Background
COVID-19 vaccine and certain ancillary supplies will be procured and distributed by the federal government at no cost to enrolled Wisconsin COVID-19 Vaccination program providers. Many COVID-19 vaccines are in development, and clinical trials are being conducted simultaneously with large-scale manufacturing. It is not known which vaccines may be approved or authorized for use by FDA or when such authorizations or approvals will take place. Our initial planning considers information put forward by the CDC, and our program plans will be flexible and accommodate multiple scenarios.

What can vaccinators expect in the next two months?
All vaccinators will need to enroll their organization in the Wisconsin program in order to receive vaccine. The steps outlined below to enroll in the Program may occur simultaneously as we receive additional information from CDC.

STEP 1: Ensure your clinic is able to submit data to the Wisconsin Immunization Registry (WIR)
Vaccinators should verify your clinic’s ability to enter information about doses administered into the WIR within 24 hours of vaccine administration and verify that you can track and report inventory.
- To verify data submission timeliness, check with your staff that administer and document immunizations or ask your electronic health record (EHR) help desk or technical staff about the process.
- If you find out that your organization does not provide data to WIR, view How can my clinic gain access to WIR for more information. There are two ways that data can be submitted to WIR:
  1. Data entry through the web-based user interface.
  2. Through a data interface where EHR systems can be configured to automatically send data to WIR.
     - Note 1: Data submitted through the second option takes more effort to set up initially, but is more efficient for your staff to keep up-to-date immunization records.
     - Note 2: Given there is a waitlist for onboarding, please begin this process as soon as possible. Onboarding to the WIR for data exchange can take several weeks to months and there is currently a waiting list.
     - Note 3: There is a possibility that some Phase 1 providers not currently in WIR may not be active for submitting data via data exchange by the time early doses of vaccine arrive. Until those Phase 1 providers are active, they should plan to submit data through, via manual data entry using WIR’s mass vaccination functionality (option 1 listed above).
- If you have any further questions, contact the WIR Help Desk at 608-266-9691 or email WIR Help (dhswirhelp@dhs.wisconsin.gov).

Barcode Scanners
The use of barcode scanners with either an EHR or WIR (Mass Vaccination functionality) is encouraged to increase accuracy and improve clinic workflow. If using barcode scanners, steps should be taken to account for placeholder expiration dates in the barcode (and on the packaging) for the initial products released. Placeholder expiration dates will need to be updated with correct expiration dates in WIR and EHR’s after the product is received using information available on the CDC website.
STEP 2: Wisconsin COVID-19 Vaccine Program: Provider Enrollment and Agreement

To receive and administer COVID-19 vaccine and ancillary supplies, vaccination providers must enroll in the United States Government (USG) COVID-19 Vaccination Program, which is coordinated through the Wisconsin Immunization program. Providers must sign and agree to conditions outlined in the CDC COVID-19 Vaccination Program Provider Agreement.

- The Provider Profile and Agreement will be available to Wisconsin providers in the near future. In preparation for enrolling, please collect the following information:
  - Identify the vaccination providers for each site.
  - Identify the vaccine provider type (For example, is your clinic a mass vaccinator, a pharmacy, a long term care facility, etc.).
  - Settings where vaccinator will administer COVID-19 vaccine (for example off-site settings such as a: child care enter, school, health care provider office, in-home, long-term care facility. Or indicate if vaccine will be given on-site).
  - Information about your patient population including the number and type of patients served (for example children, pregnant people, people who are incarcerated, people with disabilities, etc.) by age group (years 0-18, 19-64, and 65 years of age or older).
  - Identify your refrigerated, frozen, ultra-cold temperature storage capacity (how many vaccines can you store? Consider that COVID-19 vaccine may arrive during influenza season).
  - Logistical information for receiving COVID-19 vaccine shipments: Location, hours and days vaccine coordinators are available for receipt of vaccine shipments.
  - An email that must be monitored and serve as dedicated contact method for the WI COVID19 Vaccination program. A list of all licensed health providers at the clinic location who have prescribing authority (for example, MD, DO, NP, PA, RPh) include provider names, titles, and license numbers.

- The Agreement will need to be signed by the Chief Medical Officer and Chief Executive Officer (or Chief Fiduciary) acknowledging they understand the Agreement Requirements, as well as the Medical or Pharmacy director or the location’s vaccine coordinator, attesting that each vaccine storage until will maintain appropriate temperatures.

STEP 3: Participate in vaccine storage, handling, and administration trainings, as well as any relevant WIR trainings (e.g. inventory reporting)

- CDC and the vaccine manufacturers are developing storage and handle training and vaccine administration training modules in a variety of formats.
- DHS anticipates these trainings will be available in late October.
- As these trainings become available, it will be a Wisconsin COVID-19 Vaccine program requirement that all appropriate clinic staff are trained on all aspects of storage, handling, administration (i.e., reconstitution, adjuvant use, and administration techniques), safety, and reporting requirements.

STEP 4: Become familiar with vaccinefinder.org

- The website will be promoted as a way for the public to find a local vaccinator when vaccine supply has increased.
- CDC and HHS will likely require that vaccinators report their COVID-19 vaccine inventory to the website on a daily basis to indicate to the public which locations have available vaccine.
- By vaccinators updating inventory daily, the public will know which locations have vaccine on hand and which will indicate when it is appropriate to make an appointment.

**Note:** as the national plans continue to evolve, so will planning in Wisconsin. Please include in your planning efforts any safety considerations such as: your staffs’ physical safety, wellbeing, and capacity, social distancing and current infection control practices and ensure that you have adequate Personal Protective Equipment (PPE) for all staff.

**What is known about COVID-19 vaccine distribution?**

- CDC will use its current centralized distribution contract (McKesson) to fulfill orders for most COVID-19 vaccine products as approved by the Wisconsin Immunization program.
- Some vaccine products, such as those with ultra-cold temperature requirements, will be shipped directly from the manufacturer (similar to how varicella vaccine is shipped to VFC providers). NOTE: DHS does not currently advise providers to purchase ultra-cold storage equipment. Ultra-cold vaccine may be shipped from the manufacturer in coolers that are packed with dry ice that can be repacked with dry ice within 24 hours of receipt of shipment and repacked again within 5 days.
- COVID-19 Vaccination program providers will be required to manage COVID-19 vaccine inventory in WIR, or have a process in place to update WIR inventory regularly either manually or via data exchange. This information is required each time the WI Immunization Program submits a request for vaccine allocation to CDC.
- All vaccine orders will be approved by the WI Immunization Program and sent to CDC for shipment to vaccination providers.
- Vaccine (and adjuvant or diluent, if required) will be shipped to provider sites within 48 hours of order approval by the WI Immunization Program, as vaccine supply allows.
- Providers will need to accept the orders in WIR after it is delivered to their site in order to correctly update their WIR inventory.
- Ancillary supply kits and diluent (if required) will ship separately from the vaccine due to different cold chain requirements, but shipment will be timed to arrive with or before the vaccine.
- Minimum order size for CDC centrally distributed vaccines will be 100 doses per order for most vaccines. Minimum order size for direct-ship vaccines may be much larger. CDC will provide more detail as it becomes available.
- Vaccine will be sent directly to a vaccination provider site for administration (in limited situations, such as with large chain-pharmacies, vaccine may be shipped to designated depots for secondary distribution to administration sites).
- Once vaccine products have been shipped to a provider site, the federal government will not be responsible for redistributing vaccine.
- Redistribution of vaccines may occur on a limited basis if maintaining the cold chain can be guaranteed. With the challenge of meeting cold chain requirements for frozen or ultra-cold vaccines, the WI Immunization Program will be judicious in allowing redistribution and limit any redistribution to...
refrigerated vaccines only and will need to be done in accordance with stipulations set forth in the CDC Provider Agreement.

**What supplies will be provided with COVID-19 vaccine?**
Ancillary supply kits 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
- Needle information card, 1 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.

**What communication resources will be available to vaccinators?**
- CDC will develop communication resources for vaccinators and other key audiences. These resources will be available on a public-facing website currently under development.
- CDC will work with national organizations to disseminate key messages.
- When vaccine supply is available for expanded groups among the general population, a national COVID-19 vaccine finder will be available on the public-facing VaccineFinder.org website.
- A screening tool on the CDC website will help people determine their own eligibility for COVID-19 vaccine and direct them to VaccineFinder.org

**What do providers need to know about vaccine safety reporting and monitoring?**
- Clinically important adverse events following any vaccination should be reported to the [Vaccine Adverse Event Reporting System (VAERS)](https://www.vaers.hhs.gov).
- Adverse events will also be monitored through electronic health record- and claims- based systems (e.g., Vaccine Safety Datalink).
- If FDA designates a COVID-19 vaccine for Emergency Use Authorization (EUA), additional vaccine safety monitoring reporting may be required by vaccinators.