Purpose

To reduce the morbidity and mortality of the SARS-CoV-2 virus by vaccinating individuals 18 years and older in the state of Missouri who meet the criteria established by the Advisory Committee on Immunization Practices (ACIP).

Policy

- This standing order authorizes any licensed physician, assistant physician, physician's assistant, or Advanced Practice Registered Nurse to prescribe and administer this vaccine. Additionally, any medical student working under the license and direction of a licensed physician may administer this vaccine.

- This standing order authorizes any Registered Professional Nurse or Licensed Practical Nurse who is licensed by the Missouri Board of Nursing or has a privilege to practice in the State Of Missouri from another compact state to administer one of these vaccines. After receiving documented training nursing students and medical assistants (MA) working under the direction of a licensed nurse may administer the vaccine.

- This standing order authorizes any Emergency Medical Technician (EMT) or Paramedic who is licensed by the state of Missouri to administer this vaccine after receiving documented training.

- Have a current certification in basic cardiopulmonary resuscitation

- Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event of an acute anaphylactic reaction following administration of the vaccine.

- Additionally, under this standing order, licensed pharmacist, intern pharmacists and pharmacy technicians with the supervision of a Missouri licensed pharmacist may administer this vaccine, provided the pharmacist, intern pharmacist or pharmacy technician has:

    a) Documentation of completing 20 hours of practical training on immunizations approved by the Accreditation Council for Pharmacy Education (ACPE) this training which must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.

    b) Completed a minimum of two hours of ACPE- approved, immunization-related continuing pharmacy education during each state licensing period

Procedure

1. Assess adults in need of vaccination against the SARS-CoV-2 vaccine based on the following criteria
    a. Must be 18 years and older
    b. If the recipient has received a previous dose of Moderna COVID-19 vaccine, the second dose of the same brand should be administered.
    c. The vaccine is administered in a 2-dose series separated by at least 28 days however if dose was given as early as 24 days after the firs dose, then do not repeat.
    d. Moderna COVID-19 vaccine should not be administered with any other vaccines. Separate the Moderna COVID-19 vaccine from other vaccines by 14 days before or after administration of the Moderna COVID-19 vaccine.

2. Screen all adults for contraindication and precautions for the SARS-CoV-2 vaccine
    a. Contraindications
        i. Under 18 years of age

        ii. Do not give the SARS-CoV-2 vaccine to an individual who has experienced a serious reaction* (e.g., anaphylaxis) to a prior dose of SARS-CoV-2 vaccine or to any of its components. For more information on vaccine components, refer to the manufactures' package insert https://www.fda.gov/media/144637/download

        iii. Do not give the SARS-CoV-2 vaccine to an individual who has had an immediate allergic reaction of any severity to a previous dose of any mRNA COVID-19 vaccine or any of its components (including polyethylene glycol (PEG)**

        iv. Do not give the SARS-CoV-2 vaccine to an individual who has had an immediate allergic reaction of any severity to polysorbate (due to potential cross-reactivity hypersensitivity with the vaccine ingredient PEG**)

*Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticarial, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration of vaccine or Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States at https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications

** These individuals should not receive mRNA SARS-CoV-2 vaccine at this time unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available)

b. Precautions
    i. Moderate or severe acute illness with or without a fever

    ii. Severe allergic reaction (e.g., anaphylaxis) to a previous dose of any vaccine** (not including Moderna Vaccine)
        1. Action
            a. Assess the risk of vaccination
            b. Observe patient for 30 minutes following vaccination

    iii. Severe allergic reaction (e.g. Anaphylaxis) to a medication** that is injectable
        1. Action
            a. Assess the risk of vaccination
            b. Observe patient for 30 minutes following vaccination

    iv. Delay vaccination in individuals in community or outpatient settings who have a known SARS-CoV-3 exposure until quarantine period has ended, unless individual resides in congregate healthcare setting or resident of other congregate settings (e.g., correctional facilities, homeless shelter)

    v. Defer vaccination for both symptomatic and asymptomatic COVID-19 patients until they have met criteria to discontinue isolation

    vi. Delay vaccination if the individual has had passive antibody therapy for COVID-19 until 90 days have passed from completion of said therapy

** Providers may consider deferring vaccination with the mRNA SARS-CoV-2 vaccine at this time until individual has been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available) depending on risk of exposure to SARS-CoV-2 or risk of severe disease or death due to COVID-19 for further guidance visit https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications

3. Special Populations for which special counseling and a 15 minute observation period is recommended.
    a. Pregnant females are recommended for vaccine depending on

i. Level of COVID-19 community transmission (risk of acquisition)
ii. Personal risk of contraction COVID-19 to her and potential risks to the fetus
iii. The efficacy of the vaccine
iv. The known side effects of the vaccine
v. The lack of data about the vaccine during pregnancy

b. Lactating (Breastfeeding) is not a contraindication to vaccination
c. Immunocompromised
    i. Persons with HIV infection, other immunocompromising conditions, or who take immunosuppressive medications or therapies
    ii. Data not currently available to establish safety and efficacy of vaccine in these groups
    iii. These individuals may still receive COVID-19 vaccine unless otherwise contraindicated
    iv. Individuals should be counseled about:
        1. Unknown vaccine safety and efficacy profiles in immunocompromised persons
        2. Need to continue to follow all current guidance to protect themselves against COVID-19

4. Routine testing for pregnancy or Antibody testing is not recommended prior to vaccination

5. Provide

    a. Provide the Emergency Use Authorization (EUA) Fact Sheet
        i. Provide all patients (or in the case of minors or incapacitated adults their legal representative) with a copy of the Emergency Authorization Fact Sheet. Provide non-English language if one is available and desired; these can be found at: https://www.fda.gov/media/144638/download

    b. Provide the Vaccine Information Statement (VIS)
        i. Provide all patients (or in the case of minors or incapacitated adults their legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speaking patients with a copy of the VIS in their native language if one is available and desired; these can be found at www.immunize.org

6. Prepare
    a. Choose the correct needle length and gauge for an intramuscular injection

Gender and Weight of patient	Needle Gauge	Needle Length	Injection Site
Female or Male less than 130 pounds	22-25	5/8" – 1"	Intramuscular Deltoid
Female or Male 130- 152 pounds	22-25	1"	Intramuscular Deltoid
Female 153- 200 pounds	22-25	1"-1 ½"	Intramuscular Deltoid
Male 153-260 pounds	22-25	1"-1 ½"	Intramuscular Deltoid
Female 200 + pounds	22-25	1 ½"	Intramuscular Deltoid
Male 260 + pounds	22-25	1 ½"	Intramuscular Deltoid

    b. Prepare the Moderna COVID-19 vaccine
        i. Thaw the vaccine vial if frozen for 1 hour at room temperature or for 2 hours and 30 minutes in a refrigerator
        ii. Once thawed remove the cap of the Moderna vaccine
        iii. Let vial sit at room temperature for 15 minutes before administering
        iv. Document date and time the vaccine was diluted on the Moderna vaccine vial
        v. Clean top of Moderna vaccine vial with alcohol prep pad and with draw 0.5 ml of vaccine
        vi. Gently swirl the vial between each dose withdrawn
        vii. Discard open vial after 6 hours or after all doses have been removed (Whichever comes first)
        viii. Due to production at the factory a 11th dose may be possible but this should not be occurring regularly. Any remaining vaccine that does not equal a full 0.5 ml dose should not be pooled with other remaining vaccine to obtain a full 0.5 ml dose.

7. Administer

Type of Vaccine	**Age group**	**Dose**	**Route**	**Instruction**	**Dose Schedule**
Moderna	Adults 18 years and older	0.5 ml	Intramuscular	Administer vaccine in deltoid muscle	Give dose # 2 at least 28 days from dose # 1

Patients who do not receive the 2nd vaccination dose at 28 days should still receive that 2nd dose as soon as possible thereafter

All vaccine recipients should be monitored for at least 15 minutes following each vaccination dose

8. Document
    a. Consent Form: Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, the vaccine dosage, and the name and title of the person administering the vaccine. Document the VIS given, and VIS publication date.

    b. Immunization Record Card: Record the date of vaccination, and the name/location of the administering clinic and supply to recipient at time of vaccination.

    c. Documentation of the vaccination in Missouri's immunization information system- ShowMeVax within 24-48 hours following vaccination

9. Emergency Protocols
    a. If a patient experiences itching and swelling confined to the injection site where the vaccination was given, apply a cold compress to the injection site. Observe patient closely for the development of generalized symptoms until symptoms subside.

    b. If symptoms are generalized (generalized itching, redness, urticaria (hives); or include angioedema (swelling of the lips, face, or throat); shortness of breath; shock; or abdominal cramping; call 911 and notify the patient's physician. Notifications should be done by a second person while the primary healthcare professional assesses the airway, breathing, circulation and level of consciousness of the patient. Vital signs (heart rate, respirations and Blood Pressure, pulse ox) should be taken every 5 minutes.

        i. First-line treatment of an anaphylactic reaction is to administer Epinephrine 1:1000 dilution intramuscularly adult dose 0.3ml to 0.5ml with maximum dose of 0.5ml; or
        ii. To administer Epinephrine auto-injector (0.3ml)
        iii. For hives or itching, you may also administer diphenhydramine (orally or intramuscular with a standard dose of 25-50mg.) or hydroxyzine (standard oral dose is 25mg -100mg or 0.5-1.0 mg/kg.
        iv. Monitor the patient closely until EMS arrives. Monitor blood pressure and pulse every 5 minutes.
        v. If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 5-15 minutes for up to 3 doses depending on patient's response.
        vi. Record the patient's reaction to the vaccine (e.g., hives, anaphylaxis), all vital signs, and medications administered to the patient, including time dosage, response, and the name of the medical personnel who administered the medication and other relevant clinical information. Report the incident to the

Vaccine Adverse Event Reporting System (VAERS) at https://vaers.hhs.gov/reportevent.html or call 1-800-822-7967.

vii. Notify the patient's primary care physician.

This order and procedure shall be effective on December 31, 2020 and shall remain in effect until rescinded or until December 31, 2021.

December 31, 2020

Randall W. Williams, MD, FACOG, Date
Director Missouri Department of Health and Senior Services