Indiana Department of Health

Eric J. Holcomb
Governor

Kristina M. Box, MD, FACOG
State Health Commissioner

Statewide Protocol for the Administration of Vaccines by Pharmacists

A. Introduction

This protocol is pursuant to Indiana Code 16-19-4-11 which authorizes the state health commissioner or a designated public health authority who is a licensed prescriber to issue a statewide protocol allowing pharmacists or pharmacist interns to administer or dispense vaccines as recommended by the latest federal Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) immunization recommendations. The protocol outlined below is designed to reduce the morbidity and mortality of vaccine preventable disease by creating a statewide vaccination protocol to allow pharmacists to access the need for, educate patients on, administer, monitor for, and manage adverse effects related to, and document the administration of vaccines.

B. Authorization

Subject to the requirements of this Protocol, eligible providers meeting the qualifications specified in Section C below and applicable law and regulation may:

- determine the immunization needs in accordance with recommendations by the ACIP of the CDC;
- screen all patients for contraindications and precautions for vaccine(s) needed using an appropriate screening questionnaire (see Appendix A-C as examples) and vaccine-specific screening as set forth in other Appendices as stipulated in this protocol;
- administer vaccines according to directions provided in section K of this protocol; and
- administer epinephrine and/or diphenhydramine in response to an adverse reaction following vaccination as delineated in this protocol.

C. Qualifications

- A pharmacist or pharmacist intern seeking authorization to administer vaccines pursuant to this protocol shall meet the qualifications noted in 856 IAC 4-1-1.
- Pharmacist students and pharmacist interns shall be referred to as pharmacist interns in this protocol.

D. Limitations on Pharmacy-based Immunization

- Any vaccine authorized pursuant to this protocol shall not be administered to any persons under the age of eleven (11) years.
- Pursuant to 856 IAC 4-1-3, the pharmacist or pharmacist intern is prohibited from delegating the administration of the vaccine to another person.

E. Protocol, Facility, and Equipment

- Pursuant to 856 IAC 4-1-2, pharmacists and pharmacist interns who administer vaccines under this protocol shall maintain a current copy of this protocol to be available for inspection by the individual receiving the vaccination.
- Pursuant to IC 25-26-13-31.2, the name, license number, and contact information of the state health commissioner or designated public health authority whom authorized this protocol shall be posted at the location where the vaccine is administered.

F. Informed Consent

Pursuant to IC 25-26-13-31.2, Before administering a vaccine to an individual according to this protocol, the pharmacist must receive the consent of one (1) of the following:

- If the individual to whom the vaccine is to be administered is at least eleven (11) years of age but less than eighteen (18) years of age, the parent or legal guardian of the individual.
- If the individual to whom the vaccine is to be administered is at least eighteen (18) years of age but has a legal guardian, the legal guardian of the individual.
- If the individual to whom the vaccine is to be administered is at least eighteen (18) years of age but has no legal guardian, the individual.

A parent or legal guardian who is required to give consent under this subdivision must be present at the time of vaccination or must provide prior written or verbal consent for the administration of the vaccine.

Pursuant to 856 IAC 4-1-7, the pharmacist intern shall identify themselves to the patient as a pharmacist intern or pharmacist student and receive consent from the individual before being allowed to administer a vaccine.

G. Pharmacy-based Vaccination Record

Pursuant to 856 IAC 4-1-2,

- A vaccination record (see Appendix D and Appendix E as examples) shall be created for the patient;
- a copy of the patient's vaccination record and notification of vaccination to the patient's primary care provider shall be kept for seven (7) years in accordance with IC 16-39-7-1;

- the vaccination record shall contain the following information as recommended by the ACIP General Best Practice Guidelines for Immunization:
    - Patient's name
    - Patient's date of birth
    - Date the vaccine was administered
    - Vaccine administration route/site
    - Vaccine manufacturer
    - Vaccine lot number
    - Edition date of vaccine immunization schedule (VIS) distributed
    - Date of VIS was distributed to the patient
    - Name and title of pharmacist or pharmacist intern who administered the vaccine.
    - Address of location vaccine was administered

H. Reporting Requirements

- Pursuant to 856 IAC 4-1-2, the state health commissioner or a designated public health authority approving this protocol shall be notified within fourteen (14) days after administration of a vaccine. A copy of the notification shall be kept in accordance with the statues and rules of the Indiana board of pharmacy.
- Pursuant to 856 IAC 4-1-2, a pharmacist or designee shall electronically report the vaccination of each patient to an immunization data registry maintained by the state department of health under IC 16-38-5.
    - The following patients shall be excluded from immunization data registry reporting requirements:
        - a written immunization data exception form has been completed and filed in accordance with IC 16-38-5-2; or
        - the patient is a resident of or receiving services from a facility licensed under IC 16-28.
    - Pursuant to IC 16-38-5-2, the minimum vaccination data that must be provided are the following:
        - Patient identification number
        - Patient first and last name
        - Patient date of birth
        - Patient address
        - Patient race
        - Patient gender
        - Vaccine for Children program eligibility, if the patient is eligible for the Vaccine for Children program

- Dose at the administration level under the Vaccination for children program, if the patient is eligible for the Vaccine for Children program
- Vaccination presentation or vaccination code using approved Immunization Information System (IIS) code type
- Immunization Date administered
- Lot number of the administered vaccine

The State department may expand or modify the list of minimum data that must be provided under this section based on Centers for Disease Control Immunization Information System (IIS) minimum field requirements.

- Pursuant to 856 IAC 4-1-4, the pharmacist or pharmacist intern's supervising pharmacist shall report vaccination-related adverse events to the patient's primary care physician and state health commissioner or a designated public health authority who approved this protocol within seventy-two (72) hours of the pharmacist's knowledge of the adverse event.
- Pursuant to 856 IAC 4-1-4, the 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.
- Pursuant to 856 IAC 4-1-4, the qualifying pharmacist is responsible for ensuring that records of the reporting of vaccination-related adverse events is maintained by the pharmacy.

I. Management of Adverse Events

- Per ACIP General Best Practice Guidelines for Immunization, the patient who is administered a vaccine should be monitored for adverse effects for at least fifteen (15) minutes in the general vicinity of the administering pharmacist.
- In the event of an adverse reaction, the administering pharmacist is to follow the procedures for the management of the reaction. The procedures for managing adverse reactions are set forth in Appendix F and Appendix G.

J. Vaccines

- Pharmacists or pharmacist interns who administer vaccines under this protocol shall be authorized to administer any vaccine that is recommended by ACIP in the absence of contraindication to the vaccine (see Appendix H). This includes any FDA authorized COVID-19 vaccine.

This protocol shall be reviewed annually by the state department of health and revised as needed. This protocol shall remain valid for the duration of the standing order. Appendixes A-L shall be updated as necessary.

Last Updated December 10, 2020