

Proposed Rule
LSA Document #07-541

DIGEST

Adds [856 IAC 4](#) to implement the requirements of P.L.94-2007, SECTION 5, to establish the qualifications, protocols, and record keeping requirements for a pharmacist to administer immunizations under [IC 25-26-13-31.2](#). Effective 30 days after filing with the Publisher.

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

[856 IAC 4](#)

SECTION 1. [856 IAC 4](#) IS ADDED TO READ AS FOLLOWS:

ARTICLE 4. PHARMACIST VACCINATIONS ADMINISTERED VIA PROTOCOL AUTHORITY

Rule 1. Pharmacist Vaccinations Administered via Protocol Authority

[856 IAC 4-1-1](#) Education and training

Authority: [IC 25-26-13-4](#); P.L.94-2007, SECTION 5

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

Sec. 1. (a) In order to qualify to administer immunizations, a pharmacist must successfully complete a course of training in immunization that is provided by an Accreditation Council for Pharmacy Education accredited provider and meets the standards set forth by:

- (1) the Centers for Disease Control and Prevention;**
- (2) a similar health authority; or**
- (3) a professional body approved by the Indiana board of pharmacy.**

(b) The pharmacist must:

- (1) be certified in cardiopulmonary resuscitation; and**
- (2) maintain certification as required by the certifying body.**

(c) Training must include study materials and hands-on training and techniques for administering vaccines, comply with CDC and the Office of Safety and Health Administration guidelines, and provide instruction and experiential training in the following content areas:

- (1) Mechanisms of action for the following:**
 - (A) Vaccines.**
 - (B) Contraindication.**
 - (C) Drug interaction.**
 - (D) Monitoring after vaccine administration.**
- (2) Standards for immunization practices.**
- (3) Basic immunology and vaccine protection.**
- (4) Vaccine-preventable diseases.**
- (5) Recommended immunization schedule.**
- (6) Vaccine storage management.**
- (7) Biohazard waste disposal and sterile techniques.**
- (8) Informed consent.**
- (9) Physiology and techniques for vaccine administration.**
- (10) Patient pre-vaccine and post-vaccine assessment and counseling.**
- (11) Immunization record management.**
- (12) Management of adverse events, including the following:**
 - (A) Identification.**

- (B) Appropriate response.
- (C) Documentation.
- (D) Reporting.

(d) The qualifying pharmacist is responsible for maintaining records of training in the administration of immunizations and cardiopulmonary resuscitation of each pharmacist engaging in immunization practice within the pharmacy.

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

[856 IAC 4-1-2](#) Required components of immunization protocol for administering vaccinations

Authority: [IC 25-26-13-4](#); P.L.94-2007, SECTION 5

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

Sec. 2. (a) The protocol for the administration of immunizations must include the following:

(1) For each immunization to be administered by a pharmacist, the following:

- (A) The name and strength of the vaccine.
- (B) Precautions and contraindications.
- (C) The intended audience or patient population.
- (D) The appropriate dosage.
- (E) Administration schedules in accordance with the Centers for Disease Control and Prevention guidelines.
- (F) Appropriate routes of administration.
- (G) Appropriate injection sites.

(2) The length of time the pharmacist recommends an individual be observed for adverse effects, which shall be based on appropriate standards of care established by the physician approving the protocol. The location of the observation shall be in the general vicinity of the administering pharmacist to allow for ongoing evaluation.

(3) A method to address emergency situations including, but not limited to, adverse and anaphylactic reactions.

(4) Administration of epinephrine and appropriate dosages when required in the event of an adverse or anaphylactic reaction.

(5) A method to notify an individual's physician and the physician approving the protocol within fourteen (14) days after administering an immunization.

(6) A copy of the record of vaccination and notification to the primary care physician and physician approving the protocol shall be kept in accordance with the statutes and rules of the Indiana board of pharmacy.

(b) Immunization protocols must be:

- (1) approved and executed by the physician prior to implementation;**
- (2) maintained at the pharmacy; and**
- (3) renewed annually.**

(c) The qualifying pharmacist is responsible for the following:

- (1) Maintaining the immunization protocols.**
- (2) Ensuring that the protocols are renewed annually.**

(Indiana Board of Pharmacy; [856 IAC 4-1-2](#))

[856 IAC 4-1-3](#) Delegation of protocol authority

Authority: [IC 25-26-13-4](#); P.L.94-2007, SECTION 5

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

Sec. 3. The pharmacist is prohibited from delegating the administration of the immunization to another person.

(Indiana Board of Pharmacy; [856 IAC 4-1-3](#))

[856 IAC 4-1-4](#) Reporting of adverse events

Authority: [IC 25-26-13-4](#); P.L.94-2007, SECTION 5

Affected: [IC 16-38-5](#); [IC 25-26-13](#)

Sec. 4. (a) A pharmacist shall report adverse events to the patient's primary care physician and the physician who approved the immunization protocol within seventy-two (72) hours of the pharmacist's knowledge of the adverse event.

(b) A pharmacist shall report to the Vaccine Adverse Events Reporting Systems, the cooperative program for vaccine safety of the Centers for Disease Control and Prevention and the Food and Drug Administration.

(c) A pharmacist may report the immunization of each individual to the immunization data registry maintained by the state department of health under [IC 16-38-5](#).

(d) The qualifying pharmacist is responsible for ensuring that records of the reporting of adverse events is maintained by the pharmacy.

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

[856 IAC 4-1-5](#) Immunization practice voluntary

Authority: [IC 25-26-13-4](#); P.L.94-2007, SECTION 5

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

Sec. 5. (a) A pharmacist may not be required to:

- (1) administer an immunization; or
- (2) complete the accredited training program;

if the pharmacist chooses not to administer any immunization.

(b) If a pharmacist chooses not to administer any immunization, a pharmacist is not required to complete the accredited training program in order to maintain a license to practice as a pharmacist in this state.

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

[856 IAC 4-1-6](#) Pharmacist personnel training requirements

Authority: [IC 25-26-13-4](#); P.L.94-2007, SECTION 5

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

Sec. 6. The qualifying pharmacist is responsible for ensuring that all pharmacist personnel engaging in immunization practice are trained:

- (1) as required by this rule; and
 - (2) in the pharmacy's written policies and procedures of operation;
- prior to performing any immunizations.

(Indiana Board of Pharmacy; [856 IAC 4-1-6](#))

[Notice of Public Hearing](#)

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