COVID-19 Vaccine Guidance

Federal Bureau of Prisons

Clinical Guidance

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What’s New

- In most situations, the Pfizer-BioNTech or Moderna COVID-19 vaccines are preferred over the Janssen COVID-19 vaccine for primary and booster vaccinations based on the latest evidence on vaccine effectiveness, vaccine safety, and rare adverse events. However, offering the Janssen COVID-19 vaccine is preferable to not providing any COVID-19 vaccine.
- There are two approved formulations of the Pfizer-BioNTech COVID-19 vaccine. Either formulation may be used for COVID-19 vaccination in the BOP.
  - A multidose vial with a purple cap, which MUST BE DILUTED prior to use
  - A multidose vial with a gray cap, which IS NOT DILUTED prior to use.
- Update of language throughout from “additional third dose” to “third primary dose” to more closely match the CDC’s word choice and avoid confusion.
- Those who received Pfizer-BioNTech as a primary series may receive a Pfizer-BioNTech booster dose 5 months or after their 2nd primary series or third primary dose.
- Patients who received monoclonal antibody therapy for post-exposure prophylaxis (not COVID-19 treatment) should defer vaccination for 30 days.
- Alert to providers on the Rapid Plasma Reagin (RPR) test and COVID-19 vaccination: A false positive RPR test may result in some patients following COVID-19 vaccination. Treponemal tests do not appear impacted by this issue.
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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 pandemic 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.*
- Wearing masks or cloth face coverings, whichever is appropriate given the circumstances, social distancing, avoiding larger group or public gatherings, limiting travel, and washing hands frequently help reduce the chances of being exposed to the virus or spreading it to others, but these measures are not enough. Vaccines work with the immune system so it will be ready to fight the virus if a person is exposed.
- Stopping a pandemic requires using all available tools. Recommendations will continue to be updated using the latest science.
- For general guidance related to vaccines including Immunization Key Principles and Storage and Handling of Immunizations, refer to the [BOP Immunization Clinical Guidance Document](https://www.fda.gov/media/153716/download).
- 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 screened and scheduled for the vaccine, and (3) ensure that responsibility be assigned to health care personnel for patient assessment and vaccine administration. *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 COVID-19 vaccines are either approved (via a Biologic License Application) or authorized (via an Emergency Use Authorization [EUA]) for use in the United States by the U.S. Food and Drug Administration:

**Pfizer-BioNTech COVID-19 vaccine (an mRNA vaccine)**

- For persons 5 years of age and older: 2-dose primary series followed by a booster dose at least 5 months later for those 12 years of age and older
- Fact sheets for the approved and authorized Pfizer-BioNTech COVID-19 vaccine are available for the following groups:
  - Recipients and caregivers: [https://www.fda.gov/media/153716/download](https://www.fda.gov/media/153716/download)
  - Healthcare providers: [https://www.fda.gov/media/153715/download](https://www.fda.gov/media/153715/download) (grey cap, no dilution)
  - Healthcare providers: [https://www.fda.gov/media/153713/download](https://www.fda.gov/media/153713/download) (purple cap, must dilute)
  - *The FDA-approved Pfizer-BioNTech COVID-19 vaccine, Comirnaty®, may be used interchangeably with the EUA-authorized vaccine for individuals ages 12 and older. The products are legally distinct with certain differences that do not impact safety or effectiveness.*
MODERNCA COVID-19 VACCINE (AN mRNA VACCINE)
• For persons 18 years of age and older: 2-dose primary series followed by a booster dose at least 6 months later
• The EUA fact sheets for the Moderna COVID-19 vaccine are available for the following groups:
  ➢ Recipients and caregivers: https://www.fda.gov/media/144638/download
  ➢ Healthcare providers administering vaccine: https://www.fda.gov/media/144637/download

 For both the Pfizer-BioNTech and Moderna vaccines, certain immunocompromised persons should receive an additional primary (i.e., third) dose of vaccine 28 days after their second primary series vaccine dose followed by a vaccine booster dose at least 5 months later (if recipient received the Pfizer-BioNTech primary series) or 6 months later (if recipient received the Moderna primary series).

JANSEN (JOHNSON & JOHNSON) COVID-19 VACCINE (A RECOMBINANT, REPLICATION-INCOMPETENT VIRAL VECTOR VACCINE)
• For persons 18 years of age and older: 1 dose as primary dose followed by a booster dose at least 2 months later
• 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 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

B. 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.

 • 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 series, additional primary (i.e., third) doses, and booster doses.
A primary COVID-19 vaccination series consists of either a 2-dose series with an mRNA COVID-19 vaccine (i.e., Pfizer-BioNTech or Moderna) or a single dose with the Janssen COVID-19 vaccine.

In most situations, the Pfizer-BioNTech or Moderna COVID-19 vaccines are preferred over the Janssen COVID-19 vaccine for primary and booster vaccinations based on the latest evidence on vaccine effectiveness, vaccine safety, and rare adverse events. However, there are certain situations and subpopulations for which the Janssen vaccine may be offered:

- When there is a contraindication to mRNA COVID-19 vaccines (e.g., severe allergic reaction after a previous dose or to a component of an mRNA COVID-19 vaccine)
- When a person would otherwise remain unvaccinated for COVID-19 due to limited access to mRNA COVID-19 vaccines,
- When a person wants to receive the Janssen COVID-19 vaccine despite the safety concerns identified.

Those who are considering receipt of the Janssen COVID-19 vaccine should be counseled about the rare risk of TTS which can occur (typically within 2 weeks) after receipt of the vaccine and need for a booster dose 2 months or more after the initial dose.

INMATE VACCINATION

- Primary vaccination and a single booster dose should be offered to all inmates.
  - For 2-dose primary vaccination series, a medical hold should be placed in the inmate’s electronic health record when the first dose is administered and not removed until the due date of the second dose.

- Moderately or severely immunocompromised inmates are at increased risk for severe COVID-19, since they may not mount a protective immune response after their primary vaccination. In addition, their protection by primary vaccination may wane over time, making them susceptible to severe SARS-CoV-2 infection. Therefore, in addition to a booster dose, an additional primary vaccine (i.e., third) dose is recommended for mRNA COVID-19 vaccines for this group at least 28 days after completion of the 2-dose series. The BOP COVID-19 Vaccine dashboard may be used to assist institutions in identifying eligible patients based on current CDC guidance.
  - Conditions and treatments causing moderate to severe immunocompromise include:
    - Active treatment for solid tumor and hematologic malignancies
    - Receipt of solid-organ 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/mm³, 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
The Janssen COVID-19 vaccine is not authorized for use as an additional primary dose. Inmates who received a single-dose Janssen COVID-19 primary vaccine should not receive an additional primary dose. However, they should receive a booster dose, preferably with an mRNA vaccine instead of the Janssen vaccine.

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 two weeks before initiation or resumption of immunosuppressive therapies.

The inmate’s clinical team is best positioned to determine the degree of immune compromise and appropriate timing for administration of the primary series, additional primary (i.e., third) mRNA vaccine dose, booster dose, and for hematopoietic stem cell transplant and CAR-T-cell recipients, COVID-19 revaccination.

### Quarantine-specific considerations:

- Inmates admitted to **intake or exposure quarantine** may be vaccinated as long as they do not have symptoms or signs of COVID-19. Using these types of quarantines as an opportunity to vaccinate and achieve immunity can be beneficial in limiting transmission and outbreaks.

- Inmates in a **transfer quarantine or those who are scheduled for a BOP intrasystem transfer** may elect to initiate a 2-dose primary vaccination series, but will need to be placed on medical hold until the second dose is administered; there may be instances when the quarantine period may be extended. All efforts should be made to complete vaccination series prior to transfer quarantine with a preference to mRNA vaccines; however, the type of vaccine should remain a clinical decision that is made between patient and provider.
  - If a first dose of a 2-dose primary vaccination series was administered prior to any type of transfer, the inmate should be placed on a medical hold until the due date of the second dose.

- 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 two-dose mRNA COVID-19 vaccine series even if there is uncertainty about how and when the inmate will receive their second dose.
  - **Institutions should provide inmates a completed vaccination card prior to their release in order to provide them proof of vaccination.**

- **CDC guidance for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States, including discussion on vaccinating patients in quarantine, is available at:** [https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html](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.**
  - Two-dose primary vaccination series may be initiated during transfers even if there is uncertainty about how the patient will receive their second dose. Note that once the first dose has been administered, the inmate should be placed on a medical hold and not transferred until the second dose has been given or refused.
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.
  - Janssen COVID-19 vaccine components include a recombinant, replication-incompetent human adenovirus vector, which encodes for production of the SARS-CoV-2 spike (S) protein as the active ingredient and a variety of inactive ingredients, such as buffers (e.g., polysorbate).
- Do not administer the Janssen COVID-19 vaccine if an individual developed thrombosis with thrombocytopenia syndrome (TTS) following receipt of a previous Janssen COVID-19 vaccine (or other COVID-19 vaccines not currently authorized in the United States that are based on adenovirus vectors).
- 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)
  - https://www.fda.gov/media/153713/download (purple cap, must dilute)
  - 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 Janssen COVID-19 vaccine at: https://www.fda.gov/media/146304/download
  - CDC guidance on the Interim Considerations for Clinical Use of COVID-19 Vaccines Currently Approved or Authorized in the United States (Appendix C. Ingredients included in COVID-19 vaccines) at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

PRECAUTIONS:

- Individuals with a history of an immediate allergic reaction of any severity to any other vaccine or injectable therapy OR with a non-severe, immediate allergic reaction after a previous dose of COVID-19 vaccine should be assessed clinically to determine whether they can either be vaccinated or if vaccination should be deferred. In these situations, clinical assessment may include referral to an allergist-immunologist. If vaccine is administered, a 30-minute observation period should be performed after vaccination.
  - 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 and Janssen vaccine, individuals with a contraindication to mRNA COVID-19 vaccines such as a severe allergic reaction (e.g. anaphylaxis) after a previous dose or to a component of the mRNA vaccine also have a precaution to the Janssen COVID-19 vaccine, and vice versa. Consultation with an allergist-immunologist should be considered to help determine if the patient can safely receive vaccination.
• Persons who have received one mRNA COVID-19 vaccine dose but for whom the second dose is contraindicated should wait at least 28 days after the mRNA COVID-19 vaccine dose to receive the Janssen COVID-19 vaccine.

• For specific recommendations for the following precautions, refer to the CDC guidance: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Contraindications
  ➢ PEG and polysorbate allergies
  ➢ Patients who develop myocarditis or pericarditis after receipt an mRNA COVID-19 vaccine
  ➢ History of thrombosis and thrombocytopenia
  ➢ Patients with a moderate to severe acute non-COVID-19 illness

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 vaccine doses as well as those who develop SARS-CoV-2 infection between doses. There is no recommended minimal interval between infection and vaccination; however, current evidence suggests the risk of reinfection is low in the months after initial infection but may increase with time due to waning immunity.

• Patients who received monoclonal antibody therapy for treatment of COVID-19 should defer vaccination for 90 days to avoid potential interference of the treatment with vaccine-induced immune responses. This recommendation applies to people who receive monoclonal antibody therapy before receiving any vaccine dose and to those who receive monoclonal antibody therapy after the first or subsequent doses of an mRNA COVID-19 vaccine but before the next scheduled dose. In these situations, the next scheduled dose should be deferred for at least 90 days following receipt of the monoclonal therapy.

• Patients who received monoclonal antibody therapy as post-exposure prophylaxis should defer vaccination for 30 days prior to a first or subsequent dose.

• Patients with a history of multisystem inflammatory syndrome in adults (MIS-A) due to SARS-CoV-2 infection should delay vaccination until they have recovered from their illness (including return to normal cardiac function) and for 90 days after the date of diagnosis of MIS-A, recognizing that the risk of reinfection and thus, the benefit from vaccination might increase with time following initial infection. There are no data on the safety and efficacy of COVID-19 vaccines in patients with a history of MIS-A, whose mechanisms are not well understood but include a dysregulated immune response to SARS-CoV-2 infection. It is unclear if individuals are at risk of recurrence of the same dysregulated immune response following reinfection with SARS-CoV-2 or in response to vaccination. These theoretical concerns should be weighed against the known risks of COVID-19 from reinfection and the benefits of protection from a COVID-19 vaccine. A conversation between the patient and their provider may assist with decision-making about the use of a COVID-19 vaccine.

NEITHER CONTRAINDICATIONS NOR PRECAUTIONS:

• Individuals with a history of anaphylaxis due to any cause that is not related to a vaccine or injectable therapy may proceed with vaccination provided a 30-minute observation period is completed.

• Individuals with other allergies (e.g., to oral medications, including the oral equivalent of an injectable medication; food; and pets) or a family history of allergies may proceed with vaccination followed by a 15-minute observation period.
• **For mRNA COVID-19 vaccines:** 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

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.

- 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, mRNA vaccines are preferred over the Janssen COVID-19 vaccine in each of these groups.

- **Persons with a history of myocarditis or pericarditis prior 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, which may include a cardiologist, and special testing to assess cardiac recovery. 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 were enrolled in COVID-19 vaccine clinical trials, and safety and efficacy of vaccines in this population were similar to the general population.

- **Persons with a history of Guillain-Barré syndrome (GBS):** Reports of adverse events following use of the Janssen COVID-19 vaccine under EUA suggest an increased risk of GBS during the 42 days following vaccination with the highest risk observed in males aged 50-64 years. No increased risk of GBS has been identified with mRNA COVID-19 vaccines during use under EUA.

  ➤ For additional information on GBS, refer to the CDC Clinical Considerations for Janssen COVID-19 Vaccine [https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#considerations-Janssen](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#considerations-Janssen)
5. VACCINATION OF INDIVIDUALS WHO ARE PREGNANT, BREASTFEEDING/LACTATING, OR TRYING TO GET PREGNANT

COVID-19 vaccination is recommended for women who are pregnant, lactating, trying to get pregnant now, or who might become pregnant in the near future. mRNA vaccines are preferred for all vaccine-eligible populations, including for persons who are pregnant or lactating.

- **Persons with a history of Bell’s palsy:** Cases of Bell’s palsy were reported following vaccination among participants in COVID-19 vaccine clinical trials. Available data were insufficient for the FDA to conclude that these cases were causally related to vaccination. Any occurrence of Bell’s palsy following COVID-19 vaccination should be reported to VAERS.

- **Persons with a dermal filler:** Infrequently, persons who have received dermal fillers may develop swelling at or near the site of filler injection following administration of a dose of an mRNA COVID-19 vaccine. The swelling is temporary and resolves with medical treatment. Individuals should contact their healthcare provider for evaluation if they experience swelling at or near a dermal filler site following vaccination.

- **Breastfeeding/Lactating women:** There are limited data on the safety of COVID-19 vaccines in these women or their effects on the breastfed infant, milk production, and secretion. However, the COVID-19 vaccines (i.e., mRNA vaccines and the Janssen vaccine) cannot cause infection in either the lactating woman or the infant. Recent reports have shown that the antibodies developed from mRNA COVID-19 vaccination were present in breastmilk samples. More data are needed to determine if these antibodies convey protection against SARS-CoV-2 infection for neonates and infants.

- **Additional information regarding COVID-19 vaccination and pregnancy can be found on the CDC’s Interim Clinical Considerations for the Use of COVID-19 Vaccines Currently Approved or Authorized in the United States at:** [https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.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 the same patient encounter as COVID-19 vaccination.
- 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 for at least five months following 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.

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 9. 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: [https://www.fda.gov/media/153716/download](https://www.fda.gov/media/153716/download) (English) and [https://www.fda.gov/media/144625/download](https://www.fda.gov/media/144625/download) (Spanish)
    - Moderna COVID-19 Vaccine: [https://www.fda.gov/media/144638/download](https://www.fda.gov/media/144638/download) (English) and [https://www.fda.gov/media/144712/download](https://www.fda.gov/media/144712/download) (Spanish)
    - Janssen COVID-19 Vaccine: [https://www.fda.gov/media/146305/download](https://www.fda.gov/media/146305/download) (English) and [https://www.fda.gov/media/146762/download](https://www.fda.gov/media/146762/download) (Spanish)
- Before vaccination, providers should counsel recipients about the following:
  - mRNA COVID-19 vaccines are preferred over the Janssen COVID-19 vaccine for primary and booster vaccination. The recommendation is based on updated risk-benefit analyses, particularly the concern surrounding the risk of TTS and its symptoms which typically occur within two 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.
  - Expected local post-vaccination symptoms (e.g., pain; swelling; erythema at the injection site; and for mRNA COVID-19 vaccines, also localized axillary lymphadenopathy on the same side as the vaccinated arm) 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.
Use of the following medications is generally not recommended for purposes of preventing post-vaccination symptoms, unless they are part of an individual’s routine medication:

- Antipyretic or analgesic medications (e.g., acetaminophen, non-steroidal anti-inflammatory drugs) - these can be taken for the treatment of post-vaccination local or systemic symptoms, if medically appropriate.
- Aspirin or anticoagulants
- Antihistamines – some experts, however, advise antihistamine use as a means of preventing mild allergic reactions in patients who might be at higher risk for allergic reactions.

Immunocompromised persons should be counseled about the potential for a reduced immune response to COVID-19 vaccines (including those who receive an additional primary mRNA COVID-19 vaccine dose) and need to follow all current prevention measures to protect themselves against COVID-19.

Continue all current guidance for protection of oneself and others to include wearing a mask, staying at least 6 feet away from others, avoiding crowds, washing hands, and following quarantine and isolation procedures.

8. ON-SITE VACCINE RECEIPT AND STORAGE

Refer to the CDC COVID-19 Quick Reference Guidance for Health Care Professionals for additional storage considerations.

PFIZER-BIONTech COVID-19 VACCINE

- There are two approved formulations of the Pfizer-BioNTech COVID-19 vaccine. Either formulation may be used for COVID-19 vaccination in the BOP.
  - A multidose vial with a purple cap, which MUST BE DILUTED prior to use
  - A multidose vial with a gray cap, which IS NOT DILUTED prior to use.

PFIZER-BIONTech COVID-19 VACCINE (PURPLE CAP - MUST DILUTE)

- Vaccine allotments will be shipped using one of two methods:
  - Directly from the manufacturer at ultra-low temperature (ULT) (-70°C [-94°F], range -60°C to -80°C [-76°F to -112°F]) to select BOP institutions in full package quantities per institution requests.
  - Directly from the BOP Central Fill and Distribution (CFAD) site at frozen temperature (-15°C to -25°C [5°F to -13°F]) to the BOP institution that requested an allotment in partial package quantities (i.e. micro-distribution).

- Upon receipt, institutions should immediately inspect vaccine for damage, then place into refrigeration storage temperatures (2°C to 8°C [36°F to 46°F]). Placement in refrigeration must occur as soon as feasible. If there is a delay of more than 2 hours from receipt to refrigeration, Central Office must be notified.
  - Once thawed, the vaccine CANNOT be re-frozen.

- The undiluted, refrigerated vaccine must be used within 30 days of removal from ULT storage, and institutions must keep up with the 30 day timeline.
  - Vaccine not used after 30 days must be maintained in a separate area and labeled “DO NOT USE” (see Section 13. Disposal).
**PFIZER-BIONTECH COVID-19 VACCINE (GRAY CAP - DO NOT DILUTE)**

- Vaccine will be shipped by the CFAD or directly from the manufacturer in a refrigerated state between 2°C to 8°C (36°F to 46°F) to each institution in multiples of 300 doses, or in partial package quantities (i.e. micro-distribution).
- Upon receipt, sites 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.
- Vaccine has 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.**
  - Vaccine not used within 10 weeks must be maintained in a separate area and labeled “DO NOT USE” (see Section 13. Disposal).

**MODERNACOVID-19 VACCINE**

Vaccine allotments will be shipped using one of two methods:

- **Directly from the vaccine distributor in full package quantities (140 doses)**
- **Directly from the BOP Central Fill and Distribution (CFAD) site in partial package quantities at frozen temperature (-50°C to -15°C [-58°F to -5°F]) to the BOP institution that requested an allotment in partial package quantities (i.e. micro-distribution).**

- Vaccine is supplied in two, multi-dose vial types: a 5.5 ml vial and 7.5 ml vial. The number of doses in each will vary depending on the number of booster doses administered and the syringes used.
- Upon receipt, sites 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.
  - **Once thawed, the vaccine CANNOT be re-frozen.**

- If frozen prior to administration, thaw
  - 5.5 ml vials in a refrigerator (2°C to 8°C [36°F to 46°F]) for 2 hours OR at room temperature between 15°C to 25°C (59°F to 77°F) for 1 hour.
  - 7.5 ml vials 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.
    - When thawed, the vaccine should be handled with care and protected from shocks, drops, and vibration.
    - Thawed vaccine vials can be handled in room light conditions.

- **When stored refrigerated, the unpunctured vaccine vials must be used within 30 days, and institutions must keep up with the 30 day timeline.**
  - Vaccine not used after 30 days must be maintained in a separate area and labeled “DO NOT USE” (see Section 13. Disposal).

**JANSSEN COVID-19 VACCINE**

- Vaccine initially will be stored frozen by the manufacturer and shipped either by McKesson (the vaccine distributor) or the CFAD in a refrigerated state between 2°C to 8°C (36°F to 46°F) directly to each institution.
- Upon receipt, sites 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.
• If vaccine is still frozen upon receipt and needed immediately, thaw at room temperature (maximally 25°C [77°F]).
  ➤ A carton of 10 vials will take approximately 2 hours to thaw whereas an individual vial will take approximately 1 hour to thaw.
  ➤ Once thawed, the vaccine CANNOT be re-frozen.

• When stored refrigerated, unpunctured vaccine vials must be used within the expiration date of the vaccine, and institutions must keep up within this timeline.
  ➤ Vaccine not used by the expiration date must be maintained in a separate area and labeled “DO NOT USE” (see Section 13, Disposal).

9. On-Site Vaccine Preparation

**Pfizer-BioNTech COVID-19 Vaccine (Purple Cap - Must Dilute)**
• Remove thawed vaccine from the refrigerator and allow it to come to room temperature for at least 30 minutes prior to administration.
  ➤ Undiluted vaccine must NOT be out of the refrigerator for more than 2 hours.
• Verify the vaccine, vaccine formulation and expiration date located on the vial.
• Reconstitute with 1.8 ml of 0.9% sodium chloride diluent prior to use. Prepare to add diluent to the vaccine vial in the following manner:
  ➤ Invert the vaccine vial gently 10 times to mix. DO NOT SHAKE.
  ➤ Visually inspect the liquid in the vaccine vial prior to dilution. It should be a white to off-white suspension and may contain white to off-white opaque amorphous particles. Do not use if the liquid is discolored or if other particles are observed.
  ➤ Obtain the diluent vial (i.e., sterile 0.9% Sodium Chloride Injection, USP).
  ➤ Cleanse the vaccine and diluent vial stoppers with an alcohol swab.
  ➤ Withdraw only 1.8 ml from the sodium chloride vial and inject that 1.8 ml into the vaccine vial using a 3 or 5 ml syringe with a 21 gauge needle found in the shipped ancillary kits. ONLY reconstitute vaccine that will be used within 6 hours.
  ➤ Equalize pressure in the vaccine vial by withdrawing 1.8 ml of air into the empty diluent syringe prior to withdrawing the needle from the vaccine vial.
  ➤ Engage the needle safety device (if present) prior to disposal in a sharps container.
  ➤ Discard the remaining 0.9% sodium chloride solution regardless of fluid remaining. Do not reuse.
  ➤ Gently invert the vial containing the vaccine and diluent 10 times to mix. DO NOT SHAKE.
  ➤ Visually inspect the vaccine in the vial. The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.
  ➤ Label the vial and record the date and time of dilution on the label.
  ➤ The vaccine vial now contains 6 (six) separate 0.3 ml vaccine doses, each with 30 mcg of vaccine product in a labeled, multi-dose vial.
• Store the diluted, labeled, and ready to use multi-dose vaccine vial at refrigerated or room temperatures, between 2°C to 25°C (35°F to 77°F).
  ➤ Reconstituted vaccine must be used within 6 hours.
PFIZER-BIONTECH COVID-19 VACCINE (GRAY CAP - DO NOT DILUTE)

- Remove thawed vaccine from the refrigerator and allow it to come to room temperature for at least 30 minutes before vaccine administration.
- Verify the vaccine, vaccine formulation, and expiration date located on the vial.
  - Vaccine 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.]
- 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 other particles are observed.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3mL of the vaccine, preferentially using a low dead-volume syringe and/or needle.
- Each dose must contain 0.3mL 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.
  - Punctured vials must be used within 12 hours after the first puncture.

MODERN A COVID-19 VACCINE

- Remove the multi-dose vaccine vial from refrigeration and allow it to come to room temperature for at least 15 minutes before vaccine administration. Swirl the vaccine vial gently and between each withdrawal. DO NOT SHAKE and DO NOT DILUTE the vaccine.
- Visually inspect the vaccine vial 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.
- Verify the vaccine and expiration date by accessing the manufacturer’s website here: https://www.modernatx.com/covid19vaccine-eua/providers/vial-lookup. Document the lot number and the expiration date provided by the website.
- 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.
  - Punctured vials must be used within 12 hours.
- Unpunctured vials may be stored
  - Refrigerated between 2°C to 8°C (36°F to 46°F) for up to 30 days prior to first use.
  - Between 8°C to 25°C (46°F to 77°F) for a total of 24 hours to include usage time.
- Refrigerated vials not used after 30 days, unpunctured vials stored between 8°C to 25°C [46°F to 77°F] not used after 24 hours, and punctured vials not used after 12 hours, must be maintained in a separate area and labeled “DO NOT USE” (see Section 13. Disposal).
- Special considerations for transportation: Once thawed, the Moderna vaccine is sensitive to movement and institutions should refer to the following CDC guidance on transporting Moderna vaccine: https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/Moderna-Vaccine-Transport.pdf
JANSSEN COVID-19 VACCINE

- Visually inspect the vaccine vial for particulate matter and discoloration before vaccine administration.
  - The vaccine is a colorless to slightly yellow, clear to very opalescent suspension.
  - If particulate matter and/or discoloration are present, the vaccine should NOT be administered.
- Verify the vaccine and check the expiration date by:
  - Calling the manufacturer at 1-800-565-4008, or
  - Going to [www.vaxcheck.jnjexternal iconexternal icon](#) and entering the lot number
- Document the lot number and the expiration date provided.
- As the expiration date approaches, check the expiration date again by using the above process.
  Never use expired vaccine.
  - Do not discard expired vaccine and refer to Section 13. Disposal for guidance.
- Before withdrawing each dose of vaccine, carefully mix the contents of the multi-dose vial by swirling gently in an upright position for 10 seconds. DO NOT SHAKE.
- Record the date and time of first use on the vaccine vial label.
  - **Punctured vials stored refrigerated** (between 2°C to 8°C [36°F to 46°F]) must be used within 6 hours
  - **Punctured vials stored at room temperature** (maximally 25°C [77°F]) must be used within 2 hours.
  - **Unpunctured** vials may be stored at room temperature (between 9°C to 25°C [47°F to 77°F]) for no more than 12 hours.
- Unpunctured, refrigerated vials not used after 3 months; unpunctured vials out of refrigeration (i.e., stored between 8°C to 25°C [46°F to 77°F]) not used within 12 hours; punctured vials kept at room temperature (maximally 25°C [77°F]) and not used within 2 hours; and punctured vials kept between 2°C to 8°C (36°F to 46°F) and not used within 6 hours must be maintained in a separate area and labeled “DO NOT USE” (see Section 13. Disposal).

10. ADMINISTRATION

- For all multi-dose COVID-19 vaccine vials (i.e., Pfizer-BioNTech, Moderna, and Janssen):
  - 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 13. Disposal).
  - Do not pool excess vaccine from multiple vaccine vials.
- Refer to the table on the following pages for a summary of administration procedures.
<table>
<thead>
<tr>
<th>COVID-19 VACCINE BY TYPE</th>
<th>HOW SUPPLIED</th>
<th>DOSE/VOLUME/SCHEDULE</th>
<th>ROUTE</th>
<th>KEY POINTS – SEE DOCUMENT FOR DETAILS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer-BioNTech COVID-19 Vaccine mRNA vaccine</td>
<td>Suspension Multi-dose vial (contains six doses)</td>
<td>Dose/Volume Primary series, additional primary (3rd) dose and booster</td>
<td>30 mcg/0.3 ml</td>
<td>IM <em>Purple cap—MUST DILUTE</em>  <em>Gray cap—DO NOT DILUTE</em>  • Refer to Section 9 for on-site vaccine prep instructions  • Egg, cell, latex and preservative free  • Refer to Section 2 for contraindications, precautions and special populations.  • <strong>Booster dose:</strong> Any mRNA vaccine may be given at least 5 months after completion of the 2nd or, if applicable, the 3rd dose.</td>
</tr>
<tr>
<td>Moderna COVID-19 Vaccine mRNA vaccine</td>
<td>Suspension Multi-dose vial (Number/volume of doses withdrawn will vary if booster doses used)</td>
<td>Dose/Volume Primary series and additional primary (3rd) dose</td>
<td>100 mcg/0.5 ml</td>
<td>IM <em>No reconstitution required</em>  • Withdraw a maximum of 20 doses (booster and/or primary series) from each vial – DO NOT puncture the vial stopper more than 20 times.  • Use unpunctured, refrigerated vaccine within 30 days  • Use unrefrigerated (8°C to 25°C [46°F to 77°F]) and unpunctured vaccine vials within 24 hours  • After 1st dose withdrawn, use vaccine within 12 hours  • Egg, cell, latex and preservative free  • <strong>Contraindications, Precautions, and Special Populations:</strong> same as for Pfizer-BioNTech COVID-19 vaccine  • <strong>Booster dose:</strong> same as for Pfizer-BioNTech COVID-19 vaccine</td>
</tr>
<tr>
<td>Janssen COVID-19 Vaccine Recombinant, non-replicating viral vector</td>
<td>Suspension Multi-dose vial (contains five, 0.5 ml doses)</td>
<td>Dose</td>
<td>5x10^10 virus particles</td>
<td>IM <em>No reconstitution required</em>  • Use refrigerated vaccine within 3 months  • Visually inspect each dose in the dosing syringe before use  • Before withdrawing each dose, swirl gently in upright position for 10 seconds. Do NOT shake.  • Use unrefrigerated (9°C to 25°C [47°F to 77°F]) and unpunctured vaccine vials within 12 hours  • After 1st dose withdrawn, use vaccine within either 6 hours or 2 hours depending on storage temperatures  • Egg, cell, latex and preservative free  • Refer to Section 2 for contraindications, precautions and special populations.  • <strong>Booster dose:</strong> An mRNA vaccine booster dose should be given at least 2 months after the primary dose.</td>
</tr>
</tbody>
</table>
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.
- Institutions should store ancillary supplies for COVID-19 vaccines separate from other similar supplies. Sharps sent in the kits should be stored 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 reconstituted 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
  - Note: 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 an algorithm for COVID-19 vaccine schedules, refer to Appendix 4. Vaccine Schedule and Dose Algorithm for Adult Patients

- Second doses of mRNA vaccines should be given as close to the recommended interval as possible
  - The Pfizer-BioNTech COVID-19 vaccine primary series is given in 2 doses (0.3 ml each) and scheduled 21 days apart.
  - The Moderna COVID-19 vaccine primary series is given in 2 doses (0.5 ml each) and scheduled 28 days apart.

- Persons should not be scheduled to receive the second dose of an mRNA vaccine earlier than recommended; however, second doses administered on days 17-21 (Pfizer-BioNTech) and days 24-28 (Moderna) are considered valid.
  - When not feasible to adhere to the recommended interval, the second dose may be scheduled for administration any time after the recommended interval and is considered valid.
  - Second doses given more than 4 days earlier than recommended (i.e., < 17 days for Pfizer-BioNTech or < 24 days for Moderna) need to be repeated at the proper interval (i.e., 21 days for Pfizer-BioNTech or 28 days for Moderna) after the dose given early in error.

- In most circumstances, individuals initiating a 2-dose mRNA COVID-19 primary vaccine series by a particular manufacturer (i.e., Pfizer-BioNTech or Moderna) should complete their vaccination series using the same product.
  - If the first-dose vaccine product cannot be determined, an alternative mRNA COVID-19 vaccine may be administered at a minimum interval of 28 days between doses to complete the mRNA COVID-19 vaccination series. Similarly, if two doses of different mRNA COVID-19 vaccine products are inadvertently administered, the primary vaccination series is considered complete.
In limited, exceptional situations where a first dose of an mRNA COVID-19 vaccine was received but the series cannot be completed with either the same or different mRNA COVID-19 vaccine (e.g., due to a contraindication), a single dose of the Janssen COVID-19 vaccine may be considered at a minimum interval of 28 days after the mRNA COVID-19 vaccine dose. Persons who receive the Janssen COVID-19 vaccine after a dose of an mRNA COVID-19 vaccine should be considered to have received a valid, single-dose primary COVID-19 vaccination—not a mixed vaccination series.

- **When an additional primary (i.e., third) mRNA COVID-19 vaccine dose is indicated**, it should be given at least 28 days after the second dose.
  - Additional primary doses given > 4 days earlier than recommended (i.e., < 24 days) should be repeated 28 days after the dose given in error.
  - The same vaccine product as the 2-dose primary vaccine series (i.e., Pfizer-BioNTech or Moderna) should be used. However if not feasible, an alternative mRNA COVID-19 vaccine product may be administered. If a person received two different mRNA COVID-19 vaccine products for their primary series, the product used for the second dose should be used.

- **Booster doses** should be administered to all inmates.
  - Recipients who received a primary series of Pfizer-BioNTech vaccine may receive a booster dose at least 5 months after the second or additional Pfizer-BioNTech COVID-19 primary series dose (whichever is applicable).
  - Recipients who received a primary series of Moderna vaccine or heterologous (mix-and-match) vaccine for their primary series are eligible to receive a booster at 6 months after the second or additional primary mRNA COVID-19 series dose
  - Recipients who received a Janssen COVID-19 vaccine recipients are eligible to receive a booster dose 2 months after their primary dose.
  - In most circumstances, mRNA vaccines (Pfizer-BioNTech or Moderna) are preferred over the Janssen vaccine for booster vaccination.
  - Booster doses given in error earlier do not need to be repeated.

12. **Persons vaccinated outside the United States**

- The WHO has listed the following COVID-19 vaccines for emergency use:
  - Pfizer-BioNTech COVID-19 vaccines (e.g., BNT162b2, Cominarty, Tozinameran)
  - AstraZeneca-Oxford COVID-19 vaccines (e.g., ChAdOx1-S [recombinant], AZD1222, Covishield, Vaxzevria)
  - Janssen (Johnson & Johnson) COVID-19 vaccine (e.g., Ad26.COV2.S)
  - Moderna COVID-19 vaccine (e.g., mRNA 1273, Takeda, Spikevax)
  - Sinopharm-BIBP COVID-19 vaccine
  - Sinovac-CoronaVac COVID-19 vaccine
  - Bharat Biotech International COVID-19 vaccine (e.g., BBV152, COVAXIN)
  - Novavax COVID-19 vaccine (e.g., NVX-CoV2373, Covovax, Nuvaxovid)

- **Persons vaccinated with FDA-approved or authorized COVID-19 vaccines** who received all of the recommended doses of a single dose or 2-dose primary mRNA COVID-19 vaccine series are considered fully vaccinated. However, persons who received only the first dose of a 2-dose mRNA COVID-19 vaccine series should complete the series with an mRNA vaccine as close to the recommended interval as possible. All persons may receive an additional primary (i.e., third) dose
booster dose, if they are eligible according to the vaccine schedule for adults vaccinated in the United States. For more information, see Section 11. COVID-19 Vaccine Scheduling and Interchangeability.

- **Persons vaccinated with COVID-19 vaccines listed for emergency use by WHO but not FDA-approved or authorized who completed all of the recommended doses**, including those who completed a mix and match series, are considered fully vaccinated.
  - Moderately or severely immunocompromised adults should receive an additional primary (i.e., third) dose of the Pfizer-BioNTech COVID-19 vaccine (30 mcg formulation) at least 28 days after receiving the second vaccine dose of their primary series. In addition, adults should receive a booster dose of the Pfizer-BioNTech COVID-19 vaccine (30 mcg formulation) at least 6 months after completing their primary series.

- **Persons who received only the first dose of a multidose COVID-19 vaccine primary series** listed for emergency use by WHO but not FDA-approved or authorized **OR those who received all or some of the recommended doses of a COVID-19 vaccine primary series that is not listed for emergency use by WHO**:
  - Should be offered primary vaccination with an FDA-approved or authorized COVID-19 vaccine with a minimum interval of at least 28 days since receipt of the last dose of the non-FDA-approved or authorized COVID-19 vaccine.
  - After completion of primary vaccination with an FDA-approved or authorized COVID-19 vaccine, persons are considered fully vaccinated and are not recommended to receive an additional primary or booster dose.

### 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 and/or additional primary (i.e., third) vaccine dose date in the scheduler, if applicable.
- Upon exiting, do not forget to save the immunization flow sheet data.
- For 2-dose primary vaccination series, place the patient on a medical hold in BEMR after administration of the first vaccine dose. **Do not remove the medical hold** until after the second vaccine dose has been administered.
  - Patients refusing second doses should not be removed from a medical hold until the scheduled date of the second vaccine dose.
  - Institutions should provide inmates a completed vaccination card prior to their release in order to provide them proof of vaccination. A formal medical records request is not required.

- **For inmates who received COVID-19 vaccination elsewhere** (i.e., not in the BOP), this information must be documented in BEMR. Institutions should make every attempt to obtain written 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 BEMR as “History Of” along with the manufacturer name, dose number and vaccination date(s). Scan any documentation into BEMR or provide information in the comment box regarding from whom verbal verification was obtained.

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 series, both doses must be entered separately.

If proof of vaccination is not provided and cannot be verified

Obtain a signed declination of the BOP-offered COVID-19 vaccination and include prior vaccination as the reason for declination. After the declination is signed, enter the vaccination information into BEMR as “History Of” along with the vaccination date(s), if known. Do not enter a dose number if the vaccine cannot be verified.

If a vaccination has already been documented in the flow sheet, it should not be charted again (i.e. as “History Of”).

**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 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 either vaccination has been completed (including second and booster doses where applicable) or the employee’s refusal of the primary vaccination series has been documented.

  For employees receiving single-dose vaccines (i.e., the Janssen COVID-19 vaccine), ensure that all other vaccine dose information has been crossed out, initialed, and dated.

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

**Scheduling Additional Doses of Vaccine.**

- Facilities need to plan for clinic availability based on when initial doses of vaccine are administered.
- For inmates, using BEMR is the preferred method to schedule additional primary (i.e., third) and booster 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 additional doses (i.e., second doses and booster doses) and what reminders to use for determining when vaccine doses should be given (e.g., pre-determined clinic dates, use of the Manage Recipients page in VAMS to track dates for second doses, use of a spreadsheet 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, 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
    - Serious adverse events
    - Cases of Multisystem Inflammatory Syndrome
    - Cases of COVID-19 that result in hospitalization or death
  - Reporting is encouraged for any other clinically significant adverse event, 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.
- For wasted vaccine, institutions must immediately notify the BOP Chief Pharmacist or their designee with details of the wastage.
  - It is important for providers to not miss any opportunity to vaccinate every eligible person, even if that means puncturing a multi-dose vials without having enough people available to use every dose. In these cases, unused doses are not considered waste and do not require reporting to BOP Chief Pharmacist or their designee.
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 Janssen (Johnson & Johnson) COVID-19 vaccines.
<table>
<thead>
<tr>
<th>FACILITY:</th>
<th>EMPLOYEE:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SKILLS</strong></td>
<td><strong>SKILLS</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Self-Assessment</th>
<th>Supervisor/Preceptor Review</th>
<th>Needs to Improve</th>
<th>Meets or Exceeds</th>
<th>Needs to Improve</th>
<th>Meets or Exceeds</th>
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<tbody>
<tr>
<td><strong>PATIENT EDUCATION</strong></td>
<td>Welcomes patient, verifies identification, accommodates language/literacy barriers and special needs, and explains what vaccine will be given.</td>
<td>Provides Emergency Use Authorization (EUA) fact sheet and answers questions.</td>
<td>Reviews preference for mRNA COVID-19 vaccines, potential side effects, comfort measures, and after care instructions.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SCREENING/PREPAREDNESS</strong></td>
<td>Screens patient for vaccine eligibility (based on EUA and package insert), history of adverse reactions, allergies, contraindications, and precautions.</td>
<td>Ensures consent/declination form is signed and that the current EUA date is documented.</td>
<td>Uses a separate consent form for each vaccine dose for inmates and one consent form for both vaccine doses for employees.</td>
<td>Verbalizes signs and symptoms of potential medical emergency or anaphylaxis.</td>
<td>Able to initiate CPR and maintain airway, if necessary. Locates epinephrine. States procedure for responding to and reporting needle stick injuries.</td>
</tr>
<tr>
<td><strong>VACCINE STORAGE AND HANDLING – GENERAL</strong></td>
<td>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.</td>
<td>Does not store vaccines in dormitory style refrigerators.</td>
<td>Ensures refrigerator is plugged into a generator back-up plug, if available, and labeled with “Do not unplug” signage.</td>
<td>Stores vaccines in original containers with lids closed until ready for administration.</td>
<td>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.</td>
</tr>
<tr>
<td><strong>VACCINE HANDLING AND PREPARATION, PFIZER-BIONTech COVID-19 VACCINE (PURPLE CAP – MUST DILUTE)</strong></td>
<td>Demonstrates knowledge that unpunctured vials may be refrigerated (2°C to 8°C [36°F to 46°F]) for up to 30 days.</td>
<td>Removes vaccine from refrigerator and allows to come to room temperature prior to dilution (30 minutes).</td>
<td>Verifies vaccine, vaccine formulation, and expiration date, and visually inspects the vaccine vial for particulate matter and discoloration.</td>
<td>Inverts vial gently 10 times to mix. DOES NOT SHAKE the vial.</td>
<td>Obtains sterile 0.9% Sodium Chloride Injection, USP (i.e., diluent).</td>
</tr>
<tr>
<td><strong>SELF-ASSESSMENT</strong></td>
<td><strong>SUPERVISOR/ PRECEPTOR REVIEW</strong></td>
<td><strong>SKILLS</strong></td>
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<tr>
<td><strong>NEEDS TO IMPROVE</strong></td>
<td><strong>MEETS OR EXCEEDS</strong></td>
<td><strong>NEEDS TO IMPROVE</strong></td>
<td><strong>MEETS OR EXCEEDS</strong></td>
<td></td>
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</tr>
<tr>
<td><strong>VACCINE HANDLING AND PREPARATION, PFIZER-BIONTECH COVID-19 VACCINE (PURPLE CAP—MUST DILUTE) (CONTINUED)</strong></td>
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<tr>
<td>Equalizes pressure in the vaccine vial by withdrawing 1.8 ml of air into the empty diluent syringe prior to withdrawing the needle from the vaccine vial.</td>
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<tr>
<td>Engages needle safety device (if present) prior to disposal in a sharps container.</td>
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<tr>
<td>Discards remaining 0.9% sodium chloride solution regardless of fluid remaining. Does not reuse.</td>
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<tr>
<td>Gently inverts the vial with the vaccine and diluent 10 times to mix. <strong>DOES NOT SHAKE.</strong></td>
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<tr>
<td>Labels the vial and records the date and time of dilution on the label. The vaccine vial now contains 6 (six) separate 0.3 ml vaccine doses, each with 30 mcg of vaccine product in a labeled, multi-dose vial.</td>
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</tr>
<tr>
<td>Stores the diluted, labeled, and ready to use multi-dose vaccine vial at refrigerated or room temperatures between 2°C to 25°C (35°F to 77°F) for up to 6 hours.</td>
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<tr>
<td><strong>VACCINE HANDLING AND PREPARATION, PFIZER-BIONTECH COVID-19 VACCINE (GRAY CAP—DO NOT DILUTE)</strong></td>
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<tr>
<td>Demonstrates knowledge that unpunctured vials may be refrigerated (2ºC to 8ºC [36ºF to 46ºF]) for up to 10 weeks.</td>
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<tr>
<td>Removes vaccine from refrigerator and allows to come to room temperature prior to administration (30 minutes).</td>
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<tr>
<td>Verifies vaccine, vaccine formulation, and expiration date, and visually inspects the vaccine vial for particulate matter and discoloration.</td>
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<tr>
<td>Inverts vial gently 10 times to mix. <strong>DOES NOT SHAKE the vial. DOES NOT DILUTE the contents.</strong></td>
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<tr>
<td>Cleanses the vaccine vial stopper with an alcohol swab.</td>
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<tr>
<td><strong>Withdraws 0.3ml of vaccine.</strong></td>
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<tr>
<td>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.</td>
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<tr>
<td>Records the date and time of the first use on the vial label.</td>
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<tr>
<td><strong>VACCINE HANDLING AND PREPARATION, MODERNA COVID-19 VACCINE</strong></td>
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<tr>
<td>Demonstrates knowledge that unpunctured vials may be refrigerated (2ºC to 8ºC [36ºF to 46ºF]) for up to 30 days and <strong>may be moved from the storage location to clinic only once in an unfrozen state.</strong></td>
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<tr>
<td>Acknowledges that a maximum of 20 doses (booster [0.25 ml] and/or primary series [0.5 ml] doses) can be withdrawn from the vial and understands that the vial stopper should not be punctured more than 20 times.</td>
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<tr>
<td>Removes vaccine from refrigerator and verifies vaccine and expiration date. For any questions, contacts Central Office.</td>
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<tr>
<td>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. Unpunctured vials are not stored any longer than 24 hours between 8ºC to 25ºC (46ºF to 77ºF).</td>
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<tr>
<td>Swirls the vial gently and between each withdrawal. <strong>DOES NOT SHAKE the vial and does not dilute the contents.</strong></td>
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<tr>
<td>Visually inspects the vial for unexpected particulate matter and 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.</td>
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<tr>
<td>Self-Assessment</td>
<td>Supervisor/Preceptor Review</td>
<td>SKILLS</td>
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<tr>
<td>Needs to Improve</td>
<td>Meets or Exceeds</td>
<td>Needs to Improve</td>
<td>Meets or Exceeds</td>
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<tr>
<td><strong>VACCINE HANDLING AND PREPARATION, JANSSEN (JOHNSON &amp; JOHNSON) COVID-19 VACCINE</strong></td>
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<tr>
<td>Demonstrates knowledge that vials may be refrigerated (2°C to 8°C [36°F to 46°F]) for up to 3 months.</td>
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<tr>
<td>Acknowledges that each multi-dose vaccine vial contains 5 (five) separate 0.5 ml vaccine doses.</td>
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<tr>
<td>Removes vaccine from refrigerator, verifies vaccine and expiration date, and visually inspects the vaccine vial for particulate matter and discoloration.</td>
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<tr>
<td>Ensures the vaccine is thawed prior to use. For use in clinic outside of main storage site, stores in appropriate temperature monitored storage cooler at (2°C to 8°C [36°F to 46°F].</td>
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<tr>
<td>Gently swirls the multi-dose vial in an upright position for 10 seconds before withdrawing each dose of vaccine. <strong>DOES NOT SHAKE the vial.</strong></td>
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<tr>
<td>Stores the vial between 2°C to 8°C (36°F to 46°F) for up to 6 hours OR at room temperature (maximally 25°C [77°F]) for up to 2 hours after first dose has been drawn.</td>
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<tr>
<td>Records the date and time of the first use on the vial label.</td>
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<tr>
<td><strong>ADMINISTERING VACCINES</strong></td>
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<tr>
<td>Demonstrates knowledge of the appropriate route (IM), site (deltoid), vaccine dose, and the type of syringe safety device being utilized (glide, snap or retraction device).</td>
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<tr>
<td>Washes or disinfects hands before and in-between patient encounters. <strong>If gloves are worn, they are changed and hand hygiene performed between patients.</strong></td>
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<tr>
<td>Places the labeled, unexpired, multi-dose vaccine on a hard surface, cleanses the stopper with a clean alcohol wipe and allows to dry <strong>between each dose of vaccine.</strong></td>
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<tr>
<td>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.</td>
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<tr>
<td>Inserts needle into the multi-dose vaccine vial and pierces the stopper at a different site each time for each new dose.</td>
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<tr>
<td>Inverts vial and syringe and withdraws the following amount of vaccine from the multi-dose vial:</td>
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<tr>
<td>• Pfizer-BioNTech: 0.3 ml</td>
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<tr>
<td>• Moderna: 0.5 ml for full dose, 0.25 ml for booster dose</td>
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<tr>
<td>• Janssen: 0.5 ml</td>
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<tr>
<td>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.</td>
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<tr>
<td>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.</td>
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<tr>
<td>Positions patient so that muscles are relaxed and preps injection site with alcohol wipe, allowing it to dry.</td>
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<tr>
<td>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.</td>
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<tr>
<td>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.</td>
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<tr>
<td>Self-Assessment</td>
<td>Supervisor/ Preceptor Review</td>
<td>Skills</td>
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<tr>
<td>Needs to Improve</td>
<td>Meets or Exceeds</td>
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<tr>
<td></td>
<td>Needs to Improve</td>
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</tbody>
</table>

**ADMINISTERING VACCINES (CONTINUED)**

- 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.
- Identifies vials that can no longer be used by expiration date or the following:
  - **Pfizer-BioNTech (purple cap):** undiluted vaccine out of refrigeration for more than 2 hours, refrigerated undiluted vaccine not used after 30 days, or reconstituted vaccine not used within 6 hours.
  - **Pfizer-BioNTech (gray cap):** unpunctured vials out of refrigeration for more than 12 hours; punctured vials not used after 12 hours when stored between 2°C to 25°C (35°F to 77°F).
  - **Moderna:** vaccine out of refrigeration for more than 24 hours, punctured vials not used after 12 hours, refrigerated vaccine not used after 30 days, or unused vaccine from a vaccination clinic.
  - **Janssen:** unpunctured vials out of refrigeration for more than 12 hours; punctured vials not used after 6 hours when stored between 2°C to 8°C (36°F to 46°F) OR not used after 2 hours when stored at room temperature (maximally 25°C [77°F]).
- 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.
  - For wasted vaccine doses, the BOP Chief Pharmacist or designee must be contacted with details concerning the wastage.

**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, and places a medical hold until the date of the second vaccine dose, if applicable. 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.
### SKILLS CHECKLIST FOR ADULT COVID-19 VACCINE ADMINISTRATION (PAGE 5 OF 5)

<table>
<thead>
<tr>
<th>FACILITY:</th>
<th>EMPLOYEE:</th>
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</thead>
<tbody>
<tr>
<td><strong>Self-Assessment</strong></td>
<td><strong>Supervisor/Preceptor Review</strong></td>
</tr>
<tr>
<td>Needs to Improve</td>
<td>Meets or Exceeds</td>
</tr>
</tbody>
</table>

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).
- *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).

<table>
<thead>
<tr>
<th>Employee Signature:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supervisor Signature:</td>
<td>Date:</td>
</tr>
</tbody>
</table>
## APPENDIX 2. COVID-19 VACCINE ADMINISTRATION SIGNATURE SHEET

**BOP HEALTH SERVICES UNIT**

### 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
- Janssen (Johnson & Johnson) COVID-19 Vaccine
- Other:

### Signatures:

<table>
<thead>
<tr>
<th>Role</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>IP&amp;C Coordinator (Last, First) – PRINT</td>
<td>Signature</td>
<td>Date</td>
</tr>
<tr>
<td>Health Services Administrator (Last, First) – PRINT</td>
<td>Signature</td>
<td>Date</td>
</tr>
<tr>
<td>Clinical Director (Last, First) – PRINT</td>
<td>Signature</td>
<td>Date</td>
</tr>
<tr>
<td>Healthcare Provider (Last, First) – PRINT</td>
<td>Signature</td>
<td>Date</td>
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</tbody>
</table>
## APPENDIX 3. ADMINISTERING COVID-19 VACCINES

<table>
<thead>
<tr>
<th>VACCINE</th>
<th>DOSE</th>
<th>ROUTE</th>
<th>INJECTION SITE</th>
<th>KEY POINTS</th>
</tr>
</thead>
</table>
| Pfizer-BioNTech COVID-19 Vaccine (purple cap-MUST DILUTE) | 0.3 mL | IM    | Deltoid        | - Reconstitution required with 1.8 mL of 0.9% sodium chloride diluent (mixing syringe 3-5 mL with 21 gauge 1.5” mixing needle). The 1.5”, 21 gauge needles included in the ancillary kits are to be used.  
- Label reconstituted vials with date and time.  
- Each reconstituted multi-dose vial contains six (6) separate 0.3 mL vaccine doses.  
- Reconstituted vaccine must be used within 6 hours.  
- Use different vaccine vial stopper insertion points each time a vaccine dose is withdrawn.  
- Removes air bubbles from the vaccine vial while the needle is still inside the vial.  
- After 6 hours, label “DO NOT USE” and store in a place removed from vaccines in use. Discard as per BOP vaccine disposal guidance. |
| Pfizer-BioNTech COVID-19 Vaccine (gray cap-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 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 2 of 3)

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Dose</th>
<th>Route</th>
<th>Injection Site</th>
<th>Key Points</th>
</tr>
</thead>
</table>
| **Moderna COVID-19 Vaccine** | 0.5 mL full dose/ 0.25 mL booster dose | IM    | Deltoid        | No reconstitution needed.  
- The number of doses in each vial type (5.5 mL and 7.5 mL) will vary depending if booster doses are used and the syringe type. A maximum of 20 doses (booster and/or full dose) may be withdrawn.  
- 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. |
| **Janssen COVID-19 Vaccine** | 0.5 ml            | IM    | Deltoid        | No reconstitution needed.  
- Refrigerated vaccine must be used within 3 months.  
- Each multi-dose vial contains five (5) separate 0.5 ml vaccine doses.  
- Unpunctured vials out of refrigeration must be used within 12 hours.  
- Punctured vials must be used within 6 hours, if stored between 2°C to 8°C (36°F to 46°F). If stored at room temperature (maximally 25°C [77°F]), vials must be used within 2 hours.  
- Label punctured vials with date and time.  
- Use different vaccine vial stopper insertion points each time a vaccine dose is withdrawn.  
- Removes 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 of 3)

<table>
<thead>
<tr>
<th>Weight Range</th>
<th>Needle Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 130 lbs.</td>
<td>1&quot; length needle</td>
</tr>
<tr>
<td>130-152 lbs.</td>
<td>1&quot; length needle</td>
</tr>
<tr>
<td>Female 153-200 lbs.</td>
<td>1-1½&quot; length needle</td>
</tr>
<tr>
<td>Female 200+ lbs.</td>
<td>1½&quot; length needle</td>
</tr>
<tr>
<td>Male 153-260 lbs.</td>
<td>1-1½&quot; length needle</td>
</tr>
<tr>
<td>Male 260+ lbs.</td>
<td>1½&quot; length needle</td>
</tr>
</tbody>
</table>

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 90° 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.

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*References adapted from www.immunize.org/catg.d/Item#2024 (9/19) and 3084 (8/20)
APPENDIX 4. COVID-19 VACCINE SCHEDULE AND DOSE ALGORITHM FOR ADULT PATIENTS

**Primary series**

- **Janssen (Johnson & Johnson)**
  - Administer 0.5mL dose
  - ≥ 2 months later

- **Moderna (Preferred)**
  - Administer 0.5mL dose (100mcg)
    - ≥ 28 days later
    - Administer 0.5mL dose
    - Remove medical hold
    - Is inmate moderately or severely immunocompromised?
      - YES
      -Administer additional primary (3rd) dose (0.5mL/100mcg)
      - ≥ 6 months later
      - Administer Moderna booster dose (0.25mL/50mcg)
      - OR
      - Pfizer-BioNTech booster dose (0.3mL/30mcg)
      - OR
      - In limited circumstances, J&J booster dose (0.5mL)
      - Administer Moderna booster dose (0.25mL/50mcg)
      - OR
      - Pfizer-BioNTech booster dose (0.3mL/30mcg)
      - ≥ 5 months later
    - NO
    - Administer Moderna booster dose (0.25mL/50mcg)
    - OR
    - Pfizer-BioNTech booster dose (0.3mL/30mcg)
    - ≥ 5 months later

- **Pfizer-BioNTech (Preferred)**
  - Administer 0.3mL dose (30mcg)
    - ≥ 21 days later
    - Administer 0.3mL dose
    - Remove medical hold
    - Is inmate moderately or severely immunocompromised?
      - YES
      - Administer additional primary (3rd) dose (0.3mL/30mcg)
      - OR
      - In limited circumstances, J&J booster dose (0.5mL)
    - NO
  - Administer Moderna booster dose (0.25mL/50mcg)
  - OR
  - Pfizer-BioNTech booster dose (0.3mL/30mcg)
  - ≥ 5 months later

**Booster and/or additional primary (3rd) dose**

- Moderna booster dose (0.25mL/50mcg)
- OR
- Pfizer-BioNTech booster dose (0.3mL/30mcg)
- ≥ 6 months later