

ARTICLE 4. PHARMACIST VACCINATIONS ADMINISTERED VIA PROTOCOL AUTHORITY

NOTE: Emergency Rule, LSA Document #20-628(E), temporarily adds noncode provisions to 856 IAC, effective January 1, 2021. See LSA Document 20-628(E) posted at 20201223-IR-856200628ERA. LSA Document #20-628(E) expires July 1, 2023.

Rule 1. Pharmacist Vaccinations Administered via Protocol Authority

856 IAC 4-1-1 Education and training

Authority: IC 25-26-13-4; IC 25-26-13-31.5

Affected: IC 25-26-13-10

Sec. 1. (a) For purposes of this article, "pharmacist student" has the same meaning as a "pharmacist intern" registered under IC 25-26-13-10.

(b) In order to qualify to administer immunizations, a pharmacist or pharmacist intern 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.
- (c) The pharmacist or pharmacist intern must:
 - (1) be certified in cardiopulmonary resuscitation; and
 - (2) maintain certification as required by the certifying body.

(d) 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.

(e) 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.

(f) In order to administer immunizations in accordance with this article, a pharmacist intern registered under IC 25-26-13-10 must be supervised within a reasonable visual and vocal distance by:

- (1) a pharmacist;
- (2) a physician;

- (3) a physician assistant; or
- (4) an advanced practice nurse.

(Indiana Board of Pharmacy; 856 IAC 4-1-1; filed Dec 2, 2008, 4:03 p.m.: 20081231-IR-856070541FRA; filed Feb 21, 2014, 4:11 p.m.: 20140319-IR-856130449FRA; readopted filed Oct 6, 2020, 12:03 p.m.: 20201104-IR-856200443RFA)

856 IAC 4-1-2 Required components of immunization protocol for administering vaccinations

Authority: IC 25-26-13-4; IC 25-26-13-31.5

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, or pharmacist intern, 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 or pharmacist intern 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 or pharmacist intern 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 a licensed physician actively practicing with a medical office in Indiana prior to implementation;

(2) maintained at the pharmacy and available for inspection by the individual receiving the immunization; 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.

(3) Ensuring that the name, license number, and contact information of the physician who wrote the protocol is posted where the immunization is administered.

(Indiana Board of Pharmacy; 856 IAC 4-1-2; filed Dec 2, 2008, 4:03 p.m.: 20081231-IR-856070541FRA; filed Feb 21, 2014, 4:11 p.m.: 20140319-IR-856130449FRA; readopted filed Oct 6, 2020, 12:03 p.m.: 20201104-IR-856200443RFA)

856 IAC 4-1-3 Delegation of protocol authority

Authority: IC 25-26-13-4; IC 25-26-13-31.5

Affected: IC 25-26-13

Sec. 3. The pharmacist or pharmacist intern is prohibited from delegating the administration of the immunization to another person. *(Indiana Board of Pharmacy; 856 IAC 4-1-3; filed Dec 2, 2008, 4:03 p.m.: 20081231-IR-856070541FRA; filed Feb 21, 2014, 4:11 p.m.: 20140319-IR-856130449FRA; readopted filed Oct 6, 2020, 12:03 p.m.: 20201104-IR-856200443RFA)*

856 IAC 4-1-4 Reporting of adverse events

Authority: IC 25-26-13-4; IC 25-26-13-31.5

Affected: IC 16-38-5-2; IC 25-26-13

Sec. 4. (a) A pharmacist or pharmacist intern's supervising 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 or pharmacist intern's supervising 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 or designee shall report the immunization of each individual to the immunization data registry maintained by the state department of health under IC 16-38-5, unless a written immunization data exception form has been completed and filed in accordance with IC 16-38-5-2.

(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; filed Dec 2, 2008, 4:03 p.m.: 20081231-IR-856070541FRA; filed Feb 21, 2014, 4:11 p.m.: 20140319-IR-856130449FRA; readopted filed Oct 6, 2020, 12:03 p.m.: 20201104-IR-856200443RFA*)

856 IAC 4-1-5 Immunization practice voluntary

Authority: IC 25-26-13-4; IC 25-26-13-31.5

Affected: IC 25-26-13

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

(1) administer an immunization; or

(2) complete the accredited training program;

if the pharmacist or pharmacist intern chooses not to administer any immunization.

(b) If a pharmacist or pharmacist intern chooses not to administer any immunization, a pharmacist or pharmacist intern is not required to complete the accredited training program in order to maintain a license to practice as a pharmacist or pharmacist intern in this state. (*Indiana Board of Pharmacy; 856 IAC 4-1-5; filed Dec 2, 2008, 4:03 p.m.: 20081231-IR-856070541FRA; filed Feb 21, 2014, 4:11 p.m.: 20140319-IR-856130449FRA; readopted filed Oct 6, 2020, 12:03 p.m.: 20201104-IR-856200443RFA*)

856 IAC 4-1-6 Pharmacist personnel training requirements

Authority: IC 25-26-13-4; IC 25-26-13-31.5

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; filed Dec 2, 2008, 4:03 p.m.: 20081231-IR-856070541FRA; readopted filed Nov 20, 2015, 3:31 p.m.: 20151216-IR-856150250RFA; readopted filed Oct 6, 2020, 12:03 p.m.: 20201104-IR-856200443RFA*)

856 IAC 4-1-7 Consent required for pharmacist intern or pharmacist student to administer immunizations

Authority: IC 25-26-13-4; IC 25-26-13-31.5

Affected: IC 25-26-13

Sec. 7. In order for a pharmacist intern or pharmacist student to administer an immunization, the pharmacist intern or pharmacist student must identify themselves to the patient as a pharmacist intern or pharmacist student and receive consent from the patient. (*Indiana Board of Pharmacy; 856 IAC 4-1-7; filed Feb 21, 2014, 4:11 p.m.: 20140319-IR-856130449FRA; readopted filed Oct 6, 2020, 12:03 p.m.: 20201104-IR-856200443RFA*)

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