VDH VIRGINIA DEPARTMENT OF HEALTH

REVISED ORDER AUTHORIZING DISPENSING AND ADMINISTERING OF THE COVID-19 VACCINE UNDER VIRGINIA CODE 54.1-3408(P)

Date Issued: 10/22/2021

Purpose: To reduce morbidity and mortality from COVID-19 (SARS-CoV-2) by vaccinating persons who meet the criteria authorized by the Food and Drug Administration Emergency Use Authorization (EUA) and in accordance to the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) recommendations. This order is intended to supplement existing authorization under the Public Readiness and Emergency Preparedness (PREP) Act.

This order authorizes:

- pharmacists actively licensed in Virginia who are in good standing to practice in Virginia per the Virginia Board of Pharmacy to dispense and administer FDA-authorized COVID-19 vaccines;
- pharmacy technicians and pharmacy interns who have satisfied the requirements of the PREP Act acting under the supervision of a pharmacist, as defined above, who have enrolled in the CDC COVID-19 vaccination program to administer FDA-authorized COVID-19 vaccines; and
- registered nurses (RNs) and licensed practical nurses (LPNs) actively licensed in Virginia who are in good standing to practice in Virginia per the Virginia Board of Nursing to administer FDA-authorized COVID-19 vaccines at community vaccination events.

Eligible providers shall administer the COVID-19 vaccine in accordance with Virginia Code §54.1-3408 (P) as described below.

This order is effective to the earlier of two (2) years from the date of issuance or the expiration of the U.S. Department of Health and Human Services (HHS) COVID-19 public health emergency (PHE) declaration signed by Secretary Xavier Becerra, unless otherwise discontinued by the Commissioner. The site must have an approved CDC provider agreement and must adhere to all policies and procedures included in the agreement, including ensuring proper vaccine storage and handling and cold chain documentation. In addition, the site must adhere to all CDC-recommended guidelines and must comply with any applicable federal or state mandates.

The site must maintain a copy of the standing order if administering vaccine pursuant to the order.

Please call the Office of the Commissioner at (804) 864-7001 with questions about the standing order.

Eligible Vaccine Recipients*:

Pfizer-BioNTech COVID-19 Vaccine:	**Moderna COVID-19 Vaccine:**	**J&J COVID-19 Vaccine:**
Individuals 12 years of age and older requesting COVID-19 vaccination.	Individuals 18 years of age and older requesting COVID-19 vaccination.	Individuals 18 years of age and older requesting COVID-19 vaccination.

* *Order is consistent with the FDA EUA. As the EUA is modified, the standing order will be revised.*

Additional Criteria:

- An additional dose (i.e. third dose) of mRNA vaccine may be indicated following the initial 2-dose mRNA COVID-19 vaccine series for certain moderate to severe immunocompromised persons 12 years and older, separated by at least 28 days from the completion of the initial mRNA COVID-1 vaccine series. The age groups authorized to receive the additional dose are unchanged from those authorized to receive the primary vaccine series.
    - mRNA vaccines may be interchangeable for 3rd dose for those 18 years and older with the original manufacturer being recommended.
- An additional dose (i.e. booster dose) of any COVID-19 vaccine may be administered to the following populations at least 6 months following the first two doses of an mRNA vaccine series:
    - People aged 65 years and older and residents in long-term care settings
    - People aged 50-64 years with underlying medical conditions
    - People aged 18-49 years with underlying medical conditions, based on their individual benefits and risks,
    - People aged 18-64 years who are at increased risk for COVID-19 exposure and transmission because of occupation or institutional setting, based on their individual benefits and risks.
- An additional dose (i.e. booster dose) of any COVID-19 vaccine may be administered to individuals at least 2 months following their primary series of the J&J vaccine.
- COVID-19 vaccines and other vaccines may be administered without regard to timing. If multiple vaccines are administered at a single visit, administer each injection in a different injection site. For adolescents and adults, the deltoid muscle can be used for more than one intramuscular injection.
    - Label each syringe with the name and the dosage (amount) of the vaccine, lot number, the initials of the preparer, and the exact beyond-use time, if applicable.
    - Separate injection sites by 1 inch or more, if possible.
    - Administer the COVID-19 vaccines and vaccines that may be more likely to cause a local reaction (e.g., tetanus-toxoid-containing and adjuvanted vaccines) in different limbs, if possible.

Procedures:

- Screen for any vaccine precautions and contraindications using an appropriate pre-vaccine questionnaire **before** administering the vaccine.
- Provide the vaccine recipient with a copy of the current federal EUA Fact Sheet for Recipients and Caregivers.
- Provide the v-safe information sheet to vaccine recipient/caregiver.
- Obtain informed consent of the patient or parent, guardian, or person standing in loco parentis.
- Educate about where, how, and when to obtain the additionalCOVID-19 vaccination as indicated.
- Appropriate medical treatment and clinical staff able to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of COVID-19 vaccine.
- Ensure pharmacist accessibility, as defined by the PREP Act, to provide medication supervision of the vaccination site/service, to assess and evaluate individuals who present with precautions to vaccination, and to answer questions or address problems with carrying out this standing order. This may be telephone or virtual accessibility.

- Review Interim Clinical Considerations for Use of COVID-19 vaccines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html).

Product Selection/Dose:

Pfizer-BioNTech COVID-19 Vaccine: Administered intramuscularly as a series of two doses (0.3 mL each), 3 weeks (21 days) apart. A third dose (0.3 mL) administered at least 28 days following the first two doses is authorized to individuals at least 12 years of age if immunocompromised in accordance with FDA and CDC ACIP guidelines. A booster dose (0.3 mL) administered at least 6 months following the first two doses of an mRNA vaccine, or at least 2 months following the first dose of the J&J vaccine, to individuals at least 18 years of age if in accordance with FDA and CDC ACIP. Follow VDH clinical guidance for preparation and administration.

Moderna COVID-19 Vaccine: Administered intramuscularly as a series of two doses (0.5 mL each), 1 month (28 days) apart. A third dose (0.5 mL) administered at least 28 days following the first two doses is authorized to individuals at least 18 years of age if immunocompromised in accordance with FDA and CDC ACIP guidelines. A booster dose (0.25 mL) administered at least 6 months following the first two doses of an mRNA vaccine, or at least 2 months following the first dose of the J&J vaccine, to individuals at least 18 years of age if in accordance with FDA and CDC ACIP. Follow VDH clinical guidance for preparation and administration.

J&J COVID-19 Vaccine: Administered intramuscularly as a single dose (0.5 mL). Follow VDH clinical guidance for preparation and administration. A booster dose (0.5 mL) administered at least 6 months following the first two doses of an mRNA vaccine, or at least 2 months following the first dose of the J&J vaccine, to individuals at least 18 years of age if in accordance with FDA and CDC ACIP. Follow VDH clinical guidance for preparation and administration.

Contraindications:

Do not administer the Moderna COVID-19 vaccine or Pfizer BioNTech COVID-19 vaccine to anyone with a known history of an immediate or severe allergic reaction (e.g., anaphylaxis) to a prior dose of mRNA COVID-19 vaccine (i.e. Moderna or Pfizer-BioNTech COVID-19 vaccines), polysorbate, or to any component of either mRNA COVID-19 vaccine (including polyethylene glycol [PEG]) listed in the prescribing information.

Do not administer the J&J COVID-19 vaccine to anyone with known history of an immediate or severe reaction to any component of J&J COVID-19 vaccine or to any or to any component of either mRNA COVID-19 vaccine (including polyethylene glycol [PEG]) listed in the prescribing information.

Precautions:

- History of severe allergic reaction (e.g., anaphylaxis) to any other vaccine or injectable therapy
- Self-reported moderate to severe acute illness

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Directions for Use:

Pfizer-BioNTech COVID-19 Vaccine: Using aseptic technique, mix Pfizer-BioNTech COVID-19 Vaccine with 0.9% sodium chloride diluent according to manufacturer's instructions. Inject 0.3 mL by intramuscular injection into the deltoid muscle of the arm.

Moderna COVID-19 Vaccine: Using aseptic technique, withdraw 0.25mL or 0.5 mL of the Moderna COVID-19 vaccine, depending on dose, from the multi-dose vial and administer by intramuscular injection into the deltoid muscle of the arm.

J&J COVID-19 Vaccine: Using aseptic technique, withdraw 0.5 mL of the J&J COVID-19 vaccine from the multi-dose vial and administer by intramuscular injection into the deltoid muscle of the arm.

Post-vaccination Observation and Emergency Protocol:

- In accordance with ACIP's General Best Practices Guidance for Immunization, all individuals receiving a vaccine should be observed for at least 15 minutes following vaccination. Persons with a history of anaphylaxis should be observed for 30 minutes.
- Vaccine providers shall be prepared to manage medical emergencies by having a written emergency medical protocol with policies, procedures, and standing orders, as well as appropriate equipment and medications (e.g. epinephrine, diphenhydramine), in places where vaccines are provided according to CDC Clinical Considerations for Managing Anaphylaxis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis). A prescriber will need to issue a standing order for use of these drugs per Virginia Code §54.1-3408 (D).
- Report any vaccine administration errors (whether or not associated with an adverse event), serious adverse events (irrespective of attribution to vaccination), cases of Multisystem Inflammatory Syndrome in children and adults, or cases of COVID-19 that result in hospitalization or death following administration of the vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) via the VAERS online reporting tool (https://vaers.hhs.gov/reportevent.html) or by calling 1-800-822-7967.

Reporting and Follow-Up:

- Record COVID-19 vaccination in the pharmacy or medical record within 24 hours and ensure all required data elements are reported to the Virginia Immunization Information System (VIIS) within 24 hours of vaccine administration.
- Vaccine recipients and/or their parent, guardian, or person standing in loco parentis must be provided with a personal vaccine record indicating the date of vaccination, product name/manufacturer, lot number, name/location of administering pharmacy, and when the recipient needs to return for the second dose of either the Pfizer-BioNTech or the Moderna COVID-19 Vaccine.
- Additional doses of the vaccine, if indicated, must be scheduled before the individual leaves the site.

Prescriber: DocuSigned by: M. Norman Oliver, MD E9885CE3DE124C6... **Date:** 10/22/2021 | 1:28:26 PM EDT

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