IMMUNIZATIONS

STATEWIDE PROTOCOL

Iowa Board of Pharmacy

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Pharmacists, according to and in compliance with Iowa Code section 155A.46, may order and administer immunizations as outlined in this protocol. For the purpose of this protocol, "pharmacist" shall mean a qualified pharmacist or pharmacist-intern who has documented successful completion of the requirements identified in Section III (Qualifications).

I. Purpose

Immunizations serve as a tool to reduce morbidity and mortality from preventable infectious diseases. This statewide protocol is intended to ensure that immunizations may be readily obtainable by any person who meets the criteria established by the United States Centers for Disease Control (CDC) and Prevention Advisory Committee on Immunization Practices (ACIP) for immunization administration.

II. Authority

This statewide protocol is issued pursuant to Iowa Code section 155A.46 which permits the ordering and administration of immunizations by a pharmacist in compliance with this protocol. For the purpose of this protocol, the pharmacist's order shall constitute a prescription.

III. Qualifications - Pharmacist

A pharmacist administering vaccines pursuant to this protocol shall document successful completion of the requirements identified herein and shall maintain competency by completing and maintaining documentation of the continuing education requirements identified herein.

A. Initial qualification. A pharmacist shall have successfully completed an organized course of study in a college or school of pharmacy or an Accredited Council on Pharmacy Education (ACPE)-accredited continuing education program on vaccine administration that:
    a. Requires documentation by the pharmacist of current certification in basic cardiac life support through a training program designated for health care providers that includes hands-on training.
    b. Is an evidence-based course that includes study material and hands-on training and techniques for administering vaccines, requires testing with a passing score, complies with current CDC guidelines, and provides instruction and experiential training in the following content areas:
        i. Standards for immunization practices;
        ii. Basic immunology and vaccine protection;
        iii. Vaccine-preventable diseases;
        iv. Recommended immunization schedules;
        v. Vaccine storage and management;
        vi. Informed consent;
        vii. Physiology and techniques for vaccine administration;
        viii. Pre- and post-vaccine assessment, counseling, and identification of contraindications to the vaccine;
        ix. Immunization record management; and
        x. Management of adverse events, including identification, appropriate response, documentation, and reporting.
B. Continuing education. During any pharmacist license renewal period, a pharmacist who engages in the administration of vaccines shall complete and document at least one hour of ACPE-accredited continuing education with the ACPE designator "06" followed by the letter "P".

C. Certification maintained. During any period within which the pharmacist may engage in the administration of vaccines, the pharmacist shall maintain current certification in basic cardiac life support through a training program designated for health care providers that includes hands-on training.

IV. Qualifications – Technician

Following the pharmacist's clinical assessment of a patient and the pharmacist's issuance of a prescription for an immunization, the pharmacist may delegate the administration of such immunization to a registered nurse who holds an active Iowa license pursuant to Iowa Code chapter 152 or a privilege to practice pursuant to Iowa Code chapter 152E or a technician who has documented successful completion of the requirements identified herein and who administers the immunization under the supervision of the pharmacist. The technician shall maintain competency by documented completion of the continuing education requirements identified in part "C".

A. Except as provided in part "B", a technician shall have successfully completed an ACPE-accredited program on vaccine administration that is an evidence-based program that includes study material and hands-on training and techniques for administering vaccines, requires testing with a passing score, complies with current CDC guidelines, and provides instruction and experiential training in the following content areas:

    a. Standards for immunization practices;

    b. Basic immunology and vaccine protection;

    c. Vaccine-preventable diseases;

    d. Recommended immunization schedules;

    e. Vaccine storage and management;

    f. Informed consent;

    g. Physiology and techniques for vaccine administration;

    h. Immunization record management; and

    i. Identification of adverse events.

B. Continuing education. During any technician registration renewal period, a technician who engages in the administration of vaccines shall complete and document at least one hour of ACPE-approved continuing education with the ACPE topic designator of "06" followed by the letter "T" or "P".

C. Certification maintained. During any period within which a technician may engage in the administration of vaccines, the technician shall maintain current certification in basic cardiac life support through a training program designated for health care providers that includes hands-on training.

V. Authorization

This protocol authorizes a pharmacist to order and administer the following immunizations in accordance with the parameters identified herein:

A. To patients ages six months and older:
   a. An immunization for influenza, and
   b. Other immunizations in response to a public health emergency;
B. To patients ages eleven years and older:
   a. The final dose(s) in a course of vaccinations for human papillomavirus (HPV);
C. To patients ages eighteen and older:
   a. An immunization or vaccination recommended by the United States centers for disease control and prevention advisory committee on immunization practices in its approved vaccination schedule,
   b. An immunization or vaccination recommended by the United States Centers for Disease Control and Prevention for international travel, and
   c. An immunization or vaccination for COVID-19 as defined in Iowa Code section 686D.2.

VI. 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 appropriately private area for administering vaccines with the supplies and equipment listed in Appendix A.

VII. Informed Consent

Before administering a vaccine, the pharmacist shall provide to the recipient or their legal representative information about the risks and benefits associated with the vaccination.

A. Vaccine Information Statements. The pharmacist shall provide to each recipient or the recipient's legal representative a copy of the most current Vaccine Information Statement (VIS) for the vaccine to be administered. The recipient or legal representative shall be given the opportunity to read the VIS prior to administration of the vaccine and the pharmacist shall provide answers to any questions raised. Non-English speaking persons shall be provided a copy of the VIS in their native language, if available.

B. Consent Form. Prior to vaccine administration, the pharmacist must document the informed consent of the recipient or the recipient's legal representative in writing. A sample consent form is provided in Appendix D. An equivalent consent form may be used.

VIII. Record

A pharmacist administering a vaccine pursuant to this protocol must create a vaccination record for each recipient and must maintain this record in accordance with state and federal regulations. The record may include the Vaccine Administration Record in Appendix C or another record substantially equivalent. This vaccination record shall be readily retrievable and shall include the following:

(a) The name, address, date of birth, gender and telephone number of the recipient;
(b) A copy of the recipient's responses to eligibility questionnaires;
(c) The name, dose, manufacturer, expiration date, 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;
(f) A record of any adverse events or complications that arose following vaccination; and
(g) A copy of the notification letter sent to the recipient's designated primary health care provider of the vaccine administered.

IX. Verification and reporting

Prior to the ordering and administration of an immunization pursuant to this protocol, the pharmacist shall consult and review the statewide immunization registry or health information network.

As soon as reasonably possible following administration of a vaccine, the pharmacist shall report the vaccine administration to the statewide immunization registry (IRIS) or health information network and to the patient's primary health care provider, if known. If the patient does not have a primary health care provider, the pharmacist shall provide the patient with a written record of the vaccine administered to the patient and shall advise the patient to consult a physician.

Adverse Event Reporting – The pharmacist shall report any clinically significant event following vaccine administration to the Vaccine Adverse Event Reporting System (VAERS) and the recipient's primary health care provider within 24 hours, 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*. Each pharmacist administering vaccines shall follow appropriate precautions to minimize risk for spread of disease. Hands shall be cleansed with an alcohol-based waterless antiseptic hand rub or washed with soap and water between each contact. Gloves shall 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 Needlestick Injuries*. To prevent inadvertent needle-stick injury or reuse, needles and syringes shall 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.

XI. Management of Adverse Events

All vaccines have the potential to cause an adverse reaction. In order to minimize adverse reactions, recipients 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 inconvenient (e.g. soreness, itching) to severe and life threatening (e.g. anaphylaxis). If reactions occur, the pharmacist shall be prepared for their management. The procedures for managing adverse reactions are set forth in Appendix E.

XII. Vaccines

A pharmacist may order and administer US Food and Drug Administration (FDA) approved or emergency use authorized formulations of immunizations identified in Section V of this protocol, alone or in combination, 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 manufacturer package inserts and the most current ACIP recommended guidelines. A pharmacist should make a reasonable effort to ensure vaccination series initiated by the pharmacist are completed.

APPENDIX A

REQUIRED SUPPLIES AND EQUIPMENT

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

(1) A current copy of this Protocol.
(2) The most current federal VIS for vaccines being administered.
(3) Aqueous epinephrine USP (1:1000), in ampules, vials of solution, or prefilled devices (i.e. EpiPen and Epipen Jr). The amount of epinephrine stocked shall be sufficient to allow for the potential maximum number of doses prior to EMS arrival.
(4) Diphenhydramine (Benadryl) injectable solution (50 mg per mL) and/or oral 25 mg dosage form, to include tablets, capsules or liquid.
(5) Syringes: appropriate sized/type (e.g. filtered if using ampules) for emergency supplies and the vaccinations on hand.
(6) Alcohol swabs and bandages.
(7) Blood pressure monitoring device or stethoscope and sphygmomanometer (with appropriately sized cuffs).
(8) Appropriate sized pocket masks with one-way valve.

APPENDIX B

SCREENING QUESTIONNAIRE TO DETERMINE SAFETY OF ALL VACCINES

Prior to vaccine administration, the pharmacist shall assess the safety of the vaccine for a patient using a general screen questionnaire which is at least sufficiently comparable to the Screening Checklist for Contraindications to Vaccines for Adults provided by the CDC. 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. The pharmacist shall document relevant responses and explanations provided in response to the screening questions.

PRECAUTION

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

REFERRAL

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

LIVE VACCINES

Prior to the administration of a live vaccine, the pharmacist shall ask a patient the following general screening questions, in addition to the screening questionnaire used pursuant to Appendix B. Vaccine-specific screening questions shall also be asked based on the vaccine's contraindications and precautions according to ACIP guidelines and manufacturer package inserts.

1. Are you currently on home infusions or weekly injections (such as Remicade, Humira, Enbrel, Cimzia, Simponi, Simponi Aria, Xeljanz, Orencia, Arava, Actermra, Cytoxan, Rituxan, adalimumab, infliximab or etanercept), high-dose methotrexate, azathioprine or 6-mercaptopurine, antivirals, anticancer drugs or radiation treatments?
2. Have you received any vaccinations or skin tests in the past four weeks?
3. Have you received a transfusion of blood, blood products or been given a medication called immune (gamma) globulin in the past year?
4. Are you currently taking high-dose steroid therapy (prednisone >20mg/day or equivalent) for longer than two weeks?

APPENDIX C

VACCINE ADMINISTRATION RECORD

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 a copy 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 above the dotted line.

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 the administration the vaccine(s) and communicate the administration of the vaccine(s) to my primary health care provider (HCP) listed below.

_____

Patient Name (printed) Date of Birth

_____

Signature of patient or legal representative Today's Date

_____

Primary Health Care Provider

Vaccine Given: _____ VIS Date: _____
Dose: _____
Method: IM / SQ
Location: Right / Left Arm or Other _____
Lot #: _____

Manufacturer: _____

Expiration Date: _____

_____

Identification of Administering Pharmacist or Pharmacist-Intern

_____

Pharmacy name and phone number for Administering or Supervising Pharmacist

Form sent to HCP (initials and date): _____

Entered in IRIS (Initials and date): _____

APPENDIX D

MANAGEMENT OF ADVERSE REACTIONS TO VACCINE ADMINISTRATION

Prior to vaccine administration, if the patient exhibits **fright/agitation**, have the patient sit or lie down for the vaccine administration. Do not immunize a combative patient.

Following vaccine administration, the pharmacist shall observe the patient for immediate adverse reaction(s) to the vaccine(s). If no reaction is immediately evident, request that the patient remain for observation for a period of 10-15 minutes. If the patient displays any signs of any of the following reactions, the pharmacist shall execute the following procedures.

- If the patient experiences symptoms of a local reaction (e.g., **minor pain, redness, warmth, pruritus, swelling at injection site**):
    - Apply ice to the injection site
    - Consider administration of an analgesic
    - Observe the patient closely for 30 minutes, watching for generalized symptoms
    - Make sure the patient has the telephone number of a provider to contact in case condition deteriorates.
    - If the patient does not progress to any other symptoms, send patient home and contact patient 4-6 hours later to assess recovery.
- If the patient becomes **pale** and/or **feels faint**, have the patient lie flat or sit in head down position for several minutes.
- If the patient **loses consciousness**, but has a steady pulse, normal blood pressure and respirations:
    - Have the patient lie flat on their back with their feet elevated
    - Have the patient rest in a quiet area for 30 minutes after regaining consciousness
    - Notify the patient's primary care provider about the incident
    - Continue to monitor vital signs. If the patient remains unconscious for more than 3 minutes, **CALL 911**.
- If the patient's vital signs are abnormal (decreased blood pressure, increased or irregular pulse, etc.):
    - Place the patient flat on their back with their feet elevated
    - **CALL 911**.
- If the patient experiences symptoms of an anaphylactic reaction (e.g., the sudden or gradual onset of **generalized itching**, **erythema (redness)**, or **urticaria (hives)**; **angioedema (swelling of lips, face, throat; bronchospasm (wheezing)**; **shortness of breath**; **shock**; **abdominal cramping**; or **cardiovascular collapse**:
    - If symptoms are generalized, activate the emergency medical system (**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 patient)
    - Place patient in a recumbent position and elevate the legs
    - The first line therapy in anaphylaxis is epinephrine. There are no contraindications to epinephrine in the setting of anaphylaxis.
    - Administer aqueous epinephrine 1:1000 dilution intramuscularly, 0.01ml/kg/dose (adult dose ranges from 0.3ml to 0.5ml, with maximum single dose of 0.5ml)
    - If EMS has not arrived and symptoms are still present, the dose of epinephrine may be repeated every 5 to 15 minutes until emergency assistance arrives, depending on the patient's response

- OPTIONAL TREATMENT: administer diphenhydramine (either orally or intramuscularly; the standard dose is 1-2mg/kg every 4-6 hours, up to 50mg maximum single dose). Do not attempt to give oral medications to a recipient who is not fully alert and able to swallow safely.
- Monitor the patient closely and check vital signs (BP, pulse, respirations) every 2 to 5 minutes. Stay with patient until emergency assistance arrives.
- If necessary, perform cardiopulmonary resuscitation (CPR) and maintain airway.
- Keep patient in supine position unless he or she is having breathing difficulty. 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.
- Record all vital signs, medications administered to the patient (including the time, dosage, response, and the name of the person who administered the vaccine), and other relevant clinical information concurrently in an adverse reaction medication log to be maintained by the pharmacy, a copy of which may be provided to EMS and/or the patient's primary care provider. An Adverse Reaction Log form is attached as Appendix E.
- Notify the patient's primary health care provider as soon as reasonably possible. Each patient experiencing an anaphylactic reaction must be referred for evaluation, even if symptoms resolve completely. The pharmacist shall also report the adverse reaction to the VAERS within 24 hours.

APPENDIX E

ADVERSE REACTION LOG

Date and Time of Adverse Reaction(s):
_____

Name and Date of Birth of Vaccine Recipient:
_____

Name of Vaccine(s) Given:
_____

Describe adverse reaction(s): (e.g., shortness of breath, angioedema, chest Pain, syncope, rash, etc.)
_____
_____
_____
_____

Describe interventions (include medications and dosage, CPR, etc.) for adverse reaction(s):
_____
_____
_____
_____
_____
_____

Disposition: (home, EMS, etc.)
_____

_____ Date: _____
Signature of Administering Pharmacist-Intern (if applicable)

_____ Date: _____
Signature of Administering or Supervising Pharmacist

Form sent to Primary HCP (Initials and date): _____

Reported to VAERS (Initials and date): _____