Indiana Department of Health

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Statewide Protocol for the Administration of Vaccines by Other Providers

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 individuals who are licensed, certified, or registered by a board (as defined in IC 25-1-9-1), and if within the individual's scope of practice, to administer or dispense an immunization that is recommended by the federal Centers for Disease Control and Prevention Advisory Committee on Immunization Practices (ACIP) for individuals who are not less than eleven (11) years of age. This includes any FDA authorized COVID-19 vaccine. Pursuant IC 16-19-4-11, this protocol allows individuals age not less than five (5) years of age to receive FDA authorized COVID-19 vaccines. The protocol outlined below is designed to reduce the morbidity and mortality of vaccine preventable disease by creating a statewide vaccination protocol to allow providers 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 this protocol; and
- administer epinephrine and/or diphenhydramine in response to an adverse reaction following vaccination as delineated in this protocol.

C. Qualifications

- An eligible provider seeking authorization to administer vaccines pursuant to this protocol shall be licensed, certified, or registered by a board (as defined in IC 25-1-9-1) and able to administer immunizations within their scope of practice.

D. Limitations on Immunization

- Any vaccine authorized pursuant to this protocol shall not be administered to any persons under the age of eleven (11) years, except, as authorized through IC 16-19-4-11, for COVID-19 vaccines for persons aged five (5) through (10).

E. Protocol, Facility, and Equipment

- Eligible providers who administer vaccines under this protocol shall review a current copy of this protocol.

F. Patient Consent

Before administering a vaccine to an individual according to this protocol, the provider must receive the consent of one (1) of the following:

- If the individual to whom the vaccine is to be administered is at least -five (5) 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.

G. Vaccination Record

- 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 the provider who administered the vaccine
- Address of location vaccine was administered

H. Reporting Requirements

– Providers who administer vaccines under this protocol shall electronically report the vaccination of each patient to the 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
  - 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.

– The provider who administers the vaccine shall report vaccination-related adverse events the provider has knowledge of to the Vaccine Adverse Events Reporting Systems (VAERS), the cooperative program for vaccine safety of the Centers for Disease Control and Prevention and the Food and Drug Administration.

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 provider.
- In the event of an adverse reaction, the administering provider 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

- Eligible providers 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. 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 Reviewed December 29, 2022