COVID-19 Vaccine Provider Checklist

Welcome & Initial Actions
☐ Review the requirements in the CDC COVID-19 Vaccination Program Provider Agreement. This includes all the links in the Agreement
☐ Review and implement all storage and handling recommendations in CDC's Vaccine Storage and Handling Toolkit
☐ Write Standard Operating Procedures (Vaccine Management Plan) for COVID-19 vaccine and ensure staff are trained
☐ Complete on-demand COVID-19 provider training for NJIIS found on the NJIIS New Facility Enrollment page
☐ Participate in COVID-19 provider trainings and site visits as requested/required. Visits might be on-site or virtual
☐ Prepare to submit vaccine administration data into NJIIS ○ Options: NJVSS; HL7 interface with NJIIS; Excel file upload; or direct (manual) data entry ○ The interface enrollment form will need to be submitted for HL7 and Excel interfaces
☐ Enroll in Vaccines.gov (formerly called VaccineFinder) ○ Enrollment email will be sent from vaccinefinder@auth.castlighthealth.com to the email address listed in Organization Information section of the COVID-19 Provider Enrollment form ○ Enrollment link expires 7 days from the day it is sent ○ Once a password is created, you will be prompted to select one of two options for reporting: ○ Option 1: "I will be reporting vaccine inventory on behalf of all locations listed above" – if you select this option, you will be the ONLY person with access and will be solely responsible for reporting all inventory for the site(s) listed ○ Option 2: "Each of the locations listed above will be responsible for reporting their own vaccine inventory" if you select this option, an enrollment email will be sent to both the primary and backup vaccine coordinators listed in the COVID-19 Provider Enrollment form. The initial user, if not listed as one of the vaccine coordinators, will still have access. All 3 users will be able to report vaccine inventory for the site
Storage Unit Requirements
Storage units must be: ○ Pharmaceutical grade or purpose built ○ Household grade refrigerator with separate, stand-alone freezer Do **not** use the freezer section of a combination household unit to store vaccines NEVER use a dormitory-style refrigerator to store vaccines, even temporarily!
Temperature Monitoring – Digital Data Loggers (DDL)
☐ Ensure that DDLs meet CDC specifications. A DDL is required for each permanent and temporary storage unit [i] ☐ DDLs must have current and valid Certificates of Calibration [ii] ☐ Learn how to access and download your DDL data. It must be checked at least weekly and temperature data must be kept for a minimum of 3 years
☐ Place DDLs in each storage unit. Review/download data at least weekly, whenever an alarm sounds, and whenever an out-of-range current or min/max temperature is noted ☐ Ensure alarms are set correctly. DDLs should alarm ***before*** a temperature excursion would occur, so you can correct the issue before the vaccines are exposed to an out-of-range temperature (for example set minimum at 2.5°C and maximum at 7.5°C, so you can take action to keep the refrigerator in 2-8°C range) ☐ Set device to record at least every 30 minutes ☐ Ensure a backup DDL is available
☐ Keep min/max temperature logs up to date and available
☐ Post "Do Not Disconnect" signs on outlets and circuit breakers

Every Vaccination Visit
☐ Screen for vaccine eligibility (for example age, time since last vaccine, etc.)
☐ Provide any COVID-19 specific documents (EUA Fact Sheet for patients [or VIS when available], EUI Fact Sheet if applicable, V-safe enrollment document, etc.)
☐ Chart required vaccination information, including entering in NJIIS within 24 hours of administration

Daily
☐ Log min/max temperatures on paper temperature log or directly into NJIIS [iii] ○ Address all temperature excursions as soon as they are discovered and report to COVID19.Provider@doh.nj.gov [iv] ○ Reset your DDL's min/max temperatures after recording the day's temperatures (note: not all DDLs require a daily reset, check your DDL's specifications)
☐ Report COVID-19 vaccine administrations into NJIIS ○ Be sure all information entered is accurate and complete. This includes all patient demographic information. Collect and enter race/ethnicity information for each patient ○ Complete charting includes the date an EUA/VIS was given to patient, and the date that document was published ○ Ensure "inventory on hand" is decrementing correctly in NJIIS. For decrementing help, submit an NJIIS ticket
☐ Report expired, spoiled, and wasted COVID-19 vaccines into NJIIS

Weekly
☐ Download, review, and save DDL data. If you find any out-of-range temperatures, report to COVID19.Provider@doh.nj.gov immediately
☐ Review inventory in NJIIS, Vaccines.gov, and in your storage units to ensure all doses are accounted for (e.g., administered, wasted, spoiled, expired) and number of doses available is consistent
☐ Check vaccine expiration dates and rotate stock
☐ Update COVID-19 vaccine inventory in Vaccines.gov (formerly called VaccineFinder) by COB Friday

Biweekly
☐ Update NJIIS temperature logs on the 1st and 15th of the month ○ Temperatures can be saved in draft prior to the 1st and 15th

As Needed
☐ Once ordering module is available in NJIIS, if additional vaccine is needed, place order in NJIIS
☐ As soon as vaccine shipment is received, verify that quantity and lot number on order form match what you received
☐ Claim all vaccine shipments in NJIIS as soon as shipments arrive (before doses are administered)
☐ If vaccine is being redistributed to another facility, notify NJIIS **BEFORE** vaccine is moved and administered ○ Email: COVID19.Provider@doh.nj.gov ○ A signed redistribution agreement must be on file for the originating facility before redistributing ○ You must have a qualified container and packout for transfers; transporting vaccines in a cooler is unacceptable
☐ Immediately address and report all temperature excursions
☐ Review storage units and Points of Contact listed on your COVID-19 Provider Enrollment form. See below for information on how to make changes [v]
☐ If an Adverse Event occurs, submit a VAERS report ○ Healthcare providers are required to report: ▪ Vaccine administration errors (whether associated with an adverse event or not) ▪ Serious adverse events (irrespective of attribution to vaccination) ▪ Multisystem inflammatory syndrome in children (if vaccine is authorized in children) or adults ▪ Cases of COVID-19 that result in hospitalization or death after the recipient has received COVID-19 vaccine ○ Healthcare providers are encouraged to report any clinically significant adverse events that occur after vaccination

Appendix

[i] **DDL requirements as outlined in CDC Storage and Handling Toolkit:**

- Detachable probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol, glass beads, sand, or Teflon)
- Air probes are only permitted for ultra-low freezers, otherwise, probes should be buffered.
- Alarm for out-of-range temperatures
- Low battery indicator
- Current, minimum, and maximum temperature display outside of storage unit
- Recommended uncertainty of +/-0.5° C (+/-1° F)
- Memory for storing at least 4,000 readings
- Logging interval (or reading rate) that can be programmed by the user to measure and record temperatures at least every 30 minutes

DDL(s) must have at least enough probes to cover the total storage unit compartments at your site.
At minimum, your site must have at least 1 back-up DDL, which is self-sustaining and portable for transport and offsite clinic use.

[ii] **Certificate of Calibration requirements as outlined in the CDC Storage and Handling Toolkit:**

- Model/device name or number
- Serial number
- Date of calibration (report or issue date)
- Expiration date/Recalibration date
- Confirmation that the instrument passed testing
- Documented accuracy of +/-0.5°C (+/-1°F)
- Must be issued by an appropriate entity, which is indicated by one or more of the following:
    - Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 Tolerance Class F (<+/-0.5°C or <+/-1°F)
    - Performed by a laboratory accredited by International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body
    - Traceable to the standards maintained by the National Institute of Standards and Technology (NIST)

[iii] You have the option to enter minimum and maximum temperatures daily on paper logs and then transfer that data into NJIIS every 2 weeks on the 1st and 15th of the month OR enter minimum and maximum temperatures into NJIIS on a daily basis and not keep paper logs. If you use paper logs, they must be retained as temperature data as well.

[iv] All temperature excursions identified during shipping must be reported to Pfizer and McKesson the same day as delivery. In addition, please report the incident to COVID19.provider@doh.nj.gov
For Janssen or Moderna vaccines:
Phone: (833) 343-2708 Monday – Friday, 8 a.m. - 8 p.m. ET
Email: COVIDVaccineSupport@McKesson.com (only send email if after hours)
For Pfizer vaccine:
Phone: (800) 666-7248 (option 8)
Email: CVGovernment@pfizer.com

[v] To make changes to site information (Vaccine Coordinators, CEO, CMO, etc.), please submit an electronic IMM-48 form by logging into NJIIS, click on COVID from the left navigation bar, and then click on "COVID-19 IMM 48".
To update storage units, please email COVID19.Provider@doh.nj.gov with the brand, model number, and type of unit (ultra-cold freezer, freezer, or refrigerator) for approval prior to adding the new unit to NJIIS.

Additional Resources:

CDC Storage and Handling Toolkit: https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
Vaccine Information by Product: https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html
Interim Clinical Considerations: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html