

BUREAU OF PRISONS
CENTRAL FILL AND DISTRIBUTION PHARMACY
COVID-19 VACCINE MAINTENANCE PHASE
APRIL 2021

1) OBJECTIVE

The Central Fill and Distribution (CFAD) Pharmacy will be utilized as a vaccine redistribution site capable of receiving current allocations of COVID-19 vaccines. The vaccines will be stored onsite and dispersed in smaller quantities to identified institutions within the Bureau of Prisons (BOP). As the BOP transitions to a smaller maintenance based campaign aimed at vaccinating ever smaller groups of patients, it is imperative to utilize a redistribution plan instead of the current hub and spoke model. Packaging requirements and minimum order quantities by the manufacturers are well above the needed number of doses at each institution. By utilizing CFAD as a redistribution site, the BOP will decrease the number of wasted doses while still maintaining vaccination efforts.

2) METHODOLOGY

CFAD has been utilized by the BOP during this pandemic as a redistribution site for COVID rapid tests and PPE. This pharmacy has an extensive background in shipping logistics, as well as a centrally funded FedEx national contract account that can be used for this campaign. CFAD also has a refrigerator, freezer, and ultra-low temperature freezer capable of maintaining vaccine storage requirements set forth by each manufacturer. Shipping materials (tape, cardboard shipping boxes, and FedEx labels) are maintained in stock at this location for the current pandemic shipping mission. Validated parcel boxes and Phase Change Material (PCM) blocks rated for 120 hours at -25°C to -15°C used for shipping frozen medications will need to be procured for this project. The procurement process for this is on-going.

3) VACCINE

There are three COVID-19 vaccines that CFAD will store and redistribute when needed by institutions. They are Pfizer-BioNTech, Moderna, and Johnson & Johnson/Janssen. Below are the shipping requirements for each vaccine.

Pfizer-BioNTech:

Per the Pfizer-BioNTech EUA Fact Sheet (linked below) "... vials may be transported at -25°C to -15°C (-13°F to 5°F). Any hours used for transport at -25°C to -15°C (-13°F to 5°F) count against the 2-week limit for storage at -25°C to -15°C (-13°F to 5°F)".

Pfizer vaccine will be shipped to institutions at -25°C to -15°C via FedEx first overnight delivery in a 16L parcel shipper. This validated shipper will contain a TempTale data logger to ensure proper temperature is maintained throughout service. CFAD will follow all transportation guidelines set forth in the Emergency Use Authorization for the Pfizer vaccine.

<https://www.fda.gov/media/144413/download>

Moderna:

Per the Moderna EUA Fact Sheet (linked below) "If transport at -50° to -15°C (-58° to 5°F) is not feasible, available data support transportation of one or more thawed vials for up to 12 hours at 2° to 8°C". This leads to the conclusion that transport/shipping at temperatures from -25°C to -15°C (-13°F to 5°F) has no negative effect on the vaccine. Of note, these are the same conditions under which the vaccine is shipped initially.

Moderna vaccine will be shipped to institutions at -25°C to -15°C via FedEx first overnight delivery in a 16L parcel shipper. This validated shipper will contain a TempTale data logger to ensure proper temperature is maintained throughout service. CFAD will follow all transportation guidelines set forth in the Emergency Use Authorization for the Moderna vaccine.

<https://www.fda.gov/media/144637/download>

Johnson & Johnson/Janssen:

Given the extended stability of Janssen vaccine compared to the mRNA vaccines and the universal availability of proper 2°C to 8°C cold storage throughout the BOP, Janssen vaccine will typically be shipped directly to BOP sites to be kept on hand. In the rare instances where this isn't feasible, Janssen vaccine will be shipped to institutions at 2°C to 8°C via FedEx first overnight delivery in an insulated foam shipper. This shipper will contain a TempTale data logger to ensure proper temperature is maintained throughout service. CFAD will follow all transportation guidelines set forth in the Emergency Use Authorization for the Janssen vaccine.

<https://www.fda.gov/media/146304/download>

4) ORDERING

Requests for vaccines must be emailed to CFAD resource email address at BOP-HSD-CFADPharmacy-S@bop.gov with quantity and institution specified. To ensure proper cold chain is maintained and allow for unexpected shipping delays, requests will be processed Monday through Wednesday, with requests received on Thursday or Friday processed the following Monday. Requests must be received by 12:00 PM CST in order to ship same day as outlined above. The necessary ancillary kit components in sufficient quantities will be shipped separately along with vaccine shipments. Sites are responsible to request any 2nd doses required pursuant to any micro-distributions. Direct shipments per the previous process will continue to ship 2nd doses automatically. CFAD staff will email shipping info to each site, as well as BOP Chief, Pharmacy Logistics Support for inclusion in BOP decision support dashboards.