

Sample Immunization Protocol

This document is based upon South Dakota Administrative Rule 20:51:28 and South Dakota Statute 36-11-19.1.

This Protocol advises the administration of the following vaccines:

- Influenza: ≥ 6 years and older
- Emergency Vaccines in response to public health emergency: ≥ 6 years and older
- **List** - may include all Vaccines on the ACIP approved vaccination schedule: ≥18 years and older
- **List** - All vaccines recommended by the CDC for international travel: ≥18 years and older

I, _____ a licensed physician in the State(s) of _____, do hereby authorize _____ Pharmacy and the certified immunizing pharmacists listed in this protocol, to administer the vaccine listed in this protocol at the locations specified in this protocol. As the authorizing prescriber, I may review, upon request, the activities of the immunizing pharmacist administering vaccines under this protocol.

In exercising this authority, the immunizing pharmacists shall:

- Comply with the most current recommendations of the Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP)
- Provide the most current Vaccine Information Sheet (VIS) to the vaccine recipient and answer all questions prior to administering the vaccine.
- Ask a standard set of screening questions specific to the vaccine being administered and get a signed, informed consent prior to administration of vaccine.
- Document all vaccines administered, as required by South Dakota rules and statutes.
- Endeavor not to disrupt existing patient-physician relationships.
- Refer patients needing medical consultation to a physician.
- Make special efforts to identify susceptible people who have not previously been offered immunizations.

Administration of other immunizations by pharmacists

A physician may prescribe, for an individual patient by prescription or medication order, other immunizations to be administered by an authorized pharmacist.

Pharmacist Qualifications

A. The “authorized pharmacist” has successfully completed an educational program meeting the educational standards on injection administration as provided by an Accreditation Council on Pharmacy Education (ACPE) approved provider of continuing pharmaceutical education or a program deemed equivalent by the South Dakota Board of Pharmacy such as the training provided by an organized course of study in a college or school of pharmacy. The evidence-based course includes reference material and hands-on training in techniques for administering injections, requires testing with a passing score, complies with current CDC guidelines, and provides instruction and experiential training in the following competencies:

- Standards for Injections Practices
- Basic Immunology and the Human Immune Response
- Vaccine-Preventable Diseases and Mechanisms of Immunity
- Recommended Injection Schedules and Doses

- Vaccine Storage and Management
 - Informed Consent
 - Physiology and Techniques for Injection Administration
 - Pre- and Post-Injection Assessment and Counseling and Identification of Contraindications to the Vaccine
 - Immunization Record Management
 - Management of Adverse Events (including identification, appropriate response, documentation and reporting)
 - Record Keeping and Reporting Requirements
- B. Hold a current, unrestricted license to practice pharmacy in the State of South Dakota.
 - C. Hold current certification in Basic Cardiac Life Support Protocol for Healthcare Providers issued by the American Heart Association, the American Red Cross, the American Safety and Health Institute, or another course deemed equivalent by the South Dakota Board of Pharmacy.
 - D. Continuing Education: Complete and document at least two hours of continuing education related to vaccines during the pharmacist's license renewal period.
 - E. Complete an Application for Authorization to Administer Influenza Vaccinations and renew this biennially by September 30 with the South Dakota Board of Pharmacy.
 - F. Maintain documentation of the above.

Delegation:

The authorized pharmacists on this protocol may delegate to certified pharmacy interns, under the direct supervision of a certified pharmacist at the listed location of employment.

Notification Requirements

- A. Prior to administering any vaccine, the pharmacist must provide the appropriate VIS to the patient or legal representative.
- B. The pharmacy must report adverse events as required by the Vaccine Adverse Events Reporting System (VAERS) and to the primary care provider named by the patient.
- C. The authorized pharmacist shall notify the primary care provider named by the patient within 14 days of administration of the protocol vaccine.
- D. The pharmacy must report to the SD Immunization Information System (SDIIS)

Record Keeping

- A. The following records will be maintained for 5 years:
 - The name, address, and date of birth of the patient
 - The date of administration and site of injection of the vaccine
 - The name, dose, manufacturer, lot number, and expiration date of the vaccine
 - The name and address of the patient's primary health care provider named by the patient
 - The date that written report of vaccine administration was sent to the patient's primary health care provider
 - The name of the administering pharmacist
 - Consultation or other professional information provided to the patient, including a VIS with documentation of the name and edition date of this document
 - Patient or legal guardian's signature of consent

- B. These records will be stored at the address of the protocol pharmacy and must be made available to the South Dakota Board of Pharmacy upon inspection.
- C. A copy of any completed VAERS will also be scanned into the Enterprise system under Medical Authorizations.

Management of Allergic Reaction and Anaphylaxis

This provision establishes a course of action the pharmacist shall follow to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks.

In the case of a life threatening emergency, 911 will be dialed. In the course of treating an anaphylactic reaction following immunization, CDC recommendations will be followed.¹

1. Supplies to Stock
 - a. (2) Adult doses- Epinephrine Injection USP 1:1000 auto-injector such as an EpiPen[®]
 - b. (2) Child doses- Epinephrine Injection USP 1:2000 auto-injector such as an EpiPen Jr[®]
 - c. Optional: Diphenhydramine injectable (50mg/mL solution) and 25 mg or 50 mg capsules or tablets, and syrup (12.5mg/mL)
 - d. Syringes: 1-3cc, 22-25g, 1", 1.5", and 2" needles for epinephrine and diphenhydramine
 - e. Blood Pressure Cuffs, adult regular and large, and child cuffs, with stethoscope and sphygmomanometer
2. Recognition of anaphylactic reaction
 - a. Sudden onset of itching, redness, with or without hives, within several minutes after injecting a vaccine. The symptoms may be localized or generalized.
 - b. Angioedema (swelling of lips, face, throat), anxiety, difficulty swallowing, syncope, fall in blood pressure, lightheadedness, paresthesia, flushing, sweating, palpitations
 - c. Bronchospasm (wheezing), shortness of breath, tightness in chest, shock.
3. Emergency Treatment
 - a. If itching and swelling are confined to the extremity where the immunization was given, observe the patient closely for 30 minutes, watching for generalized symptoms. If no generalized symptoms occur, go to "g".
 - b. If symptoms are generalized, activate the emergency response system (911). This should be done by another employee while the vaccinator is treating/ observing the patient.
 - c. Do not give anything by mouth if the patient is not fully alert or if the patient has respiratory distress.
 - d. Administer the adult epinephrine auto-injector EpiPen[®] 0.3 mg 1:1000 USP intramuscularly (0.01mL/kg/dose with a max of 0.5mL dose) on the anterior-lateral thigh or deltoid for patients weighing approximately over 66 pounds (30kg). Diphenhydramine (at a dose approximately 1mg/ kg; maximum dose of 100mg per dose) may be used as well.
 - e. Administer child epinephrine auto injector EpiPen Jr[®] 0.15mg 1:2000 USP intramuscularly in the anterior-lateral thigh or deltoid for patients weighing approximately less than 66 pounds¹(30kg).
 - f. Monitor the patient until EMS arrives, perform CPR and maintain airway if necessary.
 - i. Keep patient in supine position unless there are breathing difficulties. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs.

- ii. Monitor vital signs frequently. If EMS has not arrived and symptoms are still present, repeat the dose of epinephrine every 15 minutes for up to 3 doses, depending on the patient's response.
- g. Patients will be referred for medical evaluation if signs of *a* or *b* listed above appear even if symptoms resolve completely. Symptoms may recur after epinephrine wears off up to 24 hours later.
- h. Record all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information.
- i. The authorizing physician and patient's primary health care provider will be notified within twenty-four (24) hours after learning of the adverse event or reaction.

Accidental Needle Injuries

In the event of an accidental needle injury, (Name of Pharmacy) staff will immediately contact the specific Health Provider for all work related injuries.

Disposal of Contaminated Needles and Supplies

All needles and contaminated supplies will be disposed of in a commercial sharps container or other suitable container and labeled as "Sharps Container". When the sharps container is 75% full it shall be sealed and collected by the authorized agent as delegated in each stores policy and procedure manual.

Observation:

Patient will be asked to remain in the pharmacy for 15 minutes after the administration of all vaccines.

This authorization shall be valid until 1 year from the date indicated on page 1 unless revoked in writing by either party.

I, Dr. _____, licensed physician in the State(s) of South Dakota, authorize (Name of Pharmacy) certified pharmacists and at the listed locations to dispense and administer the vaccine stated, and follow the vaccine protocol, as defined above.

Signature of Physician

Date

Physician Phone

Address of Physician

Physician Email

Signature of Certified Immunization Pharmacist

Date

Signature of Certified Immunization Pharmacist

Date