



# COVID-19 VACCINATION PLANNING COMMITTEE

November 4, 2020

NORTH  
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This is an **emerging, rapidly evolving situation**. Information in this presentation is current as of November 3, 2020. Please check the NDDoH Novel Coronavirus website for the most current information and guidance.

[www.health.nd.gov/coronavirus](http://www.health.nd.gov/coronavirus)

# CDC INTERIM PLAYBOOK

- Last week CDC updated the interim playbook:  
[https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim\\_Playbook.pdf](https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf).
- Most changes applicable at jurisdictional level.
- Changes you may be interested in:
  - Data loggers
  - V-safe safety monitoring
  - Inventory reporting to [vaccinefinder.org](https://vaccinefinder.org)
    - You will be auto-enrolled by CDC.

# ANCILLARY KITS

- For centrally distributed vaccines, each kit will contain supplies to administer 100 doses of vaccine, including:
  - Needles, 105 per kit (various sizes for the population served by the ordering vaccination provider) o 25-gauge, 1” (if vaccination indicated for pediatric population)
    - 22–25-gauge, 1-1.5” (adult)
  - Syringes, 105 per kit (ranging from 1–3 mL)
  - Alcohol prep pads, 210 per kit
  - 4 surgical masks and 2 face shields for vaccinators per kit
  - COVID-19 vaccination record cards for vaccine recipients, 100 per kit

# ANCILLARY KITS

- Vaccine needle guide detailing the appropriate length/gauge for injections based on route, age (for children), gender, and weight (for adults)
- If a COVID-19 vaccine that requires mixing with diluent is ordered and shipped from CDC's centralized distributor, a mixing kit that includes the necessary needles, syringes, and alcohol prep pads will also be automatically added to the order. For centrally distributed vaccines, providers will have the option to submit the order in a way that opts out of receiving the administration and mixing kits.

# ANCILLARY KITS

- For vaccines that are shipped directly from the manufacturer (vaccine A), a combined kit will be included.
  - This combined kit will include administration supplies (as noted above), mixing supplies, and vials of diluent to prepare the vaccine for use.
  - Because it contains diluent, providers will not have the option to opt out of requesting this combined ancillary kit.

# ANCILLARY KITS

- Ancillary supply kits will not include sharps containers, gloves, and bandages.
  - Gloves and vaccination?
- Additional personal protective equipment (PPE) may be needed depending on vaccination provider site needs.

# VACCINE PLANNING SCENARIOS

## ■ Vaccine A (Pfizer)

Vaccine A	
<p><b>SHIPMENT</b></p> <p><i>3 separately acquired components (mixed on site)</i></p> <ol style="list-style-type: none"> <li>Vaccine           <ul style="list-style-type: none"> <li>2 mL multidose vials (5 doses/vial)</li> <li>Direct to site from manufacturer (on dry ice) in thermal shipping container</li> <li>Thermal shipper estimated specs: 400 mm X 400 mm X 560 mm (15.75" X 15.75" X 22.0")</li> <li>Each shipper can hold up to 5 trays, and each tray will hold up to 195 vials.</li> <li>Tray (i.e., "pizza box") estimated specs: 229 mm X 229 mm X 40 mm (9" X 9" X 1.6")</li> </ul> </li> <li>Diluent and ancillary supply kits (for administration and mixing)           <ul style="list-style-type: none"> <li>Direct to site from the federal government (at room temperature)</li> </ul> </li> <li>Thermal shipper should be returned after use. Instructions for mail-back and labels will be forthcoming.</li> </ol>	<p><b>ON-SITE VACCINE STORAGE</b></p> <p><i>Ultra-Cold Temp Frozen (-60°C to -80°C)</i></p> <ul style="list-style-type: none"> <li>Freezer units capable of ultra-cold temperatures (UCTs)</li> <li>The shipping container (thermal shipper) may be used to store vaccines:           <ul style="list-style-type: none"> <li>Once received (day 1), the thermal shipper should be replenished with pelleted dry ice within 24 hours.</li> <li>Shippers should be replenished with dry ice every 5 days thereafter to maintain required temperature.</li> <li>Total amount of dry ice needed per thermal shipper "recharge" is ~23 kg.</li> <li>On day 15, transfer the vaccine to refrigerated temperatures (2°C to 8°C). Use within 5 days (120 hours).</li> <li>Shippers may only be opened two times a day.</li> </ul> </li> <li>Temperature monitoring must be in alignment with CDC guidance, irrespective of re-icing.           <ul style="list-style-type: none"> <li>Thermal shipper may be monitored using a temperature probe on the container, in alignment with guidance provided by CDC and information provided by the manufacturer.</li> <li>Direct handling of dry ice needed for re-icing the containers will require the use of <a href="#">appropriate PPE</a>.</li> </ul> </li> </ul> <p><i>Thawed but NOT diluted (2°C to 8°C)</i></p> <ul style="list-style-type: none"> <li>Product may be removed from the ultra-cold storage or thermal shipper, thawed, and stored at 2°C to 8°C for up to 5 days (discard unused doses after 5 days).</li> <li>Cannot return to ultra-cold storage or thermal shipper once thawed</li> </ul>



# VACCINE PLANNING SCENARIOS

## ■ Vaccine A

### *Diluted (room temperature)*

- If removed directly from ultra-cold storage, vaccine must be thawed ~30 minutes at room temperature before dilution.
- Once vaccine is thawed, it must be diluted within 2 hours. If unable to dilute within 2 hours, store at 2°C–8°C.
- Must use diluted vaccine within 6 hours (discard any unused diluted vaccine after 6 hours)

### ORDERS

*Large quantities, to large provider sites only*

Minimum order: ~1,000 doses

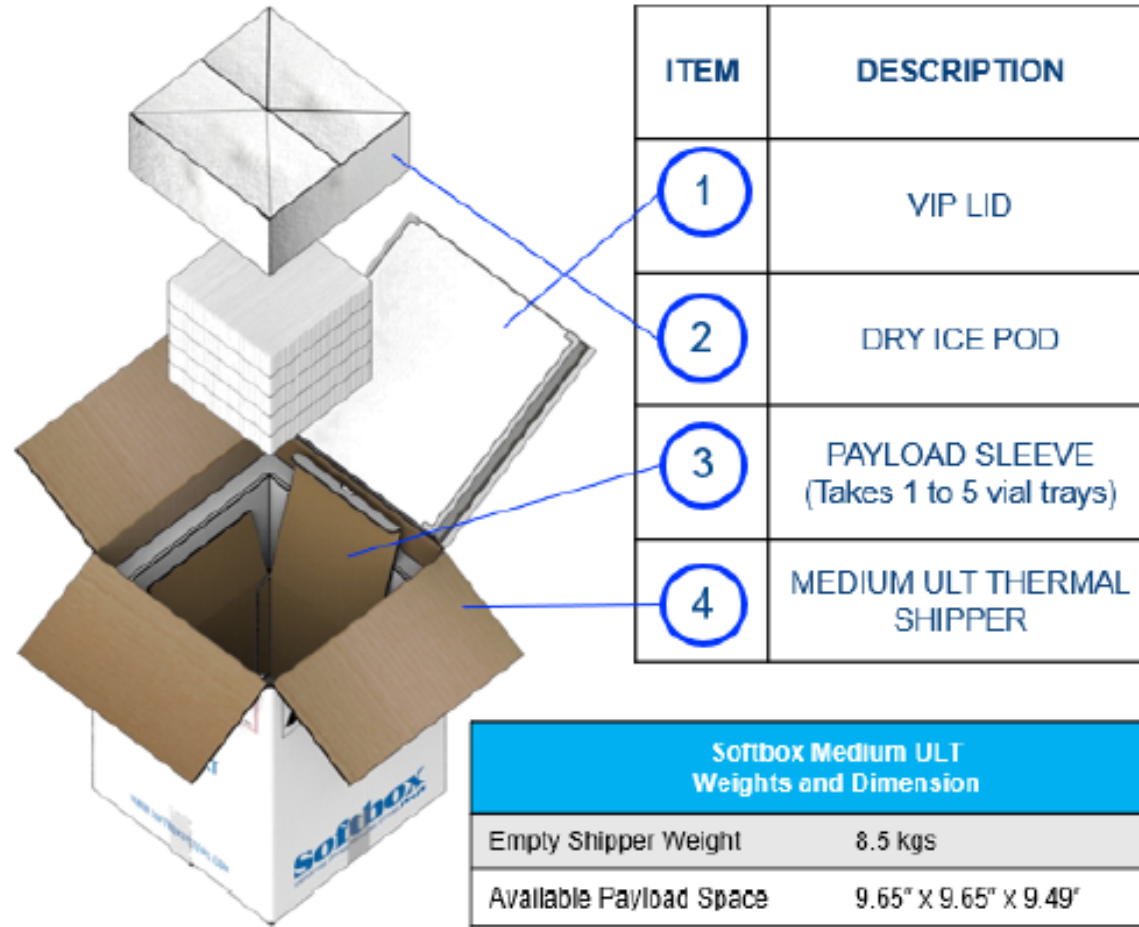
Maximum order: ~5,000 doses

### ADMINISTRATION

*2-dose series (21 days between doses)*

- On-site mixing required; dilute with diluent just prior to administration; all 5 doses must be administered within 6 hours of dilution; remainder of diluted vaccine should be discarded.
- Administer by IM injection.

## Unpackaging and Re-Icing Instructions of the Softbox Medium ULT Parcel Shipper



ITEM	DESCRIPTION
1	VIP LID
2	DRY ICE POD
3	PAYLOAD SLEEVE (Takes 1 to 5 vial trays)
4	MEDIUM ULT THERMAL SHIPPER

Weight of Vial Tray 1.038 kgs

Softbox Medium ULT Weights and Dimension	
Empty Shipper Weight	8.5 kgs
Available Payload Space	9.65" x 9.65" x 9.49"
External Dimension	15.75" x 15.75" x 22.04"
Amount of Dry Ice	23 kgs
Tare Weight w/ Dry Ice	31.5 kgs
Total Weight w/ 1 Vial Tray	32.6 kgs
Total Weight w/ 5 Vial Trays	36.7 kgs

# VACCINE PLANNING SCENARIOS

## ■ Vaccine B

### SHIPMENT

#### *2 separately shipped components*

##### Vaccine

- To central distributor (at -20°C)
- Multidose vials (10 doses/vial)

##### Ancillary supply kits

- Direct to site from USG (at room temperature)

### ON-SITE VACCINE STORAGE

#### *Frozen (-25°C to 15°C until ready for use)*

Note: This is a narrower range than for varicella-containing vaccines.

#### *Refrigerated (2°C to 8°C)*

- Must use within 7 days if the vial has not been entered.
- Thaw before use:
  - Thaw in refrigerated conditions between 2°C to 8°C for 2 hours. Let vial stand at room temperature for 15 minutes before administering.
  - Alternatively, thaw at room temperature between 20°C to 25°C for 1 hour.
  - After thawing, do not return vial to the freezer.

#### *Room temperature*

- The total time before administration and after removal from the refrigerator should be no more than 12 hours.
- Once the vial has been entered, it must be used within 6 hours (discard any unused vaccine after 6 hours).

# VACCINE PLANNING SCENARIOS

## ■ Vaccine B

### ORDERS

#### *Central distribution capacity*

- Required by Dec 2020
- Maintained at -20°C

### ADMINISTRATION

#### *2-dose series (1 month between doses)*

- No on-site mixing required
- Once thawed, swirl vaccine gently prior to withdrawing a dose. Do NOT shake.
- Administer by intramuscular (IM) injection



# OCTOBER ACIP MEETING

- AstraZeneca : AZD1222 vaccine announced removal of FDA hold 10/23, resuming Phase III trials
- Janssen: Ad26.COVS vaccine announced lifting of safety pause 10/23, resuming Phase III trials
- Pfizer/BioNtech: BNT162b2 vaccine
  - 42,133 participants enrolled as of 10/26/2020
  - 35,771 participants have received their second vaccination
  - 30% of U.S. participants enrolled have “diverse backgrounds”
- Moderna: mRNA-1273 vaccine:
  - Enrollment Complete
  - 30,000 participants enrolled as of 10/22/2020
  - 25,654 participants have received their second vaccination

# OCTOBER ACIP MEETING

- VRBPAC Update:
  - Efficacy data showing protection against SARS-CoV-2 infection or disease with a point estimate of least 50% vs. placebo comparator and an appropriately alpha-adjusted confidence interval lower bound >30%
  - At least 50% of Phase 3 study subjects followed for both safety and efficacy for at least 2 months following completion of the full vaccination regimen
  - Safety data from throughout clinical development (including well over 3,000 Phase 3 vaccine recipients) to evaluate reactogenicity, serious AEs, and AEs of special interest
  - Sufficient cases of severe COVID-19 to assess for signals of enhanced disease

# OCTOBER ACIP MEETING

- Modeling strategies for the initial allocation of COVID-19 vaccine
  - This group analyzed what the potential impact of prioritizing the COVID-19 vaccine to adults over 65, people with underlying health conditions, and/or essential workers would look like.
- Initially vaccinating high-risk adults or essential workers in phase 1B averts approximately 1-5% more **infections** compared to targeting age 65+.
- Initially vaccinating age 65+ in Phase 1B averts approximately 1-4% more **deaths** compared to targeting high risk adults or essential workers.

# ND PROVIDER ENROLLMENT

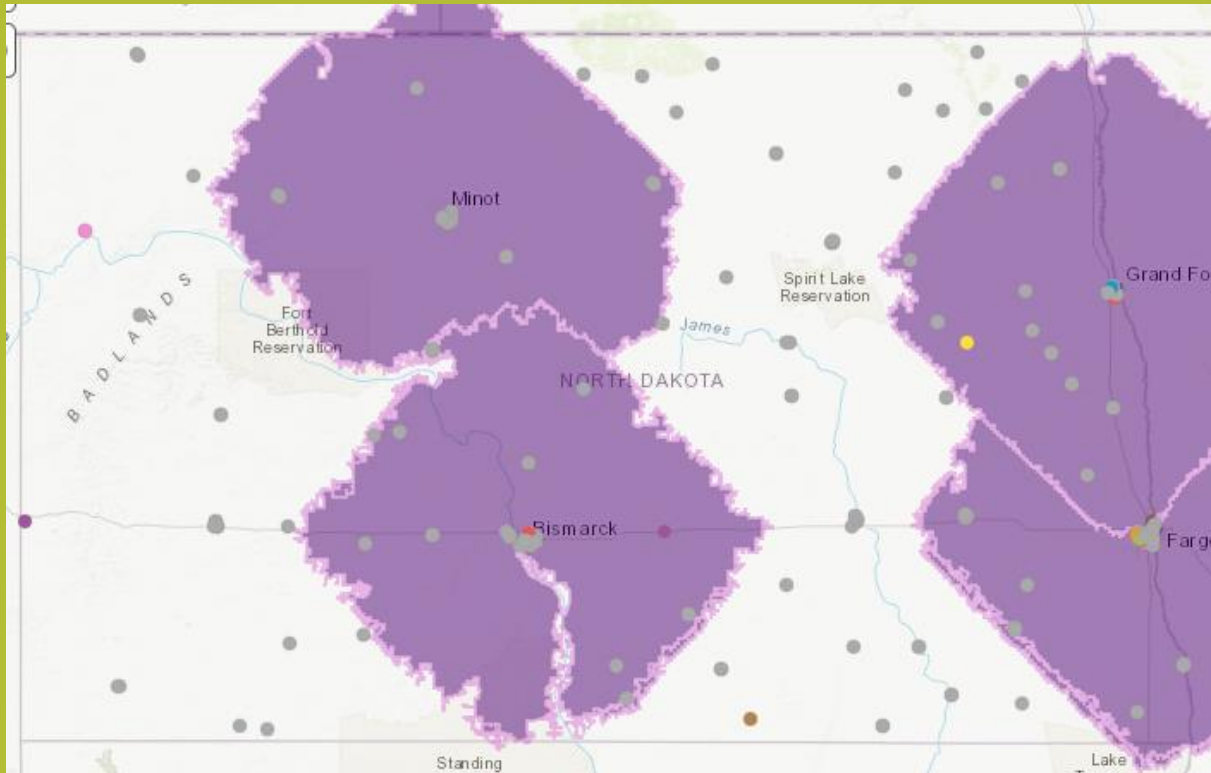
- 397 provider sites enrolled
- Currently reviewing data, validating credentials, ensuring NDIIS access.
- Missing eight critical access hospitals
- Missing a couple local public health departments



# TRIBES

- All ND Tribes have officially expressed a preference to receive vaccine from federal government or state.
- Spirit Lake and MHA Nations expressed a preference for state allocation.
- Sisseton, Turtle Mountain and Standing Rock expressed a preference for federal allocation.

# LTC AND PHARMACY PARTNERSHIP



- LTCs have until November 6<sup>th</sup> to sign up or decline federal pharmacy partnership program.
  - 67 ND LTCs outside of 75-mile radius of a CVS.
- So far, 35 LTCs in North Dakota have signed up to be vaccinated by CVS.

# HHS AUTHORIZATION – PHARM TECHS

- Pharmacists, pharmacy interns and pharmacy techs may vaccinate for COVID-19 vaccine to persons 3 and older and ACIP vaccines for persons 3 – 18.
- Supersedes state law
- Requires immunization training and CPR certification

# VACCINE ADMINISTRATION FEE

- CMS vaccine administration fee guidance released.
  - <https://www.cms.gov/covidvax>
- The Medicare payment rates will be **\$28.39** to administer single-dose vaccines.
- For a COVID-19 vaccine requiring a series of two or more doses, the initial dose(s) administration payment rate will be **\$16.94**, and **\$28.39** for the administration of the final dose in the series.



# PREPMOD

- Abbi

# TIMING OF VACCINE

- Last week, states were notified by CDC to be ready for COVID-19 vaccine by November 15<sup>th</sup>.
  - This does NOT mean that COVID-19 will be available on November 15<sup>th</sup>.
- Are YOU ready if vaccine is available on November 15<sup>th</sup>?
- Holding second doses
- Pre-positioning of vaccine...

# ND ADVISORY COMMITTEE ON COVID-19 VACCINE ETHICS

- Issue 1: Provide vaccine to referral hospitals first
  - Additional information needed. Will discuss next week.
- Issue 2: Method for allocation of vaccine to HCW in hospital
  - Two primary methods of allocation within hospitals have been proposed.
    - The first is to vaccinate critical health care workers (HCW) first that are the most difficult to replace and have high exposure (e.g., ER, ICU).
    - The second is to vaccinate all patient care providers with risk factors for adverse outcomes first.
- Recommendation
  - Hospital decision but strict guidelines
  - Either priority infrastructure method or increased risk method is a valid method.
  - Vaccination must be limited to direct patient care providers.

# HEALTH CARE WORKER PRIORITIES?

- Phase 1A: Paid and unpaid people serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials and are unable to work from home.
- ND HCW estimates: 68,864
  - Referral hospitals: 22,300
- ND initial allocation (planning)
  - 23,157 to 46,313 (if 10-20 million for U.S.)

# THROUGHPUT/CAPACITY?

- Can you administer 975 doses within 5 days?
- How many doses can you administer within 5 days?
- If 10 minutes per dose, how many nurses/days will you need to vaccinate your HCWs?

# HEALTHCARE PROVIDER/STAFF EDUCATION/COMMUNICATIONS?

- What additional materials/webinars do you need to educate your staff?



- Future meetings?



# NORTH DAKOTA IMMUNIZATION DIVISION

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Vacant CDC Public Health Advisor	Phone: Email:	The logo for North Dakota Health features the words "NORTH" and "Dakota" in a red, sans-serif font, with "Dakota" being larger and more prominent. To the right of "Dakota" is a vertical line, followed by the word "Health" in a smaller, black, sans-serif font. Below the "Dakota" text is the tagline "Be Legendary." in a small, black, sans-serif font.	



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