COVID-19 Vaccine Guidance

Federal Bureau of Prisons Clinical Guidance

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What's New

PREVIOUS VERSIONS

- Updates to Employee and Inmate consents
- Pregnancy added to Priority 2 category
- Addition of Moderna COVID-19 vaccination information throughout the document
- Updates in Vaccination of Individuals with Underlying Medical Conditions to include persons with autoimmune conditions, history of Guillain-Barré syndrome, or history of Bell's palsy.
- Updates to expiration dates: for Pfizer, dates is found on vial; for Moderna, date is found online
- Updates to Moderna Onsite Vaccine Preparation to include special considerations for transportation.
- Added Section B.4 Vaccination of individuals requiring tuberculosis (TB) testing (TST)
- Updates to Section B.5 Patient Education
- Clarification to Section B.8 Administer the COVID-19 Vaccine dosing intervals
- Clarification on TST for inmates with COVID-19 vaccination <4 weeks prior to intake
- Updated recommendations on intervals between the first and second dose
- Updated recommendations on interchangeability of vaccine products
- Updated language on vaccination of persons with a history of SARS-CoV-2 infection
- References added to CDC recommendations for persons with a history of dermal fillers
- Pfizer vaccine updated to reflect 6 doses per vial throughout

VERSION 10.0

- Updates to Section B.1 Inmate Vaccination Priorities
- Updates to Section B.2 Contraindications and Precautions
- Updated to Appendices 4 thru 6 Employee and Inmate consent forms

VERSION 11.0

- Updates added throughout document to add Janssen (Johnson & Johnson) vaccine information and the use of a one dose vaccination series.
- Updates to Section B.1 Inmate Vaccination Priorities for inmates assigned to jobs considered high priority by the BOP
- Clarification on Appendix 5. COVID-19 Vaccine Consent Form for Inmates - Spanish instructions that signatures and documentation of consent or declination are to be recorded on the English version of the inmate consent form.

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COVID-19 VACCINE

A. PURPOSE

The purpose of this guidance is to provide direction on use of COVID-19 vaccine 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. This includes use of quarantine for vaccinated persons potentially exposed to the virus.*

- 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.

➔ *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 16 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. Assess and prioritize vaccination if vaccine supplies are limited.

- Distribution and priority of vaccine administration will be directed by the Health Services Division of the BOP Central Office and through the local Clinical Director or designee based on COVID-19 risk and vaccine availability. It will align with the Centers for Disease Control and Prevention (CDC) and Advisory Committee on Immunization Practices (ACIP) recommendations for priority populations.
- Vaccine supply availability is expected to change as the BOP's COVID-19 immunization program progresses; therefore, planning should be focused and flexible. Since vaccine supply will initially be limited, allocation of vaccine doses has been prioritized by the BOP into priority levels (see below). However, vaccine supply is projected to increase over time, thus allowing for the expansion of vaccination efforts.
- Recommendations concerning BOP's priority levels and associated population groups may change based not only on vaccine availability but also on the availability of different COVID-19 vaccines, changing COVID-19 disease epidemiology, and local community factors.
- ***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 VACCINATION:

Prior to initiating inmate vaccinations, vaccinations should first be offered to BOP employees, to include PHS officers assigned to the BOP.

- Vaccinating correctional staff will serve to decrease the possible introduction of SARS-CoV-2 into institutions and thus protect inmates. In the context of limited quantities of vaccine, the BOP recommends offering vaccination to staff first as the best way to achieve the greatest public health benefit to inmates, staff, and communities.
- If available vaccine supplies are low, the following ***employee sub-priorities,*** based on job functions that pose a higher risk for transmission of infection, should be considered in the order listed. These recommendations represent general guidance and may need to be adapted to meet the needs of individual institutions.
  - Staff with potential for close contact with sick persons (e.g., healthcare workers, workers in isolation or quarantine units, and those performing COVID-19 symptom screens and temperature checks)
  - Staff who are currently on COVID-19 related Temporary Job Modifications (TJM)
  - Staff in nursing care units and other residential health care units
  - Staff involved in R&D or performing inmate transfer or escort functions
  - Staff with other potential close contact with inmates (e.g., performing pat searches, supervising inmate work details)
  - All other staff

INMATE VACCINATION:

After offering vaccinations to all employees, institutions should proceed with offering vaccine to inmates using the listed priorities.

- The recommendations represent general guidance and may need to be adapted to meet the needs of individual institutions. For COVID-19 vaccinations, facilities must consider other local factors such as outbreak history, housing unit types, and individual clinical factors when vaccine supply is limited. In addition, the types of quarantine (i.e., intake, exposure, transfer) and facility functions (i.e., transfer center, holdover sites) also must be taken into consideration.

➔ *For 2-dose vaccination series, a **medical hold** should be placed when the first dose is administered and not removed until the due date of the second dose.*

➔ *Within each priority level (see below), vaccine should be given until either all persons who requested vaccination have received it or until vaccine supply is exhausted.*

- ***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 admitted to ***transfer quarantine*** should **not** initiate a 2-dose vaccination series. However, inmates ***may be vaccinated using a single-dose COVID-19 vaccine***.
    - If a first dose of a 2-dose vaccination series was administered prior to placement into a transfer quarantine, the inmate should be placed on a medical hold until

the due date of the second dose and not transferred until the second dose has been given or refused.
    - Inmates who have received their first dose of a 2-dose vaccination series should not be scheduled for transfer or placed in transfer quarantine while awaiting their second dose.
- Inmates admitted to ***quarantine with mandatory release/transfer dates*** (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 BOP transfer center and holdover sites.*** Inmate movement is an important and necessary part of BOP operations with BOP transfer centers and holdover sites playing a pivotal role in this process across the country. The coordination of inmate movement is complex, often involving multiple institutions and agencies, and it is time-sensitive. The priorities of vaccination efforts must balance the specific vaccine administration requirements with inmate movement needs and constraints.
    - All inmates who are designated to transfer centers or holdover sites (e.g., cadre inmates) should be vaccinated in accordance with priority guidelines.
    - A single-dose COVID-19 vaccine may be administered to inmates who are passing through and in holdover status. However, 2-dose vaccination series **should not** be initiated unless an inmate is expected to remain in holdover status 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.

Priority Level 1: Inmates in health service unit job assignments, in certain housing situations, and in other job assignments considered high priority by the BOP

- Inmates assigned as health service unit workers
    - Similar to correctional staff, vaccinating these inmates will serve to decrease the possible introduction of SARS-CoV-2 to an institution.
- Inmates in nursing care centers (long-term care) or other residential health care units
- Inmates assigned to jobs considered high priority by the BOP
    - Health Services staff should refer to the COVID-19 vaccine dashboard to determine who is eligible for vaccination.

***Priority Level 2:* Inmates aged 65 years and older, those of any age meeting one or more of the below CDC criteria for "are at increased risk" for severe illness from SARS-CoV-2, and those in job assignments considered a priority by the BOP**

➔ *Note: Some inmates may have been covered in the priority 1 category*

- Health Services staff should use the BOP's electronic medical record (BEMR) and the COVID-19 vaccine dashboard to identify patients with the following conditions to prioritize for vaccination.
  - Inmates 65 years of age or older
  - Cancer
  - Chronic kidney disease
  - Chronic obstructive pulmonary disease (COPD)
  - Down Syndrome
  - Heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies
  - Immunocompromised state from solid organ transplant
  - Obesity (body mass index [BMI] of 30 kg/m^2 or greater)
  - Sickle cell disease
  - Smoking (to include current and former smokers)
  - Type 2 diabetes mellitus
  - Pregnancy (For further discussion of vaccination of pregnant or lactating people see: *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html*)

➔ *For the most current list of persons who are at increased risk for severe COVID-19 illness, refer to: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html*

- Health Services staff should refer to the COVID-19 vaccine dashboard to determine who is in a job assignment considered a priority for the BOP.

***Priority Level 3:* Inmates aged 50 through 64 years or those of any age with certain underlying medical conditions who "might be at increased risk" for severe illness from SARS-CoV-2**

➔ *Note: Some inmates may have been covered in the priority 1-2 categories*

- Health Services staff should use the BOP's electronic medical record (BEMR) and the COVID-19 vaccine dashboard to identify patients with the following conditions to prioritize for vaccination.
  - Asthma (moderate-to-severe)
  - Cerebrovascular disease (affects blood vessels and blood supply to the brain)
  - Cystic fibrosis
  - Hypertension
  - Immunocompromised state from blood or bone marrow transplant, immune deficiencies, HIV, use of corticosteroids, or use of other immune weakening medicines
  - Neurologic conditions, such as dementia
  - Liver disease
  - Overweight (BMI greater than 25 kg/m^2 but less than 30 kg/m^2)

- Pulmonary fibrosis (having damaged or scarred lung tissues)
- Thalassemia
- Type 1 diabetes mellitus

➔ *For the most current list of persons who might be at increased risk for severe COVID-19 illness, refer to: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html*

Priority Level 4: All other inmates

➢ Upon completion of vaccine administration to all staff and inmates in the above priorities, Health Services staff should schedule vaccinations for all remaining inmates.

2. Screen patients for 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.
- ***Do not administer any other vaccination (e.g., seasonal influenza vaccine) 14 days before or after*** administering any COVID-19 vaccine, including 14 days before or after any first or second COVID-19 vaccine doses.
  - If COVID-19 vaccines are inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine.
  - COVID-19 and other vaccines may be administered within a shorter period in situations where the benefits are deemed to outweigh the potential unknown risks of vaccination co-administration (e.g., tetanus toxoid-containing vaccination as part of wound management).
- ***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. 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.

4. 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.

5. 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).
  - 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)

6. On-Site vaccine receipt and storage.

PFIZER-BIONTECH COVID-19 VACCINE

- ***Vaccine allotments will be shipped 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.
- Upon receipt, hub sites will 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.
- The refrigerated vaccine should be collected by ***spoke site*** institutions (i.e., institutions that are within a 175 miles radius of the distribution point) as soon as possible.
- 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 vaccine must be used within 5 days of removal from ULT storage, and institutions must keep up with the 5 day timeline***.
    - For institutions serving as spokes, the provided temperature data logger (temp tail) 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 5 day window since they record dates and times at specific intervals. At all other times, institutions must develop their own method of documenting the 5 day timeline.
    - Vaccine doses not used after 5 days must be maintained in a separate area and labeled **"DO NOT USE"** until further instruction for disposal is available (***see Section 11 Disposal of expired or unused vaccine).***
    - 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 5 day timeline in addition to the time accounted for by the data logger.

MODERNA COVID-19 VACCINE

- Vaccine allotments will be shipped by the vaccine distributor, McKesson, in a frozen state between -25°C to -15°C (-13°F to 5°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.
  Once thawed, the vaccine CANNOT be re-frozen.
- ***When stored refrigerated, the vaccine must be used within 30 days, and institutions must keep up with the 30 day timeline.***
    - Prior to administration, thaw in refrigerator (2°C to 8°C [36°F to 46°F]) for 2 hours and 30 minutes *OR* thaw at room temperature between 15°C to 25°C (59°F to 77°F) for 1 hour.

- If unpunctured vials inadvertently have been stored out of refrigeration (i.e., between 8°C to 25°C [46°F to 77°F]), they may be kept at these temperatures no more than 12 hours.
- Punctured vials must be used within 6 hours.
- Refrigerated vials not used after 30 days, unpunctured vials stored between 8°C to 25°C [46°F to 77°F] not used after 12 hours, and punctured vials not used after 6 hours, must be maintained in a separate area and labeled **"DO NOT USE"** until further instruction for disposal is available (see ***Section 11. Disposal of expired or unused vaccine***).

➢ When thawed, the vaccine should be handled with care and protected from shocks, drops, vibration, etc.

JANSSEN COVID-19 VACCINE

➢ Vaccine initially will be stored frozen by the manufacturer and shipped by the vaccine distributor, McKesson, 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.
- Do not refreeze once thawed.

➢ ***When stored refrigerated, the vaccine must be used within 3 months, and institutions must keep up with the 3 month timeline.***

- If unpunctured vials inadvertently have been stored out of refrigeration (i.e., between 9°C to 25°C [47°F to 77°F]), they may be kept at these temperatures no more than 12 hours.
- Punctured vials must be used either
  - Within 2 hours, if kept at room temperature (maximally 25°C [77°F]), or
  - Within 6 hours, if kept between 2°C to 8°C (36°F to 46°F).
- 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"** until further instruction for disposal is available (see ***Section 11. Disposal of expired or unused vaccine***).

7. 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.
- Undiluted vaccine must *NOT* be out of the refrigerator for **more than 2 hours**.
- Verify the vaccine 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*.
  - 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.*
  - 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 from refrigeration and allow the vaccine vial to come to room temperature for at least 15 minutes.
- 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.
  - Verify the vaccine and expiration date by accessing the manufacturer's website here: *https://www.modernatx.com/covid19vaccine-eua/providers/vial-lookup*. Enter the lot number and the expiration date will be displayed.
- The vaccine vial contains 10 (ten) separate 0.5 ml vaccine doses, each with 100 mcg of vaccine product in a labeled, multi-dose vial.
- If unpunctured, vials were inadvertently stored out of refrigeration (i.e., between 8°C to 25°C [46°F to 77°F]), they may be kept at these temperatures no more than 12 hours.
- After the first dose has been withdrawn, the vial should be held between 2°C to 25°C (36°F to 77°F) for up to 6 hours.
- Record the date and time of the first use on the vial label. Discard after 6 hours and do not refreeze.

- ***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 shown 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.
- For unpunctured vials, 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
- As the expiration date approaches, check the expiration date again by using the above process. Never use expired vaccine.
  - Use CDC's expiration date tracking tool to document expiration date changes.
  - Do not discard expired vaccine and refer to ***Section 11. Disposal of expired or unused vaccine*** 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. Do not pool excess vaccine from multiple vials.
- If unpunctured, vials inadvertently were stored out of refrigeration (i.e., between 9°C to 25°C [47°F to 77°F]), they may be kept at these temperatures no more than 12 hours.
- After the first dose has been withdrawn, the vial should be held 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.

- Record the date and time of the first use on the vial label. If not used within the above timeframes, do not discard vaccine and refer to ***Section 11. Disposal of expired or unused vaccine*** for guidance.
  - Never use vaccine beyond the use time.

8. Administer the COVID-19 vaccine.

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	16 years of age and older	***Reconstitution and mixing required**** • When removed from ULT, vaccine must be used **within 5 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)

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 ten, 0.5 ml doses)	**Dose**	100 mcg	IM	18 years of age and older	***No reconstitution required*** • Use 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 12 hours** • After 1st dose withdrawn, use vaccine **within 6 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
		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.
  - ***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.

9. Document administration and schedule the second vaccine dose, if the latter is applicable.

➢ ***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.
- 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.*

➢ ***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.
  - ***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).

10. Medical emergency or anaphylaxis: Rash, difficulty breathing, itchy throat, bodily collapse, swollen tongue or throat.

- 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*

11. Report all clinically important vaccine adverse reactions.

Documentation of adverse events should occur in the following two locations:

- BOP Adverse Events dashboard
- Federal Vaccine Adverse Event Reporting System (VAERS) 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.

12. Disposal of expired or unused vaccine.

- 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 vaccine vials that are contaminated, expired or unused until further guidance is issued.
  - Label the vaccine vial "DO NOT USE" and store in a separate, designated area, away from any vaccine that is in use.

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 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				
				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.*
				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.

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)				
				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 5 (five) 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 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 10 (ten) separate 0.5 ml vaccine doses, each with 100 mcg of vaccine product.
				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 12 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 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.*
				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. Discards vaccine if it is not used within the above time frames.

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 COVID-19 VACCINE (CONTINUED)				
				Does not pool vaccine from separate multi-dose vials to create a dose of vaccine.
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 safety cap on the package covering and then inserts needle into the multi-dose vaccine vial.
				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
				Withdraws needle from the vial. Taps syringe to float air bubbles to the syringe hub and carefully expels excess air before patient injection. Verifies final vaccine dose.
				Positions patient so that muscles are relaxed and preps injection site with alcohol wipe, allowing it to dry.
				Places a clean, dry gauze between the third and fourth fingers for easy access to a gauze pad after injection.
				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 (all the way up to the syringe hub) at a 90-degree angle using a dart-like action to prevent accidental depression of the plunger during insertion of the needle. Aspiration is not necessary for IM injections in the deltoid site.
				Uses the thumb and forefinger of the non-dominant hand to hold the syringe and depresses the plunger with the dominant hand in a steady motion after the needle pierces the skin.
				Removes the needle at the same angle at which it was inserted once medication is completely injected. Engages the needle safety device appropriately.
				Disposes of the needle and syringe in a sharps container.
				Covers injection site with the gauze, using gentle pressure and applies a Band-Aid, if needed.
				Records the date and time of first use. This information must be recorded on the vial label for the Moderna and Pfizer vaccines.

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)				
				Identifies vials that can no longer be used and knows not to discard them: • *Pfizer-BioNTech:* undiluted vaccine out of refrigeration for more than 2 hours, refrigerated undiluted vaccine not used after 5 days, or reconstituted vaccine not used within 6 hours, or by expiration date. • *Moderna*: vaccine out of refrigeration for more than 12 hours, punctured vials not used after 6 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, or 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"* until further instruction is available.
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.

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

Adapted from: Skills Checklist for Pediatric Immunization. California Department of Health, Immunization Branch.

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 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 OF2)				
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. • Each reconstituted multi-dose vial contains six (6) separate 0.3 ml vaccine doses. • Reconstituted vaccine must be used within 6 hours. • After 6 hours, label "DO NOT USE" and store in a place removed from vaccines in use. Do not discard these vials and await further guidance.
Moderna COVID-19 Vaccine	0.5 mL	IM	Deltoid	• No reconstitution needed. • Each multi-dose vial contains ten (10) separate 0.5 ml vaccine doses. • Refrigerated vaccine must be used within 30 days. • Vaccine moved from refrigerator storage to a vaccination clinic cannot be placed back in storage. • Once punctured, a vial must be used within 6 hours. • Vials not refrigerated must be used within 12 hours. • After beyond use or expiration date, label "DO NOT USE" and store in a place removed from vaccines in use. Do not discard these vials and await further 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. • After beyond use or expiration date, label "DO NOT USE" and store in a place removed from vaccines in use. Do not discard these vials and await further guidance.

ADMINISTERING THE VACCINE (ADULTS): DOSE, ROUTE, SITE, AND NEEDLE SIZE (PAGE 2 OF2)

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

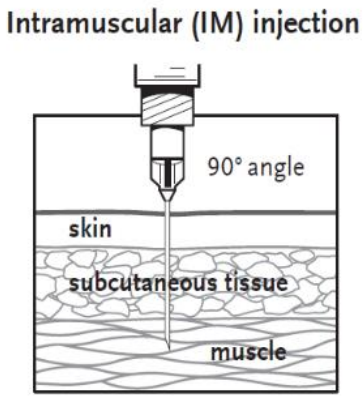
< 130 lbs.	1" length needle
130-152 lbs.	1" length needle
Female 153-200 lbs.	1-1½" length needle
Female 200+ lbs.	1½" length needle
Male 153-260 lbs.	1-1½" length needle
Male 260+ lbs.	1½" length needle

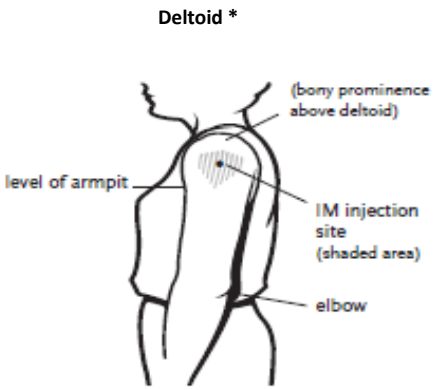
A 5/8" needle may be used for patients who weigh less than 130 lbs (60 kg) for injection in the deltoid muscle, *only* if the skin over the deltoid is stretched taut, and the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

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° 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.





*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 had any other vaccinations in the last 14 days?
☐	☐	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.

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

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

DOCUMENT VACCINE ADMINISTRATION IN BEMR FLOW SHEETS
SCAN VACCINE CONSENT IN BEMR DOCUMENT MANAGER – VACCINATION CONSENT

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.

BP-A1136 **CONSENTIMIENTO PARA LA APLICACIÓN DE LA VACUNA CONTRA LA COVID-19 - RECLUSOS**
FEBRERO DE 2021
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 alguna otra vacuna en los últimos 14 días?
☐	☐	¿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.**

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**

DOCUMENT VACCINE ADMINISTRATION IN BEMR FLOW SHEETS
SCAN VACCINE CONSENT IN BEMR DOCUMENT MANAGER – VACCINATION CONSENT

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
FEB 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.

☐ **I consent to receive the COVID-19 vaccination.**

Dose	Employee Signature	Witness Signature	Date
#1			
#2			

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 had any other vaccinations in the last 14 days?
☐	☐	☐	☐	Have you received monoclonal antibody therapy for COVID-19 in the last 90 days?

☐ **I decline to receive the COVID-19 vaccination.**

☐ I have already been vaccinated by my private provider.

☐ I plan to be vaccinated by my private 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