COVID-19 Vaccine Guidance

Federal Bureau of Prisons Clinical Guidance

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What's New

VERSION 12.0

- Pfizer-BioNTech vaccine indicated age range update to 12 years and older.
- Expansion of vaccine eligibility to contractors working within BOP facilities.
- Removal of priority levels for inmate vaccinations and additional of guidance specific to BOP holdover sites, including bus hubs and detention centers.
- COVID-19 vaccines may be administered without regard to timing of administration of other vaccines or non-COVID antibody therapies (e.g., intravenous immunoglobulin).
- COVID-19 vaccinations should be offered to all new intakes who are unvaccinated.
- The refrigerated storage for undiluted vials of Pfizer-BioNTech vaccine has changed from 5 days to 30 days.
- Updates are made throughout the document to address the new Moderna vaccine vial size of 14 doses per vial.
- Updates to the room temperature storage limitations for Moderna vaccine: up to 12 hours for punctured vials and up to 24 hours for unpunctured vials.
- Information added regarding documenting history of vaccination in *Section 10*.
- Updates to vaccine disposal *Section 13*.

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A. 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 for protection 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.
- It is recommended that each BOP facility: (1) create and implement a COVID-19 immunization plan to offer vaccine for new staff, new intakes, and any staff or inmate that have not yet been vaccinated (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 module 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).*

COVID-19 vaccines authorized for use

The following COVID-19 vaccines are authorized for use in the United States by the U.S. Food and Drug Administration through Emergency Use Authorization (EUA):

- The Pfizer-BioNTech COVID-19 vaccine (an mRNA vaccine)
  - For persons 12 years of age and older with 2 doses required
- The Moderna COVID-19 vaccine (an mRNA vaccine)
  - For persons 18 years of age and older with 2 doses required
- The Janssen (Johnson & Johnson) COVID-19 vaccine (a recombinant, replication-incompetent viral vector vaccine)
  - For persons 18 years of age and older with 1 dose required

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

PFIZER-BIONTECH COVID-19 VACCINE

The EUA fact sheets for the Pfizer-BioNTech COVID-19 Vaccine are available for the following groups:

- Recipients and caregivers: *https://www.fda.gov/media/144414/download*
- Healthcare providers administering vaccine: *https://www.fda.gov/media/144413/download*

MODERNA COVID-19 VACCINE

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*

JANSSEN COVID-19 VACCINE

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*

B. PROCEDURE

Using this document, eligible healthcare professionals (as defined by scope of duty) may vaccinate adults, who meet the indications below for COVID-19 vaccines, 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 will be 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).

EMPLOYEE AND CONTRACTOR VACCINATION:
Due to expanded vaccine supplies all employees (i.e., staff, including Public Health Service officers assigned to the BOP) and contractors should be offered vaccination regardless of job functions.

- Correctional staff and contractor vaccination serves to decrease the possible introduction of SARS-CoV-2 into institutions and thus protects inmates.

INMATE VACCINATION:

The previously developed priority levels for when vaccine supplies were limited no longer have a major role in vaccination efforts and are not routinely needed. Due to expanded vaccine supplies, vaccination should be offered to all inmates. However, special vaccine considerations apply in certain situations (see below).

➔ *For 2-dose 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.*

➢ ***Quarantine-specific considerations:***

- Inmates admitted to ***intake or exposure quarantine*** may be vaccinated. 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*** should **not** initiate a 2-dose vaccination series. Instead, inmates ***may be vaccinated using a single-dose COVID-19 vaccine, if available***.
  - If a first dose of a 2-dose 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 using a single-dose COVID-19 vaccine. They may be considered for vaccination using a 2-dose series on a case-by-case basis.
  - In situations where there is time to complete a multi-dose vaccine series prior to the inmate's departure and a single-dose vaccine is not available, vaccination may proceed. However, if there is insufficient time to complete all doses, the multi-dose COVID-19 vaccine series should not be started with the first dose unless continuity of care for the second dose can be assured at the receiving location (e.g., community or other correctional jurisdiction).

➔ *CDC guidance for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently 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

➢ ***Vaccine management at the BOP Federal Transfer Center in Oklahoma City (OKL) and BOP holdover sites, including bus hubs and detention centers.***

- A single-dose COVID-19 vaccine may be administered to inmates who are passing through and in holdover status.
- Two-dose vaccination series **should not** be initiated unless an inmate is expected to remain long enough to complete the 2-dose vaccination series. 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 known severe allergic reaction (e.g., anaphylaxis) OR with an immediate allergic reaction of any severity after a previous dose of the vaccine or a known allergy to any component of the vaccine.***
  - 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.*
  - 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**).
- For additional information on product-specific vaccine components, refer to the:
  - FDA Emergency Use Authorization (EUA) fact sheet for the Pfizer-BioNTech COVID-19 vaccine at: *https://www.fda.gov/media/144413/download*
  - 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 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:

- ***PEG and polysorbate allergies.*** The PEG in mRNA COVID-19 vaccines is structurally related to polysorbate, which is in the Janssen vaccine. Cross-reactive hypersensitivity between these compounds may occur. Persons with a contraindication to mRNA COVID-19 vaccines (including due to a known allergy to PEG) have a precaution to the Janssen COVID-19 vaccine, and persons with a contraindication to the Janssen COVID-19 vaccine (including due to a known allergy to polysorbate) have a precaution to mRNA COVID-19 vaccines. For persons with these precautions, referral to an allergist-immunologist should be considered. When vaccination is administered, it should be provided in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions with a 30 minute observation period after vaccination.
- ***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 after the first dose of an mRNA COVID-19 vaccine but before receipt of the second dose. There is

no 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. Persons who have recovered from COVID-19 may choose to delay vaccination, balancing this decision with the uncertain risks of reinfection.

- ***Patients who received monoclonal antibody therapy*** for COVID-19 should defer vaccination for at least 90 days to avoid 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 dose of an mRNA COVID-19 vaccine but before the second dose. In these situations, the second dose should be deferred for at least 90 days following receipt of the monoclonal therapy.
- ***Patients with a history of multisystem inflammatory syndrome in adults (MIS-A) due to SARS-CoV-2 infection*** should consider delaying vaccination until they have recovered from their illness 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 physician may assist with decision-making about the use of a COVID-19 vaccine.

➢ ***Individuals with a moderate/severe acute non-COVID illness*** should be assessed clinically to determine whether they can be vaccinated or whether vaccination should be deferred. If administered, a 15-minute observation period should be performed after vaccination.

➢ ***Individuals with a history of an immediate allergic reaction of any severity to any other vaccine or injectable therapy (except those related to the COVID-19 vaccines or polysorbate, as noted above) 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.

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, food, and pets) or a family history of anaphylaxis*** 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.

➔ *For expanded guidance on the interim use of COVID-19 vaccines see:*
https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

3. ***Timing of COVID-19 vaccines with other vaccinations and non-COVID antibody therapies.***
COVID-19 vaccines may be administered without regard to timing of other vaccines or non-COVID antibody therapies (e.g., intravenous immunoglobulin). This includes simultaneous administration on the same day as well as co-administration within 14 days.

- 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.

- ***Immunocompromised individuals:*** Data are not currently available to establish safety and efficacy of vaccine in these individuals (e.g., HIV infection, on immunosuppressive medication or therapies).
  - Immunocompromised persons may receive COVID-19 vaccination, since the currently authorized COVID-19 vaccines are not live vaccines and therefore can be safely administered.
  - Immunocompromised persons should be counseled about the unknown vaccine safety and efficacy profiles, the potential for a reduced immune response, and need to follow all current guidelines to protect themselves against COVID-19.
- ***Pregnant women:*** Data on the safety of COVID-19 vaccines in pregnant women are limited. Based on current knowledge, experts believe that COVID-19 vaccines are unlikely to pose a risk to the pregnant woman or fetus, because the currently authorized COVID-19 vaccines are non-replicating vaccines and cannot cause infection in either the mother or the fetus. However, the potential risks of COVID-19 vaccines to the pregnant woman and the fetus are unknown because these vaccines have not been studied in pregnant women. If a pregnant woman meets the criteria for vaccination and has no contraindications, she may choose to be vaccinated. A conversation between the patient and their healthcare provider may assist with decisions about the use of a COVID-19 vaccine. Pregnant women who choose to receive COVID-19 vaccine are encouraged to enroll in v-safe, a smartphone-based tool through which

a pregnancy registry has been established. For more information, refer to https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html.

- *Routine testing for pregnancy prior to COVID-19 vaccination is not recommended.*
- *There is no evidence that any of the COVID-19 vaccines affect future fertility.*

- ***Breastfeeding/lactating women:*** There are no data on the safety of COVID-19 vaccines in these women or their effects on the breastfed infant or milk production or excretion. Because non-live vaccines pose no risk for lactating women or their infants, COVID-19 vaccines are also not thought to be a risk. If a breastfeeding/lactating woman meets the criteria for vaccination and has no contraindications, she may choose to be vaccinated.
- ***Persons with autoimmune conditions:*** No data are currently available on the safety and efficacy of COVID-19 vaccines in these individuals. Persons with autoimmune conditions who have no contraindications to vaccination may receive any COVID-19 vaccine.
- ***Persons with a history of Guillain-Barré syndrome:*** No cases of Guillain-Barré syndrome (GBS) have been reported following vaccination among mRNA COVID-19 vaccine clinical trial participants. One case each of GBS was reported in the vaccine and placebo groups of the Janssen COVID-19 clinical trial. With few exceptions, ACIP's *general best practice guidelines for immunization* does not include history of GBS as a contraindication or precaution to vaccination. Persons with a history of GBS may receive COVID-19 vaccination. Any occurrence of GBS following COVID-19 vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS).
- ***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. However, the FDA does not consider these to be above the frequency expected in the general population and has not concluded that these cases were causally related to vaccination. In the absence of such evidence, persons with a history of Bell's palsy may receive a COVID-19 vaccine. 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. No similar occurrences were observed in the Janssen COVID-19 vaccine clinical trial. This condition appears to be temporary and there are no contraindications or precautions for persons who have received injectable dermal fillers to receive COVID-19 vaccines. However, they should be advised to contact their healthcare provider for evaluation if they experience swelling at or near a dermal filler site following vaccination.

5. Vaccination of individuals requiring tuberculosis (TB) testing.

- For employees or inmates who are recommended or required to receive annual tuberculin skin testing (TST), the TST should be placed prior to or at the same time as the COVID-19 vaccination.
- For employees or inmates who have already received the COVID-19 vaccination and annual TB testing is recommended, defer the TST until at least 4 weeks after completion of COVID-19 vaccination. If testing requirements cannot be modified to accept this delay, note that a false negative TST cannot be excluded and consideration should be given to repeating negative TST

at least 4 weeks after the completion of COVID-19 vaccination. If the result of the repeat test is positive, boosting could be a factor.

- For new intakes who have received the COVID-19 vaccine prior to their arrival at a BOP facility and 4 weeks have NOT passed since the completion of COVID-19 vaccination, perform TB symptom screening as recommended in the BOP *Tuberculosis Clinical Guidance* and perform a chest x-ray in lieu of a TST, unless contraindicated. A TST should be placed after the 4 week post-vaccination period has passed.
- 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.

6. Patient education and consent.

- Review the manufacturer-specific COVID-19 vaccine EUA 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).
  - *Appendix 4 and 5. COVID-19 Vaccine Consent Form for Inmates (English and Spanish versions)*
  - *Appendix 6. COVID-19 Vaccine Consent Form for Employees*
- Before vaccination, providers should counsel recipients about the following:
  - Expected local post-vaccination symptoms (e.g., pain; swelling; erythema at the injection site; and for mRNA COVID-19 vaccines, also localized axillary lymphadenopathy) and systemic post-vaccination symptoms (e.g., fever, fatigue, headache, chills, myalgia, and arthralgia).
  - If any new symptoms following recent Janssen COVID-19 vaccination (e.g., 1-2 weeks), such as severe headache, backache, new neurological symptoms, severe abdominal pain, shortness of breath, leg swelling, easy bruising or petechiae occur, medical attention should be sought immediately.
  - For all currently authorized COVID-19 vaccines, antipyretic or analgesic medications (e.g., acetaminophen, non-steroidal anti-inflammatory drugs) can be taken for the treatment of post-vaccination local or systemic symptoms, if medically appropriate. However, routine prophylactic administration of these medications for the purpose of preventing post-vaccination symptoms is not currently recommended, because information on the impact of such use on COVID-19 vaccine-induced antibody responses is not yet available.
  - mRNA COVID-19 vaccine efficacies cannot be directly compared to that of the Janssen COVID-19 vaccine since the latter was studied at a different time in the pandemic when there were more circulating COVID-19 variants and in different geographic regions of the world. All COVID-19 vaccines have shown high efficacy in preventing serious COVID-19 illness, hospitalization and death.
  - 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.
- Current COVID-19 vaccine EUA fact sheets for recipients can be found at:

- Pfizer- BioNTech COVID-19 Vaccine: *https://www.fda.gov/media/144414/download* (English) and https://www.fda.gov/media/144625/download (Spanish)
- Moderna COVID-19 Vaccine: *https://www.fda.gov/media/144638/download* (English) and *https://www.fda.gov/media/144712/download* (Spanish)
- Janssen COVID-19 Vaccine: *https://www.fda.gov/media/146305/download* (English only at this time)

7. On-Site vaccine receipt and storage.

PFIZER-BIONTECH COVID-19 VACCINE

- ***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, which will serve as ***hub sites*** or distribution points, ***OR***
  - ***Directly from the BOP Central Fill and Distribution (CFAD) site at ULT to the BOP institution that requested an allotment.***
- 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 following procedures are followed when the hub and spoke model for vaccine distribution is used:
  - The refrigerated vaccine should be collected by ***spoke site*** institutions (i.e., institutions that are typically within a 175 miles radius of the distribution point or hub site) as soon as possible.
  - The provided TempTale should immediately be started when the vaccine is placed into the provided cold shipper for transport. The temperature data log files created by the data logger will serve to document part of the 30 day window since they record dates and times at specific intervals. At all other times, institutions must develop their own method of documenting the 30 day timeline.
  - If the hub institution removes the vaccine from ULT storage and places it in refrigeration before it is picked up by the spoke institution, the spoke institution must account for this time as part of the 30-day timeline in addition to the time accounted for by the data logger.
  - Immediately upon return to the spoke site, the vaccine should be placed into an appropriate refrigerator for storage until it is reconstituted and used.
  - Communications will flow through the Vaccine Point of Contacts (VPOCs). Hub site VPOCs will be given notice prior to shipments and will coordinate the pick-up of vaccine with their spoke sites.
- ***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 doses not used after30 days must be maintained in a separate area and labeled **"DO NOT USE"** (see *Section 13. Disposal*).

MODERNA COVID-19 VACCINE

- Vaccine allotments will be shipped either by McKesson (the vaccine distributor) or the CFAD in a frozen state between -25°C to -15°C (-13°F to 5°F) directly to each institution.
  - Vaccine is supplied in two, multi-dose vial types: a 10 dose vial and a 14 dose vial.
  - If frozen prior to administration, thaw
    - 10 dose 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.
    - 14 dose 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, vibration, etc.
- 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.

  ➔ *Once thawed, the vaccine **CANNOT** be re-frozen.*
- ***When stored refrigerated, the unpunctured vaccine vials must be used within 30 days, and institutions must keep up with the 30 day timeline.***

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.***

8. On-Site vaccine preparation.

PFIZER-BIONTECH COVID-19 VACCINE

- ***Remove thawed vaccine from the refrigerator and allow it to come to room temperature***.
  - This will take less than 30 minutes.
  - Verify the vaccine and expiration date located on the vial.

  ➔ *Undiluted vaccine must NOT be out of the refrigerator for **more than 2 hours**.*
- ***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.

(Section continues on next page)

- 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.***

MODERNA 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.

➢ There are two different vaccine vial sizes/volumes: a 10 dose vial and a 14 dose vial. ***All doses are 0.5 ml and contain 100 mcg of vaccine product.***

➢ 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.***

(Section continues on next page)

- **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 the following information has been provided by the manufacturer to ensure stability of the vaccine:
  - Punctured vials should not be transported.
  - Care must be taken to ensure vaccine does not re-freeze during transport.
  - Vaccine must be protected as much as possible from drops, shocks, and vibration whether in the carton, vial, case or cooler.
  - Vaccine should be transported in the carton whenever possible.
    - If transport must be conducted at the vial level, the vial should be placed with dunnage (padding material like bubble wrap or similar padding) to minimize movement during transport.
  - The vaccine should always be transported in insulated containers qualified to maintain 2°C to 8°C (36°F to 46°F) for the duration of transport.
  - The transport containers must be secured when being transported to prevent unnecessary movement.
  - ***Vaccine should only be transported one time and should not be transported back again to the point of origin or to a new location.***
  - Allowable timelines for transport of thawed vaccine are listed below. Total transport time should not exceed 12 hours in total.
    - Transport while walking or using hand cart: not to exceed 1 hour
    - Vehicle transport: not to exceed 12 hours

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*.
- ***The vaccine vial contains 5 (five) separate 0.5 ml vaccine doses.***

- **After the first dose has been withdrawn**, the vial should be held between 2°C to 8°C (36°F to 46°F).
- 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).*

9. 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.

SUMMARY OF ADMINISTRATION PROCEDURES BY VACCINE TYPE (PAGE 1 OF 2)						
COVID-19 VACCINE BY TYPE	**HOW SUPPLIED**	**DOSE/VOLUME/SCHEDULE**		**ROUTE**	**AGE INDICATIONS**	**KEY POINTS – SEE DOCUMENT FOR DETAILS**
Pfizer-BioNTech COVID-19 Vaccine mRNA vaccine	Suspension **Multi-dose vial** (contains six, 0.3 ml doses after reconstitution)	**Dose**	30 mcg	IM	12 years of age and older	***Reconstitution and mixing required*** • When removed from ULT, undiluted, refrigerated vaccine must be used **within 30 days** • Once thawed, keep vaccine vial at room temp **no more than 2 hours**, *prior to dilution* • Reconstitute with **only 1.8 ml** of diluent (0.9% sodium chloride) • Use reconstituted vaccine **within 6 hours** • Egg, cell, latex and preservative free • **Contraindications:** Known severe allergy or anaphylactic reaction to any vaccine component OR to a previous dose of the vaccine • **Precautions:** 1. Current SARS-CoV-2 infection 2. Monoclonal antibody treatment within past 90 days 3. Other vaccines within the past 14 days 4. Moderate/severe acute non-COVID-19 illness 5. History of an immediate allergic reaction to another vaccine or injectable therapy • **Special populations:** underlying medical conditions, immunocompromised, pregnant, breastfeeding/lactating; persons with autoimmune conditions and history of Guillain-Barré syndrome, Bell's palsy, or dermal fillers
		Volume	0.3 ml			
		Schedule	• 2-dose series, 21 days apart • 2nd doses should be given as close to the recommended interval as possible. When not feasible to adhere to the recommended interval, the second dose may be scheduled for administration up to 6 weeks (42 days) after the first dose. • 2nd doses given earlier or later than the above intervals do not need to be repeated.			

(Table continued on next page)

SUMMARY OF ADMINISTRATION PROCEDURES BY VACCINE TYPE (PAGE 2 OF 2)						
COVID-19 VACCINE BY TYPE	**HOW SUPPLIED**	**DOSE/VOLUME/SCHEDULE**		**ROUTE**	**AGE INDICATIONS**	**KEY POINTS – SEE DOCUMENT FOR DETAILS**
Moderna COVID-19 Vaccine mRNA vaccine	Suspension **Multi-dose vial** (contains *either* 10 *or* 14 doses depending on vial size, each dose 0.5 ml)	**Dose**	100 mcg	IM	18 years of age and older	***No reconstitution required*** • Withdraw either 10 (smaller volume) or 14 doses (larger volume) from each vial • Use unpunctured, refrigerated vaccine **within 30 days** • Thawed vaccine is sensitive to movement and can only be transported from storage to the site of administration once (i.e., ***do not*** transport back to the point of origin from a vaccination clinic or to a new location) • 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 • **Contraindications, Precautions, and Special Populations:** same as for Pfizer-BioNTech COVID-19 vaccine
		Volume	0.5 ml			
		Schedule	• 2-dose series, 28 days apart • 2nd doses should be given as close to the recommended interval as possible. When not feasible to adhere to the recommended interval, the second dose may be scheduled for administration up to 6 weeks (42 days) after the first dose. • 2nd doses given earlier or later than the above intervals do not need to be repeated.			
Janssen COVID-19 Vaccine Recombinant, non-replicating viral vector	Suspension **Multi-dose vial** (contains five, 0.5 ml doses)	**Dose**	$5x10^{10}$ virus particles	IM	18 years of age and older	***No reconstitution required*** • **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 <u>either</u> 6 hours or 2 hours** depending on storage temperatures • Egg, cell, latex and preservative free • **Contraindications, Precautions, and Special Populations:** same as for mRNA COVID-19 vaccines • **Warning: maintain high index of suspicion for new symptoms 1-2 weeks after vaccination** that might represent thrombotic events or thrombocytopenia
		Volume	0.5 ml			
		Schedule	• 1 dose			

- ***Ancillary supply kits will be ordered automatically based on the number of vaccine orders and will arrive before or along with the vaccine***.
  - The kits will 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).
    - Employees should be provided with completed vaccination cards after being vaccinated.
  - 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.

- ***Specific COVID-19 vaccine considerations:***
  - mRNA COVID-19 vaccines
    - The Pfizer-BioNTech COVID-19 Vaccine series is given in 2 doses (0.3 ml each) and scheduled 21 days apart.
    - The Moderna COVID-19 Vaccine series is given in 2 doses (0.5 ml each) and scheduled 28 days apart.
    - ***Second doses of the Pfizer-BioNTech and Moderna COVID-19 vaccines should be given as close to the recommended interval as possible***.
    - Persons should not be scheduled to receive the second dose earlier than recommended; however, second doses administered on days 17-21 (Pfizer-BioNTech) and days 24-28 (Moderna) are considered valid. Second doses inadvertently given earlier than this 4-day grace period do not need to be repeated.
    - When not feasible to adhere to the recommended interval, the second dose may be scheduled for administration up to 6 weeks (42 days) after the first dose. Second doses given later than the recommended interval do not need to be repeated.
  - Janssen COVID-19 vaccine
    - Maintain a high index of suspicion for symptoms that might represent serious thrombotic events or thrombocytopenia in those who have recently received a vaccination, especially in females aged 18 through 49 years.
    - Do not treat suspected thrombotic events with heparin unless autoimmune heparin induced thrombocytopenia (HIT) testing is negative. If testing is positive

or unable to be performed, consider using non-heparin anticoagulants and high-dose intravenous immune globulin.

- ***No data exist on the safety and efficacy of a mixed-product series (i.e., interchangeability) of COVID-19 vaccines.*** Individuals initiating a 2-dose vaccine series by a particular manufacturer (i.e., Pfizer-BioNTech or Moderna) should complete the series using the same product since the vaccines are ***NOT*** interchangeable.
  - In exceptional situations in which the first-dose vaccine product cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered at a minimum interval of 28 days between doses to complete the mRNA COVID-19 vaccination series.
  - In situations where the same mRNA COVID-19 vaccine product is temporarily unavailable, it is preferable to delay the second dose (up to 6 weeks) to receive the same product.
  - If two doses of different mRNA COVID-19 vaccine products are inadvertently administered, no additional doses of either vaccine are recommended at this time.
  - The safety and efficacy of the Janssen COVID-19 vaccine administered after an mRNA COVID-19 vaccine has not been established. However, 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 Janssen vaccination—not a mixed vaccination series.
- ***Routine prophylactic administration of antipyretic or analgesic medications (e.g., acetaminophen, non-steroidal anti-inflammatory drugs) for the purpose of preventing post-vaccination symptoms is not currently recommended.*** Information on the impact of such use on COVID-19 vaccine-induced antibody responses is not available at this time. These medications may be taken for the treatment of post-vaccination local or systemic symptoms, if medically appropriate.

10. Document administration and scheduling

➢ ***Inmate Vaccine Administration Documentation.*** Administration will be documented in the Patient Medical Record (BEMR). Under flow sheets and immunization, note 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.
- Enter the second vaccine dose date in the scheduler, if applicable.
- Upon exiting, do not forget to save the immunization flow sheet data.

(Section continues on next page)

- For 2-dose vaccination series, place the patient on a medical hold in BEMR after administration of the first vaccine dose. **Do <u>not</u> 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.*
- For inmates who received COVID-19 vaccination elsewhere (i.e., not in the BOP), this information must be documented in BEMR. Institutions should attempt to obtain written confirmation of the vaccination when possible.
  - If written documentation is provided:
    - Enter vaccination information into BEMR as "History Of" along with the vaccination date(s) and scan the documentation into BEMR.
  - If proof of vaccination is not provided:
    - 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.
  - In order to accurately reflect vaccination status on the COVID-19 vaccination dashboard, the dose number must be entered when entering a vaccination history into BEMR. If an inmate received a two-dose series, both doses must be entered separately.

➢ ***Employee Vaccine Administration Documentation.*** Administration 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.

➢ ***COVID-19 Vaccine Consent Forms***

- Document the publication date of the EUA 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 (*see Appendix 4 and 5*) 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 (*see Appendix 6*) to employee records for filing after vaccination has been completed, including second vaccine doses where applicable, or the employee's refusal of vaccination has been documented. For employees receiving single-dose vaccines, ensure that second vaccine dose information has been crossed out, initialed, and dated.

Documentation of vaccine consent or declination must be obtained from every inmate and employee*. Declinations may be obtained after all those who wish to be vaccinated have completed their vaccinations.*

➢ ***Scheduling second doses of vaccine, if applicable.***

- Facilities need to plan for clinic availability based on when initial doses of vaccine are administered.

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- ***For inmates, using BEMR is the preferred method to schedule second doses.*** The COVID-19 vaccine dashboard is a tool that may be used to monitor when a second vaccine dose should be given.
- ***For employees, each facility will determine a method for scheduling second doses*** and what reminders to use for determining when second 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 spread sheet of due dates, and vaccine cards).

11. 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 the administration of a vaccine, ***immediately call a medical emergency.***
- ***Epinephrine 1:1000 IM/SQ and respiratory support should be immediately available.***
- BOP nursing and paramedic protocols are available for implementation and use in the management of allergic reactions and anaphylaxis when approved by the clinical director.
  - **The nursing protocol:** *http://sallyport.bop.gov/co/hsd/nurse/Policy_guidance.jsp*
  - **The paramedic protocol:** *http://sallyport.bop.gov/co/hsd/paramedic/index.jsp*

12. Vaccine adverse reactions.

Documentation of adverse events 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*
  - 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.

13. 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.

SKILLS CHECKLIST FOR COVID-19 VACCINE ADMINISTRATION (*PAGE 1 OF 4*)				
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 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 both 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.
VACCINE HANDLING AND PREPARATION, PFIZER-BIONTECH COVID-19 VACCINE				
				Demonstrates knowledge that unpunctured vials may be refrigerated (2°C to 8°C [36°F to 46°F]) for up to 30 days.
				Removes vaccine from refrigerator and allows to come to room temperature prior to dilution (30 minutes).
				Verifies vaccine and expiration date (Unless otherwise specified, date is found on the vial).
				Inverts vial gently 10 times to mix*. DOES NOT SHAKE the vial.*
				Obtains sterile 0.9% Sodium Chloride Injection, USP (i.e., diluent).
				Cleanses the vaccine and sodium chloride vial stoppers with an alcohol swab.
				Withdraws only 1.8 ml from the sodium chloride vial *and injects that 1.8 ml into the vaccine vial using a 3 or 5 ml syringe with a 21 or narrower gauge needle (from the shipped ancillary kits).* ***ONLY*** *reconstitutes vaccine that will be used within 6 hours.*

SKILLS CHECKLIST FOR COVID-19 VACCINE ADMINISTRATION (*PAGE 2 OF 4*)				
FACILITY:			**EMPLOYEE:**	
Self-Assessment		**Supervisor/ Preceptor Review**		**SKILLS**
Needs to Improve	**Meets or Exceeds**	**Needs to Improve**	**Meets or Exceeds**	
VACCINE HANDLING AND PREPARATION, PFIZER-BIONTECH COVID-19 VACCINE (CONTINUED)				
				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.
				Engages needle safety device (if present) prior to disposal in a sharps container.
				Discards remaining 0.9% sodium chloride solution regardless of fluid remaining. Do not reuse.
				Gently inverts the vial containing the vaccine and diluent 10 times to mix. *DO NOT SHAKE*.
				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.
				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.
VACCINE HANDLING AND PREPARATION, MODERNA COVID-19 VACCINE				
				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.**
				Acknowledges that each multi-dose vaccine vial contains either 10 or 14 separate, 0.5 ml vaccine doses each with 100 mcg of vaccine product, and understands that 10 (smaller volume vial) *OR* 14 doses (larger volume vial) should be withdrawn.
				Removes vaccine from refrigerator and verifies vaccine and expiration date. For any questions, contacts Central Office.
				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 8°C to 25°C (46°F to 77°F).
				Swirls the vial gently and between each withdrawal*. 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.
VACCINE HANDLING AND PREPARATION, JANSSEN (JOHNSON & JOHNSON) COVID-19 VACCINE				
				Demonstrates knowledge that vials may be refrigerated (2°C to 8°C [36°F to 46°F]) for up to 3 months.
				Acknowledges that each multi-dose vaccine vial contains 5 (five) separate 0.5 ml vaccine doses.
				Removes vaccine from refrigerator, verifies vaccine and expiration date, and visually inspects the vaccine vial for particulate matter and discoloration.
				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].
				Gently swirls the multi-dose vial in an upright position for 10 seconds before withdrawing each dose of vaccine. *DOES NOT SHAKE the vial.*

SKILLS CHECKLIST FOR COVID-19 VACCINE ADMINISTRATION (*PAGE 3 OF 4*)				
FACILITY:			**EMPLOYEE:**	
Self-Assessment		**Supervisor/ Preceptor Review**		**SKILLS**
Needs to Improve	**Meets or Exceeds**	**Needs to Improve**	**Meets or Exceeds**	
VACCINE HANDLING AND PREPARATION, JANSSEN (JOHNSON & JOHNSON) COVID-19 VACCINE (CONTINUED)				
				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 the first dose has been withdrawn.
				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 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 appropriate sized needle and syringe for each dose of vaccine. Opens syringe packet carefully placing the safety cap on the package covering.
				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 multi-dose vial: • *Pfizer-BioNTech:* 0.3 ml • *Moderna:* 0.5 ml • *Janssen:* 0.5 ml
				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.

SKILLS CHECKLIST FOR COVID-19 VACCINE ADMINISTRATION (*PAGE 4 OF 4*)				
FACILITY:			**EMPLOYEE:**	
Self-Assessment		**Supervisor/ Preceptor Review**		**SKILLS**
Needs to Improve	**Meets or Exceeds**	**Needs to Improve**	**Meets or Exceeds**	
ADMINISTERING VACCINES (CONTINUED)				
				Records the date and time of first use. This information must be recorded on the vial label for the Moderna and Pfizer vaccines.
				Identifies vials that can no longer be used: • *Pfizer-BioNTech:* 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, or by expiration date. • *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, or by expiration date. • *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]); or by 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. • 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.
				If an inmate received COVID-19 vaccination elsewhere (i.e., not in the BOP), knows to: • Enter vaccination information into the BEMR system as "History Of" along with the vaccination date(s), *if documentation is provided*. • 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), *if proof of vaccination is not provided*.

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

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 the FDA EUA and package insert, if the specific vaccine brand(s) is/are checked (✓) below:	
	Pfizer-BioNTech COVID-19 Vaccine
	Moderna COVID-19 Vaccine
	Janssen (Johnson & Johnson) 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 COVID-19 Vaccine	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.
Moderna COVID-19 Vaccine	0.5 mL	IM	Deltoid	• No reconstitution needed. • Two types of multi-dose vials with 0.5 ml vaccine doses: a smaller vial type containing 10 doses, and a larger vial type containing 14 doses. • 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. • Removes 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 OF3)

VACCINE	DOSE	ROUTE	INJECTION SITE	KEY POINTS
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.

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.

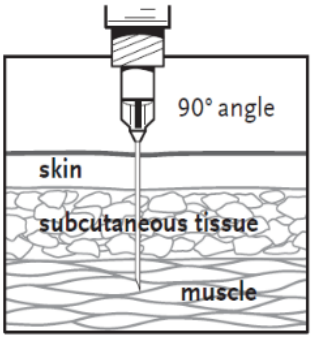
NOTE: Each location will receive an ancillary kit and product information guide separate from the vaccine product. The kits will contain a variety of needles and syringes along with other supplies (e.g., diluent, if needed). When preparing and administering vaccine, staff will need to select the correct 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*:

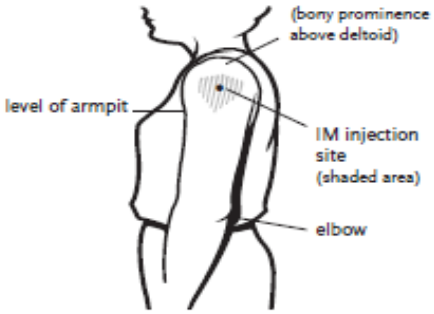
1. Use a needle long enough to reach into the muscle – for adults, 1-1½" needle.
2. The 1 ml syringe included in the ancillary kit is recommended for vaccine administration and not for mixing of the diluent with vaccine.
3. With the non-dominant hand, bunch up the muscle (for smaller muscle mass) or stretch the skin (for larger body mass).
4. With the dominant hand, insert the needle at a 90^{o} 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.

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

Intramuscular (IM) injection



Deltoid *



*References adapted from www.immunize.org/catg.d/Item # 2024 (9/19) and 3084 (8/20)

APPENDIX 4. COVID-19 VACCINE CONSENT FORM FOR INMATES - ENGLISH

The consent on the following page must be used to document all inmate consents or declinations of the COVID-19 vaccine.

COVID-19 VACCINE CONSENT - INMATE

U.S. DEPARTMENT OF JUSTICE **FEDERAL BUREAU OF PRISONS**

I have been provided a copy of the COVID-19 Vaccine **Emergency Use Authorization (EUA)** fact sheet dated _____. I have had the opportunity to ask questions about the benefits and risks of vaccination, including if I am pregnant, breastfeeding or have a weakened immune system. I will agree to complete the number of vaccine doses as appropriate and indicated by the manufacturer.

Health Questions Prior to COVID-19 Vaccination (*Check yes or no*)

Yes	No	Health Questions
☐	☐	Are you sick today?
☐	☐	Have you ever had a severe allergy (i.e., anaphylaxis) or an immediate allergic reaction of any severity to any component of this vaccine or to a previous dose of this vaccine?
☐	☐	Have you ever had an immediate allergic reaction to any other vaccine/injectable therapy?
☐	☐	Have you received monoclonal antibody therapy for COVID-19 in the last 90 days?

☐ I consent to receive the COVID-19 vaccination.

Dose # (1 or 2)	Vaccine Manufacturer	Lot Number	Expiration Date	Route	Deltoid
				IM	☐ Left ☐ Right
Inmate Signature					**Date**
Administered by Signature					**Date**
Administered by (name/title)					

☐ I decline to receive the COVID-19 vaccination.

☐ I have already been vaccinated.

☐ Other reason: _____

Inmate Signature	**Date**
Witness Signature	**Date**
(PRINT) Witness Name	

(PRINT) Inmate Name (Last, First)	**Register Number**	
Institution	**Unit**	**Work Assignment**

APPENDIX 5. COVID-19 VACCINE CONSENT FORM FOR INMATES - SPANISH

The consent on the following page is to be used for reading and interpretation related to the COVID-19 vaccine. Signatures and documentation of consent or declination are to be recorded on the English version of the inmate consent form.

DEPARTAMENTO DE JUSTICIA DE LOS ESTADOS UNIDOS **AGENCIA FEDERAL DE PRISIONES**

Se me ha entregado una copia de la ficha informativa de la **Autorización de Uso de Emergencia (EUA, Emergency Use Authorization)** de la vacuna contra la COVID-19 con fecha_____. He tenido la oportunidad de hacer preguntas sobre los beneficios y riesgos de la vacuna, incluyendo preguntas respecto de si estoy embarazada, amamantando o tengo un sistema inmunitario debilitado. Accederé a recibir el número correspondiente de dosis de la vacuna tal como sea indicado por su fabricante.

Preguntas relacionadas con la salud antes de la aplicación de la vacuna contra la COVID-19 ***(marcar "Sí" o No").***

Sí	No	Preguntas relacionadas con la salud
☐	☐	¿Está enfermo hoy?
☐	☐	¿Alguna vez ha sufrido algún tipo de alergia grave (anafilaxia, por ejemplo) o una reacción alérgica inmediata de algún tipo ante alguno de los componentes de esta vacuna **o** a una dosis previa de la misma?
☐	☐	¿Alguna vez ha tenido alguna reacción alérgica inmediata a otra vacuna o terapia inyectable?
☐	☐	¿Ha recibido terapia de anticuerpos monoclonales contra la COVID-19 en los últimos 90 días?

☐ **Doy mi consentimiento para recibir la vacuma contra la COVID-19**

Dosis n.º (1 o 2)	Fabricante de la vacuna	Número de lote	Fecha de vencimiento	Ruta	Deltoides
					□ Izquierdo □ Derecho
Firma del recluso					**Fecha**
Firma del administrador					**Fecha**
Administrado por (nombre/cargo)					

☐ **Me niego a recibir la vacuna contra la COVID-19.**

☐ Ya he sido vacunado.

☐ Otra razón: _____

Firma del recluso	**Fecha**
Firma del testigo	**Fecha**
(EN LETRA DE IMPRENTA) Nombre del testigo	

(EN IMPRENTA) Nombre del recluso (apellido, nombre)	**Número de registro**	
Institución	**Unidad**	**Asignación de trabajo**

APPENDIX 6. COVID-19 VACCINE CONSENT FORM FOR EMPLOYEES

The consent on the following page must be used to document all employee consents or declinations of the COVID-19 vaccine.

BP-A1135
MAY 21

COVID-19 VACCINE CONSENT – EMPLOYEES

U.S. DEPARTMENT OF JUSTICE **FEDERAL BUREAU OF PRISONS**

I have been provided a copy of the COVID-19 Vaccine **Emergency Use Authorization (EUA)** fact sheet dated _____. I have had the opportunity to ask questions about the benefits and risks of vaccination, including if I am pregnant, breastfeeding or have a weakened immune system. I will agree to complete the number of vaccine doses as appropriate and indicated by the manufacturer.

Health Questions Prior to COVID-19 Vaccination (*Check yes or no*)

Dose #1		Dose #2		Health Questions
Yes	No	Yes	No	
☐	☐	☐	☐	Are you sick today?
☐	☐	☐	☐	Have you ever had a severe allergy (i.e., anaphylaxis) or an immediate allergic reaction of any severity to any component of this vaccine **or** to a previous dose of this vaccine?
☐	☐	☐	☐	Have you ever had an immediate allergic reaction to any other vaccine/injectable therapy?
☐	☐	☐	☐	Have you received monoclonal antibody therapy for COVID-19 in the last 90 days?

☐ I consent to receive the COVID-19 vaccination.

Dose	Employee Signature	Witness Signature	Date
#1			
#2			

☐ I decline to receive the COVID-19 vaccination.

☐ I have already been vaccinated.
☐ I plan to be vaccinated by my private or community provider.
☐ Other reason: _____

Employee Signature	Witness Signature	Date

COVID-19 Vaccine Information

Dose	Date	Vaccine Manufacturer	Lot Number	Expiration Date	Route	Deltoid	Administered by (name/title):
#1					**IM**	☐Left ☐Right	
#2					**IM**	☐Left ☐Right	

(PRINT) Employee Name (Last, First)	Year of Birth	Institution