procedure to notify:**
 - (A) the board;**
 - (B) each organization that has contracted with the pharmacy or facility;**
 - (C) each patient of the pharmacy or facility; and**
 - (D) other appropriate agencies;**
- of an emergency and the date on which the pharmacy or facility expects to recommence the provision of service.**

(Indiana Board of Pharmacy; [856 IAC 5-1-9](#))

[856 IAC 5-1-10](#) Written program for preventative maintenance of automated medication system

Authority: [IC 25-26-13-4](#)

Affected: [IC 25-26-13](#)

Sec. 10. A pharmacy or facility that uses an automated medication system to fill prescriptions or medication orders shall maintain a written program for preventative maintenance of the system.

(Indiana Board of Pharmacy; [856 IAC 5-1-10](#))

[Notice of Public Hearing](#)

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