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October 13, 2022

Standing Order for Moderna SARS-CoV-2 Vaccine Administration

The Director of the Department of Health and Senior Services, finding it necessary to protect public health and prevent the further spread of COVID-19, pursuant to the authority granted under section 192.020, RSMo, and 19 CSR 20-20.040, hereby orders the following:

Purpose
To reduce the morbidity and mortality of the SARS-CoV-2 virus by vaccinating individuals 12 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 establishes administration parameters for any individual authorized to administer a COVID-19 vaccine by declaration of the Secretary of the Department of Health and Human Services, issued pursuant to the Public Readiness and Emergency Preparedness Act. Any healthcare provider who is authorized to administer a COVID-19 vaccine in Missouri under the March 18, 2021 DHSS Standing Orders, that is not expressly authorized to vaccinate by the declaration of the Secretary of the Department of Health and Human Services, is still authorized to administer a COVID-19 vaccine, if such individual complies with the requirements enumerated in the applicable March 18, 2021 Standing Order. All other provisions of the March 18, 2021 Standing Orders relating to administration of a COVID-19 vaccine are hereby terminated and this Order shall control.

Procedure
Primary series vaccination

1) Assess adults in need of vaccination against the SARS-CoV-2 vaccine based on the following criteria
    a) Must be 12 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 first dose, then do not repeat.
    d) Moderna COVID-19 vaccine may be administered with any other vaccines. Use a different arm for other vaccine administration. It is unknown whether reactogenicity is increased with co-administration, including with other vaccines known to be reactogenic such as adjuvanted vaccines. When deciding to co-administer with COVID-19 vaccines, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines and the reactogencity profile of the vaccines.
    e) A third dose of the Moderna vaccine may be administered for certain individuals 12 years and older with moderate to a severe immune compromise due to a medical condition or recipe of immunosuppressive medication or treatments including but not limited to

i) Immune compromised due to undergone solid organ transplantation and taking immune suppressing medications
ii) active treatment for solid tumor and hematologic malignancies
iii) Receipt of CAR-T cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy
iv) Moderate to severe primary immunodeficiency (eg., DiGeorge, Wiskott-Aldrich Syndrome
v) Advanced or untreated HIV infection
vi) Immune compromised due to "Active treatment with high-dose corticosteroids or other drugs that may suppress immune response: high-dose corticosteroids (ie.,≥ 20 mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blocker or other biologic agents that are immunosuppressive or immunomodulatory"

Booster vaccination

f) A single dose of the Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) is FDA-authorized for use in individuals 12 years of age and older as a single booster dose administered at least 2 months after either:

- **Completion of a primary vaccination with any authorized or approved monovalent* COVID-19 vaccine or**
- **Receipt of the most recent booster dose with any authorized and approved monovalent COVID-19 vaccine**

***Monovalent refers to any authorized and approved COVID-19 vaccine that contains or encodes the spike protein of only the original SARS-CoV-2 virus**

2) Screen all adults for contraindication and precautions for the SARS-CoV-2 vaccine
   a) Contraindications
      i) Under 12 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)**

*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)
        a. Action
            i. Assess the risk of vaccination
            ii. Observe patient for 30 minutes following vaccination
    iii) Polysorbate allergy is a precaution to Moderna COVID-19 vaccine (due to potential cross-reactivity hypersensitivity with the vaccine ingredient PEG)
    iv) Severe allergic reaction (e.g. Anaphylaxis) to a medication** that is injectable
        a. Action
            i. Assess the risk of vaccination
            ii. Observe patient for 30 minutes following vaccination
    v) Delay vaccination in individuals in community or outpatient settings who have a known SARS-CoV-2 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)
    vi) Defer vaccination for both symptomatic and asymptomatic COVID-19 patients until they have met criteria to discontinue isolation
    vii) People who develop myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine generally should not receive a subsequent dose of any COVID-19 vaccine (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Contraindications). If after a risk assessment, the decision is made to receive a subsequent COVID-19 vaccine dose, considerations for subsequent vaccination may include:
        - The myocarditis or pericarditis was considered unrelated to the mRNA Covid-19 vaccination, especially if the myocarditis or pericarditis occurred more than 3 weeks after the most recent doses of COVID-19 vaccine
        - Increased personal risk of severe acute COVID-19 disease
        - Increased level of COVID-19 community transmission and personal risk of infection

        If an additional dose is indicated then
        - Ensure the episode of myocarditis or pericarditis is resolved
        - For men ages 18 years and older consider using of Janssen COVID-19 vaccine instead of mRNA COVID-19 vaccines. A dose of Janssen's COVID-19 could be considered as long as the patient is made aware of the risk of Thrombosis with thrombocytopenia syndrome (TTS) https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#considerations-Janssen
    viii) People who have a history of myocarditis or pericarditis unrelated to mRNA COVID-19 vaccination (e.g., due to SARS-CoV-2 or other viruses) may receive any currently FDA-approved or FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved. This includes resolution of symptoms attributed to myocarditis or pericarditis, as well as no evidence of ongoing heart inflammation or sequelae as determined by the person's clinical team.

ix) Delay vaccination if the individual has history of MIS-C or MIS-A until 90 days have passed from the MIS-C or MIS-A diagnosis

**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
        (i) Immunocompromised
        (ii) Persons with HIV infection, other immunocompromising conditions, or who take immunosuppressive medications or therapies
        (iii) Data not currently available to establish safety and efficacy of vaccine in these groups
        (iv) These individuals may still receive COVID-19 vaccine unless otherwise contraindicated
        (v) Individuals should be counseled about:
            - Unknown vaccine safety and efficacy profiles in immunocompromised persons
            - Need to continue to follow all current guidance to protect themselves against COVID-19
            - Have individuals seeking a 3rd dose of the mRNA Moderna COVID-19 vaccine complete the Additional mRNA COVID-19 Vaccine Dose Attestation statement

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://eua.modernatx.com/covid19vaccine-eua/bivalent-dose-recipient.pdf
    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) The Moderna COVID-19 Vaccine is supplied in two multiple-dose vial presentations:
        (i) A multiple-dose vial containing a maximum of 11 doses: range 10-11 doses (0.5mL each).
    b) 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
Females and Males	22-25	1" to 1 ½"	Intramuscular Vastus Lateralis

    c) 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 opened on the Moderna vaccine vial
        (v) Clean top of Moderna vaccine vial with alcohol prep pad and withdraw:
            a. 0.5 ml of vaccine for the primary series
            b. 0.5mL of Bivalent booster vaccine
        (vi) Gently swirl the vial between each dose withdrawn
        (vii) Discard open vial after 12 hours or after all doses have been removed (whichever comes first)

7) Administer

Type of Vaccine	**Age group**	**Dose**	**Route**	**Instruction**	**Dose Schedule**
Moderna **primary series**	12 years and older	0.5mL	Intramuscular	Administer vaccine in the Deltoid muscle or the Vastus Lateralis	Give 2 doses 4 – 8 weeks apart
Moderna **primary series**	Severely or moderately immune compromised adults 12 years and older	0.5mL	Intramuscular	Administer vaccine in the Deltoid muscle or the Vastus Lateralis	Give 3 doses 1 and 2 at least 28 days apart 2 – 3 at least 28 days apart

Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) **Booster Dose**	12 years and older	0.5mL	Intramuscular	Administer vaccine in the Deltoid muscle or the Vastus Lateralis	Give 1 booster dose at least 2 months apart from the last dose in the primary series or from the last monovalent*** booster dose

*An 8-week interval may be optimal for people ages 18 years through 64 years, and especially for males ages 18 through 39 years, who are not moderately or severely immunocompromised. A shorter interval (4 weeks for Moderna) between the first and second dose remains the recommended interval for people who are moderately or severely immunocompromised; adults ages 65 years and older; and others who need early protection due to increased concern about community transmission or risk of severe disease. COVID-19 mRNA vaccines administered after the recommended time frames are valid and do not need to be repeated.

**If the same vaccine that the person received previously is not available, a mixed series of mRNA COVID-19 or a dose of Janssen COVID-19 vaccine may be administered spaced appropriately apart according to the most recent clinical guidelines that can be found here https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html HYPERLINK "https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html%20" .

***Monovalent refers to any authorized and approved COVID-19 vaccine that contains or encodes the spike protein of only the original SARS-CoV-2 virus.**

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

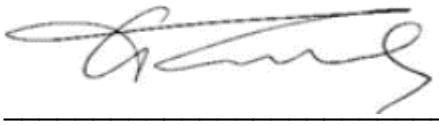
8) Document
   a) Consent Form: Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, the vaccine dosage, and the name and title of the person administering the vaccine. Document the VIS given, and VIS publication date.
   b) Immunization Record 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 October 13, 2022 and shall remain in effect until rescinded or until December 31, 2022.



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VACCINE ADMINISTRATION RESOURCE LINKS

Moderna Products
https://www.fda.gov/media/159306/download

At a Glance Schedule
https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-vacc-schedule-at-a-glance-508.pdf

Vaccine Needle Length and Gauge chart
https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf

Frequently Asked Questions by Health Care providers
https://www.cdc.gov/vaccines/covid-19/hcp/faq.html

Training Material
https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-Clinical-Training-and-Resources-for-HCPs.pdf