COVID-19 VACCINE GUIDANCE

Federal Bureau of Prisons

Clinical Guidance

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WHAT'S NEW

Updates regarding available COVID-19 vaccines and their distribution:

- The purple cap Pfizer-BioNTech monovalent COVID-19 vaccine, which required dilution, is no longer being distributed in the United States.
- Novavax, a protein subunit COVID-19 vaccine, is newly available and is a viable option for those who cannot take or complete an mRNA COVID-19 primary vaccination series (i.e., Pfizer-BioNTech, Moderna). However, myocarditis and pericarditis are a concern as for the mRNA COVID-19 vaccines.
- The BOP is currently distributing only mRNA COVID-19 vaccines based on safety and/or handling considerations. If the Novavax COVID-19 vaccine is needed, a specific request should be made through the Regional Medical Director.

Updates on bivalent COVID-19 vaccines: The mRNA COVID-19 bivalent vaccines are preferred for the booster dose and should be administered at least 2 months after the the last monovalent booster dose or the last monovalent primary vaccination series dose. Bivalent COVID-19 vacccines should NOT be used for the primary vaccination series.

Updates for moderately or severely immunocompromised persons: Certain individuals (e.g.,recipients of HCT or CAR-T-cell therapy, patients who received vaccine doses during treatment with B-cell-depleting therapies) may require revaccination of the monovalent primary vaccine series and bivalent booster doses received prior to or during treatment.

Information on timing of COVID-19 and orthopoxvirus vaccine (i.e., JYNNEOS, ACAM2000) administration: For those who received an orthopoxvirus vaccine, consideration should be given to waiting 4 weeks before a COVID-19 vaccination because of the observed risk for myocarditis and pericarditis after receipt of the ACAM2000 vaccine and COVID-19 vaccines and the unknown risk for myocarditis and pericarditis after the JYNNEOS vaccine. Persons who previously received a COVID-19 vaccine may be given orthopoxvirus vaccines without a minimum interval between vaccinations.

Updates on required reporting to VAERS, including what constitutes a serious adverse event (SAE): Vaccine administration errors, whether or not associated with an adverse event (AE), are to be reported to VAERS as are cases of myocarditis and pericarditis after an mRNA or Novavax COVID-19 vaccine. Providers should also report SAEs, regardless of whether it is thought the vaccine caused the AE, which include:

- Death
- A life-threatening AE
- Inpatient hospitalization or prolongation of an existing hospitalization
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- A congenital anomaly/birth defect
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above

Updates on wasted COVID-19 vaccine: Institutions no longer need to notify the BOP Chief Pharmacist or their designee of any wasted vaccine.

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PURPOSE

The purpose of this guidance is to provide direction on use of COVID-19 vaccines for all adults who meet the criteria established by the Bureau of Prisons (BOP), with guidance from the Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and Prevention (CDC). The goal of this guidance is to promote vaccine use as a means of controlling transmission of SARS-CoV-2 (the virus that causes COVID-19) and reducing morbidity and mortality from this infection. **THE COVID-19 VACCINATION IS AN IMPORTANT TOOL TO HELP STOP THE PANDEMIC.**

- The combination of getting vaccinated and following other CDC recommendations offers the best protection from COVID-19 at the present time.
  - *All current recommendations for preventing and managing SARS-CoV-2 infection should continue to be followed.*
- When COVID-19 is circulating in a community, wearing a high quality face covering with a good fit and comfort, social distancing, avoiding larger group or public gatherings, limiting travel, and washing hands help reduce the chances of being exposed to the virus or spreading it to others. However, these measures alone are insufficient. Vaccines work with the immune system so it will be ready to fight the virus if a person is exposed.
- For general guidance related to vaccines including Immunization Key Principles and Storage and Handling of Immunizations, refer to *BOP Immunization Clinical Guidance.*
- It is recommended that each BOP facility: (1) create and implement a COVID-19 immunization plan to offer vaccine as recommended for staff and inmates, (2) develop a plan for when and by whom staff and inmates will be scheduled for the vaccine, and (3) ensure that responsibility be assigned to health care personnel for patient assessment and vaccine administration.

- *Stopping viral transmission requires using all available tools.This document will be updated as new information becomes available (e.g., when new vaccine products become available and are used by the BOP and when vaccination indications change).*

OVERVIEW OF AVAILABLE VACCINES

The following vaccines are either approved (via a Biologic License Application) or authorized (via an Emergency Use Authorization [EUA]) for use in the U.S. by the U.S. Food and Drug Administration:

PFIZER-BIONTECH COVID-19 VACCINE (MRNA VACCINE)

- **Primary monovalent vaccination series** for persons 6 months of age and older: 2 doses or if immunocompromised, 3 doses.
- **Bivalent booster dose** for persons 5 years of age and older: 1 booster dose.
- Fact sheets for the approved and authorized Pfizer-BioNTech COVID-19 vaccine for those 12 years of age and older are available for the following groups:
  - Recipients and caregivers (primary series and bivalent booster): *https://www.fda.gov/media/153716/download*
  - Healthcare providers (primary series): *https://www.fda.gov/media/153715/download* (gray cap, no dilution)
  - Healthcare providers (bivalent booster): *https://www.fda.gov/media/161327/download* (gray and label with gray border, no dilution)

MODERNA COVID-19 VACCINE (MRNA VACCINE)

- **Primary monovalent vaccination series** for persons 6 months of age and older: 2 doses or if immunocompromised, 3 doses.
- **Bivalent booster dose** for persons 6 years of age and older: 1 booster dose.
- Fact sheets for the approved and authorized Moderna COVID-19 vaccines are available for the following groups:
  - Recipients and caregivers (primary series and bivalent booster; for those 6 years of age and older): https://www.fda.gov/media/159310/download
  - Healthcare providers (primary series; for those 12 years of age and older): https://www.fda.gov/media/157233/download (light blue border)
  - Healthcare providers (bivalent vaccine; for those 6 years of age and older): https://www.fda.gov/media/144637/download (gray border)

For both the adult Pfizer-BioNTech and Moderna monovalent primary vaccine series, certain immunocompromised persons should receive a third dose of vaccine four weeks after their second vaccine dose.

The FDA-approved Pfizer-BioNTech COVID-19 vaccine, Comirnaty®, and the Moderna COVID-19 vaccine, Spikevax®, may be used interchangeably with their respective EUA-authorized COVID-19 vaccine for individuals ages 12 years and older. The FDA-approved products are legally distinct from the EUA-authorized product with certain differences that do not impact safety or effectiveness.

NOVAVAX COVID-19 VACCINE (PROTEIN SUBUNIT VACCINE)

- **Primary monovalent vaccination series** for persons 12 years of age and older: 2 doses.
- **A bivalent mRNA booster dose** is the recommended booster dose.
- Fact sheets for the authorized Novavax COVID-19 vaccine for those 12 years of age and older are available for the following groups:
  - Recipients and caregivers: https://www.fda.gov/media/159898/download
  - Healthcare providers administering vaccine: https://www.fda.gov/media/159897/download

JANSSEN (JOHNSON & JOHNSON) COVID-19 VACCINE (RECOMBINANT, REPLICATION-INCOMPETENT ADENOVIRUS VECTOR VACCINE)

- **Primary monovalent vaccination series** for persons 18 years of age and older (in certain limited situations due to safety considerations): 1 dose or if immunocompromised, provide an additional dose of a monovalent mRNA vaccine.
- **A bivalent mRNA booster dose** is the recommended booster dose.
- The EUA fact sheets for the Janssen COVID-19 vaccine are available for the following groups:
  - Recipients and caregivers: https://www.fda.gov/media/146305/download
  - Healthcare providers administering vaccine: https://www.fda.gov/media/146304/download

CDC guidance for the Use of COVID-19 Vaccines in the United States, Interim Clinical Considerations is available at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

PROCEDURE

Using this document, eligible healthcare professionals (as defined by scope of duty) may vaccinate adults who meet the indications below, upon successful completion of the manufacturer-specific COVID-19 vaccine skills checklist and completion of the COVID-19 Vaccine Administration Signature Sheet. The signature sheet should be signed by the appropriate administrative staff and the healthcare provider who will be administering vaccine.

→ *Appendix 1. Skills Checklist for COVID-19 Vaccine Administration*

→ *Appendix 2. COVID-19 Vaccine Administration Signature Sheet*

1. VACCINATION CONSIDERATIONS

- Distribution of vaccine is directed by the Health Services Division of the BOP Central Office and through the Vaccine Point of Contact (VPOC) or their designee.
- ***At this time, the BOP is only distributing mRNA COVID-19 vaccines to institutions.***
  - Since the Janssen (Johnson & Johnson) COVID-19 vaccine may only be used in very limited situations due to safety considerations, its use is not practical in the BOP environment. No further information will be provided in this document about the Janssen COVID-19 vaccine unless relevant to medical care (i.e., someone received a dose in the past).
  - Although the Novavax COVID-19 vaccine is not currently being distributed, it is a viable option for those who cannot receive mRNA COVID-19 vaccines. Therefore, information is provided in this document. Please contact the Regional Medical Director to request the vaccine.
- ***Testing for SARS-CoV-2 infection is NOT required prior to administering the COVID-19 vaccine*** unless otherwise clinically indicated. If SARS-CoV-2 testing is performed on a COVID-19 vaccine recipient, test results will not be affected if a viral test is used (i.e., either molecular/PCR or antigen tests). Antibody testing is not currently recommended to assess for immunity to SARS-CoV-2 following COVID-19 vaccination.
- Vaccination should be offered regardless of a history of symptomatic or asymptomatic SARS-CoV-2 infection, including to those with prolonged post-COVID-19 symptoms. This applies to primary vaccination series and booster doses.
- It is important for providers to not miss any opportunity to vaccinate every eligible person, even if that means puncturing a multi-dose vial without having enough people available to use every dose.
- Primary COVID-19 vaccination series by vaccine type consist of the following:
  - mRNA COVID-19 vaccines (i.e., Pfizer-BioNTech or Moderna): 2-dose series *OR* if moderately to severely immunocompromised, a 3-dose series.
  - Novavax COVID-19 vaccine: 2-dose series for all persons.
- An individual is considered **FULLY VACCINATED**, if they have completed a primary COVID-19 vaccination series.
- An individual is considered **UP TO DATE** on COVID-19 vaccinations, if they have completed a primary vaccination series along with any recommended booster dose(s) for which they are clinically eligible.

- ***The following recommended COVID-19 vaccines*** are based on risk-benefit analyses (e.g., evidence on vaccine effectiveness, vaccine safety, and adverse events):
  - **Primary vaccination series (monovalent)**: ***Pfizer-BioNTech, Moderna, or Novavax COVID-19 vaccine***. Use the same vaccine product for all doses of the primary series. If a mixed primary series is inadvertently administered, the series is considered complete, and doses do not need to be repeated.
  - **Booster dose (bivalent):** ***Pfizer-BioNTech or Moderna COVID-19 vaccine***.
    - A monovalent Novavax booster dose (instead of a bivalent mRNA booster dose) may be used in limited situations in those who completed any FDA-approved or FDA-authorized monovalent primary series, have not received any previous booster dose(s), and are unable to receive an mRNA vaccine (i.e., mRNA vaccine contraindicated or not available) or unwilling to receive an mRNA vaccine and would otherwise not receive a booster dose.

INMATE VACCINATION

- ***A primary monovalent vaccination series and a bivalent booster dose is available and encouraged for all inmates*.**
- ***Moderately or severely immunocompromised inmates*** are at increased risk for severe COVID-19, since they may not mount a protective immune response after initial vaccination. In addition, immune protection by primary vaccination may wane over time making this population more susceptible to severe SARS-CoV-2 infection.
  - ***Conditions and treatments causing moderate to severe immunocompromise include:***
    - Active treatment for solid tumor and hematologic malignancies
    - Hematologic malignancies associated with poor responses to COVID-19 vaccines regardless of current treatment status (e.g., chronic lymphocytic leukemia, non-Hodgkin lymphoma, multiple myeloma, acute leukemia)
    - Receipt of solid-organ or islet transplant and taking immunosuppressive therapy
    - Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
    - Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
    - Advanced or untreated HIV infection (i.e., CD4 cell counts <200/mm^3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
    - Active treatment with high-dose corticosteroids (i.e., ≥ 20 mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory
  - ***For moderately or severely immunocompromised inmates who received mRNA COVID-19 vaccines***, a 3-dose monovalent primary vaccination series is recommended followed by a bivalent booster dose at least two months after the third primary series dose.

- ***For moderate or severely immunocompromised inmates who received a single primary vaccine dose of the Janssen COVID-19 vaccine***, an additional dose using an mRNA monovalent COVID-19 vaccine (i.e., Pfizer-BioNTech [30 mcg dose] or Moderna [100 mcg dose]) should be provided at least 4 weeks later followed by a bivalent mRNA booster dose at least 2 months later.
  - The Janssen COVID-19 vaccine is not authorized for use as an additional primary vaccine dose.
  - The BOP COVID-19 Vaccine dashboard may be used to assist institutions in identifying eligible patients based on current CDC guidance.
- Timing of COVID-19 vaccination should take into consideration current or planned immunosuppressive therapies and optimization of both the inmate's medical condition and response to vaccine. Whenever possible, COVID-19 vaccines should be administered at least 2 weeks before initiation or resumption of immunosuppressive therapies.
- ***Revaccination considerations:***
  - The inmate's clinical team is best positioned to determine the degree of immune compromise, need for revaccination (of one or more doses), and appropriate timing of revaccination.
  - Revaccination cannot exceed the number of primary series and booster doses currently authorized.
  - There is no need to revaccinate for prior monovalent booster doses received.
  - Recipients of HCT or CAR-T-cell therapy should undergo revaccination for the monovalent primary series and bivalent booster doses received prior to or during treatment and should start at least 3 months (12 weeks) after transplant or CAR-T-cell therapy.
  - Revaccination may also be considered for patients who received vaccine doses during treatment with B-cell-depleting therapies (e.g., rituximab, ocrelizumab) that were administered over a limited period (e.g., as part of a treatment regimen for certain malignancies). The suggested interval to start revaccination is approximately 6 months after completion of the B-cell-depleting therapy. For those who receive B-cell-depleting therapies on a continuing basis (e.g., for treatment of certain autoimmune conditions such as rheumatoid arthritis or multiple sclerosis), COVID-19 vaccines should be administered approximately 4 weeks before the next scheduled therapy.

- ***Vaccinations during exposure quarantine and movement observation periods***
  - Inmates admitted either to an ***exposure quarantine*** or a ***movement observation period*** may be vaccinated as long as they do not have symptoms or signs of COVID-19. Using these situations as an opportunity to vaccinate and achieve immunity can be beneficial in limiting transmission and outbreaks.
  - Inmates ***who are scheduled for a BOP intrasystem transfer*** may elect to initiate a primary vaccination series or receive a booster dose, whichever is appropriate. The type of vaccine used should remain a clinical decision that is made between patient and provider.

- Inmates pending immediate release (e.g., full term releases or court-ordered transfers) may be vaccinated. Per the CDC's guidance, vaccine providers may begin the primary vaccination series even if there is uncertainty about how and when a person will receive their remaining doses.
  - *Upon release, institutions will provide inmates their CDC COVID-19 vaccination card if the vaccines are administered at the institution, or provide inmates their vaccination administration record (even if with historical vaccine information administered elsewhere).*

- *CDC guidance for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States is available at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html*

- ***Vaccine management at the BOP Federal Transfer Center in Oklahoma City (OKL) and BOP holdover sites, including bus hubs and detention centers.***
  - Vaccination series may be initiated during transfers even if there is uncertainty about how the patient will receive their remaining dose(s).

2. Contraindications and Precautions

Contraindications:

- ***Do not administer COVID-19 vaccines to any person with a history of a known severe allergic reaction (e.g., anaphylaxis)*** after a previous dose or to a component of a COVID-19 vaccine OR ***with a*** known (diagnosed) allergy to a component of the vaccine.
  - Both Pfizer-BioNTech and Moderna COVID-19 vaccine components include mRNA as the active ingredient and a variety of inactive ingredients, such as lipids (e.g., polyethylene glycol [PEG]), and buffers.
  - Novavax COVID-19 vaccine components include a recombinant spike protein subunit, a potent adjuvant which enhances the immune response to the spike protein, and a variety of inactive ingredients, such as lipids and buffers (e.g., polysorbate).
  - For additional information on product-specific vaccine components, refer to the:
    - FDA fact sheet for the Pfizer-BioNTech COVID-19 vaccine at:
      - *https://www.fda.gov/media/153715/download* (grey cap, no dilution)
    - FDA Emergency Use Authorization (EUA) fact sheet for the Moderna COVID-19 vaccine at: *https://www.fda.gov/media/144637/download*
    - FDA Emergency Use Authorization (EUA) fact sheet for the Novavax COVID-19 vaccine at: *https://www.fda.gov/media/159897/download*
    - CDC guidance on an Overview of COVID-19 Vaccines at: *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/overview-COVID-19-vaccines.html#protein-subunit*

PRECAUTIONS:

- For the following individuals, a clinical assessment should be done (which may include referral to an allergist-immunologist) along with a 30-minute observation period after vaccination:
  - Those with a history of an immediate allergic reaction of any severity to any non-COVID-19 vaccine or injectable therapy, AND
  - Those with a non-severe, immediate (less than 4 hours) allergic reaction after a previous dose of one type of COVID-19 vaccine. In the latter case, the patient should be assessed clinically to determine whether they can be vaccinated with the same type of COVID-19 vaccine or with another type of COVID-19 vaccine (which may be administered in the usual vaccination setting).
- An **IMMEDIATE ALLERGIC REACTION** is defined as: any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.
- Because of potential cross-reactive hypersensitivity between ingredients in mRNA, Novavax, and Janssen COVID-19 vaccines, individuals with an allergy-related contraindication to one type of COVID-19 vaccine have a precaution to the other type of COVID-19 vaccine (e.g., a person with a contraindication to an mRNA COVID-19 vaccine has a precaution to the Novavax and Janssen COVID-19 vaccines and vice versa). Consultation with an allergist-immunologist should be considered to help determine if the patient can safely receive vaccination. In addition, healthcare providers may request a consultation from the CDC's Clinical Immunization Safety Assessment COVIDvax project by calling 1-800-232-4636, or submitting a request to: *https://wwwn.cdc.gov/dcs/ContactUs/Form*
- Persons who start but are unable to complete a primary series with the same COVID-19 vaccine due to a contraindication should wait at least 4 weeks (28 days) after their last vaccine dose to receive a different COVID-19 vaccine.
- Persons who ***develop myocarditis or pericarditis after a dose of an mRNA or Novavax COVID-19 vaccine*** generally should not receive a subsequent dose of any COVID-19 vaccine until additional safety data are available.
- ***For specific recommendations for the following precautions, refer to the appropriate CDC guidance:***
  - PEG and polysorbate allergies (Appendix E): *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-e*
  - Patients who develop myocarditis or pericarditis after receipt an mRNA or Novavax COVID-19 vaccine: *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#myocarditis-pericarditis*

VACCINATION SHOULD BE DEFERRED FOR:

- ***Patients with current SARS-CoV-2 infection until recovery from acute illness (if the person had symptoms) and criteria have been met to discontinue medical isolation.*** This recommendation applies to persons who develop SARS-CoV-2 infection before receiving any COVID-19 vaccine doses as well as those who develop SARS-CoV-2 after receiving any COVID-19 vaccine dose. There is no recommended minimal interval between infection and vaccination; however, patients who recently had SARS-CoV-2 infection may consider delaying a primary series dose or

booster dose by 3 months from symptom onset or positive test (if infection was asymptomatic). Current evidence suggests the risk of reinfection is low in the months after initial infection, and studies have shown that increased time between infection and vaccination may result in an improved immune response to vaccination.

- ***Patients with adult multisystem inflammatory syndrome (MIS-A), if less than 90 days have passed since their diagnosis and clinical recovery, including return to baseline cardiac function, have not been achieved.*** MIS-A due to SARS-CoV-2 infection or after COVID-19 vaccination is rare and not well understood. It includes a dysregulated immune response to the virus and an MIS-like illness following vaccination. The risk of recurrence of the same dysregulated immune response following reinfection with SARS-CoV-2 or COVID-19 vaccination among persons with a history of MIS-A is unknown. If MIS-A occurs after a COVID-19 vaccination, individuals should be assessed for laboratory evidence of current or prior SARS-CoV-2 infection. Consultation with an infectious disease specialist, rheumatologist, or cardiologist should be considered and include discussions regarding whether clinical recovery has been achieved, time since diagnosis, risk of severe COVID-19, benefits of protection from a COVID-19 vaccine, and timing of any immunomodulating therapies.
- ***Patients with moderate or severe illness of any type with or without fever.*** Defer vaccination until the illness has improved.

➔ *For complicated cases, healthcare providers can request a consultation from the CDC's Clinical Immunization Safety Assessment COVIDvax project at:* https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html

NEITHER CONTRAINDICATIONS NOR PRECAUTIONS:

- ***Individuals with a history of any allergy not listed above as a contraindication or precaution*** may proceed with vaccination using a 15-minute observation period after vaccination.
- ***For mRNA COVID-19 primary vaccination series: Individuals with only a delayed-onset local reaction (e.g., erythema, induration, pruritus) around the injection site area after the first vaccine dose*** should receive the second dose using the same vaccine product as the first dose at the recommended interval and preferably in the opposite arm. Delayed-onset local reactions have been reported beginning a few days through the second week after the first dose and are sometimes large.

3. TIMING OF COVID-19 VACCINES WITH OTHER VACCINES AND PASSIVE ANTIBODY PRODUCTS

- Except for orthopoxvirus vaccines (i.e., JYNNEOS, ACAM2000), COVID-19 vaccines may be administered without regard to timing of other vaccines or non-COVID-19 antibody therapies (e.g., intravenous immunoglobulin). This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day.
- For those who received an orthopoxvirus vaccine, consideration should be given to waiting 4 weeks before a COVID-19 vaccination (i.e., Pfizer-BioNTech, Moderna, Novavax) because of the observed risk for myocarditis and pericarditis after receipt of the ACAM2000 vaccine and COVID-19 vaccines and the unknown risk for myocarditis and pericarditis after the JYNNEOS vaccine. Persons who previously received a COVID-19 vaccine may be given orthopoxvirus vaccines without a minimum interval between vaccinations.

- In persons who previously received a COVID-19 vaccine, administration of tixagevimab/cilgavimab (EVUSHELD™) for pre-exposure prophylaxis should be deferred for at least 2 weeks after vaccination.
- When deciding whether to co-administer vaccine(s), providers should consider the reactogenicity profile of all the vaccines, whether the patient is at risk for a vaccine-preventable disease (e.g., occupational exposure), and whether they are behind or at risk of becoming behind on recommended vaccines.
- If multiple vaccines are administered at a single visit:
  - The deltoid muscle can be used for more than one intramuscular injection; however, **injection sites should be separated by one (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.

4. VACCINATION OF INDIVIDUALS WITH UNDERLYING MEDICAL CONDITIONS

COVID-19 vaccines may be administered to persons with underlying medical conditions who have no contraindications to vaccination. Information on groups with specific underlying medical conditions is included below. As with the general population, the monovalent mRNA and Novavax COVID-19 vaccines are preferred for the primary vaccination series over the Janssen COVID-19 vaccine in each of these groups. An mRNA bivalent COVID-19 vaccine is preferred for the booster dose.

- ***Persons with a history of myocarditis or pericarditis unrelated to COVID-19 vaccination:*** Persons with a history of myocarditis or pericarditis unrelated to mRNA COVID-19 vaccination may receive any currently FDA-approved or 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 patient's clinical team. All cases of myocarditis or pericarditis following COVID-19 vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS).
- ***Persons with autoimmune conditions:*** Persons with autoimmune conditions may receive any currently FDA-approved or authorized COVID-19 vaccine. However, if an individual is immunocompromised because of medications, such as high-dose corticosteroids or biologic agents, they should follow vaccine schedules for those who are moderately or severely immunocompromised.
- ***Persons with a history of Guillain-Barré syndrome (GBS):*** Reports of adverse events following use of the Janssen COVID-19 vaccine suggest an increased risk of GBS during the 42 days following vaccination with the highest risk observed in those aged 40-64 years. Most GBS reports have been in males. No increased risk of GBS has been identified with use of mRNA COVID-19 vaccines.
  - *For additional information on GBS, refer to the following:*
    - CDC Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendices, References, and Previous Updates (Appendix A) at: *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-a*.

  - CDC FAQs for the Interim Clinical Considerations for COVID-19 Vaccination (Special Populations and Situations) at: *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/faq.html#special-populations*.

- ***Persons with a history of Bell's palsy:*** Rare cases of Bell's palsy were reported following vaccination among participants in mRNA COVID-19 vaccine clinical trials. The FDA was not able to determine whether these cases were causally related to vaccination. Persons with a history of Bell's palsy may receive any currently FDA-approved or FDA-authorized COVID-19 vaccine: mRNA (i.e., Moderna or Pfizer-BioNTech) and Novavax COVID-19 vaccines are recommended for the primary series and an age-appropriate mRNA vaccine is recommend for the booster dose. Any occurrence of Bell's palsy following COVID-19 vaccination should be reported to VAERS.

5. Vaccination of Individuals Who Are Pregnant, Breastfeeding/Lactating, or Trying to Get Pregnant

All available evidence supports the safety of administering currently available COVID-19 vaccines before, during, and after pregnancy. It is important to stay up to date on COVID-19 vaccinations, since vaccination reduces the risk of developing COVID-19 and reduces the severity of disease if a breakthrough infection occurs. The mRNA and Novavax COVID-19 vaccines are preferred for all vaccine-eligible populations, including women who are pregnant or lactating.

- ***Evidence continues to build that COVID-19 vaccines are not associated with fertility problems in women or men.*** Pregnancy testing is not a requirement prior to receiving any approved COVID-19 vaccine, and it is not necessary to delay pregnancy after vaccination.
- ***Pregnant and recently pregnant women with COVID-19 are at increased risk for severe illness*** (e.g., hospitalization, intensive care unit admission, mechanical ventilation, death) when compared with non-pregnant women. Additionally, pregnant women with COVID-19 are at increased risk for preterm birth and stillbirth and might be at increased risk for other pregnancy complications.
  - A growing body of evidence on the safety and effectiveness of COVID-19 vaccination indicates that ***the benefits of vaccination outweigh any known or potential risks of COVID-19 vaccination during pregnancy***. Side effects can occur after COVID-19 vaccination in pregnant people, similar to those among non-pregnant people. Acetaminophen can be offered as an option for pregnant people experiencing fever (fever has been associated with adverse pregnancy outcomes) or other post-vaccination symptoms.
  - Women who choose to receive COVID-19 vaccine may wish to participate in CDC's v-safe COVID-19 Pregnancy Registry. The registry is for v-safe participants who self-identify as pregnant at the time of vaccination or shortly thereafter (within 30 days of vaccination). To participate, a woman must be enrolled in v-safe, a smartphone-based system that uses text messaging and web surveys to provide personalized health check-ins after receipt of a COVID-19 vaccine.

    → *For more information, refer to* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafepregnancyregistry.html *and* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html.

- ***Breastfeeding/Lactating women:*** There are limited data on the safety of COVID-19 vaccines in these women or their effects on the breastfed infant, and milk production and excretion, because this population was not included in clinical trials. However, COVID-19 vaccines cannot cause infection in either the lactating woman or the infant. There has been no evidence to suggest that COVID-19 vaccines are harmful to either women who have received a vaccine and are breastfeeding or to their infants. Recent reports have shown that the antibodies developed from mRNA COVID-19 vaccination are present in breastmilk samples, which could help protect the neonate and infant. More data are needed to determine what level of protection these antibodies might provide.

- ***Scientific studies to date have shown no safety concerns for babies born to people who were vaccinated against COVID-19 during pregnancy.***

➔ *Additional information regarding COVID-19 vaccination and pregnancy can be found on the CDC's COVID-19 Vaccines While Pregnant or Breastfeeding at:* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html

6. Tuberculosis (TB) and Syphilis testing Considerations

- TB testing should not be delayed because of COVID-19 vaccine administration. Testing for TB infection using the tuberculin skin test (TST) may be performed before, during, or after a COVID-19 vaccination patient encounter. Similarly, a COVID-19 vaccine should not be delayed because of testing for TB infection. TB skin tests and TB blood tests are not expected to affect the safety or the effectiveness of COVID-19 vaccines.
- For additional guidance regarding the management of testing due to a suspected TB exposure or TB disease and for other types of TB testing (e.g., interferon gamma release assays [IGRAs]), refer to the CDC guidance, the BOP *Tuberculosis Clinical Guidance*, Regional IP&Cs and/or Regional Medical Directors.
- Falsely reactive Rapid Plasma Reagin (RPR) test results have been reported with certain RPR tests lasting more than 5 months following mRNA COVID-19 vaccination in some individuals. Treponemal testing for syphilis such as Treponema pallidum particle agglutination (TP-PA) and treponemal immunoassays do not appear to be impacted by this issue. No comparison data are currently available for the Novavax COVID-19 vaccine. Serologic assays with results that do not fit the clinical picture following COVID-19 vaccination should be repeated.

7. Patient education and consent

- Review the manufacturer-specific COVID-19 vaccine fact sheet with the patient and have them sign the BOP COVID-19 immunization consent/declination form (Refer to *Section 13. Documentation* for more information on vaccine consent).
  - ▸ Consent forms for employees and inmates (English and Spanish) are located in BEMR and also on the COVID-19 Vaccine Resources Page on Sallyport.
  - ▸ Current COVID-19 vaccine fact sheets for recipients can be found at:
    - Pfizer- BioNTech COVID-19 Vaccine (monovalent and bivalent): *https://www.fda.gov/media/153716/download* (English) https://www.fda.gov/media/144625/download (Spanish)

  - Moderna COVID-19 Vaccine (monovalent and bivalent):
    https://www.fda.gov/media/159310/download (English)
    https://www.fda.gov/media/162884/download (Spanish)
  - Novavax COVID-19 Vaccine (monovalent):
    https://www.fda.gov/media/159898/download (English)
    https://www.fda.gov/media/161220/download (Spanish)

- Before vaccination, providers should counsel recipients about the following:
  - **mRNA or Novavax monovalent COVID-19 vaccines are preferred over the Janssen COVID-19 vaccine for the primary vaccination series and booster vaccination.** The recommendation is based on risk-benefit analyses, particularly the concern surrounding the risk of TTS and its symptoms which typically occur within 2 weeks after Janssen COVID-19 vaccine receipt. Immediate medical care should be sought in the event of shortness of breath, chest pain, leg swelling, persistent abdominal pain, severe or persistent headaches or blurred vision, and easy bruising or tiny blood spots under the skin beyond the site of the injection.
  - **mRNA COVID-19 vaccine bivalent booster doses are preferred over the Novavax and Janssen COVID-19 vaccines.** A monovalent Novavax booster dose may be used in limited situations for persons 18 years of age and older who completed a primary series using any COVID-19 vaccine, have not received any previous booster dose(s), and are unable or unwilling to receive an mRNA COVID-19 vaccine. See above regarding concerns associated with the Janssen COVID-19 vaccine.
  - Expected local post-vaccination symptoms (e.g., pain, swelling, erythema at the injection site) and systemic post-vaccination symptoms (e.g., fever, fatigue, headache, chills, myalgia, and arthralgia). Most systemic post-vaccination symptoms are mild to moderate in severity and resolve within 1-3 days of onset or after vaccination.
    - Localized axillary lymphadenopathy on the same side as the vaccinated arm may occur following vaccination with the mRNA and Novavax COVID-19 vaccines.
    - Temporary swelling at or near the site of a dermal filler injection (usually the face or lips) following a dose of an mRNA COVID-19 vaccine also may occur.
  - Rare risk of myocarditis and pericarditis following receipt of mRNA or Novavax COVID-19 vaccines, especially in males ages 12–39 years. Counseling should include the need to seek care if symptoms of myocarditis or pericarditis develop after vaccination, particularly in the week after vaccination.
  - Antipyretic or analgesic medications can be taken for the treatment of post-vaccination local or systemic symptoms but should not be used prophylactically for prevention of post-vaccination symptoms.
  - Immunocompromised persons should be aware about the potential for a reduced immune response to COVID-19 vaccines and need to follow all current prevention measures to protect themselves against COVID-19.
  - Continue all current guidance, as appropriate, for protection of oneself and others to include wearing a high quality face mask, staying at least 6 feet away from others, avoiding

crowds, washing hands, and following any observation periods, exposure quarantine and isolation procedures.

8. On-Site vaccine receipt and storage

Refer to CDC's U.S. COVID-19 Product Information for additional storage considerations at https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html.

Pfizer-BioNTech COVID-19 Vaccines

- Two COVID-19 vaccine formulations, which DO NOT require dilution prior to use, are authorized and/or approved for use.
  - The **monovalent primary series vaccine** is supplied in a multi-dose vial with a gray cap and gray label border.
  - The **bivalent booster vaccine** is supplied in a single or multi-dose vial with a gray cap and gray label border.
- Vaccine allotments will be shipped in a refrigerated state (2°C to 8°C [36°F to 46°F]) either:
  - ***Directly from the manufacturer*** to select BOP institutions in full package quantities (multiples of 300 doses) per institution requests, or
  - ***Directly from the BOP Central Fill and Distribution (CFAD) site*** to the BOP institution that requested an allotment in partial package quantities (i.e., micro-distribution).
- Upon receipt, institutions will immediately inspect vaccine for damage, then place into refrigeration storage temperatures (2°C to 8°C [36°F to 46°F]) using an appropriate refrigerator. Ensure that monovalent vaccines are not confused with bivalent vaccines by keeping them separate and appropriately labeled in the refrigerator.
- Both vaccine formulations have a 10-week refrigerated expiration date, which should be marked on the carton upon arrival.
- ***When stored refrigerated, unpunctured vaccine vials must be used within 10 weeks, and institutions must keep up with the 10-week timeline.***
- Both vaccine formulations may be stored at room temperature (8°C to 25°C [46°F to 77°F]) for a total of 12 hours prior to the first puncture. After first puncture, vials should be held between 2°C to 25°C (35°F to 77°F) and used within 12 hours.
- Any vaccine not used within its appropriate timeframe must be maintained in a separate area and labeled **"DO NOT USE"** (see *Section 16. Disposal*).

Moderna COVID-19 Vaccines

- The following COVID-19 vaccine formulations, neither of which require dilution prior to use, are approved and/or authorized for use:
  - A **monovalent primary series vaccine** supplied in a multi-dose vial with a red cap and a blue border label.
  - A **bivalent booster vaccine** supplied in a multi-dose vial with a dark blue cap and a gray border label.

- The ***monovalent primary series vaccine is supplied in two, multi-dose vial types***: a 5.5 mL vial and a 7.5 mL vial. The number of doses in each will vary depending on the needle and syringe type used.
- Vaccine allotments will be shipped at frozen temperature (-50°C to -15°C [-58°F to 5°F]) either:
  - ***Directly from the manufacturer*** to select BOP institutions in full package quantities (multiples of 140 doses) per institution requests, or
  - ***Directly from the CFAD site*** to the BOP institution that requested an allotment in partial package quantities (i.e., micro-distribution).
- Upon receipt, institutions will immediately inspect vaccine for damage, then place into refrigeration storage temperature (2°C to 8°C [36°F to 46°F]) using an appropriate refrigerator. During storage, minimize exposure to room light and ensure that monovalent and bivalent vaccines are kept separate and appropriately labeled in the refrigerator.

  *Once thawed, the vaccine **CANNOT** be re-frozen. It should be handled with care and protected from shocks, drops, and vibration. Vials can be handled in room light conditions.*
- Procedure for thawing vaccine vials, if they are frozen prior to administration:
  - Monovalent vaccine vials:
    - 5.5 mL vials – thaw in a refrigerator (2°C to 8°C [36°F to 46°F]) for 2.5 hours ***OR*** at room temperature between 15°C to 25°C (59°F to 77°F) for 1 hour.
    - 7.5 mL vials – thaw in a refrigerator (2°C to 8°C [36°F to 46°F]) for 3 hours ***OR*** at room temperature between 15°C to 25°C (59°F to 77°F) for 1.5 hours.
  - Bivalent vaccine vials:
    - Thaw in a refrigerator (2°C to 8°C [36°F to 46°F]) for 2 hours, letting each vial stand at room temperature for 15 minutes before administering, ***OR***
    - Thaw at room temperature between 15°C to 25°C (59°F to 77°F) for 45 minutes.

    Let each vial stand at room temperature for 15 minutes before administering.
- ***When stored refrigerated, the unpunctured vaccine vials must be used within 30 days, and institutions must keep up with the 30-day timeline.***
- The vaccine may be stored at room temperature (8°C to 25°C [46°F to 77°F]) for a total of 24 hours, which includes 12 hours after vial puncture.
- Any vaccine not used within its appropriate timeframe must be maintained in a separate area and labeled **"DO NOT USE"** (see *Section 16. Disposal*).

NOVAVAX COVID-19 VACCINE

- The monovalent primary series vaccine, which may also be used in limited circumstances as a first booster dose, is supplied in a multi-dose vial.
- Although not currently being shipped, vaccine allotments would be shipped in a refrigerated state (2°C to 8°C [36°F to 46°F]). Information regarding the process for ordering and shipping will be provided to institutions as needed.
- Upon receipt, institutions will immediately inspect vaccine for damage, check the expiration date by scanning the QR on the outer carton or by going to: *www.novavaxcovidvaccine.com*, and

then place into refrigeration storage temperature (2°C to 8°C [36°F to 46°F]) using an appropriate refrigerator.

➔ ***DO NOT freeze the vaccine and do protect it from light.***

- ***When stored refrigerated, unpunctured vaccine vials must be used by the expiration date of the vaccine, and institutions must keep up within this timeline.***
- After first puncture, the vial should be held at room temperature between 2° to 25°C (36° to 77°F) and used within 6 hours.
- Any vaccine not used within its appropriate timeframe or any vaccine vial that has been punctured 20 times must be maintained in a separate area and labeled "DO NOT USE" (see Section *16. Disposal*).

9. On-Site vaccine preparation

Pfizer-BioNTech Mono and Bivalent COVID-19 Vaccines (gray cap with gray label border - DO NOT DILUTE)

- Remove vaccine from the refrigerator and verify the vaccine, vaccine formulation (mono versus bivalent vaccine), and expiration date located on the vial.
- Allow the vaccine vial to come to room temperature (up to 25°C [77°F]) for 30 minutes before vaccine administration.

  ➔ *Vaccine may be stored at room temperature (up to 25˚C [77˚F]) for a total of 12 hours prior to the first puncture.*
- Gently invert the vaccine vial 10 times to mix. **DO NOT SHAKE** and **DO NOT DILUTE** the vaccine.
- Visually inspect the liquid in the vaccine vial. Prior to mixing, it may contain white to off-white opaque amorphous particles. After mixing, the vaccine should appear as a white to off-white suspension with no visible particles. Do not use if the liquid is discolored or if particles are observed after mixing.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the vaccine, preferentially using a low dead-volume syringe and/or needle.
- Each dose must contain 0.3 mL of vaccine.
- **After the first dose has been withdrawn**, the vaccine vial should be held between 2°C to 25°C (35°F to 77°F).
- Record the date and time of first use on the vaccine vial label.

➔ *Vaccine vials should be used within 12 hours after the first puncture according to the revised Full EUA Prescribing Information dated 31 August 2022, even though vial labels and cartons may state that a vial should be used within 6 hours after the first puncture.*

- Any vaccine not used within its appropriate timeframe must be maintained in a separate area and labeled **"DO NOT USE"** (see *Section 16. Disposal*).

MODERNA MONO AND BIVALENT COVID-19 VACCINES

- Remove thawed vaccine from refrigeration and verify the vaccine, vaccine formulation (mono versus bivalent), and the vaccine expiration date by accessing the manufacturer's website at *https://modernacovid19global.com/vial-lookup*. Document the lot number and the expiration date provided by the website.
- Allow the vaccine to come to room temperature for at least 15 minutes before vaccine administration.
  - *Vaccine may be stored between 8°C to 25°C (46°F to 77°F) for a total of 24 hours, which includes a maximum of 12 hours after the first puncture.*
- Swirl the vaccine vial gently and between each withdrawal. **DO NOT SHAKE** and **DO NOT DILUTE** the vaccine.
- Visually inspect the vaccine vial for particulate matter and discoloration before vaccine administration.
  - The vaccine is a white to off-white suspension, and it may contain white or translucent product-related particulates.
  - If other particulate matter and/or discoloration are present, the vaccine should NOT be administered.
- Thawed vaccine vials can be handled in room light.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.5 mL of the vaccine, preferentially using a low dead-volume syringe and/or needle.
- Each dose must contain 0.5 mL of vaccine.
- **After the first dose has been withdrawn**, the vaccine vial should be held between 2°C to 25°C (36°F to 77°F).
- Record the date and time of first use on the vaccine vial label.
  - ***After first puncture, vials must be used within 12 hours.***
- Any vaccine not used within its appropriate timeframe must be maintained in a separate area and labeled "**DO NOT USE**" (see *Section 16. Disposal*).
- ***Special considerations for transportation:*** **Once thawed,** the vaccine is sensitive to movement, and institutions should refer to the following CDC guidance on transporting the vaccine: *https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/Moderna-Vaccine-Transport.pdf*

NOVAVAX MONOVALENT COVID-19 VACCINE

- Remove vaccine from the refrigerator, verify the vaccine, and verify the expiration date by scanning the QR on the outer carton or by going to: *www.novavaxcovidvaccine.com*.
- Visually inspect the vaccine vial for particulate matter and discoloration before vaccine administration.
  - The vaccine is a colorless to slightly yellow, clear to mildly opalescent suspension, free from visible particles.
  - If particulate matter and/or discoloration are present, the vaccine should NOT be administered.

- Gently swirl the vaccine vial before each dose withdrawal. **DO NOT SHAKE**.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.5 mL of the vaccine. Ensure the syringe is not cold to touch.
- Each dose must contain 0.5 mL of vaccine.
- **After the first dose has been withdrawn**, the vaccine vial should be held between 2°C to 25°C (36°F to 77°F).
- Record the date and time of first use on the vaccine vial label.

  ➔ ***After first puncture, vials must be used within 6 hours.***

- Any vaccine not used within its appropriate timeframe must be maintained in a separate area and labeled "**DO NOT USE**" (see *Section 16. Disposal*).

10. ADMINISTRATION

- For all multi-dose COVID-19 vaccine vials:
  - Pierce the stopper at a different site each time a new dose is withdrawn.
  - Remove air bubbles while the needle is still inside the vaccine vial.
  - If the amount of vaccine remaining in a vial cannot provide a full dose, discard the vaccine vial and contents (see *Section 16. Disposal*).
  - Do not pool excess vaccine from multiple vaccine vials.
- Refer to the table on the following pages for a summary of administration procedures.

SUMMARY OF ADULT ADMINISTRATION PROCEDURES BY VACCINE TYPE (PAGE 1 OF 2)					
COVID-19 VACCINE BY TYPE	**HOW SUPPLIED**	**DOSE/VOLUME/SCHEDULE**		**ROUTE**	**KEY POINTS – SEE DOCUMENT FOR DETAILS**
Pfizer-BioNTech COVID-19 Vaccine mRNA vaccine	Suspension **Multi-dose vials for monovalent and bivalent vaccines** (contain 6 doses) **Single dose vial for bivalent vaccine** (contains 1 dose)	**Dose/Volume** *Monovalent primary series (2 or 3 doses) and Bivalent booster*	30 mcg/0.3 mL	IM	Both monovalent and bivalent vaccines: *Gray caps with gray label borders* *DO NOT DILUTE* • On-site vaccine prep instructions: see *Section 9*. • **Vaccine vial timelines** ○ Use unpunctured, refrigerated vials within 10 weeks. ○ Use unpunctured, unrefrigerated (8°C to 25°C [46°F to 77°F]) vials **within 12 hours**. ○ After 1st dose withdrawn, use vials **within 12 hours**. • Egg, cell, latex, and preservative free. • Contraindications, precautions and special populations: see *Section 2*. • **Monovalent primary series schedule** ○ Interval between 1st and 2nd dose: **3-8 weeks** ➔ *Use shorter interval if immunocompromised, age ≥ 65 years, at increased risk for severe disease, or if increased concern based on the determined BOP level of operation. Otherwise, use longer interval if age ≤ 64 years.* ○ Interval between 2nd and 3rd dose (immunocompromised only): **≥ 4 weeks** • **Bivalent booster schedule:** Any mRNA vaccine may be given at least 2 months after any previous vaccine dose (primary series or monovalent booster).

SUMMARY OF ADULT ADMINISTRATION PROCEDURES BY VACCINE TYPE (PAGE 2 OF 2)					
COVID-19 VACCINE BY TYPE	**HOW SUPPLIED**	**DOSE/VOLUME/SCHEDULE**		**ROUTE**	**KEY POINTS – SEE DOCUMENT FOR DETAILS**
Moderna COVID-19 Vaccine mRNA vaccine	Suspension **Monovalent primary series vaccine:** red cap with blue border label; 2 multi-dose vial types (5.5 mL, 7.5 mL). Number of doses vary based on vial, syringe, and needle type used. **Bivalent booster vaccine:** dark blue cap with gray border label. Contains 5 doses.	**Dose/Volume** *Monovalent primary series (2 or 3 doses)* *Bivalent booster*	100 mcg/0.5 mL 50 mcg/0.5 mL	IM	***No reconstitution required**** • On-site vaccine prep instructions: see *Section 9*. • **Vaccine vial timelines** ○ Use unpunctured, refrigerated vials **within 30 days.** ○ Use unpunctured, unrefrigerated (8°C to 25°C [46°F to 77°F]) vials **within 24 hours.** ○ After 1st dose withdrawn, use vials **within 12 hours.** • Egg, cell, latex and preservative free. • Contraindications, precautions, and special populations: see *Section 2*. • **Monovalent primary series schedule** ○ Interval between 1st and 2nd dose: **4-8 weeks** with same interval considerations as for the Pfizer-BioNTech COVID-19 vaccine. ○ Interval between 2nd and 3rd dose (immunocompromised only): **≥ 4 weeks** • **Bivalent booster schedule:** same as for the Pfizer-BioNTech COVID-19 vaccine.
Novavax COVID-19 Vaccine Protein subunit, adjuvanted vaccine	Suspension **Multi-dose vials for monovalent vaccine** (contain 10 doses)	**Dose/Volume** *Primary series (2 doses)*	0.5 mcg rS with 50 mcg Matrix-M™ adjuvant/0.5 mL	IM	***DO NOT dilute**** • On-site vaccine prep instructions: see *Section 9*. • **Vaccine vial timelines** ○ Use unpunctured, refrigerated vials by the expiration date**.** ○ After 1st dose withdrawn, keep vials at 2 °C to 25°C (36°F to 77°F) and use **within 6 hours**. • Egg, cell, latex, and preservative free. • Contraindications, precautions and special populations: see *Section 2*. • **Monovalent primary series schedule** • Interval between 1st and 2nd dose: **3-8 weeks** with same interval considerations as for the Pfizer-BioNTech COVID-19 vaccine. • **Bivalent booster schedule:** Any mRNA vaccine may be given at least 2 months after any previous vaccine dose (primary series or monovalent booster).

- ***Ancillary supply kits are ordered automatically based on the number of vaccine orders and will arrive before or along with the vaccine***.
  - The kits contain syringes, needles for reconstitution (if needed) and administration, diluent (if needed), vaccination cards, and a limited amount of PPE supplies (i.e., face shields and gowns).
  - Gloves and sharps containers are not included in the kits.
  - Sharps sent in the kits should be stored, inventoried and disposed of in accordance with BOP policy.
- ***Vaccine administration procedure***
  - ***To prevent syncope,*** have the patient sit or lie down for vaccination and consider observing the patient for 15 minutes after receipt of the vaccine.
  - Administer the prepared vaccine intramuscularly (22-25 g, 1-1½" needle) in the deltoid muscle; alternatively, the anterolateral thigh also may be used.

    See Appendix 3. Administering Vaccines: Dose, Route, Site, and Needle Size
  - A 5/8" needle may be used for patients who weigh less than 130 lbs (60 kg) for injection in the deltoid muscle, *only* if the skin over the deltoid is stretched taut, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

11. COVID-19 Vaccine Scheduling & Interchangeability

For algorithms on COVID-19 vaccine schedules, refer to CDC's COVID-19 Vaccination Schedule Infographics at: https://www.cdc.gov/vaccines/covid-19/images/COVID19-vaccination-schedule-most-people.png and https://www.cdc.gov/vaccines/covid-19/images/COVID19-vaccination-schedule-immunocompromised.png.

- ***The mRNA COVID-19 vaccine primary series is given in 2 or 3 doses (30 mcg/0.3 mL each for Pfizer-BioNTech, 100 mcg/0.5 mL each for Moderna) scheduled 3-8 weeks apart (Pfizer-BioNTech) or 4-8 weeks apart (Moderna).***
  - ***Use the shorter interval*** for those who are immunocompromised, 65 years of age and older, in need of rapid protection due to concerns about the risk of severe disease, or when SARS-CoV-2 transmission levels in the community and/or facility are high (i.e., Level 2 or 3 Operations as per the *Modified Operation Matrix* available on Sallyport).
  - ***Use the longer interval*** for those who are less than 65 years of age, particularly males under the age of 40 years. Data have shown that a longer interval may increase vaccine effectiveness and immunogenicity while decreasing the risk of myocarditis and pericarditis.
  - ***If a person is immunocompromised, schedule a third dose*** at least 4 weeks after the second dose.
  - If an immunocompromised person received two different mRNA COVID-19 vaccine products for the first two doses of their primary mRNA vaccination series, the product used for the second dose should be used for the third dose to complete the vaccine series.

- ***The Novavax COVID-19 vaccine primary series is given in two doses (5 mcg with 50 mcg adjuvant/0.5 mL) scheduled 3-8 weeks apart.***
  - The same considerations regarding shorter and longer intervals between the first and second doses apply as for the mRNA COVID-19 vaccines (see above).
  - There is NO recommendation to administer a third dose for immunocompromised individuals.
- ***Primary vaccination doses of COVID-19 vaccines*** should be given as close to the recommended interval as possible.
  - Persons should not be scheduled to receive primary series vaccination doses earlier than recommended; however, doses administered up to 4 days before the minimum interval, known as the 4-day grace period, are considered valid. When not feasible to adhere to the recommended interval:
    - Doses administered any time ***after*** the recommended interval and are considered valid.
    - Doses administered prior to the 4-day grace period ***should be repeated by at least the minimum interval*** with the repeat dose spaced from the date of the dose given early in error.
- In most circumstances, individuals initiating a primary COVID-19 vaccination series by a particular manufacturer should complete their vaccination series using the same product.
  - In limited, exceptional situations where a first dose of a 2- or 3-dose primary vaccination series was received but the series cannot be completed with the same vaccine product (e.g., due to a contraindication, unknown previous vaccine product, incorrect vaccine product inadvertently administered), a different COVID-19 vaccine (i.e., Pfizer-BioNTech, Moderna or Novavax) may be administered to complete the primary series at a minimum interval of 28 days from the last COVID-19 vaccine dose and provided the indicated number of doses is administered.
- ***A bivalent booster dose should be administered to all inmates.***
  - In most circumstances, bivalent mRNA vaccines (Pfizer-BioNTech or Moderna) are preferred for the administration of booster vaccination and should be administered at least 2 months after the final primary vaccine series dose or after the last monovalent booster dose. Either bivalent mRNA vaccine product may be used, regardless of the primary series product used.
    - A monovalent Novavax booster dose may be used in limited situation in adults who completed a primary series with any COVID-19 vaccine, have not received any previous booster dose(s), and are unwilling to receive an mRNA vaccine. The monovalent Novavax booster dose is administered at least 6 months after completion of a primary series.
  - A booster dose given in error prior to the 4-day grace period ***should be repeated.*** Space the repeat dose after the dose given in error by at least 2 months.

12. Persons Vaccinated Outside the United States

- Recommendations for persons vaccinated outside of the United States depend on the number and type of vaccine(s) received for the primary vaccination series and whether a booster dose or doses were received.
- For specific recommendations, refer to the CDC guidance: *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-b*

13. Documentation

Inmate Vaccine Administration Documentation

Administration will be documented in the BEMR immunization flow sheet. Select the COVID-19 immunization administered from the drop-down menu. Record the dose number, location, lot number, dosage, route, expiration date, and provider.

- If vaccine was not given, record the reason(s) (e.g., medical contraindication, refusal).
- Utilize the comments section as needed, to include documenting diluent lot# and expiration date.
- Enter the second or third primary vaccine dose date or booster date in the scheduler, if applicable.
- Upon exiting, do not forget to save the immunization flow sheet data.

*Institutions will **provide inmates** a completed CDC COVID-19 vaccination card as proof of vaccination upon release. A formal medical records request is not required.*

- ***For inmates who received COVID-19 vaccination elsewhere*** (i.e., not in the BOP), enter vaccination information into BEMR as "History Of" along any available information to include manufacturer name, dose number, vaccination date(s) and location.
  - Scan any supporting documentation into BEMR document manager (using the scan type of "civilian records") or provide information in the comment box regarding source of information. Once scanned, CDC COVID-19 Vaccination Cards should be returned to the inmate.
  - In order to accurately reflect vaccination status on the COVID-19 vaccination dashboard, the dose number and vaccination date must be entered when entering a vaccination history into BEMR. If an inmate received a 2-dose or 3-dose series, ***all doses must be entered separately***.
  - ***If vaccination history is not reliable,*** obtain a signed declination of the BOP-offered COVID-19 vaccination and include prior vaccination as the reason for declination. There should also be an explanation as to why the reported vaccination history does not seem reliable (e.g., can't remember the name of the vaccine, estimated date, or location of administration).
  - If a vaccination has already been documented in the flow sheet, it should not be charted again.

EMPLOYEE VACCINE ADMINISTRATION DOCUMENTATION

When BOP has provided the vaccination, this will be documented in the Vaccine Administration Management System (VAMS) – a system developed by the CDC for COVID-19 vaccine management – no later than 24 hours after vaccine administration. Employees should also be provided with completed CDC COVID-19 vaccination cards after being vaccinated.

COVID-19 VACCINE CONSENT FORMS

- Document the publication date of the fact sheet.
- Document the vaccine and dose being given and have the patient sign consent or declination.
- The person administering the immunization signs and dates the form.
- Disposition of the completed, signed consent forms
  - ***Inmates:*** Scan a separate inmate consent form for each administered or declined dose of vaccine into the Document Manager in BEMR.
  - ***Employees:*** Provide a hard copy of the signed employee consent form to employee records for filing after any vaccination has been completed (including second and booster doses where applicable) or the employee's refusal of the primary vaccination series has been documented.

➔ ***Documentation of vaccine consent or declination must be obtained from every inmate***.

SCHEDULING ADDITIONAL DOSES OF VACCINE

- Vaccines are readily available at all facilities. Vaccine administration should be made available for "walk-ins" or during sick-call clinics. Alternatively, facilities should plan for clinic availability and be able to offer vaccination on a daily/weekly basis.
- ***For inmates, using BEMR scheduler is the preferred method to schedule subsequent vaccine doses.***
- The COVID-19 vaccine dashboard is a tool that may be used to monitor when additional vaccine doses should be given.
- ***For employees, each facility will determine a method for scheduling vaccination administration clinics*** and what reminders to use for determining when follow-up vaccine doses should be given (e.g., pre-determined clinic dates, use of the Manage Recipients page in VAMS to track dates for subsequent doses, use of a spread sheet of due dates, and/or vaccine cards).

14. MEDICAL EMERGENCY OR ANAPHYLAXIS

Rash, difficulty breathing, itchy throat, bodily collapse, swollen tongue or throat maybe all be signs of anaphylaxis.

- In the event of a medical emergency related to vaccination, ***immediately call a medical emergency.***
- ***Epinephrine 1:1000 IM/SQ and respiratory support should be immediately available.***
- BOP nursing and paramedic protocols are available on Sallyport for implementation and use in the management of allergic reactions and anaphylaxis when approved by the clinical director.

15. VACCINE ADVERSE REACTIONS

Documentation of adverse events (AEs), even if it is uncertain whether the vaccine caused the event, should occur in the following two locations:

- BOP Adverse Events dashboard ***for inmates only***
- Federal Vaccine Adverse Event Reporting System (VAERS) *for* ***staff AND inmates*** at: *https://vaers.hhs.gov/reportevent.html*
  - Vaccination providers are required by the FDA to report to VAERs any of the following after COVID-19 vaccination:
    - Vaccine administration errors, whether or not associated with an AE
    - Serious adverse events, regardless of whether it is thought the vaccine caused the AE, which include:
      - Death
      - A life-threatening AE
      - Inpatient hospitalization or prolongation of an existing hospitalization
      - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
      - A congenital anomaly/birth defect
      - An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above
    - Cases of myocarditis and pericarditis after an mRNA or Novavax COVID-19 vaccine
    - Cases of MIS (a Multisystem Inflammatory Syndrome)
    - Cases of COVID-19 that result in hospitalization or death
  - Reporting is encouraged for any other AE, even if it is uncertain whether the vaccine caused the event.
  - Complete reports online in one sitting or by using a writable PDF form. For further assistance email *info@VAERS.org* or call (800) 822-7967.

16. DISPOSAL

- Syringes and needles used for vaccination should be placed in hard, lockable biohazard containers and bagged in biohazard bags just as any other vaccine.
- Institutions must store nonviable vaccine vials (unpunctured and punctured) that are contaminated, expired or unused in a separate, designated area away from any vaccine that is in use. Label the vaccine vials “DO NOT USE”.
  - Nonviable and unpunctured vaccine vials should be returned to the manufacturer following the normal pharmacy procedures for return of expired medications.
  - Nonviable and punctured vaccine vials should be disposed of in hot trash. This includes left over vaccine doses.

APPENDIX 1. SKILLS CHECKLIST FOR COVID-19 VACCINE ADMINISTRATION

The checklist on the following pages can be used as an assessment tool for healthcare staff who administer the Pfizer-BioNTech, Moderna, and/or Novavax COVID-19 vaccines.

SKILLS CHECKLIST FOR ADULT COVID-19 VACCINE ADMINISTRATION (*PAGE 1 OF 5*)				
FACILITY:			**EMPLOYEE:**	
Self-Assessment		**Supervisor/ Preceptor Review**		**SKILLS**
Needs to Improve	**Meets or Exceeds**	**Needs to Improve**	**Meets or Exceeds**	
PATIENT EDUCATION				
				Welcomes patient, verifies identification, accommodates language/literacy barriers and special needs, and explains what vaccine will be given.
				Provides Emergency Use Authorization (EUA) fact sheet and answers questions.
				Reviews preference for mRNA COVID-19 vaccines, potential side effects, comfort measures, and after care instructions.
SCREENING/PREPAREDNESS				
				Screens patient for vaccine eligibility (based on EUA and package insert), history of adverse reactions, allergies, contraindications, and precautions.
				Ensures consent/declination form is signed and that the current EUA date is documented. Uses a separate consent form for each vaccine dose for inmates and one consent form for all primary series vaccine doses for employees.
				Verbalizes signs and symptoms of potential medical emergency or anaphylaxis.
				Able to initiate CPR and maintain airway, if necessary. Locates epinephrine.
				States procedure for responding to and reporting needle stick injuries.
VACCINE STORAGE AND HANDLING – GENERAL				
				Documents refrigerator temperatures with a temperature digital data logger twice daily on clinic days. Acknowledges that temperature data for vaccines is stored for at least 3 years.
				Does not store vaccines in dormitory style refrigerators.
				Ensures that food and beverages are not stored in a refrigerator with vaccines.
				Ensures refrigerator is plugged into a generator back-up plug, if available, and labeled with “Do not unplug” signage.
				Stores vaccines in original containers with lids closed until ready for administration.
				Positions vaccines 2-3 inches from walls, floor, ceiling and door of refrigerator and not directly under cooling vent, in deli or fruit or vegetable drawers, or refrigerator door.
				Uses appropriate storage coolers with temperature monitoring when moving vaccines to clinics outside of main storage.

SKILLS CHECKLIST FOR ADULT COVID-19 VACCINE ADMINISTRATION (*PAGE 2 OF 5*)				
Self-Assessment		**Supervisor/ Preceptor Review**		**SKILLS**
Needs to Improve	**Meets or Exceeds**	**Needs to Improve**	**Meets or Exceeds**	
VACCINE HANDLING AND PREPARATION, PFIZER-BIONTECH MONOVALENT AND BIVALENT VACCINE (GRAY CAPS-DO NOT DILUTE)				
				Demonstrates knowledge that unpunctured vials may be refrigerated (2°C to 8°C [36°F to 46°F]) for up to 10 weeks.
				Ensures monovalent vaccines are not confused with bivalent vaccines by keeping them separate and appropriately labeled in the refrigerator.
				Removes vaccine from refrigerator and verifies the vaccine, vaccine formulation, expiration date, and visually inspects the vaccine vial for particulate matter and discoloration.
				Inverts vial gently 10 times to mix*. DOES NOT SHAKE the vial. DOES NOT DILUTE the contents.*
				Ensures that unpunctured vials are not stored any longer than 12 hours between 8°C to 25°C (46°F to 77°F).
				Cleanses the vaccine vial stopper with an alcohol swab.
				Withdraws 0.3 mL of vaccine (for both vaccine formulations).
				Stores the vial between 2°C to 25°C (35°F to 77°F) for up to 12 hours *after first dose* has been drawn.
				Records the date and time of the first use on the vial label.
VACCINE HANDLING AND PREPARATION, MODERNA VACCINE (MONOVALENT, 2 VIAL TYPES: BOTH RED CAPS; BIVALENT: DARK BLUE CAP)				
				Demonstrates knowledge that unpunctured vials may be refrigerated (2°C to 8°C [36°F to 46°F]) for up to 30 days and **may be moved from the storage location to clinic only once in an unfrozen state.**
				Ensures monovalent and bivalent vaccines are kept separate and appropriately labeled in the refrigerator.
				Removes vaccine from refrigerator and verifies the vaccine, vaccine formulation, and expiration date.
				Ensures the vaccine is thawed and that the vial has been allowed to come to room temperature for 15 minutes prior to drawing up vaccine for administration.
				DOES NOT SHAKE the vial and does not dilute the contents.
				Visually inspects the vial for unexpected particulate matter and/or discoloration. The vaccine is a white to off-white suspension, and it may contain white or translucent product-related particulates. The vaccine should NOT be used if other particulate matter and/or discoloration are present.
				Ensures that unpunctured vials are not stored any longer than for a total 24 hours between 8°C to 25°C (46°F to 77°F).
				Cleanses the vaccine vial stopper with an alcohol swab.

SKILLS CHECKLIST FOR ADULT COVID-19 VACCINE ADMINISTRATION (*PAGE 3 OF 5*)				
Self-Assessment		**Supervisor/ Preceptor Review**		**SKILLS**
Needs to Improve	**Meets or Exceeds**	**Needs to Improve**	**Meets or Exceeds**	
VACCINE HANDLING AND PREPARATION, MODERNA VACCINE (MONOVALENT, 2 VIAL TYPES: BOTH RED CAPS; BIVALENT: DARK BLUE CAP) (CONTINUED)				
				Swirls the vial gently and ***withdraws 0.5 mL of vaccine (for both vaccine formulations).***
				Stores the vial between 8°C to 25°C (46°F to 77°F) for up to 12 hours *after first dose* has been drawn, which includes the maximum 24-hour total at room temperature.
				Records the date and time of the first use on the vial label.
VACCINE HANDLING AND PREPARATION, NOVAVAX MONOVALENT COVID-19 VACCINE				
				Demonstrates knowledge that unpunctured vials may be stored refrigerated (2°C to 8°C [36°F to 46°F]) and must be used by the expiration date.
				Acknowledges that each multi-dose vaccine vial contains 10 (ten) separate 0.5 mL vaccine doses.
				Removes vaccine from refrigerator, verifies the vaccine and expiration date (by scanning the QR on the outside carton or by referring to *www.novavaxcovidvaccine.com*), and visually inspects the vaccine vial for particulate matter and discoloration before administration.
				DOES NOT SHAKE the vial.
				Cleanses the vaccine vial stopper with an alcohol swab
				Swirls the vial gently and ***withdraws 0.5 mL of vaccine.***
				Stores the vial between 2° to 25°C (36° to 77°F) for up to 6 hours *after first dose* has been drawn.
				Records the date and time of the first use on the vial label.
ADMINISTERING VACCINES				
				Demonstrates knowledge of the appropriate route (IM), site (deltoid), vaccine type and dose, and the type of syringe safety device being utilized (glide, snap or retraction device).
				Washes or disinfects hands before and in-between patient encounters. *If gloves are worn, they are changed and hand hygiene performed between patients.*
				Places the labeled, unexpired, multi-dose vaccine on a hard surface, cleanses the stopper with a clean alcohol wipe and allows to dry ***between each dose of vaccine***.
				Utilizes a new and appropriately sized needle and syringe for each dose of vaccine. Opens syringe packet carefully placing the safety cap on the package covering.
				Adheres to the following specific vaccine requirements: • *Moderna and Novavax:* Swirls the vial gently between each dose withdrawal. *DOES NOT SHAKE the vial.*

SKILLS CHECKLIST FOR ADULT COVID-19 VACCINE ADMINISTRATION (*PAGE 4 OF 5*)				
FACILITY:			**EMPLOYEE:**	
Self-Assessment		**Supervisor/ Preceptor Review**		**SKILLS**
Needs to Improve	**Meets or Exceeds**	**Needs to Improve**	**Meets or Exceeds**	
ADMINISTERING VACCINES (CONTINUED)				
				Inserts needle into the multi-dose vaccine vial and pierces the stopper at a different site each time for each new dose.
				Inverts vial and syringe and withdraws the following amount of vaccine from the vaccine vials: • *Pfizer-BioNTech:* 0.3 mL (mono and bivalent doses) • *Moderna:* 0.5 mL (mono and bivalents doses) • *Novavax;* 0.5 mL (monovalent doses)
				Does not pool excess vaccine doses from multiple vials to obtain a vaccine dose. Discards the vaccine vial and contents, if a full vaccine dose cannot be withdrawn from a given vaccine vial.
				Removes air bubbles from the vaccine vial while the needle is still inside the vial, withdraws needle from the vial, and verifies final vaccine dose.
				Positions patient so that muscles are relaxed and preps injection site with alcohol wipe, allowing it to dry.
				Holds the syringe and needle in the dominant hand and either bunches up muscle using the non-dominant hand or gently stretches the skin around the injection site.
				Inserts the needle at a 90-degree angle using a dart-like action to prevent accidental depression of the plunger during insertion of the needle. Aspiration is not necessary for IM injections in the deltoid site.
				Uses the thumb and forefinger of the non-dominant hand to hold the syringe and depresses the plunger with the dominant hand in a steady motion after the needle pierces the skin.
				Removes the needle at the same angle at which it was inserted once medication is completely injected. Engages the needle safety device appropriately.
				Disposes of the needle and syringe in a sharps container.
				Covers injection site with the gauze, using gentle pressure and applies a Band-Aid, if needed.
				Records the date and time of first use on the vial label.

SKILLS CHECKLIST FOR ADULT COVID-19 VACCINE ADMINISTRATION (*PAGE 5 OF 5*)				
FACILITY:			**EMPLOYEE:**	
Self-Assessment		**Supervisor/ Preceptor Review**		**SKILLS**
Needs to Improve	**Meets or Exceeds**	**Needs to Improve**	**Meets or Exceeds**	
ADMINISTERING VACCINES (CONTINUED)				
				Identifies vials that can no longer be used by expiration date or the following: • *Pfizer-BioNTech (gray caps):* unpunctured vials out of refrigeration for more than 12 hours; punctured vials not used within 12 hours after first dose when stored between 2°C to 25°C (35°F to 77°F); unused vaccine from a vaccination clinic, or refrigerated vaccine not used within 10 weeks • *Moderna*: vaccine out of refrigeration for more than 24 hours; punctured vials not used within 12 hours; refrigerated vaccine not used within 30 days; or unused vaccine from a vaccination clinic. • *Novavax*: punctured vials not used within 6 hours after first dose when stored between 2°C to 25°C (36°F to 77°F); unused vaccine from a vaccination clinic, or refrigerated vaccine not used by the expiration date.
				Maintains vials that can no longer be used in a separate area labeled *"DO NOT USE"* and demonstrates knowledge of BOP vaccine disposal procedures: • Nonviable, unpunctured vaccine vials are returned to the pharmacy. • Nonviable, punctured vaccine vials, are disposed of in hot trash.
DOCUMENTATION				
				Documents the vaccine dose in the appropriate place (consent forms, BEMR, and VAMS) to include dose number, date, lot number, manufacturer, site, and name/initials. Provides vaccination cards to employees.
				Addresses future appointments through the BEMR scheduler for inmates. For employees, follows institution plans.
				Demonstrates the ability to properly document a vaccine adverse event (AE) in VAERS and in the BOP Medication Event dashboard, and identifies which healthcare personnel to notify in the case of an AE.
				If an inmate received COVID-19 vaccination elsewhere (i.e., not in the BOP), knows to: • Make every effort to verify confirmation of the vaccination. • If written documentation is provided or if vaccination is verified verbally from a reliable primary source (e.g., clinic, pharmacy, government agency or office) or transfer paperwork, enter vaccination information into the BEMR system as "History Of" along with the manufacturer name, dose number, and vaccination date(s). Scan documentation into BEMR document manager (scan type: civilian records). • *If proof of vaccination is not provided and cannot be verified*, document declination of the BOP-offered COVID-19 vaccination, *including prior vaccination as the reason for declination,* before entering vaccination information into the BEMR system as "History Of" along with the vaccination date(s).

Employee Signature:	**Date:**
Supervisor Signature:	**Date:**

APPENDIX 2. COVID-19 VACCINE ADMINISTRATION SIGNATURE SHEET

Institution:	
Authorization is given for the checked (✓) categories of healthcare providers to use the checked (✓) COVID-19 vaccine(s) (below) for administration without individual patient medication orders. Healthcare providers who are authorized to administer vaccines should have demonstrated vaccine administration skills (see skill checklist). File a copy of this Signature Sheet in each authorized healthcare provider's credential file.	
	Registered Nurses
	Advanced Practice Providers
	Licensed Practical Nurses
	Paramedics
	Pharmacists
	Dentists
	Other:
The following COVID-19 vaccine(s) is/are approved for use in this facility, in accordance with FDA approval or the FDA EUA and package insert, if the specific vaccine brand(s) is/are checked (✓) below:	
	Pfizer-BioNTech COVID-19 Vaccine (Comirnaty® or under EUA)
	Moderna COVID-19 Vaccine (Spikevax® or under EUA)
	Novavax COVID-19 Vaccine
	Other:
Signatures:	

IP&C Coordinator (Last, First) – PRINT	*Signature*	*Date*
Health Services Administrator (Last, First) – PRINT	*Signature*	*Date*
Clinical Director (Last, First) – PRINT	*Signature*	*Date*
Healthcare Provider (Last, First) – PRINT	*Signature*	*Date*

APPENDIX 3. ADMINISTERING COVID-19 VACCINES

ADMINISTERING THE VACCINE (ADULTS): DOSE, ROUTE, SITE, AND NEEDLE SIZE (PAGE 1 OF3)				
VACCINE	**DOSE**	**ROUTE**	**INJECTION SITE**	**KEY POINTS**
Pfizer-BioNTech Monovalent and Bivalent COVID-19 Vaccines (both gray caps-DO NOT DILUTE)	0.3 mL	IM	Deltoid	• No reconstitution needed. • Refrigerated vaccine must be used within 10 weeks. • Each multi-dose vial contains six (6) separate 0.3 mL vaccine doses. • Unpunctured vials out of refrigeration must be used within 12 hours. • Once punctured, label the vial with the date and time and use within 12 hours (storing between 2°C to 25°C (35°F to 77°F) • Use different vaccine vial stopper insertion points each time a vaccine dose is withdrawn. • Remove air bubbles from the vaccine vial while the needle is still inside the vial. • After beyond use or expiration date, label "DO NOT USE" and store in a place removed from vaccines in use. Discard as per BOP vaccine disposal guidance.
Moderna COVID-19 Vaccines (Monovalent, 2 Vial Types: both red caps; Bivalent: dark blue cap)	0.5 mL	IM	Deltoid	• No reconstitution needed. • The number of monovalent vaccine doses in each vial type (5.5 mL and 7.5 mL) will vary depending on the number of doses administered and the syringe type used. • A maximum of five (5) booster doses may be withdrawn from each bivalent vaccine vial. • Refrigerated vaccine must be used within 30 days. • Vials not refrigerated must be used within 24 hours. • Once punctured, label the vial with the date and time and use within 12 hours. • Use different vaccine vial stopper insertion points each time a vaccine dose is withdrawn. • Remove air bubbles from the vaccine vial while the needle is still inside the vial. • Vaccine moved from refrigerator storage to a vaccination clinic cannot be placed back in storage. • After beyond use or expiration date, label "DO NOT USE" and store in a place removed from vaccines in use. Discard as per BOP vaccine disposal guidance.

ADMINISTERING THE VACCINE (ADULTS): DOSE, ROUTE, SITE, AND NEEDLE SIZE (PAGE 2 OF 3)				
VACCINE	**DOSE**	**ROUTE**	**INJECTION SITE**	**KEY POINTS**
Novavax Monovalent COVID-19 Vaccine	0.5 mL	IM	Deltoid	• No reconstitution needed. • Refrigerated vaccine must be used by the expiration date. • Each multi-dose vial contains ten (10) separate 0.5 mL vaccine doses. • Once punctured, label the vial with the date and time and use within 6 hours (storing between 2°C to 25°C (35°F to 77°F) • Use different vaccine vial stopper insertion points each time a vaccine dose is withdrawn. • Remove air bubbles from the vaccine vial while the needle is still inside the vial. • After beyond use or expiration date, label "DO NOT USE" and store in a place removed from vaccines in use. Discard as per BOP vaccine disposal guidance.

ADMINISTERING THE VACCINE (ADULTS): DOSE, ROUTE, SITE, AND NEEDLE SIZE (PAGE 3 OF3)

Administer IM injections in the deltoid muscle, with a 22-25 gauge needle. Choose needle length based on person's age and body mass:

< 130 lbs.	1" length needle
130-152 lbs.	1" length needle
Female 153-200 lbs.	1-1½" length needle
Female 200+ lbs.	1½" length needle
Male 153-260 lbs.	1-1½" length needle
Male 260+ lbs.	1½" length needle

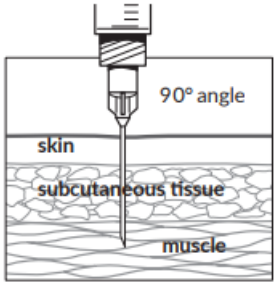
A 5/8" needle may be used for patients who weigh less than 130 lbs (60 kg) for injection in the deltoid muscle, *only* if the skin over the deltoid is stretched taut, and the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

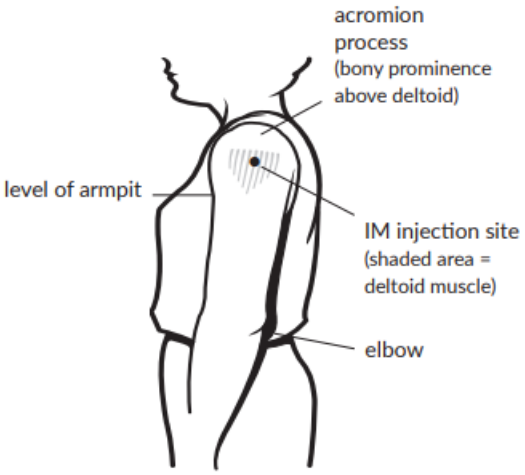
NOTE: Each location will receive an ancillary kit and product information guide separate from the vaccine product. The kits will contain a variety of needles and syringes along with other supplies (e.g., diluent, if needed). When preparing and administering vaccine, staff will need to select the correct syringe size and needle gauge/length appropriate for the activity (vaccine preparation vs. vaccine administration) and for the patient's size. Guidance may be found in the ASPR/CDC "Product Information Guide for COVID-19 Vaccines and Associated Products" sent to the VPOCs and in BOP guidance.

How to administer an intramuscular vaccine*:

1. Use a needle long enough to reach into the muscle – for adults, 1-1½" needle.
2. The 1 mL syringe included in the ancillary kit is recommended for vaccine administration and not for mixing of the diluent with vaccine.
3. With the non-dominant hand, bunch up the muscle (for smaller muscle mass) or stretch the skin (for larger body mass).
4. With the dominant hand, insert the needle at a 90º angle to the skin with a quick thrust.
5. Push down on the plunger and inject the entire contents of the syringe. There is no need to aspirate.
6. Remove the needle and apply pressure to the injection site with a dry gauze. Hold in place for several seconds.
7. If there is any bleeding, cover the injection site with a bandage.
8. Engage the needle safety mechanism and put the used needle and syringe in a sharps container.

Intramuscular (IM) injection





* References adapted from *Administering Vaccines to Adults: Dose, Route, Site, and Needle Size (immunize.org)* and *How to administer intramuscular and subcutaneous vaccine injections (immunize.org)*