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New York State Department of Health (NYSDOH) COVID-19 Policy for Predrawn Vaccine

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Background

Although standards for vaccine administration typically do not include predrawing (also known as “prefilling”) of syringes due to concerns over compromising or wasting vaccine, the Centers for Disease Control and Prevention (CDC) has permitted predrawing for COVID-19 vaccines, subject to certain qualifications. Specifically, the CDC recommends transporting COVID-19 vaccines in vials but notes that if there are instances when the only option is to transport vaccine in a predrawn syringe, providers should follow [U.S. Pharmacopeia \(USP\) guidance](#) for vaccine preparation and transport.

Healthcare entities that have determined that it is appropriate to use predrawn syringes should develop policies and protocols to avoid compromising and wasting vaccine and to maintain the cold chain, consistent with the recommendations detailed herein.

This document applies only to providers vaccinating homebound individuals, and vaccination for individuals in nursing homes and adult care facilities.

Policy & Protocol Development

If a healthcare entity determines that use of predrawn syringes is necessary and appropriate, its policies for predrawn syringes for COVID-19 vaccines should:

- Explain the need for predrawn syringes.
- Detail the settings and circumstances in which predrawn syringes will be used, including how often, when, and for how long. Parties must ensure that predrawn syringes are only used as a last resort when the only option is to transport vaccine in predrawn syringes.
- Align with the most recent NYSDOH [Distribution of the Vaccine](#), applicable Executive Orders, and FDA Emergency Use Authorizations for COVID-19 vaccines.
- Follow guidance outlined in [CDC’s Vaccine Storage and Handling Toolkit](#) and the [USP COVID-19 Vaccine Handling Toolkit: Operational Considerations for Healthcare Practitioners](#)

Key recommendations for entities’ policies and procedures include, but are not limited to:

- Store predrawn syringes at the manufacturer-recommended temperatures throughout the day.
- Dedicate an area or room for vaccine preparation.
 - Set up separate administration and vaccine preparation stations and clearly label predrawn syringes for each vaccine type to prevent medication errors.

- Draw up only those doses that can be administered before their beyond-use time as outlined by the manufacturer. As of April 2021, manufacturers specify:
 - Administration of Pfizer vaccine within six (6) hours of dilution.
 - Administration of Moderna vaccine within 12 hours of initial vial puncture.
 - Administration of Janssen vaccine within two (2) hours of initial vial puncture if vaccine is stored at room temperature OR within six (6) hours of initial vial puncture if vaccine is refrigerated at all times other than while preparing, drawing up and administering the vaccine.
- Use aseptic technique during vaccine preparation to ensure the quality and safety of the vaccine products.
- Follow manufacturer instructions for vaccine preparation.
- Label predrawn syringes prepared for administration with legible, identifying information to prevent errors during storage, dispensing, transport and administration.
- If the vaccines are sent outside the facility in which they were prepared for administration, designate a person to ensure that the site where the vaccines will be administered has the phone number and can reach for the facility that prepared the vaccine syringes.
- Carefully consider the number of predrawn syringes needed to avoid drawing up unnecessary doses.
- Use predrawn syringes with earliest beyond-use time first to avoid waste.
- Discard any remaining vaccine in predrawn syringes at the end of the workday. Never transfer predrawn, reconstituted vaccine back into a vial for storage.
 - All discarded doses must continue to be reported to the Department of Health.
 - Providers must have a standby eligible list to ensure doses are not wasted, consistent with DOH guidance.

A healthcare entity that elects to establish a predrawn syringe policy is responsible for ensuring that such policies and protocols follow all applicable state and federal laws and guidance and established best practices, including but not limited to recommendations in the CDC's *Vaccine Storage and Handling Toolkit* and the *USP COVID-19 Vaccine Handling Toolkit: Operational Considerations for Healthcare Practitioners*.

Maintenance of Policies and Protocols

All healthcare entities that are licensed by NYSDOH and that elect to establish and implement a pre-drawn syringe policy, including but not limited to hospitals, nursing homes, licensed and certified home health care agencies, and hospice agencies, shall maintain a written record of such policies and procedures, and a written record of any material changes thereto, and make such written record available at the request of the NYSDOH, including at time of inspection.

Additional Guidance

As a reminder, all healthcare entities that elect to establish predrawn syringe policies and protocols should also refer and adhere to all other applicable New York State and federal vaccine guidance, including but not limited to the NYSDOH [COVID-19 Vaccine Information for Providers](#).