COVID VACCINE INFORMATION FOR PHARMACIES

October 22nd, 2020

PHARMACIST IMPACT

More than 25% of annual influenza vaccinations are administered within pharmacies

More than 50% of shingles vaccines are administered by pharmacists.

## Coronavirus Vaccine Tracker

By Jonathan Corum, Suí-Lee Wee and Carl Zimmer  Updated October 3, 2020

Current as of:  
October 7th, 2020


<table>
<thead>
<tr>
<th>Technology platform</th>
<th>U.S. government funding or advance commitment</th>
<th>Number of contracted or optioned doses</th>
<th>Dosage</th>
<th>Current Clinical Trial Phase</th>
<th>Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>AstraZeneca</td>
<td>nonreplicating adenovirus vector $1.2 Billion</td>
<td>300 million</td>
<td>Two shots</td>
<td>Phase 3 (8/31)</td>
<td>Refrigerated</td>
</tr>
<tr>
<td>Johnson &amp; Johnson</td>
<td>nonreplicating adenovirus vector $456 million in early R&amp;D funding, additional $1 billion for doses if approved</td>
<td>100 million, option for 200 million more</td>
<td>Testing one and two shot regimens</td>
<td>Phase 3 (9/23)</td>
<td>Refrigerated</td>
</tr>
<tr>
<td>Moderna</td>
<td>mRNA $955M in R&amp;D funding, up to $1.525 billion for delivery</td>
<td>100 million, option for 400 million more</td>
<td>Two shots</td>
<td>Phase 3 (9/27)</td>
<td>Ultra-cold</td>
</tr>
<tr>
<td>Novavax</td>
<td>adjuvanted recombinant protein subunit $1.6 Billion</td>
<td>100 million</td>
<td>Two shots</td>
<td>Phase 3 (9/24)</td>
<td>Refrigerated</td>
</tr>
<tr>
<td>Pfizer/BioNTech</td>
<td>mRNA $1.95 Billion if vaccine is approved</td>
<td>100 million, option for 300 million more</td>
<td>Two shots</td>
<td>Phase 2/3 (9/27)</td>
<td>Ultra-cold</td>
</tr>
<tr>
<td>Sanofi/GSK</td>
<td>adjuvanted recombinant protein subunit $1.1 Billion</td>
<td>100 million, option for 500 million more</td>
<td>Two shots</td>
<td>Phase 1½ (9/13)</td>
<td>Refrigerated</td>
</tr>
<tr>
<td>Merck/IAVI</td>
<td>recombinant vesicular stomatitis virus $138 Million</td>
<td>Unable to find information</td>
<td>Unknown</td>
<td>Trials have not begun</td>
<td>Likely Ultra-cold (Same tech as Ebola Vaccine)</td>
</tr>
</tbody>
</table>

POTENTIAL LOGISTICS CHALLENGES

- Limited vaccine availability initially
- Most vaccines require 2 doses, separated by 21 or 28 days.
- Vaccine products will NOT be interchangeable
  - Schedule follow up appointments
  - Provide vaccine record cards
  - Educate patients about VaxView
- Vaccine storage temperatures
- Reporting requirements

The COVID-19 Vaccination Program will require a phased approach

*Planning should consider that there may be initial age restrictions for vaccine products.
**See Section 4: Critical Populations for information on Phase 1 subset and other critical population groups.
Looking Up Immunization History

VaxViewNM.org
Allows patients, parents, and guardians to look up their vaccine records
Easy to use
Requires access to a computer or smartphone
Flyers available at: https://www.nmhealth.org/publication/view/marketing/5214/

Looking Up Immunization History
Consider registering all pharmacists and/or pharmacy technicians as NMSIIIS users so that they may utilize immunization history functions.
Chains may give read-only access
Do I need to prepare for Ultra-Cold Chain Vaccines?

- If multiple vaccines are available, retail pharmacies will receive only vaccines with conventional storage requirements.
- Hospital pharmacies are more likely to receive ultra-cold vaccine.
- The CDC is preparing logistics strategies in the case that there is only an ultra-cold chain vaccine approved.

Scenarios the CDC has Presented as Planning Exercises

Availability Assumptions

<table>
<thead>
<tr>
<th>Vaccine availability under EUA by</th>
<th>Candidate</th>
<th>End of Oct 2020</th>
<th>End of Nov 2020</th>
<th>End of Dec 2020</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer</td>
<td><em>UAE doses</em></td>
<td><em>UAE doses</em></td>
<td><em>UAE doses</em></td>
<td>Central distribution capacity required 12-8°C</td>
<td></td>
</tr>
</tbody>
</table>

Distribution, Storage, Handling, and Administration Assumptions

SECURITY PROTOCOLS

- Policy to distribute to eligible locations
- Distribution of vaccine to eligible locations
- Distribution and storage of vaccine to eligible locations

DOSE LIMITS

- Per dose limits
- Per container limits
- Per shipment limits

ADMINISTRATION

- On-site administration
- Off-site administration
- Refrigerated administration
- Frozen administration

Vaccine A Storage Assumptions

Vaccine A Stability:
Ultra-Low Temperature (ULT) Storage: 6 Months
Thawed but not reconstituted (2-8°C): 5 Days
Reconstituted (Room Temperature): 6 Hours

Diluent Stability:
Stable at room temperature

Other considerations:
- Vaccine A will be provided in multidose vials
- Vaccine A must be thawed (30 minutes prior to use)
- Vaccine A must be mixed with diluent
- 2nd dose at 21 days

ULT SHIPPING CONTAINERS

- Will hold 1000 doses of vaccine
- May be opened a maximum of 2x per day
- Require replenishment with dry ice pellets in 24 hours of receipt and again in 5 days
- May be replenished with 23 kg (50.6 lb) of dry ice to extend shelf life
- Re-usable
  - Return is required within 10-13 days.
- Shipping container dimensions 2’x2’x1.5’
- Shipping container weight 70-90lbs.

Training Considerations:

- Dry ice handling and PPE requirements
- Monitoring of temperature probes
- Procedure for ensuring container is not opened more than 2x/day
- Return procedures for shipping containers
Storage Considerations:

- If dry ice is held in a small enclosed environment open the door for a few minutes prior to walking in.
- If transporting dry ice, make sure vehicle windows are cracked open to ensure ventilation.

Do I need to prepare for Ultra-Cold Chain Vaccines?

- All pharmacies should stay up to date on information from the CDC and HHS regarding potential ultra-cold chain storage requirements.
- Pharmacies should plan for ultra-cold chain logistics even if it is unlikely their location will receive ultra-cold chain vaccine.
SUPPLY CONSIDERATIONS FOR ULT VACCINE

DRY ICE PELLETS
PLASTIC ICE SCOOP

Insulated Gloves
Safety Glasses

ULTRA LOW TEMPERATURE DATA LOGGER WITH AUDIBLE ALARM
Do I need to prepare for Ultra-Cold Chain Vaccines?

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COVID-19 Vaccine Provider Enrollment

Mandatory enrollment forms are being piloted. Stay tuned...
- Enroll in the federal COVID-19 Vaccination Program through the New Mexico Immunization Program
- Sign and agree to the conditions in the CDC COVID-19 Vaccination Program Provider Agreement.

Steps to Take Immediately
- If you are not enrolled in NMSIIS, enroll now. Contact the NMSIIS help desk today.
- If you are enrolled but not a data exchange provider, contact NMSIIS help desk today.

Immunization & NMSIIS Help Desk
1-833-882-6454
NMSIIS DATA EXCHANGE INFORMATION

NMSIIS Data Exchange Locations:
https://www.nmhealth.org/publication/view/general/5490/

How to Become a Data Exchange Provider:
Contact the NMSIIS Help Desk and ask to become a Data Exchange Provider

Immunization & NMSIIS Help Desk
1-833-882-6454

FEDERAL COVID-19 VACCINE PROVIDER REQUIREMENTS

- Administer COVID-19 vaccine in accordance with ACIP recommendations.
- Within 24 hours of administering a dose of COVID-19 vaccine and adjuvant (if applicable), record in the vaccine recipient's record and report required information to the relevant state, local, or territorial public health authority.
- Not sell or seek reimbursement for COVID-19 Vaccine and any adjuvant, syringes, needles, or other constituent products and ancillary supplies provided by the federal government.
- Administer COVID-19 vaccine regardless of the vaccine recipient's ability to pay.
- Provide an Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as applicable, to each vaccine recipient/parent/legal representative prior to vaccination.
- Comply with CDC requirements for vaccine management, including storage and handling, temperature monitoring at all times, complying with jurisdiction's instructions for dealing with temperature excursions, and monitoring expiration dates.
FEDERAL COVID-19 VACCINE PROVIDER REQUIREMENTS

- Report COVID-19 vaccines and adjuvants that were unused, spoiled, expired, or wasted as required by the jurisdiction's immunization program.
- Comply with federal instruction regarding disposal of unused COVID-19 vaccine and adjuvant.
- Report adverse events to the Vaccine Adverse Event Reporting System (VAERS).
- Provide a completed COVID-19 vaccination record card to every vaccine recipient/parent/legal representative.
- Comply with the U.S. Food and Drug Administration’s requirements, including EUA-related requirements, if applicable. Providers must also administer COVID-19 vaccine in compliance with all applicable state and territorial vaccine laws.

Allocation

The federal government will determine the amount of COVID-19 vaccine designated for each jurisdiction.

New Mexico Immunization program will be responsible for managing and approving orders from enrolled providers within the state.

*Placing should consider that there may be initial age restrictions for vaccine products.
**See Section 4: Critical Populations for information on Phase 1 subset and other critical population groups.
Two Supply Routes

FEDERAL GOVERNMENT
- IHS
  - Tribal governments have option of obtaining through IHS or the state
- VA
- 16 PARTNER PHARMACIES
  - 85% of pharmacies in the US
  - Retail chains with 200+ stores
  - 3 largest independent pharmacy networks
  - Federal government will be releasing partner names upon finalization of contracts

STATE GOVERNMENT
- All facilities not supplied directly by the federal government

Vaccine Ordering & Inventory Tracking

Minimum order size: 100 doses per order
- Some ultra-cold vaccine (if authorized for use or approved) may be shipped directly from the manufacturer in larger quantities (minimum of 1000 doses).

Federal Government Supply Chain
- Vaccine allocation and centralized distribution will utilize HHS’s Vaccine Tracking System (VTrckS)
- [https://www.cdc.gov/vaccines/programs/vtrcks/index.html](https://www.cdc.gov/vaccines/programs/vtrcks/index.html)
- IHS, private partners, and VA will receive training.

State Government Supply Chain
- Ordering will occur through NMSIIS.
Ancillary Supply Kits

Will come automatically with vaccine order. 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)
- Syringes, 105 per kit
- 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
- For COVID-19 vaccines that require reconstitution with diluent or mixing with adjuvant at the point of administration, mixing kits with syringes, needles, and other needed supplies will also be included.

Do NOT include:
- Sharps containers, gloves, bandages or other PPE.

COVID-19 VACCINES & ANCILLARY SUPPLY KITS

WILL BE SUPPLIED AT NO COST TO PROVIDERS
Ordering & Distribution

Turn-Around Time

COVID-19 vaccine will be shipped direct to vaccination provider sites within 48 hours of order approval.

Ancillary supply kits (and diluent, if applicable) will ship separately from vaccine but should arrive before or on the same day as vaccine.

Some vaccine may be distributed to health department for further distribution to administration sites.
Inventory Tracking

- Inventory reporting will be required
  - Inventory frequency in unknown at this time
  - At a minimum inventory reporting will be with each vaccine order
  - Federal partners may have daily reporting requirements
- CDC is still releasing inventory reporting requirements

Vaccine Billing

- CDC will allow administration fees to be billed to insurances.
  - Vaccine providers MUST administer COVID-19 vaccine regardless of the vaccine recipient's ability to pay.
- CDC will share more information about reimbursement claims for administration fees as it becomes available.
POSSIBLE REIMBURSEMENT FOR VACCINES ADMINISTERED TO THE UNINSURED

Vaccine Administration Reporting

- Facilities **WITH** data exchange on NMSIIS can report administration in their EHR **alone**.
- Facilities **WITHOUT** data exchange on NMSIIS must report administration on their EHR and on NMSIIS.

State law requires **ALL** providers to report vaccine administration in NMSIIS regardless of their supply chain.

Reporting will be required by the CDC **WITHIN 24 HOURS** of administration.

CARES Act Provider Relief Fund

The Provider Relief Funds supports American families, workers, and the heroic healthcare providers in the battle against the COVID-19 outbreak. HHS is distributing $175 billion to hospitals and healthcare providers on the front lines of the coronavirus response.
When does Pharmacy Come In?

During Phase 1, administration sites may be more limited to settings that can optimize reaching the target population while meeting the early requirements for storage and handling of vaccine product.

During Phase 2, an expanded administration network would, for instance, likely include adult and pediatric healthcare providers and pharmacies. These considerations will be part of planning done by the jurisdictions discussed in the Distribution section.
LTCF COVID-19 VACCINE

FEDERAL PHARMACY PARTNERSHIP

- CDC partnership with CVS and Walgreens Pharmacies
- COVID-19 vaccination clinics at long-term care facilities
- Federal pharmacy partner will conduct end to end management
  - Scheduling, Vaccine ordering, Vaccine reporting to states/CDC
  - Will provide facility a vaccine administration report for their records.
- All services will be provided free of charge to the patient and facility
- The focus will be for residents. However, any unvaccinated facility staff can receive a vaccine during these clinics
- Neither CMS nor the state will mandate COVID-19 vaccine. Patient and staff vaccination is voluntary.
- Enrollment is through a national survey running through November 2nd.
- Facilities may opt-out and choose to administer vaccine utilizing their own staff or a local pharmacy partner

When does Pharmacy Come In?

**Phase 1-OUTREACH CLINICS**

**Phase 1-A:**
- Paid and unpaid persons 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.

**Phase 1-B:**
- Other essential workers
- People at higher risk of severe COVID-19 illness, including people 65 years of age and older
When will more information be available?

The state is receiving new information daily from the CDC and HHS. We will continue to update you as more information becomes available.

The information in this slide set may change. Please continue to stay up-to-date on available information.

Please start logistics planning

Please sign up as a COVID-19 provider when the form is released

Please participate in outreach clinics
LINKS & RESOURCES

From the Factory to the Frontlines
The Operation Warp Speed Strategy for Distributing a COVID-19 Vaccine

What This Strategy Aims To Do

hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf

https://www.nmhealth.org/about/phd/idb/imp/