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December 13, 2022

Standing Order for Moderna COVID-19 Vaccine Administration for Infants and Children 6 Months through 5 Years of Age

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 6 months through 5 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 listed in Attachment A to this Order, that is not expressly authorized to vaccinate by the declaration of the Secretary of the Department of Health and Human Services, is authorized to administer a COVID-19 vaccine, if such individual complies with the requirements enumerated Attachment A.

Procedure

1. Assess children in need of vaccination against the SARS-CoV-2 vaccine based on the following criteria
    a. Must be 6 months of age and older
    b. Any minor authorized to receive this vaccine under this order, shall only receive such with the consent of a parent or guardian, or in compliance with Sections 431.056, 431.058, or 431.061, RSMo.
    c. Administer Moderna COVID-19 Vaccine intramuscularly as a series of two doses at least 28 days apart.
    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 reactogenicity profile of the vaccines.
    e. A third dose of Moderna COVID-19 vaccine may be administered for certain individuals 6 months 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
        - Immune compromised due to undergone solid organ transplantation and taking immune suppressing medications
        - Immune compromised active treatment for solid tumor and

hematologic malignancies
- Immune compromised receipt of CAR-T cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate to severe primary immunodeficiency (eg., DiGeorge, Wiskott-Aldrich Syndromes)
- Immune compromised due to Advanced or untreated HIV infection
- Immune compromised due to "Active treatment with high-dose corticosteroids or other drugs that may suppress immune response: high-dose corticosteroids , 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"

f. **Booster vaccination**
- **A single dose of the Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) is FDA-authorized for use in individuals 6 months through 5 years of age as a single booster dose administered at least 2 months after the final dose of Moderna monovalent COVID-19 vaccine primary series.**

***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 children for contraindication and precautions for the SARS-CoV-2 vaccine
   a. Contraindications
      i. Under 6 months of age
      ii. Do not administer Moderna COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine. For more information on vaccine components, refer to the manufactures' package insert Moderna HCP Fact Sheet 6m-5y 06172022 (fda.gov)
      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. 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)
iii. Polysorbate allergy is a precaution to Moderna COVID-19 vaccine (due to potential cross-reactivity hypersensitivity with the vaccine ingredient PEG)
iv. Defer vaccination for both symptomatic and asymptomatic COVID-19 patients until they have completed their isolation period and recover from their illness
v. Delay vaccination if the individual has had passive antibody therapy for COVID-19 until 90 days have passed from completion of said therapy
vi. Delay vaccination if infant or child has history of MIS-C until 90 days have passed from the MIS-C diagnosis

3. Special Populations for which special counseling is recommended
    a. 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 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: Moderna Recipients FS 6m-5y 06172022 (fda.gov)
    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 the vaccine
    a. Choose the correct needle length for an intramuscular injection

Age of child oradolescent	**needle length**	**injection site**
Infants 6 through 11 months of age	1" needle	Anterolateral aspect of the thigh

Toddlers 1 to 3 years of age	1" needle	Anterolateral aspect of the thigh
Children 3 years and older	5/8" to 1 "	Deltoid
	1" to 1.25" needle	Anterolateral aspect of the thigh

b. Prepare the Moderna COVID-19 vaccine
- Thaw the vaccine vial if frozen for 1 hour at room temperature or for 2 hours and 30 minutes in a refrigerator
- Once thawed remove the cap of the Moderna vaccine
- Let vial sit at room temperature for 15 minutes before administering
- Document date and time the vaccine was opened on the Moderna vaccine vial
- Clean top of Moderna vaccine vial with alcohol prep pad and withdraw:
- Gently swirl between each dose drawn
- 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 2 dose primary series	6 months through 5 years of age	0.25mL	Intramuscular	Administer vaccine intramuscularly	1 and 2 separate by 4-8 weeks apart
Moderna 3 dose primary series	6 months through 5 years of age	0.25mL	Intramuscular	Administer vaccine intramuscularly	1 and 2 separate by 4 weeks 2 and 3 separate by 4 weeks
Bivalent Booster	6 months through 5 years of age	0.2mL	Intramuscular	Administer vaccine intramuscularly	Dose should be separated by at least 8 weeks from the last dose in the primary series

*Patients who do not receive the 2nd vaccination dose at 28 days should still receive that 2nd dose as soon as possible thereafter. Effectiveness of vaccination when the second dose is given beyond the 6 weeks interval from the first dose administration is unknown. For the most recent updated clinical guidelines visit https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

** In exceptional situations in which the mRNA vaccine product administered for a previous dose(s) of the primary series cannot be determined or is not available either age-appropriate available mRNA COVID-19 vaccine product may be administered at a minimum interval of 28 days between doses to complete the mRNA COVID-19 primary vaccination series.

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

8. Document Vaccination
   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/EUA given, and VIS/EUA publication date.

b. Immunization Record Card: Record the date of vaccination, and the name/location of the administering clinic.
c. Documentation of the vaccination in Missouri's immunization information system

9. Emergency medical protocol for management of anaphylactic reaction in children
    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 resolve.
    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.

First Line Treatment Epinephrine

Age group	**Range of weight**		**Epinephrine dose**	
			1.0 mg/mL aqueous solution (1:1000 dilution); intramuscular. Minimum dose: 0.05 mL	Epinephrine auto injector or prefilled syringe *(0.1mg 0.15mg, 0.3mg)*
6 months of age	Up to 19 lbs.	Up to 8.5 kg.	0.05mL (mg)	0.1mg**
7 – 36 months	20-32 lbs.	9-14.5 kg.	0.1mL (or mg)	0.1 mg**
37 – 59 months	33-39 lbs.	15-17.5 kg.	0.15mL (mg)	0.15 mg/dose

*If weight known, then dose by weight is preferred, if unknown then dose by age is appropriate.
*Rounded weight at the 50th percentile for each age range
** 0.1 mg auto injector is licensed for use in infants and children who weight 7.5-14 kg.

May use Diphenhydramine (Benadryl) as a second line treatment

Age group	**Range of weight**		**Diphenhydramine *(Benadryl)* dose 1mg/kg**
7 – 36 months	20-32 lbs.	9-14.5 kg.	10-15 mg/dose
37 – 59 months	33-39 lbs.	15-17.5 kg.	15-20 mg/dose

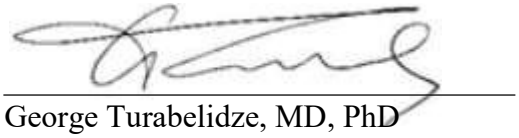
*If weight known then dose by weight is preferred, if unknown then dose by age is appropriate.
*Rounded weight at the 50th percentile for each age range
**AAP. Red Book: 2018–2021, 31st ed. (p. 66). Diphenhydramine maximum single dose for children younger than age 12 years is 40 mg.

i. Monitor the patient closely until EMS arrives. Monitor blood pressure and pulse every 5 minutes.
ii. If EMS has not arrive and symptoms are still present, repeat dose of epinephrine every 5-15 minutes for up to 3 doses depending on patient's response.
iii. 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.

iv. Notify the patient's primary care physician.

This order and procedure shall be effective on December 13, 2022 and shall remain in effect until rescinded or until March 31, 2023.



George Turabelidze, MD, PhD
State Epidemiologist

Attachment A
to Missouri Department of Health and Senior Services
Standing Order for Moderna COVID-19
Vaccine Administration for Children 6 Months through 5 Years of Age

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

- The 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 Missourifrom another compact state to administer this vaccine. After receiving documented training nursing students and medical assistants (MA) working under the direction of a licensed nurse may administer this vaccine.

- The order authorizes Advanced Emergency Medical Technicians, Emergency Medical Technician-Paramedics, Emergency Medical Technician-Basics and Emergency MedicalResponders to administer this vaccine, whose authorized scope of practice includes administering immunizations via the intramuscular route

- The order authorizes licensed pharmacist, intern pharmacists and pharmacy technicians with thesupervision of a Missouri licensed pharmacist to administer this vaccine, provided the pharmacist, intern pharmacist or pharmacy technician has:

    a) Documentation of completing 20 hours of practical training on immunizations approvedby the Accreditation Council for Pharmacy Education (ACPE) this training must includehands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines; and
    b) Complete a minimum of two hours of ACPE-approved, immunization-related continuingpharmacy education during each state licensing period.

- The order authorizes any of the following individuals to administer this vaccine, provided that such individual held a license, certification, or could have otherwise lawfully administered this vaccine under this order within the last five years. If such individual held a license or certification, such must have been active with no disciplinary action nor under an investigation prior to the date it went inactive, expired or lapsed and must not have been revoked by the licensing authority, in an alternative to discipline program, surrendered while under suspension, surrendered following an arrest, and the individual cannot be on the List of Excluded Individuals/Entities maintained by the Office of the Inspector General. Prior to administering thevaccine, such individual shall: (1) complete the Centers for Disease Control and Prevention COVID-19 Vaccine Training Modules https://www2.cdc.gov/vaccines/ed/covid19/ ; (2) document their identification and prior license, certification, or experience that would have allowed such individual to lawfully administer this vaccine under this order within the last five years; and (3) certify that the individual does not have any condition or impairment which in anyway affects their ability to administer the vaccine in a competent and safe manner, including but not limited to: (a) a mental, emotional, nervous or sexual disorder; (b) an alcohol or substance abuse disorder;

or (c) a physical disease or condition. Such individual shall initially be under the observation of a currently practicing Missouri licensed or certified healthcare professional adequately experienced in vaccination, who shall review the submitted documentation, initially observe, and confirm the competency of such individual to prepare and administer the vaccine.

If such currently practicing Missouri licensed or certified healthcare professional, who is observing the individual, is unable to confirm the competency of such individual, such individualwill not be permitted to administer a vaccine.

- licensed physician;
- assistant physician;
- physician's assistant;
- Advanced Practice Registered Nurse;
- 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 compactstate to administer this vaccine;
- Advanced Emergency Medical Technicians, Emergency Medical Technician-Paramedics,Emergency Medical Technician-Basics and Emergency Medical Responders, whose authorized scope of practice includes administering immunizations via the intramuscular route;
- licensed pharmacist;
- pharmacy technicians with the supervision of a Missouri licensed pharmacist to administerthis 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 trainingmust include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines; and
    b) Completed a minimum of two hours of ACPE- approved, immunization-relatedcontinuing pharmacy education during each state licensing period.

- The order authorizes any healthcare provider who is licensed or certified in any state to prescribe, dispense, and/or administer a vaccine, to administer this vaccine. Such individual shallalert the relevant licensing body within the State of Missouri of their intention to administer a COVID-19 vaccine in Missouri and provide their professional credentials to such licensing body.

- Any individual authorized to administer this vaccine under the order shall be certified to providecardiopulmonary resuscitation, or in the case of a medical student or former healthcare provider without current certification to administer cardiopulmonary resuscitation, such individual may only administer the vaccine in the presence of someone with current certification to administer cardiopulmonary resuscitation

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