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 December 15, 2023
APPROVED by the Board of Medical Examiners December 20, 2023

[redacted]

Linda J. Bell, M.D.
Chair, Joint Pharmacist Administered Vaccines Committee

[redacted]

Anne G. Cook, MD, FACP
President, South Carolina Board of Medical Examiners

PROTOCOL FOR ADMINISTRATION OF VACCINES BY PHARMACISTS

Table of Contents

PROTOCOL FOR ADMINISTRATION OF VACCINES BY PHARMACISTS

I. Introduction

To help increase the vaccination rates in South Carolina, the South Carolina General Assembly enacted an amendment to the Pharmacy Practice Act that authorizes the Board of Medical Examiners to determine whether a specific vaccine is appropriate for administration by a licensed pharmacist without a written order or prescription of a practitioner. If a vaccine is approved for administration, the Board of Medical Examiners shall issue a written protocol for the administration of vaccines by licensed pharmacists without an order or prescription of a practitioner.

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 of the US Centers for Disease Control (CDC) and Prevention (ACIP)[1];

(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;

(c) administer vaccines according to directions provided in section XII of 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

A pharmacist or pharmacy intern supervised by a pharmacist seeking authorization to administer vaccines pursuant to this Protocol shall meet the following qualifications:

(a) Licensure -The pharmacist must be licensed and in good standing with the South Carolina Board of Pharmacy. The pharmacy intern must be certified and in good standing with the South Carolina Board of Pharmacy.

(b) Basic Life Support (BLS) or Cardiopulmonary Resuscitation (CPR) Certification -The pharmacist and pharmacy intern 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 -The pharmacist and pharmacy intern must complete an approved pharmacy-based immunization training program that is accredited by the Accreditation Council for Pharmacy Education (ACPE) 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 CDC 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:

[1] 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.

(a) mechanisms of action for vaccines, contraindications, drug interactions, and monitoring after vaccine administration;
(b) standards for vaccination practices;
(c) basic immunology and vaccine protection;
(d) vaccine-preventable diseases;
(e) recommended immunization 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;
(n) needle stick management.

A list of approved programs is specified in Appendix A.

(d) Continuing Education -The pharmacist 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 requirements.
(e) Liability Insurance -The pharmacist must maintain liability insurance that covers the administration of vaccines.

IV. Limitations on Pharmacy-based Vaccination

(a) Age -The administration of the non-influenza vaccines without a written order or prescription pursuant to this Protocol must not be to any persons under the age of eighteen (18) years. The administration of influenza vaccines without a written order or prescription pursuant to this Protocol may not be to any persons under the age of three (3) years.
(b) Delegation -A pharmacist may not delegate the administration of vaccines to a pharmacy technician or any other person who is not a pharmacist or pharmacy intern meeting the requirements set forth in III (a), (b) and (c) of this Protocol and any other applicable law and regulation. The qualified pharmacy intern must be under the direct supervision of the pharmacist.
(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.

V. Protocol, Facility and Equipment

Pharmacists who administer vaccines under this Protocol shall maintain a current copy of this Protocol at each location at which a pharmacist administers a vaccine, and an appropriate area for administering vaccines with the supplies and equipment listed in Appendix B.

VI. Informed Consent

Before receiving the vaccine, the vaccinee (or his or her legal representative) must be given information about the risks and benefits associated with vaccination.

(a) Consent Form -Any pharmacist administering vaccines pursuant to this Protocol must document the vaccinee or the vaccinee's legal representative's informed consent in writing prior to administration of a vaccine. Either the pharmacist or the qualified pharmacy intern and the supervising pharmacist must be identified on the consent form. The required consent form language is provided in Appendix E.

(b) Vaccine Information Statements - Each vaccinee, or his or her legal representative, must be provided with a copy of the most current Vaccine Information Statement (VIS) for the vaccine provided. The vaccinee or legal 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. Well-visits

A pharmacist or qualified pharmacy intern supervised by a pharmacist administering the influenza vaccine to children three (3) years of age and older must inform the patient's parent(s) or guardian(s) on the importance of well-visits to ensure that all other vaccinations are up-to-date.

VIII. Pharmacy-based Vaccination Record

A pharmacist or qualified pharmacy intern supervised by a pharmacist administering a vaccine pursuant to this Protocol must create a vaccination record for each vaccinee, and must maintain this record for a period of at least ten (10) years for patients at least 18 years old and at least thirteen (13) years for patients less than 18 years old. 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 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 administering pharmacy intern; and
(h) A copy of the notification letter sent to the vaccinee's designated primary care practitioner of any vaccine administered.

IX. Reporting Requirements

(a) Personal Immunization Record -The pharmacist must encourage all vaccinees to carry a personal immunization record card in their wallet. The pharmacist must provide and record the date of vaccination on the vaccinee's personal immunization record card.

(b) Medical Home Notification -Vaccinees must be informed regarding the importance of having a medical home and receiving other preventive medical services. When a vaccinee receives a vaccine, this shall be reported to their designated primary care practitioner. The required language is provided in the reporting form in Appendix F.

(c) Immunization Registry – A pharmacist administering vaccinations without an order or prescription of a practitioner shall 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.

(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.

X. Vaccination Safety

(a) Infection Control and Sterile Technique -Pharmacists and qualified pharmacy interns administering vaccines 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 pharmacist 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 and qualified pharmacy interns who administer vaccines shall receive the hepatitis B vaccine series unless: (1) the pharmacist has previously received the complete hepatitis B vaccination series, (2) antibody testing has revealed that the pharmacist or qualified pharmacy intern is immune, (3) the vaccine is contraindicated for medical reasons, or
(4) the pharmacist or qualified pharmacy intern signs a Hepatitis B Vaccine Declination statement.

(d) Occupational Safety and Health Administration (OSHA) Compliance -Pharmacists 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 and qualified pharmacy interns must obtain the weight of all patients under the age of 12 prior to administering the influenza 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 pharmacists must be prepared with procedures for their management. The procedures for managing adverse reactions are set forth in Appendix G.

XII. Supply Considerations

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

XIII. Vaccines

Pharmacists may administer US Food and Drug Administration (FDA) approved[2] 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 diptheria/Tetanus, disptheria, 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)	

[2] 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 and pharmacy interns seeking authorization to administer vaccines complete an accredited training course. 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 submission 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) 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.

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 adult EpiPens (delivering a single dose of 0.3 mg/0.3 mL) and at least four 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.

APPENDIX C

GENERAL SCREENING QUESTIONNAIRE TO DETERMINE SAFETY OF ALL VACCINES

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

(a) Are you sick today? If yes, ask these additional questions:
    (1) Do you have a new fever?
    (2) Do you have a cough?
    (3) Do you have diarrhea?
    (4) Have you been vomiting?

(b) Have you ever fainted or felt dizzy after receiving a vaccine?

(c) Have you ever had a reaction after receiving a vaccine?

(d) Do you have a long-term health problem with heart disease, lung disease, asthma, kidney disease, neurologic or neuromuscular disease, liver disease, metabolic disease (e.g., diabetes), or anemia or another blood disorder?

(e) Do you have a weakened immune system because of HIV/AIDS or another disease that affects the immune system, long-term treatment with drugs such as high-dose steroids, or cancer treatment with radiation or drugs?

(f) Do you have allergies to latex, medications, food or vaccines? (Examples: eggs, bovine protein, gelatin, gentamicin, polymyxin, neomycin, phenol, yeast or thimerosal)

(g) Have you ever had a seizure disorder for which you are on seizure medications, a brain disorder, Guillain-Barré syndrome or other nervous system problems?

(h) For women: Are you pregnant or considering becoming pregnant in the next month?

Precaution

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

Referrals

Potential 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.

APPENDIX D

GENERAL SCREENING QUESTIONNAIRE TO DETERMINE SAFETY OF LIVE VACCINES

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

(a) Do you consider yourself to be, or have you ever been told by a physician that you are, immunosuppressed?

(b) Are you currently on home infusions or weekly injections (such as Remicade, Humira, Enbrel, Cimzia, Simponi, Simponi Aria, Xeljanz, Orencia, Arava, Actemra, Cytoxan, Rituxan, adalimumab, infliximab, or etanercept), high-dose methotrexate, azathioprine or mercaptopurine, antivirals, anticancer drugs, or radiation treatments?

(c) Have you received any vaccinations or skin tests in the past four weeks?

(d) Have you received a transfusion of blood, blood products or been given a medication called immune (gamma) globulin in the past year?

(e) Are you currently taking high-dose steroid therapy (prednisone >20mg/day or equivalent) for longer than two weeks?

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 are providing your primary care provider with records of the vaccine(s) administered here so that your medical records may be complete, but be sure to take your personal record with you to your next appointment as well.

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

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

_____
Vaccine recipient's name

_____
Vaccine recipient's date of birth

_____
Vaccine Recipient's (or legal representative's) signature

_____
Date

_____
VIS Date

_____
Vaccine recipient's designated 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: _____

_____
Administering Pharmacist or Pharmacy Intern

_____
Pharmacist Supervising Administering Pharmacy Intern (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 kg2	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 doses, depending on the patient's response.

(e) Antihistamines may be given for hives or itching. Administer diphenhydramine either orally or by intramuscular injection. The standard dose is 1-2 mg/kg every 4-6 hours, up to 100 mg maximum single dose for adults, and 40 mg maximum single dose for children and adolescents. Do not attempt to give oral medications to a vaccinee who is not fully alert and able to swallow safely. Refer to the dosing chart below:

				Diphenhydramine dose calculations based on 1 mg/kg
	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 every 4- 6 hours. 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)[2]**	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.

[2] 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 H

HUMAN PAPILLOMAVIRUS (HPV)

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.

Special Clinical Considerations

I. Formulations

(a). Cervarix Human Papillomavirus Bivalent (16 and 18) Vaccine Recombinant

(1). Females age 9 – 45

(2). **Not approved for males**

(b) Gardasil® Human Papillomavirus Quadrivalent (6, 11, 16 and 18) Vaccine Recombinant

(1) Females and Males age 9 – 45

(c) Gardasil® 9 Human Papillomavirus 9- valent (6, 11, 16, 18, 31, 33, 45, 52 and 58) Vaccine, Recombinant – expected to replace Gardasil, yet both are available in US at least through 2015

(1) Females and Males age 9 – 45

II. Administration Intervals

(a) All three vaccines should be administered in a 3- dose schedule, with the second dose administered 1 to 2 months after the first dose and the third dose 6 months after the first dose. The minimum interval between the first and the second doses of vaccine is 4 weeks. The minimum interval between the second and the third doses is 12 weeks. The minimum interval between the first and third dose is 24 weeks.

(b) 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.

Special Counseling Information

III. Patient should be advised:

(a) Patients should seek routine annual examinations with their primary care provider, to include age-appropriate sexual health counseling.

(b) Women should obtain cervical cancer screening per standard of care:

(1) Cervical cancer screening via Papanicolaou (Pap) testing should start at age 21; and

(2) Cervical cancer screening via Pap and HPV co-testing should begin at age 30;

(c) Vaccines will not protect against disease from all HPV types;

(d) Vaccines will not protect patient against HPV that the patient already has; and

(e) Vaccines are not a treatment for HPV infection.

IV. References:

(a) Centers for Disease Control and Prevention. (2015). *Use of 9- valent human papillomavirus (HPV) vaccine: Updated HPV vaccination recommendations of the advisory committee on immunizations practices*. Retrieved from https://www.cdc.gov/mmwr/pdf/wk/mm6411.pdf

(b) GlaxoSmithKline. (2015). *Cervarix: Highlights of prescribing information*. Retrieved from https://www.fda.gov/media/78013/download

(c) Merck & Co, Inc. (2011). *Gardasil: Highlights of prescribing information.* Retrieved from http://www.merck.com/product/usa/pi_circulars/g/gardasil/gardasil_pi.pdf

(d) Merck & Co, Inc. (2014). *Gardasil 9: Highlights of prescribing information.* Retrieved from https://www.merck.com/product/usa/pi_circulars/g/gardasil_9/gardasil_9_pi.pdf

APPENDIX I

PNEUMOCOCCAL VACCINES

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. New Pneumococcal Vaccine

Recommendations

Adults aged ≥65 years. Adults aged ≥65 years who have not previously received PCV or whose previous vaccination history is unknown should receive 1 dose of PCV (either PCV20 or PCV15). When PCV15 is used, it should be followed by a dose of PPSV23 (Table 1).

Adults aged 19–64 years with certain underlying medical conditions or other risk factors. Adults aged 19–64 years with certain underlying medical conditions or other risk factors who have not previously received PCV or whose previous vaccination history is unknown should receive 1 dose of PCV (either PCV20 or PCV15). When PCV15 is used, it should be followed by a dose of PPSV23.

Clinical Guidance

Dosing schedule. When PCV15 is used, the recommended interval between administration of PCV15 and PPSV23 is ≥1 year. A minimum interval of 8 weeks can be considered for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak to minimize the risk for IPD caused by serotypes unique to PPSV23 in these vulnerable groups.

Adults with previous PPSV23 only. Adults who have only received PPSV23 may receive a PCV (either PCV20 or PCV15) ≥1 year after their last PPSV23 dose. When PCV15 is used in those with history of PPSV23 receipt, it need not be followed by another dose of PPSV23.

Adults with previous PCV13. The incremental public health benefits of providing PCV15 or PCV20 to adults who have received PCV13 only or both PCV13 and PPSV23 have not been evaluated. These adults should complete the previously recommended PPSV23 series. For adults who have received PCV13 but have not completed their recommended pneumococcal vaccine series with PPSV23, one dose of PCV20 may be used if PPSV23 is not available.

Coadministration with other vaccines. PCV15, PCV20, or PPSV23 can be co-administered with QIV in an adult immunization program, as concomitant administration (PCV15 or PPSV23 and QIV [Fluarix], PCV20 and adjuvanted QIV [Fluad]) has been demonstrated to be immunogenic and safe. However, slightly lower pneumococcal serotype-specific OPA GMTs or geometric mean concentrations were reported when pneumococcal vaccines were co-administered with QIV compared with when pneumococcal vaccines were given alone. Currently, no data are available on coadministration with other vaccines (e.g., tetanus, diphtheria, acellular pertussis vaccine, hepatitis B, or zoster vaccine) among adults. Evaluation of coadministration of PCV15, PCV20, or PPSV23 with COVID-19 vaccines is ongoing.

Before administering PCV20, PCV15, or PPSV23, health care providers should consult relevant package inserts regarding precautions and contraindications. Adverse events occurring after administration of any vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS).

TABLE 1. Recommendations for use of 15-valent pneumococcal conjugate vaccine in series with 23-valent pneumococcal polysaccharide vaccine or 20-valent pneumococcal conjugate vaccine in pneumococcal conjugate vaccine-naïve adults aged ≥19 years — United States, 2022

Medical indication group	Specific underlying medical condition	Age group, yrs	
		19–64	≥65
None	None	None	1 dose of PCV20 or 1 dose of PCV15 followed by a dose of PPSV23 ≥1 years later*
Underlying medical conditions or other risk factors	Alcoholism Chronic heart disease† Chronic liver disease Chronic lung disease¶ Cigarette smoking Diabetes mellitus Cochlear implant CSF leak Congenital or acquired asplenia Sickle cell disease or other hemoglobinopathies Chronic renal failure** Congenital or acquired immunodeficiencies**,†† Generalized malignancy** HIV infection** Hodgkin disease** Iatrogenic immunosuppression**,§§ Leukemia** Lymphoma** Multiple myeloma** Nephrotic syndrome** Solid organ transplant**	1 dose of PCV20 or 1 dose of PCV15 followed by a dose of PPSV23 ≥1 years later§	1 dose of PCV20 or 1 dose of PCV15 followed by a dose of PPSV23 ≥1 years later*

Abbreviations: CSF = cerebrospinal fluid; PCV15 = 15-valent pneumococcal conjugate vaccine; PCV20 = 20-valent pneumococcal conjugate vaccine; PPSV23 = 23-valent pneumococcal polysaccharide vaccine.

* Adults with immunocompromising conditions, cochlear implant, or CSF leak might benefit from shorter intervals such as ≥8 weeks. These vaccine doses do not need to be repeated if given before age 65 years.
† Includes congestive heart failure and cardiomyopathies.
§ Adults with immunocompromising conditions, cochlear implant, or CSF leak might benefit from shorter intervals such as ≥8 weeks.
¶ Includes chronic obstructive pulmonary disease, emphysema, and asthma.
** Indicates immunocompromising conditions.
†† Includes B- (humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders (excluding chronic granulomatous disease).
§§ Diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids and radiation therapy.

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 18 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 COVD-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
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.

Recommendations
Adults aged ≥60 years. Adults aged ≥60 years

Clinical Guidance
Shared Clinical Decision-Making for Adults Aged ≥60 years.

Unlike routine and risk-based vaccine recommendations, recommendations based on shared clinical decision-making do not target all persons in a particular age group or an identifiable risk group. For RSV vaccination, the decision to vaccinate a patient should be based on a discussion between the health care provider and the patient, which might be guided by the patient's risk for disease and their characteristics, values, and preferences; the provider's clinical discretion; and the characteristics of the vaccine. As part of this discussion, providers and patients should consider the patient's risk for severe RSV-associated disease. Epidemiologic evidence indicates that persons aged ≥60 years who are at highest risk for severe RSV disease and who might be most likely to benefit from vaccination include those with chronic medical conditions such as lung diseases, including chronic obstructive pulmonary disease and asthma; cardiovascular diseases such as congestive heart failure and coronary artery disease; moderate or severe immune compromise (either attributable to a medical condition or receipt of immunosuppressive medications or treatment); diabetes mellitus; neurologic or neuromuscular conditions; kidney disorders, liver disorders, and hematologic disorders; persons who are frail; persons of advanced age; and persons with other underlying conditions or factors that the provider determines might increase the risk for severe RSV-associated respiratory disease. Adults aged ≥60 years who are residents of nursing homes and other long-term care facilities are also at risk for severe RSV disease.

Chronic underlying medical conditions associated with increased risk • Lung disease (such as chronic obstructive pulmonary disease and asthma) • Cardiovascular diseases (such as congestive heart failure and coronary artery disease) • Moderate or severe immune compromise* • Diabetes mellitus • Neurologic or neuromuscular conditions • Kidney disorders • Liver disorders • Hematologic disorders • Other underlying conditions that a health care provider determines might increase the risk for severe respiratory disease Other factors associated with increased risk • Frailty • Advanced age • Residence in a nursing home or other long-term care facility • Other underlying factors that a health care provider determines might increase the risk for severe respiratory disease.

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

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.

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 influenza vaccines met noninferiority criteria for immunogenicity with the exception of a lower antibody response to the influenza 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. 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.

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

Dosing schedule.[1]

TABLE. RSV Vaccines With Approvals Received

Vaccine	Manufacturer	Indication	Dose
RSVpreF vaccine (Abrysvo)	Pfizer	Prevent RSV-associated LRTI in adults ≥60 y	One 120-µg dose IM injection
Adjuvanted RSV vaccine (Arexvy)	GSK	FDA-approved for prevention of RSV-associated LRTI in adults ≥60 y	One 120-µg dose IM injection (0.5 mL)

[1] IM, intramuscular; LRTI, lower respiratory tract illness, RSV, respiratory syncytial virus; y, year(s)

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 eighteen 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 eighteen 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

(a) 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.

(b) 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.

(c) Pfizer. (2023). *Abrysvo U.S. Physician Prescribing Information*. Retrieved from https://www.pfizer.com/products/product-detail/abrysvotm.