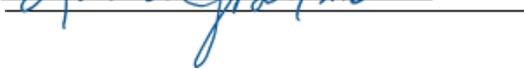


**PROTOCOL FOR ADMINISTRATION OF VACCINES BY PHARMACISTS
SUBMITTED BY THE JOINT PHARMACIST ADMINISTERED VACCINES COMMITTEE
AND REVIEWED, REVISED AND APPROVED BY
THE SOUTH CAROLINA BOARD OF MEDICAL EXAMINERS**

**REVISED by the Joint Pharmacist Administered Vaccines Committee October 21, 2024
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**Linda J. Bell, M.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

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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 the current schedule recommended by the Advisory Committee on Immunization Practices (ACIP) of the US Centers for Disease Control and Prevention (CDC)²;
- (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, hydroxyzine 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.

¹ See S.C. Code Ann. §40-43-190.

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

- (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 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 a vaccine, the vaccinee (or his or her legal guardian/representative) must be given information about the risks and benefits associated with the 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, 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 the vaccinee's 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-2* contains a VAERS form and *Appendix G-3* 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 individual 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) Obtaining Weight of Children-Pharmacists, pharmacy interns, and eligible pharmacy technicians administering vaccines pursuant to this Protocol must obtain the weight of all patients under the age of 12 prior to administering a vaccine. The child should be weighed in the pharmacy prior to administration, and the weight should be documented in the appropriate unit of measurement relative to the dosing tables for rescue medications.
- (f) 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 pharmacist 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, and adhere to dosing and administration information provided by the package inserts and ACIP 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 diphtheria/Tetanus, diphtheria, 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 (MCV4 and MenB)	

³ As to COVID-19 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 training³ 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.

³ See Section III for specific requirements for pharmacists, eligible pharmacy technicians, and pharmacy interns. Page 9 of 51

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 (i.e., EpiPen). If an EpiPen is to be stocked, at least four (4) adult EpiPens (delivering a single dose of 0.3 mg/0.3 mL) and at least four (4) pediatric EpiPens (delivering a single dose of .15 mg/.15 ml) should be available.
- (d) Diphenhydramine (Benadryl) injectable solution (50 mg per mL) and oral 25 mg dosage form, to include tablets, capsules or liquid.
- (e) Hydroxyzine hydrochloride in tablets of 10mg, 25mg, and 50mg and/or 10mg/5ml liquid.
- (f) A scale capable of weighing children ages three (3) and older.
- (g) Syringes, if commercially available: 1-mL and 3-mL, 22g and 25g, 1-inch, and 1 ½-inch needles for epinephrine and diphenhydramine.
- (h) Alcohol swabs and bandages.
- (i) Blood pressure monitoring device or stethoscope and sphygmomanometer (with pediatric, adult and extra-large cuffs).
- (j) Adult and pediatric size pocket masks with one-way valve.
- (k) Flashlight with extra batteries (for examination of mouth and throat).
- (l) Time-keeping device with ability to count seconds.
- (m) Telephone access.
- (n) 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 to use 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-complaint under this Protocol. Also, the pharmacist should be familiar with how to operate the required devices.

APPENDIX C

GENERAL SCREENING QUESTIONNAIRE TO DETERMINE SAFETY OF ALL VACCINES

Below is a list of general screening questions a pharmacist, pharmacy intern, or eligible pharmacy technician 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 the manufacturer's package insert. 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 fever?
 - (2) Do you have a new 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 vaccines with any contraindications and/or complex medical issues including immunosuppression or history of Guillain-Barré syndrome should be referred to their primary care provider for vaccination.

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, pharmacy intern, or eligible pharmacy technician 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 and the manufacturer's package insert.

- (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 immunosuppressive home infusions or weekly/monthly injections (such as Remicade, Humira, Enbrel, Cimzia, Simponi, Simponi Aria, Xeljanz, Orencia, Arava, Actemra, Cytoxan, Rituxan, adalimumab, infliximab, etanercept, etc.), 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 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. 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 will be providing the designated physician or primary care provider (as listed below) 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 attached Vaccine Information Statement for the [NAME OF] vaccine. I understand the risks and benefits and have had sufficient time to thoughtfully consider whether to accept or decline this vaccine. I have been provided an opportunity to ask questions, which have been answered to my satisfaction. I wish to receive the [NAME OF] vaccine, and I am in no way being unduly influenced, coerced, or otherwise forced to receive this vaccine, and hereby give consent for [PHARMACIST OR PHARMACY INTERN/PHARMACY TECHNICIAN WITH SUPERVISING PHARMACIST NAME(S)] to administer the [NAME OF] vaccine.

**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 of 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	1–6 months	9–19 lb	4–8.5 kg	0.05 mL (or mg)	off label
	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
Teens	11–12 years	77–99 lb	35–45 kg	0.35–0.4 mL (or mg)	0.3 mg/dose
	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 three (3) 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, up to 100 mg maximum single dose for adults, and 40 mg maximum single dose for children and adolescents. Do not administer more than one (1) dose of diphenhydramine. 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
	Age group	Range of Weight (lb)	Range of weight (kg) ¹	Liquid: 12.5 mg/5 mL Tablets: 25 mg or 50 mg
Infants and Children	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
	8-12 years	57-99 lb	26-45 kg	25–50 mg/dose
Teens	13 years & older	100+ lb	46+ kg	50 mg/dose (up to 50 mg or 100 mg single dose)

(f) Hydroxyzine may be administered orally. The recommended oral dose is 0.5—1 mg/kg body weight. Do not administer more than one (1) dose. Refer to the dosing chart below:

				Hydroxyzine dose calculations based on 0.5 mg/kg
	Age group	Range of Weight (lb)	Range of weight (kg) ¹	Liquid: 10 mg/5 mL Tablets: 10 mg or 25 mg
Infants and Children	7-36 months	20-32 lb	9-14 kg	5-7.5 mg/dose
	37-59 months	33-39 lb	15-17.5 kg	7.5-10 mg/dose
	5-7 years	40-56 lb	18-22.5 kg	10-12.5 mg/dose
	8-10 years	57-76 lb	26-34.5 kg	12-15 mg/dose
Teens	11-12 years	77-99 lb	35-45 kg	15-25 mg/dose
	13 years & older	100+ lb	46+ kg	25 mg/dose (50-100 mg, maximum per day)

(g) Monitor the vaccinee closely and check vital signs (blood pressure, pulse, and respirations) every 2 to 5 minutes.

(h) Stay with vaccinee until EMS arrives.

(i) If necessary, perform cardiopulmonary resuscitation (CPR) and maintain airway.

(j) 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.

(k) 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. An Adverse Reaction Medication Log form is attached hereto as *Appendix G-1*.

(l) 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.

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

References

- (a) Immunization Action Coalition. *Medical Management of Vaccine Reactions in Adult Patients*. Retrieved from <http://www.immunize.org/catg.d/p3082.pdf>. January 30, 2016.
- (b) Immunization Action Coalition. *Medical Management of Vaccine Reactions in Children and Teens*. Retrieved from <http://www.immunize.org/catg.d/p3082a.pdf>. November 9, 2020.

APPENDIX G-1

Adverse Reaction Medication Log

Date and Time of Adverse Reaction: _____

Signature of Administering Pharmacy Intern (if applicable)

Date: _____

Signature of Administering or Supervising Pharmacist

Date: _____

Appendix G-2

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>

		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: _____		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: _____
2. Date of birth: (mm/dd/yyyy) _____	3. Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown	11. Other illnesses at the time of vaccination and up to one month prior: _____
4. Date and time of vaccination: (mm/dd/yyyy) _____ Time: hh:mm _____ <input type="checkbox"/> AM <input type="checkbox"/> PM	5. Date and time adverse event started: (mm/dd/yyyy) _____ Time: hh:mm _____ <input type="checkbox"/> AM <input type="checkbox"/> PM	
6. Age at vaccination: _____ Years _____ Months	7. Today's date: (mm/dd/yyyy) _____	12. Chronic or long-standing health conditions: _____
8. Pregnant at time of vaccination?: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown (If yes, describe the event, any pregnancy complications, and estimated due date if known in item 18)		

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM		INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN	
13. Form completed by: (name) _____ Relation to patient: <input type="checkbox"/> Healthcare professional/staff <input type="checkbox"/> Patient (yourself) <input type="checkbox"/> Parent/guardian/caregiver <input type="checkbox"/> Other: _____ Street address: _____ <input type="checkbox"/> Check if same as item 1 City: _____ State: _____ ZIP code: _____ Phone: () _____ Email: _____		15. Facility/clinic name: _____ Fax: () _____ Street address: _____ <input type="checkbox"/> Check if same as item 13 City: _____ State: _____ ZIP code: _____ Phone: () _____	
14. Best doctor/healthcare professional to contact about the adverse event: Name: _____ Phone: () _____ Ext: _____		16. Type of facility: (Check one) <input type="checkbox"/> Doctor's office, urgent care, or hospital <input type="checkbox"/> Pharmacy or store <input type="checkbox"/> Workplace clinic <input type="checkbox"/> Public health clinic <input type="checkbox"/> Nursing home or senior living facility <input type="checkbox"/> School or student health clinic <input type="checkbox"/> Other: _____ <input type="checkbox"/> 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				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	
18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.) Use Continuation Page if needed				21. Result or outcome of adverse event(s): (Check all that apply) <input type="checkbox"/> Doctor or other healthcare professional office/clinic visit <input type="checkbox"/> Emergency room/department or urgent care <input type="checkbox"/> Hospitalization: Number of days (if known) _____ Hospital name: _____ City: _____ State: _____ <input type="checkbox"/> Prolongation of existing hospitalization (vaccine received during existing hospitalization) <input type="checkbox"/> Life threatening illness (immediate risk of death from the event) <input type="checkbox"/> Disability or permanent damage <input type="checkbox"/> Patient died – Date of death: (mm/dd/yyyy) _____ <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Congenital anomaly or birth defect <input type="checkbox"/> None of the above		
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)?: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown						

ADDITIONAL INFORMATION						
22. Any other vaccines received within one month prior to the date listed in item 4: Use Continuation Page if needed				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	
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) <input type="checkbox"/> Yes _____ <input type="checkbox"/> No <input type="checkbox"/> Unknown						
24. Patient's race: <input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> Native Hawaiian or Other Pacific Islander (Check all that apply) <input type="checkbox"/> White <input type="checkbox"/> Unknown <input type="checkbox"/> Other: _____						
25. Patient's ethnicity: <input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> 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: <input type="checkbox"/> Active duty <input type="checkbox"/> Reserve <input type="checkbox"/> National Guard <input type="checkbox"/> Beneficiary <input type="checkbox"/> Other: _____	28. Vaccinated at Military/DoD site: <input type="checkbox"/> Yes <input type="checkbox"/> 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
 - Other (specify)
 - In nose/intranasal
 - Unknown

For body site, the options include:

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

Appendix G-3

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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> A. Thrombocytopenic purpura (7-30 days) B. Vaccine-strain measles viral infection in an immunodeficient recipient <ul style="list-style-type: none"> ○ 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)	<ul style="list-style-type: none"> A. Paralytic polio <ul style="list-style-type: none"> ○ 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 <ul style="list-style-type: none"> ○ 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> A. Anaphylaxis or anaphylactic shock (3 days) B. Disseminated varicella vaccine-strain viral disease. <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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. Accessed 2 October 2024.

APPENDIX H

Human Papillomavirus (HPV) Vaccine

Human Papillomavirus (HPV):

Human Papillomavirus (HPV) is a common virus that can cause various cancers later in life. HPV infections are very common and HPV acquisition generally occurs soon after first sexual activity. HPV is spread through intimate skin-to-skin contact such as vaginal, anal, or oral sex with someone who is infected with the virus, even without signs or symptoms. Most HPV infections (9 out of 10) resolve on their own within 2 years, but sometimes infections last longer and can cause cancer later in life of the cervix, vagina, vulva, penis, anus, or back of the throat, including the base of the tongue and tonsils. HPV vaccination helps protect individuals, including children, from new HPV infections and HPV-associated diseases including some cancers. HPV vaccination is most effective when given to an individual prior to being exposed to the virus.

Human Papillomavirus (HPV) Vaccine¹:

Below is general information a pharmacist should be familiar with prior to the administration of these vaccines. Vaccine-specific screening questions should also be asked based on the vaccine's contraindications and precautions according to current ACIP guidelines and the manufacturer's package insert.

Recommendations:

Children and Adults aged 9 through 26 years.²

- Routine vaccination is recommended at age 11 or 12 years, but can be given as early as 9 years.
- Catch-up recommendations apply to persons not vaccinated at age 11 or 12 years:
 - o To all individuals through age 26 years.
 - o To adults 27 through 45 years, through shared clinical decision-making (see box below) as public health benefit of HPV vaccination in this age range is minimal, but might benefit some individuals in this age range.
- Pregnancy, Breastfeeding, and Lactation
 - o HPV vaccination should be delayed until after pregnancy; however, pregnancy testing is not needed before vaccination.
 - o Persons who are breastfeeding or lactating can receive the HPV vaccine.

¹ In the event of a conflict between any information in this Appendix and the manufacturers' package inserts or ACIP recommendations, pharmacists administering vaccines under this protocol should adhere to ACIP recommendations and the respective manufacturer package insert.

² This protocol only allows for vaccination of individuals 16 years and older without a prescription.

Considerations for shared clinical decision-making regarding HPV vaccination of adults aged 27-45 years

Ideally, HPV vaccination should be given in early adolescence because vaccination is most effective before exposure to HPV through sexual activity. For adults aged 27 through 45 years who are not adequately vaccinated, clinicians can consider discussing HPV vaccination with persons who are most likely to benefit. HPV vaccination does not need to be discussed with most adults aged >26 years.

- HPV is a very common sexually transmitted infection. Most HPV infections are transient and asymptomatic and cause no clinical problems.
- Although new HPV infections are most commonly acquired in adolescence and young adulthood, some adults are at risk for acquiring new HPV infections. At any age, having a new sex partner is a risk factor for acquiring a new HPV infection.
- Persons who are in a long-term, mutually monogamous sexual partnership are not likely to acquire a new HPV infection.
- Most sexually active adults have been exposed to some HPV types, although not necessarily all of the HPV types targeted by vaccination.
- No clinical antibody test can determine whether a person is already immune or still susceptible to any given HPV type.
- HPV vaccine efficacy is high among persons who have not been exposed to vaccine-type HPV before vaccination.
- Vaccine effectiveness might be low among persons with risk factors for HPV infection or disease (e.g., adults with multiple lifetime sex partners and likely previous infection with vaccine-type HPV), as well as among persons with certain immunocompromising conditions.
- HPV vaccines are prophylactic (i.e., they prevent new HPV infections). They do not prevent progression of HPV infection to disease, decrease time to clearance of HPV infection, or treat HPV-related disease.

Available Vaccines:

There are 3 vaccines licensed for use in the United States; however, as of late 2016, only the 9vHPV (Gardasil 9) is distributed in the United States. The quadrivalent (4vHPV, Gardasil™ by Merck) and the bivalent (2vHPV Cervarix™ by GSK) are not distributed in the United States currently.

Vaccine	Indication	Vaccine Components	Other Ingredients/ Components
9-valent (9vHPV, Gardasil® 9 by Merck)	For females and males 9-45 years of age for prevention of certain HPV associated diseases (cancers, warts, and lesions) caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, or 58.	Major capsid (L1) protein of HPV Types 6, 11, 16, 18, 31, 33, 45, 52, and 58	Aluminum (provided as AAHS), sodium chloride, L-histidine, polysorbate 80, sodium borate, yeast protein, and water for injection.

Dosage, Schedule, and Route of Administration

- Each dose is 0.5mL of Gardasil 9 administered intramuscularly (IM) either in the deltoid or anterolateral area of the thigh.
- Series should be administered at 0, 1-2, and 6 months for individuals 15-45 years at initial vaccination. The minimum interval between dose 1 and 2 is 4 weeks, between dose 2 and 3 is 12 weeks, and between dose 1 and dose 3 is 5 months; repeat dose if administered too soon.
- If a dose is missed, the patient **does not have to start over**. The series should be continued where the patient left off to complete the series.

Vaccine Preparation

- Do not dilute or mix Gardasil 9 with other vaccines.
- Shake well immediately before use to maintain suspension of the vaccine.
- Gardasil 9, after agitation, is a white cloudy liquid. Vaccine should be inspected visually for

particulate matter and discoloration prior to administration. Do not use the product if particulates are present or if it appears discolored.

Coadministration with other vaccines:

Concomitant administration of Gardasil 9 with Menactra and Adacel did not interfere with the antibody responses to any of the vaccines when compared with non-concomitant administration of Gardasil 9 with Menactra and Adacel.

Special Counseling Information

Patients should be advised of the following:

- Patients should seek routine annual examinations with their primary care provider, to include age-appropriate sexual health counseling.
- Women should obtain cervical cancer screening per standard of care:
 - o Cervical cancer screening via Papanicolaou (Pap) testing should start at age 21; and
 - o Cervical cancer screening via Pap and HPV co-testing should begin at age 30;
- Vaccines will not protect against disease from all HPV types;
- Vaccines will not protect patients against HPV that they already have; and
- Vaccines are not a treatment for HPV infection.

Storage:

Store Gardasil 9 vials or syringes refrigerated at 2 to 8°C (36 to 46°F). Do not freeze. Protect from light. Administer as soon as possible after being removed from refrigeration.

Contraindications:

- Hypersensitivity, including severe allergic reactions to yeast (a vaccine component of Gardasil 9), or after a previous dose of Gardasil 9 or Gardasil.
- Severe allergic reaction (e.g. anaphylaxis) to a vaccine component.

Most Common Adverse Reactions:

Gardasil 9- most common (≥10%) local and systemic adverse reactions reported were injection-site pain, injection site swelling, injection-site erythema, and headache.

Adverse Events:

Adverse events occurring after administration of any vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS).

References:

1. CDC. July 4, 2024. *About HPV*. https://www.cdc.gov/hpv/about/index.html#cdc_disease_basics_overview-what-it-is. Accessed October 11, 2024.
2. CDC. December 6, 2023. Child Immunization Schedule Notes. <https://www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-notes.html#note-hpv>. Accessed October 11, 2024.
3. Meites E, Szilagyi PG, Chesson HW, Unger ER, Romero JR, Markowitz LE. Human Papillomavirus Vaccination for Adults: Updated Recommendations of the Advisory Committee on Immunization Practices. *MMWR Morb Mortal Wkly Rep* 2019;68:698-702. DOI: <http://dx.doi.org/10.15585/mmwr.mm6832a3>.
4. GARDASIL® 9. [Package Insert]. March 2024. https://www.merck.com/product/usa/pi_circulars/g/gardasil_9/gardasil_9_pi.pdf. Accessed October 11, 2024.

Appendix I

Pneumococcal Vaccines

Pneumococcal Infections:

Pneumococcal infections are caused by *Streptococcus pneumoniae* (pneumococcus), a gram-positive, facultative anaerobic bacterium. Pneumococcus can colonize the upper respiratory tract, most commonly in young children, and is transmitted to others through contact with respiratory droplets from a person with pneumococcal colonization in the upper respiratory tract. Certain individuals with pneumococcal colonization might develop invasive pneumococcal disease (IPD). IPD is infection of normally sterile sites, including pneumonia with bacteremia, meningitis, osteomyelitis, septic arthritis, and bacteremia without a focus of infection; examples of noninvasive disease include pneumonia without bacteremia, sinusitis, or otitis media. In adults, pneumococcal pneumonia is the most common type of pneumococcal disease, and pneumococcus is the most common bacterial cause of pneumonia that results in hospitalization. Among individuals <19 years, *Streptococcus pneumoniae* continues to be a common bacterial etiology of acute respiratory infections, including pneumonia and acute otitis media (AOM), and invasive diseases such as bacteremia and meningitis. Pneumococcal vaccines target the more common *Streptococcus pneumoniae* serotypes.

Pneumococcal Vaccine¹:

Below is general information a pharmacist should be familiar with prior to the administration of these vaccines. Vaccine-specific screening questions should also be asked based on the vaccine's contraindications and precautions according to current ACIP guidelines and the manufacturer's package insert.

Recommendations:

Children 16-18 years²:

- **Individuals 6-18 years with any risk condition* and no previous PCV13, PCV15, or PCV20 Vaccination (see table below)**
 - o a single dose of PCV15 or PCV20 is recommended ≥8 weeks after the most recent dose of pneumococcal vaccination, regardless of whether the child has previously received PPSV23, even if PCV7 was received.
 - If PCV15 is used, it should be followed by a dose of PPSV23, if not previously given, at least 8 weeks after the last PCV dose, if not previously given.
 - If PCV20 is used, no PPSV23 is needed.

- **Individuals 2-18 years with any risk condition* vaccinated previously with PCV13 or PCV15 and completed series before age 6 years**
 - o Individuals that completed their PCV doses with ≥1 dose of PCV20, no additional doses of pneumococcal vaccine are indicated.

¹ In the event of a conflict between any information in this Appendix and the manufacturers' package inserts or ACIP recommendations, pharmacists administering vaccines under this protocol should adhere to ACIP recommendations and the respective manufacturer package insert.

² This protocol only allows for vaccine administration of individuals ≥16 years without a prescription.

- If the PCV doses were completed using PCV13 or PCV15 (no PCV20), either a dose of PCV20 or ≥1 dose of PPSV23 is recommended at least 8 weeks after the last PCV dose to complete the recommended vaccine series.
 - When PPSV23 is used instead of PCV20 for children 2-18 years with an immunocompromising condition, either PCV20 or a 2nd dose of PPSV23 is recommended ≥5 years after the first PPSV23 dose.
- **Individuals 6-18 years with a risk condition* Vaccinated Previously only by PCV13 at or after age 6 years**
 - 1 dose of either PCV20 or ≥1 PPSV23 at least 8 weeks after the last PCV13 dose
 - If PPSV23 is used instead of PCV20 for children 6-18 years with an immunocompromising condition, either PCV20 or a 2nd dose of PPSV23 dose is recommended ≥5 years after the first PPSV23 dose.
- **Children aged <19 years who are hematopoietic stem cell transplant (HSCT) recipients:**
 - Receive 4 doses of PCV20, starting 3-6 months after HSCT. Administer 3 doses of PCV20, 4 weeks apart starting 3-6 months after HSCT. Administer the 4th PCV20 dose ≥6 months after the 3rd dose of PCV20 or ≥12 months after HSCT, whichever is later.
 - If PCV20 is not available, 3 doses of PCV15 4 weeks apart, followed by a single dose of PPSV23 ≥1 year after HSCT, can be administered. For patients with chronic graft versus host disease (GVHD) who are receiving PCV15, a 4th dose of PCV15 can be administered in place of the PPSV23 because these children are less likely to respond to PPSV23.
 - A patient's clinical team is best informed to determine the appropriate time of vaccination.

***Risk conditions include:** cerebrospinal fluid leak; chronic heart disease; chronic kidney disease (excluding maintenance dialysis and nephrotic syndrome, which are included in immunocompromising conditions); chronic liver disease; chronic lung disease (including moderate persistent or severe persistent asthma); cochlear implant; diabetes mellitus; immunocompromising conditions (on maintenance dialysis or with nephrotic syndrome; congenital or acquired asplenia or splenic dysfunction; congenital or acquired immunodeficiencies (including B-(humoral) or T-lymphocyte deficiency; complement deficiencies, particularly C1, C2, C3, and C4 deficiency; and phagocytic disorders (excluding chronic granulomatous disease)); diseases and conditions treated with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas, Hodgkin disease, and solid organ transplant; HIV infection; and sickle cell disease or other hemoglobinopathies.

Risk-based pneumococcal vaccine recommendations for PCV unvaccinated children and adolescents with risk conditions—United States, 2023

Risk group/Condition	PCV* for children aged <6 yrs	PCV* for persons aged 6–18 yrs	PPSV23 for children aged ≥2 yrs with no previous PCV20 receipt	
	Recommended	Recommended	Recommended	Single revaccination 5 yrs after first dose
Children with chronic medical conditions				
Chronic heart disease ¹	Y	Y	Only if PCV13 or PCV15 used	N
Chronic kidney disease (excluding maintenance dialysis and nephrotic syndrome, which are included in immunocompromising conditions)	Y	Y	Only if PCV13 or PCV15 used	N
Chronic liver disease	Y	Y	Only if PCV13 or PCV15 used	N
Chronic lung disease (including moderate persistent or severe persistent asthma)	Y	Y	Only if PCV13 or PCV15 used	N
Diabetes mellitus	Y	Y	Only if PCV13 or PCV15 used	N
Cerebrospinal fluid leak	Y	Y	Only if PCV13 or PCV15 used	N
Cochlear implant	Y	Y	Only if PCV13 or PCV15 used	N
Children with immunocompromising conditions				
Maintenance dialysis or with nephrotic syndrome	Y	Y	Only if PCV13 or PCV15 used	Only if no previous receipt of PCV20
Congenital or acquired asplenia, or splenic dysfunction	Y	Y	Only if PCV13 or PCV15 used	Only if no previous receipt of PCV20
Congenital or acquired immunodeficiencies ²	Y	Y	Only if PCV13 or PCV15 used	Only if no previous receipt of PCV20
Diseases and conditions treated with immunosuppressive drugs or radiation therapy ³	Y	Y	Only if PCV13 or PCV15 used	Only if no previous receipt of PCV20
HIV infection	Y	Y	Only if PCV13 or PCV15 used	Only if no previous receipt of PCV20
Sickle cell disease or other hemoglobinopathies	Y	Y	Only if PCV13 or PCV15 used	Only if no previous receipt of PCV20
Solid organ transplant	Y	Y	Only if PCV13 or PCV15 used	Only if no previous receipt of PCV20

Abbreviations: N = no; PCV = pneumococcal conjugate vaccine; PCV15 = 15-valent PCV; PCV20 = 20-valent PCV; PPSV23 = 23-valent pneumococcal polysaccharide vaccine; Y = yes.

* Either PCV15 or PCV20 can be used.

¹ Recommendations are of particular importance for children with cyanotic congenital heart disease and cardiac failure.

² Includes B- (humoral) or T-lymphocyte deficiency; complement deficiencies, particularly C1, C2, C3, and C4 deficiency; and phagocytic disorders (excluding chronic granulomatous disease).

³ Including malignant neoplasms, leukemias, lymphomas, and Hodgkin disease.

Adults aged ≥65 years:

Risk or age group	Vaccine received previously	Options for vaccination
Adults aged ≥65 years	None or PCV7 only at any age	A single dose of PCV21, PCV20, or PCV15. If PCV15 is administered, a single dose of PPSV23* should be administered ≥1 year after the PCV15 dose. A minimum interval of 8 weeks can be considered if PCV15 is used in adults with an immunocompromising condition, [†] cochlear implant, or CSF leak.
	PPSV23 only	A single dose of PCV21, PCV20, or PCV15 ≥1 year after the last PPSV23 dose.
	PCV13 only	A single dose of PCV21, PCV20, or PPSV23≥1 year after the PCV13 dose. When PPSV23 is used for adults with an immunocompromising condition, [†] cochlear implant, or CSF leak, administer PPSV23 ≥8 weeks after the PCV13 dose.
	PCV13 at any age and PPSV23 at age <65 years	A single dose of PCV21, PCV20, or PPSV23. If PCV21 or PCV20 is used, it should be administered ≥5 years after the last pneumococcal vaccine dose. If PPSV23 is used, it should be administered ≥1 year after the PCV13 dose (or ≥8 weeks since the PCV13 dose for adults with an immunocompromising condition, [†] cochlear implant, or CSF leak) and ≥5 years after the previous PPSV23 dose.
	PCV13 at any age and PPSV23 at age ≥65 years	Shared clinical decision-making is recommended regarding administration of either a single dose of PCV21 or PCV20 for any adult aged ≥65 years who has completed the recommended vaccination series with both PCV13 and PPSV23 (i.e., PPSV23 administered at age ≥65 years) but PCV21, PCV20 or PCV15 not yet received. If a decision to administer PCV21 or PCV20 is made, a single dose is recommended ≥5 years after the last pneumococcal vaccine dose.

Abbreviations: CSF = cerebrospinal fluid; PCV = pneumococcal conjugate vaccine; PCV7 = 7-valent PCV; PCV13 = 13-valent PCV; PCV15 = 15-valent PCV; PCV20 = 20-valent PCV; PCV21 = 21-valent PCV; PPSV23 = 23-valent pneumococcal polysaccharide vaccine.

* For adults who have received PCV15 but have not completed their recommended pneumococcal vaccine series with PPSV23, 1 dose of PCV21 or PCV20 may be used if PPSV23 is not available.

[†] Chronic renal failure, nephrotic syndrome, immunodeficiency, iatrogenic immunosuppression, generalized malignancy, HIV infection, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplant, congenital or acquired asplenia, or sickle cell disease or other hemoglobinopathies.

[§] Alcoholism; chronic heart disease, including congestive heart failure and cardiomyopathies; chronic liver disease; chronic lung disease, including chronic obstructive pulmonary disease, emphysema, and asthma; cigarette smoking; or diabetes mellitus.

Note: As of October 23, 2024, the pneumococcal conjugate vaccine (PCV) is recommended for all PCV-naïve adults aged ≥50 years. When more information is available, the chart above will be updated.

Shared Clinical Decision-Making

PCV20 or PCV21 Vaccination for Adults 65 Years or Older

Adults 65 years of age or older have the option to receive supplemental PCV20 or PCV21 (not both) if they previously completed the pneumococcal vaccine series with both PCV13 and PPSV23 and meet the following criteria:

- Previously received one dose of PCV13 (but not PCV15, PCV20, or PCV21) at any age, and
- Previously received all recommended doses of PPSV23 (including 1 dose of PPSV23 at or after 65 years of age)

The determination to administer PCV20 or PCV21 is based on a shared clinical decision-making (SCDM) process between a patient and their health care provider. SCDM recommendations are optional and informed by the characteristics, values, and preferences of the patient, and the clinical discretion of the health care provider.

If you discuss supplemental PCV20 or PCV21 vaccination with a patient 65 years of age or older who previously completed the pneumococcal vaccine series with both PCV13 and PPSV23:

Remember:



PCV20 or PCV21 is not routinely recommended for these individuals as their risk of disease is lower due to prior vaccinations. Their remaining risk depends on:

- Their risk of exposure to serotypes contained in PCV20 or PCV21
- The presence of underlying medical conditions or other risk factors that increase the risk of developing severe disease
- Time since last pneumococcal vaccination (i.e., 5 or more years)

Consider:



Increased risk of exposure to PCV20 or PCV21 serotypes may occur among people who are living in:

- Nursing homes or other long-term care facilities
- Areas with low pediatric pneumococcal conjugate vaccine uptake

If exposed, people with one or more of the following health issues are at increased risk of developing severe pneumococcal disease:

- Immunocompromising condition*
- Cochlear implant
- Cerebrospinal fluid leak
- One or more of these chronic medical conditions: alcoholism; chronic heart, liver, or lung disease; cigarette smoking; or diabetes

Protection against disease from both PCV13 and PPSV23 is expected to decrease over time.

If you vaccinate:



If you and your patient decide PCV20 or PCV21 is appropriate, give one dose of PCV20 or PCV21 (no preference) at least 5 years after the patient's last pneumococcal vaccine dose.

PCV20 and PCV21 should not be administered to a patient who has had a severe allergic reaction (e.g., anaphylaxis) to a:

- Previous dose of PCV
- Component of the vaccine
- Vaccine containing diphtheria toxoid
- Component of a vaccine containing diphtheria-toxoid

*Chronic renal failure, nephrotic syndrome, immunodeficiency, iatrogenic immunosuppression, generalized malignancy, HIV, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplant, congenital or acquired asplenia, sickle cell disease or other hemoglobinopathies.



Additional Information:

CDC Adult Immunization Schedule by Age:
www.cdc.gov/vaccines/imz/immz-schedules/adult-ages.html

CDC PneumoRecs VaxAdvisor App for Vaccine Providers:
www.cdc.gov/pneumococcal/hcp/vaccine-recommendations/app.html

CDC Pneumococcal Vaccine Recommendations:
www.cdc.gov/pneumococcal/hcp/vaccine-recommendations/index.html

ACIP Contraindications Guidelines for Immunization:
www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html

Adults aged 19–64 years with certain immunocompromising conditions, a CSF leak, a cochlear implant, or chronic medical conditions.

Risk or age group	Vaccine received previously	Options for vaccination
Adults aged 19–64 years with an immunocompromising condition, [†] a CSF leak, or a cochlear implant	None or PCV7 only at any age	A single dose of PCV21, PCV20, or PCV15. If PCV15 is used, administer a single dose of PPSV23* ≥8 weeks after the PCV15 dose.
	PPSV23 only	A single dose of PCV21, PCV20, or PCV15 ≥1 year after the last PPSV23 dose.
	PCV13 only	A single dose of PCV21, PCV20, or PPSV23. If PCV21 or PCV20 is used, it should be administered ≥1 year after the PCV13 dose. If PPSV23 is used, administer PPSV23 ≥8 weeks after the PCV13 dose. When PPSV23 is used instead of PCV21 or PCV20 for these adults, a single dose of PCV21, PCV20 or PPSV23 dose is recommended ≥5 years after the first PPSV23 dose.
	PCV13 and 1 dose of PPSV23	A single dose of PCV21 or PCV20, or ≥1 dose of PPSV23. If PCV21 or PCV20 is used, it should be administered ≥5 years after the last pneumococcal vaccine dose. When a second PPSV23 dose is used instead of PCV21 or PCV20, it should be administered ≥8 weeks after the PCV13 dose and ≥5 years after the first PPSV23 dose. The pneumococcal vaccination recommendations should be reviewed again when the person reaches age 65 years. If PCV21 or PCV20 is used in place of any dose of PPSV23, the series is complete, and it need not be followed by additional pneumococcal vaccine doses.
	PCV13 and 2 doses of PPSV23	The pneumococcal vaccination recommendations should be reviewed again when the person turns age 65 years. Alternatively, a single dose of either PCV21 or PCV20 should be administered ≥5 years after the last pneumococcal vaccine dose. If PCV21 or PCV20 is used, the series is complete, and it need not be followed by additional pneumococcal vaccine doses.
Adults aged 19–64 years with chronic medical conditions [‡]	None or PCV7 only at any age	A single dose of PCV21, PCV20, or PCV15. If PCV15 is administered, a single dose of PPSV23* should be administered ≥1 year after the PCV15 dose.
	PPSV23 only	A single dose of PCV21, PCV20, or PCV15 ≥1 year after the last PPSV23 dose.
	PCV13 only	A single dose of PCV21, PCV20, or PPSV23 ≥1 year after the PCV13 dose.
	PCV13 and 1 dose of PPSV23	The pneumococcal vaccination recommendations should be reviewed again when the person reaches age 65 years.

Abbreviations: CSF = cerebrospinal fluid; PCV = pneumococcal conjugate vaccine; PCV7 = 7-valent PCV; PCV13 = 13-valent PCV; PCV15 = 15-valent PCV; PCV20 = 20-valent PCV; PCV21 = 21-valent PCV; PPSV23 = 23-valent pneumococcal polysaccharide vaccine.

* For adults who have received PCV15 but have not completed their recommended pneumococcal vaccine series with PPSV23, 1 dose of PCV21 or PCV20 may be used if PPSV23 is not available.

[†] Chronic renal failure, nephrotic syndrome, immunodeficiency, iatrogenic immunosuppression, generalized malignancy, HIV infection, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplant, congenital or acquired asplenia, or sickle cell disease or other hemoglobinopathies.

[‡] Alcoholism; chronic heart disease, including congestive heart failure and cardiomyopathies; chronic liver disease; chronic lung disease, including chronic obstructive pulmonary disease, emphysema, and asthma; cigarette smoking; or diabetes mellitus.

Note: As of October 23, 2024, the pneumococcal conjugate vaccine (PCV) is recommended for all PCV-naïve adults aged ≥50 years. When more information is available, the chart above will be updated.

Available Vaccines:

Vaccine	Indication	Vaccine Components	Other Ingredients/ Components
PCV15 (Vaxneuvance® by Merck)	Prevention of invasive disease caused by <i>Streptococcus pneumoniae</i> serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F in individuals 6 weeks of age and older.	<i>S. pneumoniae</i> polysaccharide serotypes 1, 3, 4, 5, 6A, 6B 7F, 9V,14, 18C, 19A, 19F, 22F, 23F, and 33F individually conjugated with CRM197 carrier protein.	L-histidine, polysorbate 20, sodium chloride, and aluminum as aluminum phosphate adjuvant.
PCV20 (Prenar 20® by Pfizer)	Prevention of invasive disease caused in individuals 6 weeks and older and prevention of pneumonia in individuals 18 and older caused by <i>Streptococcus pneumoniae</i> serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F. Also indicated for prevention of otitis media caused by various <i>S. pneumoniae</i> serotypes in those 6 weeks to 5 years old.	<i>S. pneumoniae</i> serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F saccharides, CRM197 carrier protein.	Polysorbate 80, succinate buffer, sodium chloride, aluminum as aluminum phosphate adjuvant.
PCV21 (Capvaxive™ by Merck)	Prevention of invasive disease and pneumonia caused by <i>Streptococcus pneumoniae</i> serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and older.	Pneumococcal polysaccharide antigen (each polysaccharide serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B (de-O-acetylated prior to conjugation), 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B) individually conjugated to CRM197 carrier protein.	L-histidine, polysorbate 20, sodium chloride, and water for injection.
PPSV23 (Pneumovax® 23 by Merck)	Prevention of pneumococcal disease caused by serotypes 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, and 33F contained in the vaccine.	Polysaccharides from <i>Streptococcus pneumoniae</i> serotypes 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, and 33F in isotonic saline solution.	Phenol (preservative).

Dosage and Route of Administration:

- **PCV15, PCV20, PCV21:** 0.5mL dose administered intramuscularly.
- **PPSV23:** 0.5mL dose administered intramuscularly or subcutaneously.

Vaccine Preparation:

- **PCV15:** Hold the prefilled syringe horizontally and shake vigorously immediately prior to use to obtain an opalescent suspension. Do not use the vaccine if it cannot be resuspended. If particulate matter or discoloration is observed, do not use.
- **PCV20:** Do not mix Prevnar 20 with other vaccines/products in the same syringe. Hold the pre-filled syringe horizontally and shake vigorously until the vaccine is a homogeneous white suspension. Do not use the vaccine if it cannot be re-suspended. Do not use if large particulate matter or discoloration is found.
- **PCV21:** Capvaxive is a colorless, clear to opalescent solution. If particulate matter or discoloration is observed, do not use.
- **PPSV23:** Pneumovax 23 is a clear, colorless solution. If particulate matter or discoloration present, do not administer the vaccine. Do not mix Pneumovax 23 with other vaccines in the same syringe or vial.

Coadministration with other vaccines:

In children, any PCV can be administered at the same time as other routine childhood vaccinations, including COVID-19 vaccines, in separate syringes and using different injection sites. Coadministration of PCV 13, PCV15, and PCV20 were studied with vaccines containing diphtheria, tetanus, acellular pertussis, inactivated poliovirus, *Haemophilus influenzae* type b, hepatitis B, measles, mumps, rubella, rotavirus, and varicella, but PCV15 and PCV20 have not been studied with meningococcal vaccine. The same precautions used for coadministration of PCV13 and meningococcal vaccines should be applied when PCV15 or PCV20 is used.

PCV15, PCV20, or PPSV23 can be co-administered with QIV in an adult immunization program, as concomitant administration (specifically, PCV15 or PPSV23 and IIV4 [Fluarix], and PCV20 and adjuvanted IIV4 [Fluad]) has been demonstrated to be immunogenic and safe. However, slightly lower pneumococcal serotype-specific OPA GMTs or geometric mean concentrations were reported for certain serotypes when pneumococcal vaccines were co-administered with IIV4 compared with when pneumococcal vaccines were given alone. Among adults ≥ 65 years who received 2 doses of BNT162b2 COVID-19 vaccine with the second dose of BNT162b2 administered ≥ 6 months previous, slightly lower pneumococcal serotype-specific OPA GMTs were reported when PCV20 was coadministered with BNT162b2 versus PCV20 alone; however, this difference was not statistically significant. In adults aged ≥ 50 years who received 2 doses of adjuvanted recombinant zoster vaccine (RZV), immune responses to coadministration of RZV and PPSV23 were noninferior to those in this age group who received the vaccines in sequence. Evaluation of coadministration of PCV15 or PPSV23 with COVID-19 vaccines among adults ≥ 50 years is ongoing. Currently, no data are available on coadministration with other vaccines (e.g., tetanus, diphtheria, acellular pertussis vaccine, or hepatitis B) among adults.

PCV21 routinely administered with other age-appropriate doses of vaccines at the same visit is recommended for adults who have no specific contraindication to vaccination at the time of the health care visit.

Storage:

- **PCV15:** Store Vaxneuvance refrigerated 2-8°C (36-46°F). Do not freeze. Protect from light.
- **PCV20:** Store Prevnar 20 refrigerated 2-8°C (36-46°F). Syringes should be stored in the refrigerator horizontally to minimize the resuspension time. Do not freeze. Discard if frozen. Administer as soon as possible after being removed from refrigeration.
- **PCV21:** Store Capvaxive refrigerated 2-8°C (36-46°F). Do not freeze. Protect from light.
- **PPSV23:** Store Pneumovax 23 refrigerated 2-8°C (36-46°F).

Contraindications:

- **PCV15, PCV20, PCV21:** Severe allergic reaction (e.g., anaphylaxis) to any component of the respective vaccine or to diphtheria toxoid.
- **PPSV23:** Severe allergic reaction (e.g., anaphylaxis) to any component of Pneumovax.

Most Common Adverse Reactions:

PCV15: In children (2-17 years old), injection-site pain, myalgia, injection-site swelling, injection-site erythema, fatigue, headache, and injection-site induration. In adults (≥18 years old), injection-site pain, fatigue, myalgia, headache, injection-site swelling, injection-site erythema, and arthralgia.

PCV20: Most common (≥10%) in individuals 15 months to 17 years old were irritability, pain at the injection site, drowsiness, fatigue and muscle pain, decreased appetite, injection site swelling and injection site redness and headache, and fever. For those 18-59 years old, the most common (≥10%) were pain at the injection site, muscle pain, fatigue, headache, arthralgia, and injection site swelling. For those ≥60 years old, the most common (≥10%) were pain at the injection site, muscle pain and fatigue, headache, and arthralgia.

PCV21: Most common (≥10%) in those 18-49 years old were injection-site pain, fatigue, headache, myalgia, injection-site erythema, and injection-site swelling. For individuals ≥50 years old, the most common (≥10%) were injection-site pain, fatigue, and headache.

PPSV23: Most common (≥10%) were injection-site pain/soreness/tenderness, injection-site swelling/induration, headache, injection-site erythema, asthenia and fatigue, and myalgia. For those ≥65 years, adverse reactions were higher following revaccination than initial vaccination.

Adverse Events:

Adverse events occurring after administration of any vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS).

References:

1. Kobayashi M, Farrar JL, Gierke R, et al. *Use of 15-Valent Pneumococcal Conjugate Vaccine Among U.S. Children: Updated Recommendations of the Advisory Committee on Immunization Practices—United States, 2022.* MMWR Morb Mortal Wkly Rep 2022;71:1174-1181. DOI: <http://dx.doi.org/10.15585/mmwr.mm7137a3>.

2. CDC. September 12, 2024. *Pneumococcal Vaccine Recommendations*. <https://www.cdc.gov/pneumococcal/hcp/vaccine-recommendations/index.html>. Accessed October 13, 2024.
3. ACIP Updates: Recommendations for Use of 20-Valent Pneumococcal Conjugate Vaccine In Children—United States, 2023. *MMWR Morb Mortal Wkly Rep* 2023;72:1072. DOI: <http://dx.doi.org/10.15585/mmwr.mm7239a5>.
4. Kobayashi M, Pilishvili T, Farra JL, et al. Pneumococcal Vaccine for Adults Aged ≥19 Years: Recommendations of the Advisory Committee on Immunization Practices, United States, 2023. *MMWR Recomm Rep* 2023;72(No. RR-3):1-39. DOI: <http://dx.doi.org/10.15585/mmwr.rr7203a1>.
5. CAPVAXIVE™. [Package Insert]. June 2024. https://www.merck.com/product/usa/pi_circulars/c/capvaxive/capvaxive_pi.pdf. Accessed October 13, 2024.
6. CDC. September 11, 2024. *Shared Clinical Decision-Making PCV20 or PCV21 Vaccination for Adults 65 Years or Older*. <https://www.cdc.gov/vaccines/hcp/admin/downloads/job-aid-SCDM-pneumococcal-508.pdf>. Accessed October 13, 2024.
7. Kobayashi M, Leidner AJ, Gierke R, et al. Use of 21-Valent Pneumococcal Conjugate Vaccine Among U.S. Adults: Recommendations of the Advisory Committee on Immunization Practices—United States, 2024. *MMWR Morb Mortal Wkly Rep* 2024;73:793-798. DOI: <http://dx.doi.org/10.15585/mmwr.mm7336a3>.
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9. PREVNAR 20®. [Package Insert]. April 2023. <https://labeling.pfizer.com/ShowLabeling.aspx?id=15428>. Accessed October 14, 2024.
10. PNEUMOVAX® 23. [Package Insert]. April 2023. https://www.merck.com/product/usa/pi_circulars/p/pneumovax_23/pneumovax_pi.pdf. Accessed October 14, 2024.

APPENDIX J

COVID-19 VACCINES

Pharmacists may administer COVID-19 vaccines that are FDA approved or have been granted an Emergency Use Authorization (EUA) to individuals 16 years of age and older. The vaccines must be administered in accordance with CDC guidelines.

**The addition of COVID-19 vaccines to this protocol is separate and apart from any authority that may be granted to pharmacists, pharmacy interns, and/or pharmacy technicians to administer COVID-19 vaccines pursuant to the Public Readiness and Emergency Preparedness (PREP) Act, as amended by the 2020 Coronavirus Aid, Relief, and Economic Security (CARES) Act. To the extent this Protocol, S.C. Code Ann. § 40-43-190, and/or any other provision of South Carolina law contains any legal requirement that is different from, or is in conflict with, any requirement applicable under the PREP Act, the PREP Act preempts such South Carolina law. 42 U.S.C.A. § 247d-6d. In other words, individuals administering COVID-19 vaccines in compliance with the PREP Act are not required to comply with any provision of South Carolina law that is different from, or is in conflict with, any requirement applicable under the PREP Act. For a full overview of the PREP Act, please see the Pharmacy Board's Guidance Documents available on its website at <https://llr.sc.gov/bop/>.

APPENDIX K

Respiratory Syncytial Virus (RSV) Vaccine for Adults

Respiratory Syncytial Virus (RSV):

Respiratory syncytial virus (RSV) is a highly contagious virus that is easily spread from person to person, most often through coughing or sneezing, that causes infections of the lungs and breathing passages in individuals of all age groups. It typically presents with mild, cold-like symptoms. RSV is particularly common in children. Usually, most young children have been infected with RSV by the time they reach 2 years of age. Some individuals, especially infants and older adults, are more like to develop severe RSV disease requiring hospitalization. In the U.S., RSV is seasonal and tends to start in the fall and peak in the winter.

Respiratory Syncytial Virus (RSV) Vaccine¹:

Below is general information a pharmacist should be familiar with prior to the administration of these vaccines. Vaccine-specific screening questions should also be asked based on the vaccine's contraindications and precautions according to current ACIP guidelines and the manufacturer's package insert.

Recommendations:

A single dose of any FDA-approved RSV Vaccine for:

- All Adults aged ≥ 75 years old.
 - Adults aged 60-74 years old who are at increased risk for severe RSV disease.
- ***Adults previously vaccinated should not receive another dose.***

Risk factors for severe respiratory syncytial virus disease among adults aged 60–74 years*

- Chronic cardiovascular disease (e.g., heart failure, coronary artery disease, or congenital heart disease [excluding isolated hypertension])
- Chronic lung or respiratory disease (e.g., chronic obstructive pulmonary disease, emphysema, asthma, interstitial lung disease, or cystic fibrosis)
- End-stage renal disease or dependence on hemodialysis or other renal replacement therapy
- Diabetes mellitus complicated by chronic kidney disease, neuropathy, retinopathy, or other end-organ damage, or requiring treatment with insulin or sodium-glucose cotransporter-2 (SGLT2) inhibitor
- Neurologic or neuromuscular conditions causing impaired airway clearance or respiratory muscle weakness (e.g., poststroke dysphagia, amyotrophic lateral sclerosis, or muscular dystrophy [excluding history of stroke without impaired airway clearance])
- Chronic liver disease (e.g., cirrhosis)
- Chronic hematologic conditions (e.g., sickle cell disease or thalassemia)
- Severe obesity (body mass index ≥ 40 kg/m²)
- Moderate or severe immune compromise[†]
- Residence in a nursing home
- Other chronic medical conditions or risk factors that a health care provider determines would increase the risk for severe disease due to viral respiratory infection (e.g., frailty,[§] situations in which health care providers have concern for presence of undiagnosed chronic medical conditions, or residence in a remote or rural community where transportation of patients with severe RSV disease for escalation of medical care is challenging[¶])

Abbreviation: RSV = respiratory syncytial virus.

¹ In the event of a conflict between any information in this Appendix and the manufacturers' package inserts or ACIP recommendations, pharmacists administering vaccines under this protocol should adhere to ACIP recommendations and the respective manufacturer package insert.

* Patient attestation is sufficient evidence of the presence of a risk factor. Vaccinators should not deny RSV vaccination to a person because of lack of medical documentation.

† A list of moderately or severely immunocompromising conditions can be found in the COVID-19 vaccination interim clinical considerations. <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromised>

§ Frailty is a multidimensional geriatric syndrome that reflects a state of increased vulnerability to adverse health outcomes. Although no consensus definition exists, one frequently used tool for determination is the Fried frailty phenotype assessment (<https://pubmed.ncbi.nlm.nih.gov/11253156/>) in which frailty is defined as a clinical syndrome with three or more of the following symptoms present: unintentional weight loss (10 lbs [4.5 kg] in the past year), self-reported exhaustion, weakness (grip strength), slow walking speed, or low physical activity.

¶ Health care providers caring for adults aged 60–74 years residing in these communities may use clinical judgement, knowledge of local RSV epidemiology, and community incidence of RSV-associated hospitalization to recommend vaccination for a broader population in this age group.

Available Vaccines:

Vaccine	Indication	Vaccine Components	Other Ingredients/ Components
RSVpreF vaccine (Abrysvo® by Pfizer)	Prevention of LRTD caused by RSV in individuals ≥60 years of age and older and pregnant individuals at 32-26 gestational age for prevention LRTD and severe LRTD caused by RSV in infants from birth- 6 months of age ²	RSV stabilized prefusion F proteins (RSV preF and RSV preF B)	Tromethamine, tromethamine hydrochloride, sucrose, mannitol, polysorbate 80, sodium chloride
Adjuvanted RSV Vaccine (Arexvy by GSK)	Prevention of LRTD caused by RSV in individuals ≥60 years of age and in individuals 50-59 years of age at increased risk ³	Recombinant RSVPreF3 antigen, MPL, QS-21	Trehalose, sodium chloride, potassium dihydrogen phosphate, dipotassium phosphate, polysorbate 80, disodium phosphate anhydrous, DOPC, and cholesterol.
mRESVIA® by Moderna	Prevention of LRTD caused by RSV in individuals ≥60 years or older.	Nucleoside modified mRNA encoding the RSV F glycoprotein stabilized in the prefusion conformation (pre-F protein)	total lipid content (SM-102 (heptadecan-9-yl 8-((2-hydroxyethyl)(6-oxo-6-(undecyloxy)hexyl) amino) octanoate), polyethylene glycol 2000 dimyristoyl glycerol [PEG2000-DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine[DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate trihydrate, sucrose, and water for injection.

² See Appendix L for RSV vaccination to pregnant individuals.

³ ACIP has only recommended vaccination in all adults ≥75 years of age and those 60-74 years of age at increased risk for RSV disease.

Dosage, Schedule, and Route of Administration

RSV vaccines should be administered as a single dose of 0.5mL as an intramuscular injection.

Coadministration with other vaccines:

Coadministration of RSV vaccines with other adult vaccines during the same visit is acceptable. Available data on immunogenicity of coadministration of RSV vaccines and other vaccines are currently limited. Coadministration of RSV and seasonal influenza vaccines met noninferiority criteria for immunogenicity with the exception of the Flu A/Darwin H3N2 strain when GSK RSV vaccine (Abrexvy) was co-administered with adjuvanted quadrivalent inactivated influenza vaccine; the clinical significance of this is unknown. Administering RSV vaccine with one or more other vaccines at the same visit might increase local or systemic reactogenicity. Data regarding the safety of coadministration with other recommend vaccines for this age group are lacking. When deciding whether to co-administer other vaccines with RSV vaccine, providers should consider whether the patient is up to date with currently recommended vaccines, the feasibility of the patient returning for additional vaccine doses, risk for acquiring vaccine-preventable disease, vaccine reactogenicity profiles, and patient preferences.

Storage:

Prior to reconstitution or thawing:

Abrysvo-Store vaccine prior to reconstitution refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton. Do not freeze. Discard if carton has been frozen.

Arexvy-Store both components prior to reconstitution refrigerated between 2°C to 8°C (36°F to 46°F). Store in the original package in order to protect vials from light. Do not freeze. Discard if either component has been frozen.

mRESVIA-

- Store frozen between -40°C to -15°C (-40°F to 5°F).
- During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
- Pre-filled plastic syringes may be stored refrigerated between 2°C to 8°C (36°F to 46°F) for up to 90 days prior to use. Pre-filled plastic syringes should not be refrozen. (ex. If syringes are shipped at refrigerated temperatures, 2°C to 8°C (36°F to 46°F), then the syringes should not be refrozen and should be stored at 2°C to 8°C (36°F to 46°F) until use.)

After reconstitution or thawing:

Abrysvo- The reconstituted vaccine should be a clear and colorless solution. After reconstitution, inspect for particulate matter and discoloration. If either is present, discard vaccine. Use immediately or store at room temperature (59-86°F). Discard reconstituted vaccine if not used within 4 hours.

Arexvy- The reconstituted vaccine should be an opalescent, colorless to pale brownish liquid. After reconstitution, inspect for particulate matter and discoloration. If either is present, do not administer the vaccine. Use immediately or store, protected from light, in the refrigerator 2°C to 8°C (36°F to 46°F) or at room temperature (up to 77°F). Discard reconstituted vaccine if not used within 4 hours.

mRESVIA- mRESVIA is a white to off-white suspension that may contain visible white or translucent product-related particulates. Do not administer if the vaccine is discolored or contains other particulate. After thawing, do not refreeze. Do not shake. Pre-filled plastic syringes can be stored at 8°C to 25°C (46°F to 77°F) for a total of 24 hours after being removed from refrigerated conditions. Do not return to refrigerator after standing at room temperature. Discard thawed pre-filled syringes if not used within this time frame.

Thawing Instructions for mRESVIA:

Configuration	Thaw in Refrigerator	Thaw at Room Temperature
Carton of one pre-filled syringe in single blister pack	Thaw between 2°C to 8°C (36°F to 46°F) for 60 minutes. Let each pre-filled syringe stand at room temperature for between 10 and 20 minutes before administering the vaccine.	Thaw between 15°C to 25°C (59°F to 77°F) for 45 minutes. If MRESVIA is thawed at room temperature, the vaccine is ready to be administered.
Carton of 10 pre-filled syringes in blister packs	Thaw between 2°C to 8°C (36°F to 46°F) for 155 minutes. Let each pre-filled syringe stand at room temperature for between 10 and 20 minutes before administering the vaccine.	Thaw between 15°C to 25°C (59°F to 77°F) for 140 minutes. If MRESVIA is thawed at room temperature, the vaccine is ready to be administered.

Contraindications:

History of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine to be administered.

Warnings and precautions:

- A. Persons with acute, moderate or severe illness with or without fever should delay immunization until symptoms have improved.
- B. Immunosuppressed people may have a diminished response.

Most Common Adverse Reactions:

Abrysvo-In individuals 60 years of age and older, the most commonly reported (≥10%) adverse reactions were fatigue, headache, pain at the injection site, and muscle pain.

Arexvy-In individuals 60 years of age and older, the most commonly reported adverse reactions (≥10%) were injection site pain, fatigue, myalgia, headache, and arthralgia.

mRESVIA-most commonly reported (≥10%) adverse reactions were injection-site pain, fatigue, headache, myalgia, arthralgia, axillary (underarm) swelling or tenderness, and chills.

Adverse Events:

Adverse events occurring after administration of any vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS).

References:

1. FDA. August 7, 2024. *Respiratory Syncytial Virus (RSV). FDA has approved vaccines and monoclonal antibodies for RSV.* <https://www.fda.gov/consumers/covid-19-flu-and-rsv/respiratory-syncytial-virus-rsv>. Accessed October 6, 2024.
2. Britton A, Roper LE, Kotton CN, et al. Use of Respiratory Syncytial Virus Vaccines in Adults Aged ≥60 Years: Updated Recommendations of Advisory Committee on Immunization Practices—United States, 2024. *MMWR Morb Mortal Wkly Rep* 2024;73:696-702. DOI: <http://dx.doi.org/10.15585/mmwr.mm7332e1>.
3. CDC. July 3, 2024. Healthcare Providers: RSV Vaccination for Adults 60 Years of Age and Over. <https://www.cdc.gov/vaccines/vpd/rsv/hcp/older-adults.html>. Accessed October 6, 2024.
4. ABRYSVO®. [Package Insert]. August 2024. <https://labeling.pfizer.com/ShowLabeling.aspx?id=19589>. Accessed October 6, 2024.
5. AREXVY. [Package Insert]. August 2024. https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Arexvy/pdf/AREXVY.PDF Accessed October 6, 2024.
6. MRESVIA™. [Package Insert]. October 2024. https://static.modernatx.com/pm/6cef78f8-8dad-4fc9-83d5-d2fbb7cff867/36130c97-6fb0-4bea-9f2e-fb5be7a90729/36130c97-6fb0-4bea-9f2e-fb5be7a90729_viewable_rendition_v.pdf. Accessed October 6, 2024.

APPENDIX L

Respiratory Syncytial Virus (RSV) Vaccine (Pregnant People)

Below is general information a pharmacist should be familiar with prior to the administration of the Abrysvo (Pfizer, Inc.) vaccine to pregnant people at 32 to 36 completed gestational weeks during September through January as a single dose. Vaccine-specific screening questions should also be asked based on the vaccine's contraindications and precautions according to current ACIP guidelines.

Recommendations

Pregnant people at 32 weeks and zero days' gestation to 36 weeks and 6 days' gestation between September and January. Pregnant people at 32 weeks and zero days' gestation to 36 weeks and 6 days' gestation between September and January.

Clinical Guidance

Seasonal Administration of RSVpreF Vaccine. Maternal RSVpreF vaccine should be administered to pregnant people during September (1-2 months before the anticipated start of the RSV season) through January (2-3 months before the anticipated end of the RSV season) to target vaccine to pregnant people whose infants will be in their first months of life, when protection from maternal vaccination would be at its highest, during the RSV season.

Additional Vaccine Doses in Subsequent Pregnancies. Currently, no data are available on either the efficacy of the first lifetime dose to protect infants born after subsequent pregnancies or the safety of additional doses given during subsequent pregnancies. Additional data are needed to determine whether additional seasonal doses during subsequent pregnancies are indicated, and ACIP might update recommendations in the future, as data become available.

Use of Nirsevimab and Maternal RSVpreF Vaccine. Either maternal RSVpreF vaccination during pregnancy at 32 to 36 weeks' gestation or nirsevimab immunization for infants aged <8 months who are born during or are entering their first RSV season is recommended to prevent RSV-associated LRTI in infants, but administration of both products is not needed for most infants. Providers who care for pregnant people should discuss the relative advantages and disadvantages of both maternal RSVpreF vaccination and nirsevimab and consider patient preferences when determining whether to vaccinate the pregnant person or to rely on administration of nirsevimab to the infant.

Pharmacists may **not** vaccinate anyone under the age of sixteen (16) without a written order or prescription for non-influenza vaccines, so should the nirsevimab for the infant appear to be the preferred choice, the patient should be referred to his or her pediatrician. See S.C. Code Ann. § 40-43-190 ("The administration of vaccines as authorized in this section must not be to a person under the age of sixteen (16) years [but for influenza].")

Contraindications

History of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine.

Warnings and Precautions

- A. People with acute, moderate or severe illness with or without fever should delay immunization until symptoms have improved.
- B. Potential risk for preterm birth and hypertensive disorders of pregnancy.
- C. Immunosuppressed people may have a diminished response.

Coadministration with Other Vaccines

In accordance with CDC's General Best Practices Guidelines for Immunization, maternal RSVpreF vaccine can be administered to pregnant people with other recommended vaccines, such as tetanus, diphtheria, and pertussis (Tdap), influenza, and COVID-19 vaccines, without regard to timing, including simultaneous vaccination at different anatomic sites on the same day.

Adverse events occurring after administration of any vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS).

Administration and Dosage

For intramuscular use only.

Administer as a single approximately 0.5 mL dose.

References

1. Centers for Disease Control and Prevention. (2023). *ACIP Evidence to Recommendations for Use of Pfizer RSVpreF in Pregnant People*. Retrieved from <https://www.cdc.gov/vaccines/acip/recs/grade/pfizer-RSVpreF-pregnant-people-etr.html>.
2. Centers for Disease Control and Prevention. (2023). *of the Pfizer Respiratory Syncytial Virus Vaccine During Pregnancy for the Prevention of Respiratory Syncytial Virus–Associated Lower Respiratory Tract Disease in Infants: Recommendations of the Advisory Committee on Immunization Practices*. Retrieved from <https://www.cdc.gov/mmwr/volumes/72/wr/mm7241e1.htm>.
3. Pfizer. (2023). *Abrysvo U.S. Physician Prescribing Information*. Retrieved from <https://www.pfizer.com/products/product-detail/abrysvotm>.



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: 803-896-4596

llr.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 vaccinations 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 N

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.