

**PROTOCOL FOR ADMINISTRATION OF VACCINES BY PHARMACISTS
SUBMITTED BY THE JOINT PHARMACIST ADMINISTERED VACCINES COMMITTEE
AND REVIEWED, REVISED AND APPROVED BY
THE SOUTH CAROLINA BOARD OF MEDICAL EXAMINERS**

**REVISED by the Joint Pharmacist Administered Vaccines Committee March 4, 2026
APPROVED by the Board of Medical Examiners May 4, 2026**



**Shuler Spigener, Pharm.D.
Chair, Joint Pharmacist Administered Vaccines Committee**



**Christopher C. Wright, M.D.
President, South Carolina Board of Medical Examiners**

PROTOCOL FOR ADMINISTRATION OF VACCINES BY PHARMACISTS

Table of Contents

I.	Introduction	3
II.	Authorization.....	3
III.	Qualifications	3
IV.	Limitations on Pharmacy-based vaccination.....	5
V.	Protocol, Facility and Equipment.	5
VI.	Informed Consent	5
VII.	Mental Health and Routine Well-visits.....	6
VIII.	Pharmacy-based Vaccination Record	6
IX.	Reporting Requirements	7
X.	Vaccination Safety	7
XI.	Management of Adverse Events	8
XII.	Supply Considerations.....	8
XIII.	Vaccines	8
	Appendix A: Approved Pharmacy-Based Immunization Training Programs.....	9
	Appendix B: Required Supplies and Equipment	10
	Appendix C: General Screening Questionnaire to Determine Safety of All Vaccines	11
	Appendix D: General Screening Questionnaire to Determine Safety of Live Vaccines.....	12
	Appendix E: Consent for Vaccine.....	13
	Appendix F: Notification Letter	14
	Appendix G: Procedures for Management of Adverse Reactions to Vaccines.....	15
	Appendix G-1: VAERS Form	17
	Appendix G-2: VAERS Table of Reportable Events Following Vaccination	21
	Appendix H: Authorized Vaccination Provider Form	26
	Appendix I: S.C. Code Ann. §40-43-190 Administration of vaccines, informed consent, administrators, recordkeeping	27

PROTOCOL FOR ADMINISTRATION OF VACCINES BY PHARMACISTS

I. Introduction

In 2010, to help increase the vaccination rates in South Carolina, the South Carolina General Assembly amended the Pharmacy Practice Act by adding S.C. Code Ann. § 40-43-190 that directed the Board of Medical Examiners to issue a protocol authorizing pharmacists to administer influenza vaccines and certain medications without a practitioner order and S.C. Code Ann. § 40-43-200 which created the Joint Pharmacist Administered Influenza Vaccines Committee under the Board of Medical Examiners. Since 2010, additional amendments have been made to these sections which changed the name of the Committee to the Joint Pharmacist Administered Vaccines Committee as well as expanded the vaccines that can be given, the patient minimum age, and the licensed pharmacy personnel that can administer the vaccines pursuant to the protocol. The Committee makes recommendations and the Board of Medical Examiners determines whether a specific vaccine is appropriate for administration by licensed pharmacists and pharmacy interns or eligible pharmacy technicians under the direct supervision of a qualified pharmacist without a written order or prescription of a practitioner.¹ For any recommended vaccine by the Committee, the Committee must also submit a proposed written protocol for the purpose of authorizing pharmacists to administer the vaccine.

II. Authorization

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

- (a) determine the vaccination needs in accordance with current recommendations by the Advisory Committee on Immunization Practices (ACIP) of the US Centers for Disease Control and Prevention (CDC)², the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), or the American College of Obstetricians and Gynecologists (ACOG);
- (b) screen all patients for contraindications and precautions for vaccine(s) needed using screening questions for all vaccines (Appendix C), live vaccines (Appendix D), and vaccine-specific screening as set forth in other Appendices as stipulated in this Protocol and the respective manufacturer's package insert for a specific vaccine;
- (c) administer or delegate to a qualified pharmacy intern or qualified pharmacy technician the administration of vaccines according to directions provided in this Protocol; and
- (d) administer epinephrine and/or diphenhydramine in response to acute allergic reactions precipitated by vaccination as delineated in this Protocol.

III. Qualifications

Pharmacists and pharmacy interns or eligible pharmacy technicians supervised by a qualified pharmacist seeking authorization to administer vaccines pursuant to this Protocol shall meet the following qualifications:

- (a) Licensure:
 - (1) Pharmacists must be licensed and in good standing with the South Carolina Board of Pharmacy. Only pharmacists who have completed the required training and have a current BLS or CPR certification as set forth in this Section may supervise a pharmacy intern or eligible pharmacy technician administering vaccines pursuant to this protocol.
 - (2) Pharmacy interns must be certified and in good standing with the South Carolina Board of Pharmacy.
 - (3) Pharmacy Technicians, to be eligible to administer vaccines under this Protocol, must be registered as a state certified pharmacy technician **OR** be registered as a non-state certified

¹ See S.C. Code Ann. §40-43-190.

² In the event of a conflict between information provided in package inserts and recommended guidelines, pharmacists administering vaccines pursuant to this Protocol should adhere to respective guidelines.

pharmacy technician but have administered vaccinations and received training pursuant to the federal Public Readiness and Emergency Preparedness (PREP) Act prior to July 2, 2024, and be registered with the Board of Pharmacy as an authorized vaccination provider. Any such pharmacy technician's registration must be in good standing with the South Carolina Board of Pharmacy.

- (b) Basic Life Support (BLS) or Cardiopulmonary Resuscitation (CPR) Certification - Pharmacists, pharmacy interns, and eligible pharmacy technicians must complete one of the certification courses listed below, possess a valid course completion card, and the certification must be renewed every 2 years:
- (1) The American Heart Association BLS for Healthcare Providers Course or
 - (2) The American Red Cross Adult and Pediatric CPR/AED Course.
- (c) Training - Pharmacists, pharmacy interns, and eligible pharmacy technicians must complete a pharmacy-based immunization training program that is accredited by the Accreditation Council for Pharmacy Education (ACPE). Pharmacists, in lieu of an ACPE approved course, may complete an approved program by a similar health authority or professional body approved by the Board of Pharmacy and the Board of Medical Examiners.
- (1) For pharmacists and pharmacy interns, the training program must comply with current CDC guidelines and must include study materials, hands-on training, and techniques for administering vaccines. It must also provide instruction and experiential training in the following content areas:
 - mechanisms of action for vaccines, contraindications, drug interactions, and monitoring after vaccine administration;
 - standards for vaccination practices;
 - basic immunology and vaccine protection;
 - vaccine-preventable diseases;
 - recommended immunization schedules;
 - vaccine storage management;
 - biohazard waste disposal and sterile techniques;
 - informed consent;
 - physiology and techniques for vaccine administration;
 - pre-vaccine and post-vaccine assessment and counseling;
 - vaccine record management;
 - management of adverse events, including identification, appropriate response, emergency procedures, documentation, and reporting;
 - understanding of vaccine coverage by federal, state, and local entities;
 - needle stick management.

Note: A list of approved programs is specified in Appendix A.

- (2) For eligible pharmacy technicians, the training program must, at a minimum, include all of the following:
 - hands-on injection technique
 - the recognition and treatment of emergency reaction to vaccines
 - physiology and techniques for vaccine administration
- (d) Continuing Education-Pharmacists and eligible pharmacy technicians must complete at least one hour of CME category I, or ACPE-approved continuing education related to the administration of vaccines as part of his or her annual license renewal requirements.

- (e) Liability Insurance -Pharmacists, pharmacy interns, and eligible pharmacy technicians must maintain and/or be covered by liability insurance that covers him or her for administration of vaccines. It is the responsibility of the pharmacist, pharmacy intern, or eligible pharmacy technician to ensure that he or she has the appropriate liability insurance coverage when administering vaccines pursuant to this protocol.

IV. Limitations on Pharmacy-based Vaccination

- (a) Age - The following restrictions apply to vaccinations provided pursuant to this Protocol.
 - (1) Administration of non-influenza vaccines must not be to any persons under the age of sixteen (16).
 - (2) The administration of influenza vaccines may not be to any persons under the age of three (3).
 - (3) The administration of a vaccine to a person less than sixteen (16) is only authorized when the vaccinee's parent, caretaker (with written parental consent), or legal guardian is present at the time the vaccine is administered.
- (b) Delegation - A pharmacist may not delegate the administration of vaccines to any person who is not a pharmacist, pharmacy intern, or eligible pharmacy technician meeting the requirements set forth in Section III of this Protocol and any other applicable law and regulation. The pharmacy intern and eligible pharmacy technician must be under the direct supervision of a qualified pharmacist as set forth in Section III of this protocol when administering vaccines pursuant to this Protocol.
- (c) Patient Specific Factors- Potential vaccinees with any contraindications and/or complex medical issues including immunosuppression or history of Guillain-Barré syndrome should be referred to their primary care practitioner for vaccine administration.

V. Protocol, Facility and Equipment

Pharmacists who administer vaccines or delegate the administration of vaccines to qualified pharmacy interns and pharmacy technicians under this Protocol shall:

- (a) maintain a current copy of this Protocol at each location where a vaccine is administered; and
- (b) have an appropriate area for administering vaccines with the supplies and equipment listed in Appendix B.

VI. Informed Consent

Before receiving the vaccine, the vaccinee (or his or her legal representative) must be given information about the risks and benefits associated with vaccination as outlined in the most current version of the Vaccine Information Sheet (VIS) for the vaccine to be administered. This requirement is satisfied by providing a copy of the most current version of the respective VIS to the vaccinee and/or their guardian/representative **prior to administration**.

- (a) Any pharmacist, pharmacy intern, or eligible pharmacy technician administering vaccines pursuant to this Protocol must obtain signed written informed consent prior to vaccine administration from:
 - (1) the vaccinee;
 - (2) if the individual is a minor, by a parent or legal guardian; or
 - (3) for an individual who is incapacitated or without sufficient mental capacity, by a designated health care agent pursuant to a health care power of attorney.

- (b) The Consent form must:
- (1) be signed and dated;
 - (2) include an explanation of the vaccine or treatment that is written in a language that is understandable to the average lay person;
 - (3) include a statement that the individual agrees to the administration of the vaccine or treatment, that the individual has had time to thoughtfully and voluntarily accept or decline the vaccine or treatment free from coercion; and
 - (4) if the vaccine or treatment is an investigational medical product or is made available through an Emergency Use Authorization (EUA) by the federal Food and Drug Administration (FDA), a statement acknowledging its investigational nature and the civil liability protections afforded it by law.
 - (5) Additionally, the administering pharmacist, pharmacy intern, or eligible pharmacy technician must be identified on the consent form. If the administration is done by a pharmacy intern or eligible pharmacy technician, the supervising pharmacist must also be identified on the consent form. A sample consent form is provided in Appendix E.
- (c) Vaccine Information Statements - Each vaccinee, or his or her legal guardian/representative, must be provided with a copy of the most current Vaccine Information Statement (VIS) for the vaccine to be administered. The vaccinee or legal guardian/representative must be given the opportunity to read the VIS **prior to administration** of the vaccine, and the pharmacist must provide answers to any questions raised. Non-English-speaking persons must receive a copy of the VIS in their native language, if available.

VII. Mental Health and Routine Well-visits

If the person receiving a vaccine is under the age of eighteen (18) years, a pharmacist must inform the patient and their caregiver of the importance of mental health and routine well care visits with a pediatrician or other licensed primary care provider and refer patients as appropriate. Routine well care visits are important to ensure all other vaccinations are up-to-date.

VIII. Pharmacy-based Vaccination Record

A pharmacist, pharmacy intern, or eligible pharmacy technician administering a vaccine pursuant to this Protocol must create a vaccination record for each vaccinee, and this record must be maintained in the pharmacy for a period of at least ten (10) years from the date of the last vaccination or dispensing for adults and at least thirteen (13) years from the date of the last vaccination or dispensing for minors. This vaccination record must be readily accessible and shall include the following:

- (a) The name, address, date of birth, gender and telephone number of the vaccinee;
- (b) A copy of the vaccinee's responses to eligibility questionnaires;
- (c) The name, dose, manufacturer, and lot number of the vaccine administered;
- (d) The date of the administration of the vaccine and the injection site;
- (e) A signed and dated written consent form by which the vaccine recipient acknowledges receipt of the VIS and consents to the administration of the vaccine;
- (f) A record of any adverse events or complications that arose following vaccination;
- (g) The name, address, license number, and telephone number of the administering pharmacist or the pharmacist supervising the administration by a pharmacy intern or eligible pharmacy technician; and
- (h) A copy of the notification letter sent to the vaccinee's designated primary care practitioner of any vaccine administered.

IX. Reporting Requirements

- (a) Personal Immunization Record -The pharmacist must encourage all vaccinees to carry a personal immunization record card in their wallet. The pharmacist must provide and record the date of vaccination on the vaccinee's personal immunization record card.
- (b) Medical Home Notification -Vaccinees must be informed regarding the importance of having a medical home and receiving other preventive medical services. When a vaccinee receives a vaccine, this shall be reported to their designated physician or primary care practitioner. The required language is provided in the reporting form in Appendix F.
- (c) Immunization Registry – A pharmacist administering vaccines or supervising the administration of vaccinations by a pharmacy intern or eligible pharmacy technician pursuant to this Protocol shall report administration of all vaccinations to the South Carolina Immunization Registry in compliance with regulations established by the Department of Public Health as required.
- (d) Adverse Event Reporting -The pharmacist shall report any clinically significant event that occurs following vaccine administration to the Vaccine Adverse Event Reporting System (VAERS), even if it is not certain that the event was caused by the vaccine. Clinically significant events include, but are not limited to: death, hypersensitivity reactions, and those events described in the manufacturer's package insert as contraindications to additional doses of vaccine. Appendix G-1 contains the VAERS form and Appendix G-2 contains a Table of Reportable Events Following Vaccination.

X. Vaccination Safety

- (a) Infection Control and Sterile Technique -Pharmacists, pharmacy interns, and eligible pharmacy technicians administering vaccines pursuant to this Protocol must follow appropriate precautions to minimize risk for spread of disease. Hands must be cleansed with an alcohol-based waterless antiseptic hand rub or washed with soap and water before and after contact with each patient. Gloves must be worn if the individual administering the vaccine is likely to come into contact with potentially infectious body fluids or has open lesions on his or her hands. Needles used for injections must be sterile and disposable to minimize the risk for contamination.
- (b) Prevention of Needle-stick Injuries -To prevent inadvertent needle-stick injury or reuse, needles and syringes must be discarded immediately after use in labeled, puncture-proof containers located in the same room where the vaccine is administered. Needles must not be recapped before being placed in the container. Safety needles or needle-free injection devices should be used to reduce the risk for injury.
- (c) Hepatitis B Vaccine -Pharmacists, pharmacy interns, and eligible pharmacy technicians who administer vaccines pursuant to this Protocol shall receive the hepatitis B vaccine series unless:
 - (1) the pharmacist has previously received the complete hepatitis B vaccination series,
 - (2) antibody testing has revealed that the qualified individual is immune,
 - (3) the vaccine is contraindicated for medical reasons, or
 - (4) the qualified individual signs a Hepatitis B Vaccine Declination statement.
- (d) Occupational Safety and Health Administration (OSHA) Compliance -Pharmacists, both those who administer and those who supervise the administration of vaccines, must document compliance with OSHA regulations and applicable state law and regulations regarding the storage and disposal of injection supplies and the disposal of, and prevention of exposure to, biological hazards.
- (e) Flumist—Because Flumist is a live attenuated intranasal influenza vaccine, extra caution should be exercised in determining if any contraindications are present.

XI. Management of Adverse Events

All vaccines have the potential to cause an adverse reaction. In order to minimize adverse reactions, vaccinees must be carefully screened for precautions and contraindications before the vaccine is administered. Even with careful screening, reactions may occur. These reactions can vary from trivial and inconvenient (e.g., soreness, itching) to severe and life threatening (e.g., anaphylaxis). If reactions occur, the pharmacists must be prepared with procedures for their management. The procedures for managing adverse reactions are set forth in Appendix G.

XII. Supply Considerations

The supply of vaccines and the timing of distribution cannot be guaranteed. If supplies of the vaccines are delayed or limited, the pharmacist must comply with state and national guidance and directives for the tiered use of vaccines, and must cooperate with health officials and local practitioners to ensure that limited supplies of vaccines are targeted to and reserved for those persons at higher risk for disease and disease-related complications.

XIII. Vaccines

Pharmacists may administer or supervise the administration by a qualified pharmacy intern or qualified pharmacy technician for US Food and Drug Administration (FDA) approved³ formulations of the vaccines listed below, alone or in combination, without an order from a licensed practitioner provided they follow all requirements set forth in this Protocol, assess patient eligibility according to indications, precautions, and contraindications recommended in current guidelines from the ACIP, AAP, AAFP, or ACOG, and adhere to dosing and administration information provided by the package inserts and ACIP, AAP, AAFP, or ACOG recommended guidelines. Pharmacists must make every effort to assure that vaccination series are completed.

1. Haemophilus Influenzae	8. Pneumococcal
2. Hepatitis A	9. Tetanus and diptheria/Tetanus, diptheria, and pertussis (Td/Tdap)
3. Hepatitis B	10. Varicella
4. Human Papillomavirus	11. Zoster
5. Influenza	12. COVID-19
6. Measles, Mumps, Rubella	13. Respiratory Syncytial Virus (RSV)
7. Meningococcal	

³ As to vaccines, this includes vaccines that have been granted an Emergency Use Authorization (EUA) by the FDA.

APPENDIX A

APPROVED PHARMACY-BASED IMMUNIZATION TRAINING PROGRAMS

The Pharmacy Practice Act requires that pharmacists, pharmacy interns, and eligible pharmacy technicians seeking authorization to administer vaccines complete an accredited or approved training⁴ course as outlined in Section III of this Protocol.

For pharmacists and pharmacy interns, the course must comply with current CDC guidelines, as those guidelines may be revised from time to time, and must include study materials, hands-on training, and techniques for administering vaccines, and must provide instruction and experiential training in the following content areas:

- (a) mechanisms of action for vaccines, contraindications, drug interactions, and monitoring after vaccine administration;
- (b) standards for adult immunization practices;
- (c) basic immunology and vaccine protection;
- (d) vaccine preventable diseases;
- (e) recommended vaccination schedules;
- (f) vaccine storage management;
- (g) biohazard waste disposal and sterile techniques;
- (h) informed consent;
- (i) physiology and techniques for vaccine administration;
- (j) pre-vaccine and post-vaccine assessment and counseling;
- (k) vaccine record management;
- (l) management of adverse events, including identification, appropriate response, emergency procedures, documentation, and reporting;
- (m) understanding of vaccine coverage by federal, state, and local entities; and (n) needle stick management.

A pharmacist or qualified pharmacy intern may demonstrate satisfaction of the training criteria for this Protocol by completion of the following:

- (a) A certificate of achievement for the American Pharmacists Association's "Pharmacy-based Immunization Delivery" training program; or
- (b) A certificate of achievement for the Ohio Pharmacists Association Immunization Training Program; or
- (c) For pharmacists, a certificate of achievement for completion of alternative training programs jointly pre-approved by the South Carolina Board of Pharmacy and the South Carolina Board of Medical Examiners.

For eligible pharmacy technicians, the training program must, at a minimum, include all of the following:

- hands-on injection technique
- the recognition and treatment of emergency reaction to vaccines
- physiology and techniques for vaccine administration

**** NOTE:** A non-state certified pharmacy technician who did NOT administer under and receive training pursuant to the federal PREP Act prior to July 2, 2024 is **NOT** permitted to administer vaccines pursuant to this Protocol even if they obtain/obtained the required training and BLS/CPR certification on or after July 2, 2024.

⁴ See Section III for specific requirements for pharmacists, eligible pharmacy technicians and pharmacy interns

APPENDIX B

REQUIRED SUPPLIES AND EQUIPMENT

The following items must be available in the area where vaccines are administered:

- (a) A current copy of this Protocol.
- (b) A supply of the most current federal VIS for vaccines being administered, or electronic access to these statements.
- (c) Aqueous epinephrine USP (1:1000), in ampules, vials of solution, or prefilled devices (e.g., EpiPen). If an EpiPen is to be stocked, at least four adult EpiPens (delivering a single dose of 0.3 mg/0.3 mL) should be available. At least four pediatric EpiPens (delivering a single dose of .15 mg/.15 ml) should be available if pediatric patients are immunized.
- (d) Diphenhydramine (Benadryl) injectable solution (50 mg per mL) and oral 25 mg dosage form, to include tablets, capsules or liquid.
- (e) Syringes and other supplies to meet the need of administering vaccinations
- (f) Blood pressure monitoring device or stethoscope and sphygmomanometer (with pediatric*, adult and extra-large cuffs).
- (g) Adult and pediatric* size pocket masks with one-way valve.
- (h) Access to device to keep time in seconds, light to examine mouth and throat, and ability to call emergency personnel. This may include a cell phone.
- (i) Equipment to enable the vaccinee to sit or lie down if he or she experiences an adverse reaction to the vaccine, such as a mat or a reclining chair.

NOTE: All required devices as listed above **MUST** be ready and operational to be compliant under this protocol. For those devices requiring batteries, failing to have batteries in a device or having a device with dead batteries, would be non-compliant under this Protocol. Also, the pharmacist should be familiar with how to operate the required devices.

*pediatric supplies are required if pediatric patients are immunized

APPENDIX C

GENERAL SCREENING QUESTIONNAIRE TO DETERMINE SAFETY OF ALL VACCINES

Below is a list of general screening questions a pharmacist or qualified pharmacy intern must ask a patient prior to administration of any vaccine. Vaccine-specific screening questions must also be asked based on the vaccine's contraindications and precautions according to current ACIP guidelines and manufacturer's package inserts. Pharmacists must document relevant responses and explanations provided in response to the screening questions.

- (a) Are you sick today? If yes, ask these additional questions:
 - (1) Do you have a new fever?
 - (2) Do you have a cough?
 - (3) Do you have diarrhea?
 - (4) Have you been vomiting?
- (b) Have you ever fainted or felt dizzy after receiving a vaccine?
- (c) Have you ever had a reaction after receiving a vaccine?
- (d) Do you have a long-term health problem with heart disease, lung disease, asthma, kidney disease, neurologic or neuromuscular disease, liver disease, metabolic disease (e.g., diabetes), or anemia or another blood disorder?
- (e) Do you have a weakened immune system because of HIV/AIDS or another disease that affects the immune system, long-term treatment with drugs such as high-dose steroids, or cancer treatment with radiation or drugs?
- (f) Do you have allergies to latex, medications, food or vaccines? (Examples: eggs, bovine protein, gelatin, gentamicin, polymyxin, neomycin, phenol, yeast or thimerosal)
- (g) Have you ever had a seizure disorder for which you are on seizure medications, a brain disorder, Guillain-Barré syndrome or other nervous system problems?
- (h) For women: Are you pregnant or considering becoming pregnant in the next month?

Precaution

Precaution must be taken before administering any vaccine to potential vaccinees with moderate or severe acute illness, with or without fever. Vaccination should be delayed until the illness has resolved.

Referrals

Potential vaccinees with any contraindications and/or complex medical issues including immunosuppression or history of Guillain-Barré syndrome should be referred to their primary care provider.

Resources

Additional screening questionnaires, including vaccine-specific questionnaires, can be found at <http://www.immunize.org/clinical/topic/screening-checklists>.

NOTE: Although a qualified pharmacy intern or qualified pharmacy technician may ask/obtain the responses to the questionnaire, the supervising pharmacist should review the questionnaire to ensure the vaccine is appropriate and safe for the patient to receive.

APPENDIX D

GENERAL SCREENING QUESTIONNAIRE TO DETERMINE SAFETY OF LIVE VACCINES

Below is a list of screening questions a pharmacist must ask a patient prior to administration of a live vaccine (in addition to the questions listed in Appendix C). This is a list of general questions. Vaccine-specific screening questions must also be asked based on the vaccine's contraindications and precautions according to ACIP guidelines.

- (a) Do you consider yourself to be, or have you ever been told by a physician that you are, immunosuppressed?
- (b) Are you currently on home infusions or weekly injections (such as Remicade, Humira, Enbrel, Cimzia, Simponi, Simponi Aria, Xeljanz, Orencia, Arava, Actemra, Cytosan, Rituxan, adalimumab, infliximab, or etanercept), high-dose methotrexate, azathioprine or mercaptopurine, antivirals, anticancer drugs, or radiation treatments?
- (c) Have you received any vaccinations or skin tests in the past four weeks?
- (d) Have you received a transfusion of blood, blood products or been given a medication called immune (gamma) globulin in the past year?
- (e) Are you currently taking high-dose steroid therapy (prednisone >20mg/day or equivalent) for longer than two weeks?

Resources

Additional screening questionnaires, including vaccine-specific questionnaires, can be found at <http://www.immunize.org/clinical/topic/screening-checklists>.

NOTE: Although a qualified pharmacy intern or qualified pharmacy technician may ask/obtain the responses to the questionnaire, the supervising pharmacist should review the questionnaire to ensure the vaccine is appropriate and safe for the patient to receive.

APPENDIX E

CONSENT FOR VACCINE ADMINISTRATION

This pharmacy is providing necessary vaccines to you in a safe and convenient setting in order to promote adherence to current immunization guidelines recommended by the CDC and ACIP, AAP, AAFP, or ACOG. It does not take the place of an ongoing relationship with your primary care provider to address ongoing medical issues and other types of preventive care. We are providing your primary care provider with records of the vaccine(s) administered here so that your medical records may be complete, but be sure to take your personal record with you to your next appointment as well.

Please review the statement below confirming your consent for vaccination and provide the information requested.

I have read, or had explained to me, the Vaccine Information Statement for the [NAME OF] vaccine. I understand the risks and benefits, and have been provided an opportunity to ask questions, which have been answered to my satisfaction. I wish to receive the [NAME OF] vaccine and hereby give consent for [PHARMACIST OR PHARMACY INTERN AND SUPERVISING PHARMACIST NAME(S)] to administer the [NAME OF] vaccine and communicate the administration of the vaccine to my primary care practitioner, who is listed below.

**Include if applicable to the vaccine being administered*

I further understand that **the [NAME OF] vaccine is not approved by the FDA** and is an investigational medical product and/or is being made available through an Emergency Use Authorization (EUA). EUA means the vaccine is being made available without FDA approval due to a public health emergency. I understand that because the [NAME OF] vaccine is investigational in nature and/or is available through an EUA, this means that it has not undergone rigorous scientific evaluation by the FDA. **I acknowledge that the manufacturer of the vaccine, the FDA, my doctor, the individual administering the vaccine, and any other covered person assisting in providing me access to this vaccine CANNOT be taken to court for money damages related to me receiving this vaccine**, including for any injuries, or any other type of loss, such as (i) death; (ii) physical, mental, or emotional injury, illness, disability, or condition; (iii) fear of such injury, including medical monitoring costs; or (iv) loss of or damage to property, including business interruption loss.

Vaccine Recipient's Name

Vaccine Recipient's Date of Birth

Vaccine Recipient's Legal Guardian's/Representative's Name (if applicable)

Date

Vaccine Recipient's (or legal guardian's/representative's) Signature

Date

VIS Date

Vaccine Recipient's Designated Physician or Primary Care Practitioner

APPENDIX F

NOTIFICATION LETTER

Dear Healthcare Provider at [vaccinee's primary care clinic]:

We have recently provided vaccination services to one of your patients. A personal immunization record card was filled out and given to the patient. We want to make certain that you also have this information so that you can update your patient's medical record. Please contact us if you have any questions about this information.

Vaccinee's name:

Vaccinee's Date of Birth:

The vaccine that was given on _____ is listed below.

Vaccine Given: _____

Dose: _____

Method: IM/SQ /IN

Location: Right / Left Arm

Lot #: _____

Manufacturer: _____

Expiration Date: _____

Name of Administering ☐ Pharmacist ☐ Pharmacy Intern ☐ Pharmacy Technician

Name Pharmacist Supervising the Pharmacy Intern or Pharmacy Technician (If applicable)

Contact Information for Administering or Supervising Pharmacist

APPENDIX G

PROCEDURES FOR MANAGEMENT OF ADVERSE REACTIONS TO VACCINES Anaphylactic Reactions

Signs and symptoms of anaphylactic reaction include:

- (a) the sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives);
- (b) angioedema (swelling of the lips, face, or throat);
- (c) bronchospasm (wheezing);
- (d) shortness of breath;
- (e) shock;
- (f) abdominal cramping; or
- (g) cardiovascular collapse.

The following procedures should be used to manage anaphylactic reactions following vaccination:

- (a) If itching and swelling are confined to the injection site where the vaccination was given, observe the vaccinee closely for at least 30 minutes, watching for the development of generalized symptoms.
 - (b) If symptoms are generalized, activate the emergency medical system (e.g., call 911) immediately. This should be done by a second person, while the pharmacist assesses the level of consciousness, circulation, airway and breathing of the vaccinee.
 - (c) Place vaccinee in a recumbent position and elevate legs.
 - (d) The first-line therapy in anaphylaxis is epinephrine. There are no contraindications to epinephrine in the setting of anaphylaxis.
- (1) Administer aqueous epinephrine 1:1000 dilution intramuscularly, 0.01mL/kg/dose (adult dose ranges from 0.3mL to 0.5mL, with a maximum single dose of 0.5mL), as indicated:

				Epinephrine Dose	
	Age Group	Range of Weight (lb)	Range of Weight (kg) ¹	1.0 mg/ml aqueous solution (1:1000 dilution); intramuscular. Minimum dose: 0.05 mL	Epinephrine autoinjector or prefilled syringe (0.1 mg, 0.15 mg, 0.3mg)
Infants and Children	7–36 months	20–32 lb	9–14.5 kg ²	0.1 mL (or mg)	0.1 mg ²
	37–59 months	33–39 lb	15–17.5 kg	0.15 mL (or mg)	0.15 mg/dose
	5–7 years	40–56 lb	18–25.5 kg	0.2–0.25 mL (or mg)	0.15 mg/dose
	8–10 years	57–76 lb	26–34.5 kg	0.25–0.3 mL (or mg)	0.15 mg or 0.3 mg/dose
	11–12 years	77–99 lb	35–45 kg	0.35–0.4 mL (or mg)	0.3 mg/dose
Teens	13 years & older	100+ lb	46+ kg	0.5 mL (or mg) – max. dose	0.3 mg/dose

¹ Rounded weight at the 50th percentile for each age range.

² 0.1 mg autoinjector is licensed for use in 7.5 to 14 kg infants and children.

The site of injection can be gently massaged to facilitate absorption.

- (2) If EMS has not arrived and symptoms are still present, the dose of epinephrine may be repeated every 5 to 15 minutes for up to doses, depending on the patient's response.
- (e) Antihistamines may be given for hives or itching. Administer diphenhydramine either orally or by intramuscular injection. The standard dose is 1-2 mg/kg every 4-6 hours, up to 100 mg maximum single dose for adults, and 40 mg maximum single dose for children and adolescents. Do not attempt to give oral medications to a vaccinee who is not fully alert and able to swallow safely. Refer to the dosing chart below:

				Diphenhydramine dose calculations based on 1 mg/kg
				Liquid: 12.5 mg/5 mL Tablets: 25 mg or 50 mg
Infants and Children	Age group	Range of Weight (lb)	Range of weight (kg) ¹⁵	
	7-36 months	20-32 lb	9-14.5 kg	10-15 mg/dose
	37-59 months	33-39 lb	15-17.5 kg	15-20 mg/dose
	5-7 years	40-56 lb	18-25.5 kg	20-25 mg/dose
Teens	8-12 years	57-99 lb	26-45 kg	25-50 mg/dose
	13 years & older	100+ lb	46+ kg	50 mg/dose (up to 50 mg or 100 mg single dose)

- (f) Monitor the vaccinee closely and check vital signs (blood pressure, pulse, and respirations) every 2 to 5 minutes.
- (g) Stay with vaccinee until EMS arrives.
- (h) If necessary, perform cardiopulmonary resuscitation (CPR) and maintain airway.
- (i) Keep vaccinee in supine position unless he or she is having breathing difficulty. If breathing is difficult, vaccinee's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs.
- (j) Record all vital signs, medications administered to the vaccinee (including the time, dosage, response, and the name of the person who administered the medication), and other relevant clinical information contemporaneously in an adverse reaction medication log to be maintained by the pharmacy, a copy of which may be provided to EMS and/or the vaccinee's primary care provider.
- (k) Notify the vaccinee's primary care practitioner as soon as possible. All vaccinees experiencing anaphylactic reactions must be referred for evaluation, even if symptoms resolve completely.

References

- (a) Immunization Action Coalition. *Medical Management of Vaccine Reactions in Adult Patients*. Retrieved from <http://www.immunize.org/catg.d/p3082.pdf>. Accessed March 4, 2026.
- (b) Immunization Action Coalition. *Medical Management of Vaccine Reactions in Children and Teens*. Retrieved from <http://www.immunize.org/catg.d/p3082a.pdf>. Accessed March 4, 2026.

⁵ Rounded weight at the 50th percentile for each age range.

Appendix G-1

VAERS Reporting Form

This form can be completed online at <https://vaers.hhs.gov>

A fillable pdf version of this form can be downloaded from <https://vaers.hhs.gov/uploadFile/index.jsp>

VAERS Vaccine Adverse Event Reporting System www.vaers.hhs.gov		Adverse events are possible reactions or problems that occur during or after vaccination. Items 2, 3, 4, 5, 6, 17, 18 and 21 are ESSENTIAL and should be completed. Patient identity is kept confidential. Instructions are provided on the last two pages.																				
INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE (Use Continuation Page if needed)																						
1. Patient name: (first) _____ (last) _____ Street address: _____ City: _____ State: _____ County: _____ ZIP code: _____ Phone: () _____ Email: _____ 2. Date of birth: (mm/dd/yyyy) _____ 3. Sex: ☐ Male ☐ Female ☐ Unknown 4. Date and time of vaccination: (mm/dd/yyyy) _____ Time: hh:mm _____ ☐ AM ☐ PM 5. Date and time adverse event started: (mm/dd/yyyy) _____ Time: hh:mm _____ ☐ AM ☐ PM 6. Age at vaccination: _____ Years _____ Months 7. Today's date: (mm/dd/yyyy) _____ 8. Pregnant at time of vaccination?: ☐ Yes ☐ No ☐ Unknown (If yes, describe the event, any pregnancy complications, and estimated due date if known in item 18)	9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination: _____ 10. Allergies to medications, food, or other products: _____ 11. Other illnesses at the time of vaccination and up to one month prior: _____ 12. Chronic or long-standing health conditions: _____																					
INFORMATION ABOUT THE PERSON COMPLETING THIS FORM																						
13. Form completed by: (name) _____ Relation to patient: ☐ Healthcare professional/staff ☐ Patient (yourself) ☐ Parent/guardian/caregiver ☐ Other: _____ Street address: _____ ☐ Check if same as item 1 City: _____ State: _____ ZIP code: _____ Phone: () _____ Email: _____ 14. Best doctor/healthcare professional to contact about the adverse event: Name: _____ Phone: () _____ Ext: _____																						
INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN																						
15. Facility/clinic name: _____ Fax: () _____ Street address: _____ ☐ Check if same as item 13 City: _____ State: _____ ZIP code: _____ Phone: () _____																						
16. Type of facility: (Check one) ☐ Doctor's office, urgent care, or hospital ☐ Pharmacy or store ☐ Workplace clinic ☐ Public health clinic ☐ Nursing home or senior living facility ☐ School or student health clinic ☐ Other: _____ ☐ Unknown																						
WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?																						
17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given) Use Continuation Page if needed																						
Vaccine (type and brand name) select select select select	Manufacturer select select select select	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 20%;">Lot number</th> <th style="width: 15%;">Route</th> <th style="width: 15%;">Body site</th> <th style="width: 10%;">Dose number in series</th> </tr> </thead> <tbody> <tr><td>select</td><td>select</td><td>select</td><td>select</td></tr> <tr><td>select</td><td>select</td><td>select</td><td>select</td></tr> <tr><td>select</td><td>select</td><td>select</td><td>select</td></tr> <tr><td>select</td><td>select</td><td>select</td><td>select</td></tr> </tbody> </table>	Lot number	Route	Body site	Dose number in series	select	select	select	select	select	select	select	select	select	select	select	select	select	select	select	select
Lot number	Route	Body site	Dose number in series																			
select	select	select	select																			
select	select	select	select																			
select	select	select	select																			
select	select	select	select																			
18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.) Use Continuation Page if needed																						
19. Medical tests and laboratory results related to the adverse event(s): (include dates) Use Continuation Page if needed																						
20. Has the patient recovered from the adverse event(s)?: ☐ Yes ☐ No ☐ Unknown																						
21. Result or outcome of adverse event(s): (Check all that apply) ☐ Doctor or other healthcare professional office/clinic visit ☐ Emergency room/department or urgent care ☐ Hospitalization: Number of days (if known) _____ Hospital name: _____ City: _____ State: _____ ☐ Prolongation of existing hospitalization (vaccine received during existing hospitalization) ☐ Life threatening illness (immediate risk of death from the event) ☐ Disability or permanent damage ☐ Patient died – Date of death: (mm/dd/yyyy) _____ ☐ Congenital anomaly or birth defect ☐ None of the above																						
ADDITIONAL INFORMATION																						
22. Any other vaccines received within one month prior to the date listed in item 4: Use Continuation Page if needed																						
Vaccine (type and brand name) select select	Manufacturer select select	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 20%;">Lot number</th> <th style="width: 15%;">Route</th> <th style="width: 15%;">Body site</th> <th style="width: 10%;">Dose number in series</th> <th style="width: 10%;">Date Given</th> </tr> </thead> <tbody> <tr><td>select</td><td>select</td><td>select</td><td>select</td><td></td></tr> <tr><td>select</td><td>select</td><td>select</td><td>select</td><td></td></tr> </tbody> </table>	Lot number	Route	Body site	Dose number in series	Date Given	select	select	select	select		select	select	select	select						
Lot number	Route	Body site	Dose number in series	Date Given																		
select	select	select	select																			
select	select	select	select																			
23. Has the patient ever had an adverse event following any previous vaccine?: (If yes, describe adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name) ☐ Yes ☐ No ☐ Unknown																						
24. Patient's race: ☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander (Check all that apply) ☐ White ☐ Unknown ☐ Other: _____																						
25. Patient's ethnicity: ☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown																						
26. Immuniz. proj. report number: (Health Dept use only) _____																						
COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS																						
27. Status at vaccination: ☐ Active duty ☐ Reserve ☐ National Guard ☐ Beneficiary ☐ Other: _____																						
28. Vaccinated at Military/DoD site: ☐ Yes ☐ No																						

17. Enter all vaccines given on the date listed in item 4 (continued):					Dose number in series
Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	
select			select	select	select
select			select	select	select
select			select	select	select
select			select	select	select

22. Any other vaccines received within one month prior to the date listed in item 4 (continued):					Dose number in series	Date Given
Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site		
select			select	select	select	
select			select	select	select	
select			select	select	select	
select			select	select	select	
select			select	select	select	
select			select	select	select	

Use the space below to provide any additional information (indicate item number):

COMPLETING THE VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS) FORM

GENERAL INSTRUCTIONS

- Submit this form electronically using the Internet. For instructions, visit www.vaers.hhs.gov/uploadfile/.
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366.
- If you need additional help submitting a report you may call the VAERS toll-free information line at 1-800-822-7967, or send an email to info@vaers.org.
- Fill out the VAERS form as completely as possible and use the **Continuation Page** if needed. Use a separate VAERS form for each individual patient.
- If you do not know exact numbers, dates, or times, please provide your best guess. You may leave these spaces blank if you are not comfortable guessing.
- You can get specific information on the vaccine and vaccine lot number by contacting the facility or clinic where the vaccine was administered.
- Please report all significant adverse events that occur after vaccination of adults and children, even if you are not sure whether the vaccine caused the adverse event.
- Healthcare professionals should refer to the VAERS Table of Reportable Events at www.vaers.hhs.gov/reportable.html for the list of adverse events that must be reported by law (42 USC 300aa-25).
- Healthcare professionals treating a patient for a suspected vaccine adverse event may need to contact the person who administered the vaccine in order to exchange information and decide how best to complete and submit the VAERS form.

SPECIFIC INSTRUCTIONS

Items 2, 3, 4, 5, 6, 17, 18 and 21 are **ESSENTIAL** and should be completed.

- **Items 4 and 5:** Provide dates and times as specifically as you can and enter as much information as possible (e.g., enter the month and year even if you don't know the day). If you do not know the exact time, but know it was in the morning ("AM") or afternoon or evening ("PM"), please provide that information.
- **Item 6:** If you fill in the form by hand, provide age in years. If a child is less than 1 year old, provide months of age. If a child is more than 1 year old but less than 2 years old, provide year and months (e.g., 1 year and 6 months). If a child is less than 1 month of age when vaccinated (e.g., a birth dose of hepatitis B vaccine) then answer 0 years and 0 months, but be sure to include the patient's date of birth (item 2) and date and time of vaccination (item 4).
- **Item 8:** If the patient who received the vaccine was pregnant at time of vaccination, select "Yes" and describe the event, any pregnancy complications, and estimated due date if known in item 18. Otherwise, select "No" or "Unknown."
- **Item 9:** List any prescriptions, over-the-counter medications, dietary supplements, herbal remedies, or other non-traditional/alternative medicines being taken by the patient when the vaccine(s) was given.
- **Item 10:** List any allergies the patient has to medications, foods, or other products.
- **Item 11:** List any short-term or acute illnesses the patient had on the date of vaccination AND up to one month prior to this date (e.g., cold, stomach flu, ear infection, etc.). This does **NOT** include the adverse event you are reporting.
- **Item 12:** List any chronic or long-standing health conditions the patient has (e.g., asthma, diabetes, heart disease).
- **Item 13:** List the name of the person who is completing the form. Select the "Check if same as item 1" box if you are the patient or if you live at the same address as the patient. The contact information you provided in item 1 will be automatically entered for you. Otherwise, please provide new contact information.
- **Item 14:** List the doctor or other healthcare professional who is the best person to contact to discuss the clinical details of the adverse event.
- **Item 15:** Select the "Check if same as item 13" box if the person completing the form works at the facility that administered the vaccine(s). The contact information provided in item 13 will be automatically entered for you. Otherwise, provide new contact information.
- **Item 16:** Select the option that best describes the type of facility where the vaccine(s) was given.

- **Item 17:** Include only vaccines given on the date provided in item 4. The vaccine route options include:

• Injection/shot (intramuscular, subcutaneous, intradermal, jet injection, and unknown)	• By mouth/oral • In nose/intranasal	• Other (specify) • Unknown
---	---	--

For body site, the options include:

• Right arm • Left arm • Arm (side unknown)	• Right thigh • Left thigh • Thigh (side unknown)	• Nose • Mouth	• Other (specify) • Unknown
---	---	---	--

For vaccines given as a series (i.e., 2 or more doses of the same vaccine given to complete a series), list the dose number for the vaccine in the last column named "Dose number in series."
- **Item 18:** Describe the adverse event(s), treatment, and outcome(s). Include signs and symptoms, when the symptoms occurred, diagnosis, and treatment. Provide specific information if you can (e.g., if patient had a fever, provide the temperature).
- **Item 19:** List any medical tests and laboratory results related to the adverse event(s). Include abnormal findings as well as normal or negative findings.
- **Item 20:** Select "Yes" if the patient's health is the same as it was prior to the vaccination or "No" if the patient has not returned to the same state of health prior to the vaccination, and provide details in item 18. Select "Unknown" if the patient's present condition is not known.
- **Item 21:** Select the result(s) or outcome(s) for the patient. If the patient did not have any of the outcomes listed, select "None of the above." Prolongation of existing hospitalization means the patient received a vaccine during a hospital stay and an adverse event following vaccination occurred that resulted in the patient spending extra time in the hospital. Life threatening illness means you believe this adverse event could have resulted in the death of the patient.
- **Item 22:** List any other vaccines the patient received within one month prior to the vaccination date listed in item 4.
- **Item 23:** Describe the adverse event(s) following any previous vaccine(s). Include patient age at vaccination, dates of vaccination, vaccine type, and brand name.
- **Item 24:** Check all races that apply.
- **Item 25:** Check the single best answer for ethnicity.
- **Item 26:** For health department use only.
- **Items 27 and 28:** Complete only for U.S. Military or Department of Defense related reports. In addition to active duty service members, Reserve and National Guard members, beneficiaries include: retirees, their families, survivors, certain former spouses, and others who are registered in the Defense Enrollment Eligibility Reporting System (DEERS).

GENERAL INFORMATION

- VAERS (www.vaers.hhs.gov) is a national vaccine safety monitoring system that collects information about adverse events (possible reactions or problems) that occur during or after administration of vaccines licensed in the United States.
- VAERS protects patient identity and keeps patient identifying information confidential.
- The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule permits reporting of protected health information to public health authorities including the Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) (45 CFR § 164.512(b)).
- VAERS accepts all reports without judging the importance of the adverse event or whether a vaccine caused the adverse event.
- Acceptance of a VAERS report by CDC and FDA does not constitute admission that the vaccine or healthcare personnel caused or contributed to the reported event.
- The National Vaccine Injury Compensation Program (VICP) is administered by the Health Resources and Services Administration (HRSA). The VICP is separate from the VAERS program and reporting an event to VAERS does not constitute filing a claim for compensation to the VICP (see www.hrsa.gov/vaccinecompensation/index.html).
- Knowingly filing a false VAERS report with the intent to mislead the Department of Health and Human Services is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment.

VAERS Table of Reportable Adverse Events following Vaccination

VAERS Table of Reportable Events Following Vaccination*	
Vaccine/Toxoid	Event and interval from vaccination
Tetanus in any combination; DTaP, DTP, DTP-Hib, DT, Td, TT, Tdap, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV	A. Anaphylaxis or anaphylactic shock (3 days) B. Brachial neuritis (28 days) C. Shoulder Injury Related to Vaccine Administration (2 days) D. Vasovagal syncope (1 hour) E. Any acute complications or sequelae (including death) of above events (interval - not applicable) F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Pertussis in any combination; DTaP, DTP, DTP-Hib, Tdap, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV	A. Anaphylaxis or anaphylactic shock (3 days) B. Encephalopathy or encephalitis (7 days) C. Shoulder Injury Related to Vaccine Administration (2 days) D. Vasovagal syncope (1 hour) E. Any acute complications or sequelae (including death) of above events (interval - not applicable) F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Measles, mumps and rubella in any combination; MMR, MMRV, MM	A. Anaphylaxis or anaphylactic shock (3 days) B. Encephalopathy or encephalitis (15 days) C. Shoulder Injury Related to Vaccine Administration (2 days) D. Vasovagal syncope (1 hour) E. Any acute complications or sequelae (including death) of above events (interval - not applicable) F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Rubella in any combination; MMR, MMRV	A. Chronic arthritis (42 days) B. Any acute complications or sequelae (including death) of above event (interval - not applicable) C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)

VAERS Table of Reportable Events Following Vaccination*	
Vaccine/Toxoid	Event and interval from vaccination
Measles in any combination; MMR, MMRV, MM	A. Thrombocytopenic purpura (7-30 days) B. Vaccine-strain measles viral infection in an immunodeficient recipient ○ Vaccine-strain virus identified (interval - not applicable) ○ If strain determination is not done or if laboratory testing is inconclusive (12 months) C. Any acute complications or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Oral Polio (OPV)	A. Paralytic polio ○ in a non-immunodeficient recipient (30 days) ○ in an immunodeficient recipient (6 months) ○ in a vaccine-associated community case (interval - not applicable) B. Vaccine-strain polio viral infection ○ in a non-immunodeficient recipient (30 days) ○ in an immunodeficient recipient (6 months) ○ in a vaccine-associated community case (interval - not applicable) C. Any acute complication or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Inactivated Polio in any combination-IPV, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV	A. Anaphylaxis or anaphylactic shock (3 days) B. Shoulder Injury Related to Vaccine Administration (2 days) C. Vasovagal syncope (1 hour) D. Any acute complication or sequelae (including death) of the above event (interval - not applicable) E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)

VAERS Table of Reportable Events Following Vaccination*	
Vaccine/Toxoid	Event and interval from vaccination
Hepatitis B in any combination- HepB, HepA-HepB, DTaP-HepB-IPV, Hib-HepB	A. Anaphylaxis or anaphylactic shock (3 days) B. Shoulder Injury Related to Vaccine Administration (2 days) C. Vasovagal syncope (1 hour) D. Any acute complications or sequelae (including death) of the above event (interval - not applicable) E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
<i>Haemophilus influenzae</i> type b in any combination (conjugate)- Hib, Hib-HepB, DTaP-IPV/Hib, Hib-MenCY	A. Shoulder Injury Related to Vaccine Administration (2 days). B. Vasovagal syncope (1 hour) C. Any acute complication or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Varicella in any combination- VAR, MMRV	A. Anaphylaxis or anaphylactic shock (3 days) B. Disseminated varicella vaccine-strain viral disease. - o Vaccine-strain virus identified (not applicable) - o If strain determination is not done or if laboratory testing is inconclusive (42 days) C. Varicella vaccine-strain viral reactivation (not applicable) D. Shoulder Injury Related to Vaccine Administration (2 days) E. Vasovagal syncope (1 hour) F. Any acute complication or sequelae (including death) of above events (interval - not applicable) G. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Rotavirus (monovalent or pentavalent) RV1, RV5	A. Intussusception (1–21 days) B. Any acute complication or sequelae (including death) of above events (interval - not applicable) C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)

VAERS Table of Reportable Events Following Vaccination*	
Vaccine/Toxoid	Event and interval from vaccination
Pneumococcal conjugate (7-valent or 13-valent) PCV7, PCV13	A. Shoulder Injury Related to Vaccine Administration (2 days) B. Vasovagal syncope (1 hour) C. Any acute complication or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Hepatitis A in any combination- HepA, HepA-HepB	A. Shoulder Injury Related to Vaccine Administration (2 days) B. Vasovagal syncope (1 hour) C. Any acute complication or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Seasonal influenza--trivalent inactivated influenza, quadrivalent inactivated influenza, live attenuated influenza-IIV, IIV3, IIV4, RIV3, ccIIV3, LAIV4	A. Anaphylaxis or anaphylactic shock (3 days) B. Shoulder Injury Related to Vaccine Administration (2 days) C. Vasovagal syncope (1 hour) D. Guillain-Barre' Syndrome (3-42 days) E. Any acute complication or sequelae (including death) of above events (interval - not applicable) F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Meningococcal - MCV4, MPSV4, Hib-MenCY, MenACWY, MenB	A. Anaphylaxis or anaphylactic shock (3 days) B. Shoulder Injury Related to Vaccine Administration. (2 days) C. Vasovagal syncope (1 hour) D. Any acute complication or sequelae (including death) of above events (interval - not applicable) E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Human Papillomavirus (Quadrivalent, Bivalent, or 9 valent)-9vHPV4, 4vHPV, 2vHPV	A. Anaphylaxis or anaphylactic shock (3 days) B. Shoulder Injury Related to Vaccine Administration (2 days) C. Vasovagal syncope (1 hour) D. Any acute complication or sequelae (including death) of above events (interval - not applicable) E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)

VAERS Table of Reportable Events Following Vaccination*	
Vaccine/Toxoid	Event and interval from vaccination
Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, and/or pregnant women after addition of a vaccine to the Vaccine Injury Table	A. Shoulder Injury Related to Vaccine Administration (2 days) B. Vasovagal syncope (1hour) C. Any acute complication or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
* Effective date: January 8, 2024. The Reportable Events Table (RET) reflects what is reportable by law (42 USC 300aa-25) to the Vaccine Adverse Event Reporting System (VAERS) including conditions found in the manufacturers package insert. In addition, healthcare professionals are encouraged to report any clinically significant or unexpected events (even if you are not certain the vaccine caused the event) for any vaccine, whether or not it is listed on the RET. Manufacturers are also required by regulation (21CFR 600.80) to report to the VAERS program all adverse events made known to them for any vaccine.	

A list of vaccine abbreviations is located at: <https://www.cdc.gov/vaccines/terms/vacc-abbrev.html>

References:

Department of Health & Human Services. January 8, 2024. Vaccine Adverse Event Reporting System (VAERS): VAERS Table of Reportable Events Following Vaccination. [https://vaers.hhs.gov/docs/VAERS Table of Reportable Events Following Vaccination.pdf](https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf). Accessed 2 October 2024.



South Carolina Department of Labor, Licensing and Regulation

South Carolina Board of Pharmacy

110 Centerview Dr. • Columbia • SC • 29210

P.O. Box 11927 • Columbia • SC 29211-1927

Phone: 803-896-4700 • Contact: pharmacy@llr.sc.gov • Fax: 803-896-4596llr.sc.gov/bop**Vaccination Provider Registration**

Nonstate-certified pharmacy technicians can use this form to register as a vaccination provider as required under S.C. Code Ann. § 40-43-190(B)(4)(b)(ii) to administer vaccinations pursuant to the Protocol for Administration of Vaccines by Pharmacists. Once completed, log into your e-service account and upload: <https://eservice.llr.sc.gov/DocumentSubmission/>.

NOTE: The only nonstate-certified pharmacy technicians eligible to provide vaccinations under the Protocol for Administration of Vaccines by Pharmacists are those technicians that trained and administered vaccines under the federal Public Readiness and Emergency Preparedness (PREP) Act prior to July 2, 2024 as outlined in S.C. Code Ann. § 40-43-190(B)(4)(b)(ii).

Name: _____

License/Registration No.: _____

Eligibility Questions

1. Did you complete a practical training program prior to July 2, 2024 pursuant to the federal PREP Act that was approved by the Accreditation Council for Pharmacy Education (ACPE) and included hands-on injection technique and recognition and treatment of emergency reactions to vaccines?
☐ Yes ☐ No
2. Did you provide vaccines pursuant to the PREP Act prior to July 2, 2024?
☐ Yes ☐ No
3. Do you currently have a certification for completion of either the American Heart Association BLS for Healthcare Providers Course or the American Red Cross Adult and Pediatric CPR/AED Course?
☐ Yes ☐ No

Acknowledgement

By signing below, I understand that as a vaccination provider and while providing vaccine administrations pursuant to the Protocol for Administration of Vaccines by Pharmacists, I am required to:

- 1) be supervised by a pharmacist that has received the required training under the protocol,
- 2) maintain a current certification through an approved basic life support or CPR provider-level course (renewed every 2 years) as outlined in the protocol, and
- 3) complete no less than one (1) hour of continuing education each license year regarding administration of vaccines.

Signature_____
Date

Appendix I

S.C. Code Ann. § 40-43-190

Administration of vaccines, informed consent, administrators, recordkeeping

Effective date: July 2, 2024

(A)(1) Upon recommendation of the Joint Pharmacist Administered Vaccines Committee, the Board of Medical Examiners shall determine whether a specific vaccine is appropriate for administration by a pharmacist without a written order or prescription of a practitioner pursuant to this section. If a vaccine is approved, the Board of Medical Examiners shall issue a written protocol for the administration of vaccines by pharmacists without an order or prescription of a practitioner.

(2) The administration of vaccines as authorized in this section must not be to a person under the age of sixteen years; provided, however, that:

(a) the influenza vaccine may be administered to a person twelve years of age or older pursuant to protocol issued by the Board of Medical Examiners;

(b) the influenza vaccine may be administered to a person under the age of twelve pursuant to protocol issued by the Board of Medical Examiners upon recommendation of the Joint Pharmacist Administered Vaccines Committee;

(c) a pharmacist who has completed the training described in subsection (B)(1) may administer other vaccines approved by the Centers for Disease Control to a person of any age pursuant to a written order or prescription of a practitioner for a specific patient of that practitioner; and

(d) if the person receiving a vaccine is under the age of eighteen years, a pharmacist must inform the patient and their caregiver of the importance of mental health and routine well care visits with a pediatrician or other licensed primary care provider and refer patients as appropriate.

(e) a pharmacist shall only administer a vaccine to a person less than sixteen years of age if that person's caretaker (with written parental consent), parent, or legal guardian is present at the time the vaccine is administered.

(3) The written protocol must further authorize pharmacists to administer without an order or prescription of a practitioner those medications necessary in the treatment of adverse events. These medications must be used only in the treatment of adverse events and must be limited to those delineated within the written protocol.

(4) The Board of Medical Examiners must issue the written protocol upon its approval of the vaccine for administration pursuant to this section.

(5) A pharmacist who has completed the training described in subsection (B)(1) may administer a vaccine approved by the Centers for Disease Control pursuant to written order or prescription of a practitioner for a specific patient of that practitioner.

(B) The written protocol must provide that:

(1) A pharmacist seeking authorization to administer a vaccine approved pursuant to this section shall successfully complete a course of training accredited by the Accreditation Council for Pharmacy Education or a similar health authority or professional body approved by the Board of Pharmacy and the Board of Medical Examiners. Training must comply with current Centers for Disease Control guidelines and must include study materials, hands-on training, and techniques for administering vaccines and must provide instruction and experiential training in the following content areas:

(a) mechanisms of action for vaccines, contraindications, drug interactions, and monitoring after vaccine administration;

(b) standards for adult vaccination practices;

(c) basic immunology and vaccine protection;

(d) vaccine-preventable diseases;

- (e) recommended vaccination schedules;
- (f) vaccine storage management;
- (g) biohazard waste disposal and sterile techniques;
- (h) informed consent;
- (i) physiology and techniques for vaccine administration;
- (j) prevaccine and postvaccine assessment and counseling;
- (k) vaccination record management;
- (l) management of adverse events, including identification, appropriate response, emergency procedures, documentation, and reporting;
- (m) understanding of vaccine coverage by federal, state, and local entities;
- (n) needle-stick management.

(2) A pharmacist administering vaccinations without an order or prescription of a practitioner pursuant to this section shall:

- (a) obtain the informed consent of the person being vaccinated or that person's guardian;
- (b) maintain a copy of the vaccine administration in that person's record and provide a copy to the person or the person's guardian;
- (c) notify that person's designated physician or primary care provider of a vaccine administered;
- (d) report administration of all vaccinations to the South Carolina Immunization Registry in compliance with regulations established by the Department of Health and Environmental Control as the department may require; provided, however, that the phase-in schedule provided in Regulation 61-120 for reporting vaccinations does not apply to vaccinations administered pursuant to this section;
- (e) maintain a current copy of the written protocol at each location at which a vaccination is administered pursuant to this section.

(3) For purposes of this section, "informed consent" means a written document that is signed and dated by an individual; or if the individual is a minor, by a parent or legal guardian; or if the individual is incapacitated or without sufficient mental capacity, by a designated health care agent pursuant to a health care power of attorney, that at a minimum includes:

- (a) an explanation of the vaccine or treatment that is written in language that is understandable to the average lay person;
- (b) language that clearly indicates that the individual agrees to the administration of the vaccine or treatment, that the individual has had time to thoughtfully and voluntarily accept or decline the vaccine or treatment free from coercion; and
- (c) if the vaccine or treatment is an investigational medical product or is made available through an Emergency Use Authorization by the federal Food and Drug Administration, a statement acknowledging its investigational nature and the civil liability protections afforded it by law.

(4) A pharmacy intern or pharmacy technician may administer vaccinations under the direct supervision of a pharmacist who has completed vaccination training as required by item (1) if the pharmacy intern or pharmacy technician:

- (a) is certified through a basic life support or CPR provider-level course that is approved by the Board of Medical Examiners and the Board of Pharmacy and completes a practical training program that is approved by the Accreditation Council for Pharmacy Education (ACPE) which includes, at a minimum, hands-on injection technique and the recognition and treatment of emergency reactions to vaccines; and
- (b) if a pharmacy technician, the pharmacy technician must be:
 - (i) state-certified; or
 - (ii) nonstate-certified but administered vaccinations and received training pursuant to

the federal Public Readiness and Emergency Preparedness (PREP) Act prior to the effective date of this section and registers with the Board of Pharmacy as an authorized vaccination provider.

(5) A pharmacist or pharmacy technician administering vaccinations shall, as part of the current continuing education requirements, complete no less than one hour of continuing education each license year regarding administration of vaccinations.

(C) Informed consent must be documented in accordance with the written protocol issued pursuant to this section.

(D) All records required by this section must be maintained in the pharmacy for a period of at least ten years from the date of the last vaccination or dispensing for adults and at least thirteen years from the date of the last vaccination or dispensing for minors.

(E) All documentation, records, and copies required by this section may be stored electronically.