October 16, 2020

Robert R. Redfield, MD
Director
U.S. Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
1600 Clifton Road NE
Atlanta, GA 30329

Re: The Maryland COVID-19 Vaccination Plan

Dear Director Redfield:

The Maryland Department of Health (MDH) is pleased to submit its COVID-19 Vaccination Plan (Plan). The Plan has been completed according to the COVID-19 Vaccination Interim Playbook for Jurisdiction Operations provided by the U.S. Centers for Disease Control and Prevention (CDC) and provides a robust framework for Maryland's COVID-19 vaccination program.

Maryland values our strong partnership with CDC and our joint work to date on strengthening our response to COVID-19. Our partnership with the federal government is essential in ensuring that we have a strong Maryland COVID-19 vaccination program that enhances the Maryland Strong: Roadmap to Recovery.

If you have any questions, please do not hesitate to contact me at robert.neall@maryland.gov or my Director of Governmental Affairs, Webster Ye at webster.ye@maryland.gov. Governor Hogan can be reached through Maryland's Director of Federal Relations, Tiffany Waddell, at tiffany.waddell@maryland.gov.

Sincerely,

Robert R. Neall
Secretary

Maryland

DEPARTMENT OF HEALTH

COVID-19 Vaccination Plan

October 16, 2020

Version 1.0

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Record of Changes

Date of original version: October 16, 2020

Date Reviewed	Change Number	Date of Change	Description of Change	Name of Author

COVID-19 Mass Vaccination Plan
Executive Summary

Background: In response to the COVID-19 pandemic, the federal government has entered into agreements with pharmaceutical companies to produce COVID-19 vaccines. The vaccines must be safe and effective in diminishing the severity of symptoms to gain FDA Emergency Use Authorization or full licensing.

The Maryland Department of Health (MDH) has engaged a multi-agency planning group to align federal guidance to the existing state and local infrastructure to ensure safe, equitable, and efficient vaccination against Covid-19. Under this plan MDH will assure that COVID-19 vaccine will be available for all Maryland residents who wish to be vaccinated.
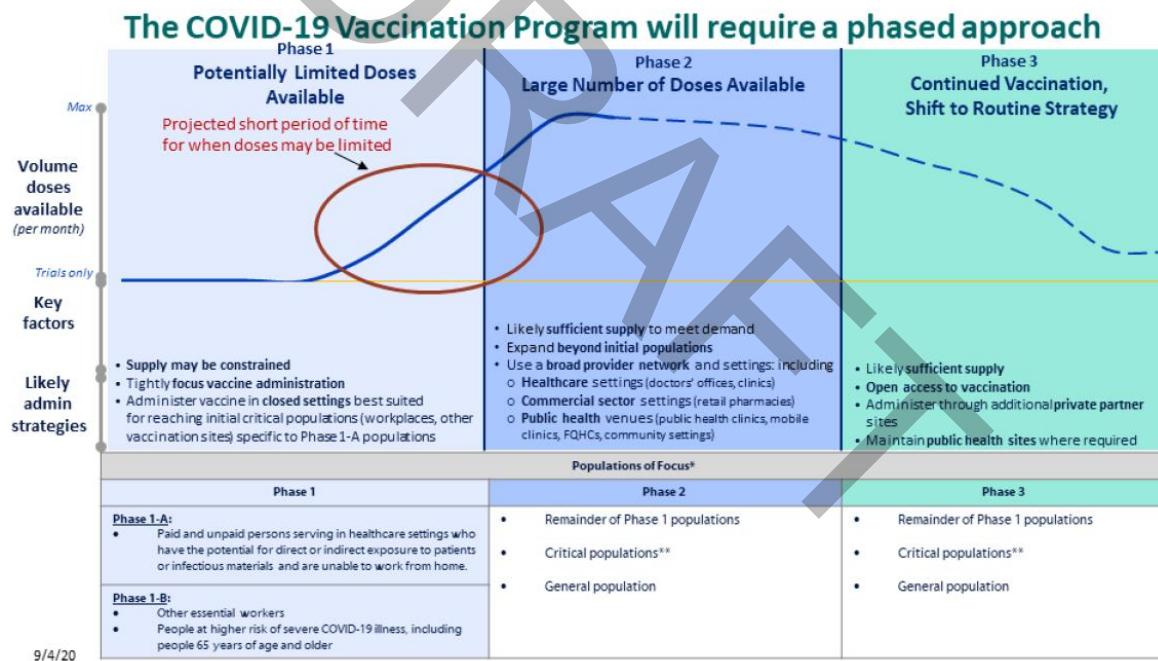
Key Planning Assumptions: At this time there are no vaccines that have been approved for use by the FDA. Maryland's plan will continue to evolve and incorporate information, as it is made available, from federal partners, the Maryland Immunization Technical Advisory Group, and community stakeholders. Some key assumptions based on current information provided by CDC include:

- Vaccine Handling and Storage Considerations
  - COVID-19 vaccine and ancillary supplies will be procured and distributed by the federal government at no cost to enrolled COVID-19 vaccination providers. MDH plans to purchase additional supplies as needed for local health department vaccination clinics.
  - Cold chain storage and handling requirements for each vaccine product will vary from refrigerated (2°C) to frozen (-20°C) to ultra-cold (-60° to -80°C) temperatures. Ongoing vaccine stability testing may impact these requirements.
  - Two doses of COVID - 19 vaccine will likely be needed, separated by >21 or >28 days.
    - Second-dose reminders for patients will be necessary.
    - Both doses will need to be the same vaccine product.
- Vaccine Supplies and Allocation
  - Limited COVID-19 vaccine doses may be available in Fall 2020. Vaccine supply will likely increase substantially in 2021.
  - The limited initial vaccine availability will be prioritized for the highest risk groups until vaccines are more readily available.
  - Allocation of vaccine to states by the federal government will be based on multiple factors, including:
    - The size of priority populations
    - Current local spread/prevalence of COVID-19
    - Vaccine availability
- Vaccine Priority Groups
  - Since there will be limited amounts of vaccine initially available, prioritization of vaccine candidates may be required. Recommendations on prioritization will depend on vaccine supply and information about the efficacy of the vaccines in various populations. The initial highest priority groups may include:
    - Healthcare personnel likely to be directly exposed to or treat people with suspected or confirmed COVID-19

- People at increased risk for severe illness from COVID-19, including those with underlying medical conditions and people 65 years of age and older
- Other essential workers, who by the nature of their position, are unable to reduce their risk of exposure (e.g. first responders)
- Communications and Outreach
  - Public demand for COVID-19 vaccination may be high among some segments of the population. However, current surveys indicate a high degree of vaccine hesitancy. A segmented approach sensitive to social and cultural nuances of Marylanders will be necessary to gain vaccine trust.

Planning and Implementation:

MDH will focus this plan on two major phases of vaccine availability and distribution. Phase 1 will be when there is limited vaccine availability and will focus on target/priority groups to receive vaccination (CDC Phase 1-Potentially Limited Doses Available). Phase 2 will be wide scale distribution vaccine associated with broad availability to the general population (CDC Phase 2-Large Number of Doses Available & Phase 3-Continued Vaccination, Shift to Routine Strategy). This approach is taken to simplify communication messaging and simplify planning. The primary components of Maryland's COVID-19 Vaccination Plan are outlined below.

The COVID-19 Vaccination Program will require a phased approach

	Phase 1 Potentially Limited Doses Available	Phase 2 Large Number of Doses Available	Phase 3 Continued Vaccination, Shift to Routine Strategy
Volume doses available (per month)	Projected short period of time for when doses may be limited		

Key factors		• Likely sufficient supply to meet demand
		• Expand beyond initial populations
		• Use a broad provider network and settings: including
		  ○ Healthcare settings (doctors' offices, clinics)
		  ○ Commercial sector settings (retail pharmacies)
		  ○ Public health venues (public health clinics, mobile clinics, FQHCs, community settings)	

Likely admin strategies	• Supply may be constrained • Tightly focus vaccine administration • Administer vaccine in closed settings best suited for reaching initial critical populations (workplaces, other vaccination sites) specific to Phase 1-A populations		• Likely sufficient supply • Open access to vaccination • Administer through additional private partner sites • Maintain public health sites where required

Populations of Focus*		
Phase 1	**Phase 2**	**Phase 3**
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	• Remainder of Phase 1 populations • Critical populations** • General population	• Remainder of Phase 1 populations • Critical populations** • General population

9/4/20

*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.

1. **Organizational Structure and Partner Involvement**

   The MDH Center for Immunization (CFI) will lead the operational aspects of the plan implementation and the MDH Office of Preparedness and Response (OP&R) will assume planning and coordination and logistical responsibilities, with other MDH programs and agencies, including MEMA, MIEMSS, MSP and others, taking on roles and responsibilities as the operational needs evolve.

COVID-19 Vaccination Incident Command Structure

COVID-19 Vaccination Incident Command Structure

- SARS-CoV-2 Vaccine Technical Advisory Group
- Incident Commander
- SARS-CoV-2 Vaccine Stakeholder Group

- Communications
- Legal

- Planning
- Operations
- Logistics
- Finance/Administration

- Documentation
- Surveillance/Epidemiology
- Volunteer Management
- Procurement

- Evaluation
- Distribution Registration Ordering Security
- Resource Management PPE Ancillaries Cold Chain Transport
- Fiscal Processing

- Core Planning Group EMS Hospitals Law Enforcement EMA LHDs Schools/Universities
- Dispensing

- Vulnerable Population/ Outreach MHHD Aging Behavioral Health Home Care DDA/MDoD LTCs Corrections Human Services MD Tribal Communities MIA
- Open PODs: LHDs PCPs FQHCs Pharmacies

- Closed PODs: Continuity of Government Hospitals EMS

- Scheduling/Training

- Tracking/ Data Reporting

2. **Phased Approach for Vaccination/Critical Populations**

   Phase 1: Limited Vaccine Availability: Target/Priority Group Determination for Vaccination (CDC Phase 1)

   Initial COVID-19 vaccination efforts will be made available to those at highest risk of developing complications from COVID-19 and those in critical workforce/infrastructure industries. Vaccine distribution during Phase 1 will be limited to those employers/work sites (hospitals, long term care (LTC) and skilled nursing facilities (SNFs), essential employee occupational health) and to Maryland local health departments (LHDs). CDC has engaged in direct negotiations with two national retail chain pharmacies to provide COVID vaccinations to residents and/or staff at LTC/SNF facilities that request assistance.

   Phase 2: Wide Scale Vaccine Availability: General Public Phase (CDC Phases 2 and 3)

   Phase 2 will begin based on:
   - availability of COVID-19 vaccine
   - notification by CDC and state authorities that the general public Phase can begin and/or
   - achievement of targeted metrics for vaccination of high priority Phase 1 groups.

3. **Provider Recruitment and Enrollment**

   MDH is currently recruiting and enrolling healthcare providers (HCPs), local health departments (LHDs), employee occupational health and pharmacists in Maryland's Vaccine Program Immunization Information System (ImmuNet) to ensure that there will be sufficient vaccinators throughout the state.

4. **Vaccine Allocation, Ordering, Distribution, and Inventory Management**

   MDH will require preregistration of Phase 1 vaccine sites and registration of priority vaccine candidates at each site. Vaccine orders will be placed in ImmuNet, which will then be uploaded to the CDC Vaccine Tracking System (VTrckS) vaccine ordering system for shipping directly to the hospital/work site location. MDH will track vaccine inventory and administration via ImmuNet.

5. **Vaccine Storage and Handling**

   COVID-19 vaccine products are temperature sensitive and will need to be stored and handled correctly to ensure vaccine viability prior to administration to a patient. CDC is currently developing storage and handling guidelines for COVID-19 vaccines and will release them as an addendum to the current *Vaccine Storage and Handling Toolkit* Vaccine Administration Documentation and Reporting.

6. **Vaccination Second-Dose Reminders**

   For most COVID-19 vaccines, two doses of vaccine will be required separated by >21 or >28 days. Second dose reminders will be provided to patients in several ways. Marylanders may choose to register in PrepMod, a free online service that connects patients and vaccine providers. Reminders may be sent via PrepMod to registered patients. Alternatively, patients may be scheduled for second doses from provider-based systems. Maryland also has a consumer vaccination portal, Maryland MyIR, which allows registered users to obtain their current vaccination records from ImmuNet. MyIR can also be used to issue reminder/recall messages if two doses of COVID-19 are required.

7. **Requirements for Immunization Information Systems (IIS): ImmuNet and PrepMod**

   ImmuNet is the cornerstone of the state's COVID-19 vaccination plan. ImmuNet will be the place where providers register to become a COVID-19 provider, order COVID-19 vaccine, track delivery of vaccine, report doses administered, and determine when second doses are due.

   Maryland will also use PrepMod as the main vaccine management system during Phase 1. LHDs and FQHCs will use PrepMod in Phase 2 as well. PrepMod is an online clinic management & appointment scheduling system developed in Maryland and used by Maryland local health departments to conduct mass vaccination/school-located clinics.

8. **Vaccination Program Communication**

   Communications regarding COVID-19 vaccine will focus on three main areas: 1) Safety and efficacy of vaccine, 2) vaccination of priority groups, and 3) vaccination of the general population. MDH will coordinate with trusted community partners, priority group representatives, and representatives of vulnerable populations, along with a marketing vendor, to develop and disseminate messaging.

9. **Vaccine Safety Monitoring**

   With the rapid development and licensing of the COVID-19 vaccines, vaccine safety monitoring is a high priority to establish and maintain confidence in the vaccine. CDC and the FDA continuously monitor the safety of vaccines. Three main systems are used to monitor the safety of vaccines: MDH participates in the Vaccine Adverse Event Reporting System (VAERS), Vaccine Safety Datalink (VSD), and Clinical Immunization Safety Assessment Project.

10. **Vaccination Program Monitoring**

    Monitoring of the COVID-19 vaccination program will be critical to the program's success. *The Weekly Flu Vaccination Dashboard* and *the COVID-19 Vaccination Response Dashboard* will use data related to flu and COVID vaccination that are collected from various sources. MDH will also have Maryland specific dashboards based on information collected in ImmuNet. MDH will have a flu and Covid-19 dashboard, which will include both cases and vaccine status.

FOREWORD

SARS-CoV-2, the virus that causes COVID-19, first appeared in Wuhan, China in December 2019.   Since that time, it has spread to many countries and was declared a pandemic on March 11, 2020 by the World Health Organization (WHO). In order to limit the spread of COVID-19, many countries, including the United States, implemented enhanced disease surveillance and control measures such as stay at home orders to encourage physical distancing, requiring the use of facial coverings, and promoting increased hand hygiene.

Immunization with a safe and effective vaccine is another critical component of containing and limiting the spread of COVID-19 related illnesses.   The United States has established a goal to have enough vaccine for all people in the United States who wish to be vaccinated. The Maryland Department of Health (MDH) is developing a plan on achieving this goal for Maryland residents.

This is the first version of the Maryland Department of Health COVID-19 Vaccination Plan (Version 1.0), which incorporates the assumptions, guidance, and requirements in the Centers for Disease Control and Prevention (CDC) COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations, issued on September 16, 2020. The plan focuses on the key areas of ordering, distribution, communication, and data reporting of COVID-19 vaccinations in Maryland. As additional information and guidance are available, including through stakeholder engagement, the plan will evolve and be updated to meet the needs of all Maryland residents.

Purpose: To provide a plan for the distribution, administration, recording, and communication of COVID-19 vaccines administered in the state of Maryland.

Background: COVID-19 vaccine research and development began in March 2020. The US Department of Health and Human Services (HHS) is working with partners to develop vaccine candidates. Thoughtful allocation of COVID-19 vaccines will be critical to prevent morbidity and mortality and reduce the impact of COVID-19 on society. The Advisory Committee on Immunization Practices (ACIP) and others will provide recommendations on priority groups and when groups should be vaccinated. Guidance on determining and providing vaccine to priority groups will be based on the principles included in the CDC "Interim Updated Planning Guidance on Allocating and Targeting Pandemic Influenza Vaccine During an Influenza Pandemic".

The main anticipated roles for the Maryland Department of Health (MDH) - Center for Immunization (CFI) will be working with the MDH Office of Preparedness and Response (OP&R) and a multi-agency workgroup to assess priority groups, conduct provider onboarding and enrollment, coordinate vaccine ordering and distribution, track and monitor vaccine usage, document doses administered, report on vaccine status, and implement a broad communications and outreach initiative. In order to be prepared to distribute COVID-19 vaccines for administration and to record administered COVID-19 vaccines doses as soon as the vaccine is available, CFI conducted an assessment of current systems and processes and initiated the development of a plan in April 2020.

Planning Assumptions: Assumptions are based on guidance listed in the September 15, 2020 HHS/CDC document COVID-19 Vaccination Program Interim Playbook for Jurisdictional Operations and the Operation Warp Speed distribution process (Appendix 1)

COVID -19 VACCINE

- Limited COVID-19 vaccine may be available by early November 2020 if a COVID-19 vaccine is authorized or licensed by FDA by that time, but COVID-19 vaccine supply is expected to increase substantially in 2021.
- Initially available COVID-19 vaccines will either be approved as licensed vaccines or authorized for use under an "Emergency Use Authorization (EUA)" issued by the FDA.
- Cold chain storage and handling requirements for each COVID-19 vaccine product will vary from refrigerated (2°C to 8°C) to frozen (-15°C to -25°C) to ultra-cold (-60°C to -80°C) temperatures, and ongoing stability testing may impact these requirements. *Note: These temperatures are based on information available as of September 15, 2020. Updated information will be provided as it becomes available.*
- Maryland will develop strategies to ensure the correct match of COVID-19 vaccine products and dosing intervals. Once authorized or approved by the FDA, two doses of COVID-19 vaccine, separated by either 21 or 28 days, will be required for most COVID-19 vaccine products, and second-dose reminders for patients will be necessary. Both doses will need to match each other (i.e., be the same vaccine product).
- Some COVID-19 vaccine products will likely require reconstitution with diluent or mixing adjuvant at the point of administration.

COVID-19 VACCINE ALLOCATION

- Final decisions are still being made about use of initially available supplies of COVID-19 vaccines. These decisions will be informed by the proven efficacy of the vaccines coming out of Phase 3 clinical trials, but populations of focus for initial COVID-19 vaccination may include:
  - Healthcare personnel likely to be directly exposed to or treat people with suspected or confirmed COVID-19
  - People at increased risk for severe illness from COVID-19, including those with underlying medical conditions and people 65 years of age and older
  - Other essential workers, who by the nature of their position, are unable to reduce their risk of exposure (e.g. first responders)
- Allocation of COVID-19 vaccine to jurisdictions will be based on multiple factors, including:
  - Critical populations recommended by the Advisory Committee on Immunization Practices (ACIP) with input from the National Academies of Sciences, Engineering, and Medicine
  - Current local spread/prevalence of COVID-19
  - COVID-19 vaccine production and availability
- Jurisdictions should anticipate that allocations may shift during the response based on supply, demand, efficacy within certain groups, and risk.
- Each jurisdiction should plan for high-demand and low-demand scenarios.

COVID-19 VACCINATION PROVIDER OUTREACH AND ENROLLMENT

- To receive and administer COVID-19 vaccine and ancillary supplies, vaccination providers must enroll in the United States Government COVID-19 Vaccination Program, coordinated through Maryland's immunization program, by signing and agreeing to conditions outlined in the CDC COVID-19 Vaccination Program Provider Agreement.
- CDC will make this agreement available to Maryland's immunization program for use in conducting outreach and enrolling vaccination providers. Maryland will be required to maintain these agreements on file for a minimum of three years.
- Maryland will collect and submit to CDC information on each enrolled vaccination provider/site, including provider type and setting, patient population (i.e. number and type of patients served), refrigerated/frozen/ultra-cold temperature storage capacity, and logistical information for receiving COVID-19 vaccine shipments.
- Some multijurisdictional vaccination providers (e.g. select large drugstore chains, the Indian Health Service, other federal providers) will enroll directly with CDC to order and receive COVID-19 vaccine. These direct partners will be required to report vaccine supply and uptake information back to each respective jurisdiction. CDC will share additional information when available on these procedures to ensure jurisdictions have full visibility for planning and documentation purposes.
- Jurisdictions may choose to partner with commercial entities to reach the initial populations of focus.
- Routine immunization programs will continue.

- COVID-19 vaccine and ancillary supplies will be procured and distributed by the federal government at no cost to enrolled COVID-19 vaccination providers. CDC will share more information about reimbursement claims for administration fees as it becomes available.
- CDC will use its current centralized distribution contract to fulfill orders for most COVID-19 vaccine products as approved by jurisdiction immunization programs. Some vaccine products, such as those with ultra-cold temperature requirements, will be shipped directly from the manufacturer.
- Maryland-enrolled vaccination providers will be required to follow Maryland's vaccine ordering procedures.
- COVID-19 vaccination providers will be required to report COVID-19 vaccine inventory each time a COVID-19 vaccine order is placed.
- Vaccine orders will be approved and transmitted in CDC's VTrckS by jurisdiction immunization programs for vaccination providers they enroll.
- Vaccine (and adjuvant or diluent, if required) will be shipped to provider sites within 48 hours of order approval by the immunization program if supply is available. Ancillary supply kits and diluent (if required) will ship separately from the vaccine due to different cold chain storage requirements, but shipment will be timed to arrive with or before the vaccine.
- Ancillary supply kits will include needles, syringes, alcohol prep pads, COVID-19 vaccination record cards for each vaccine recipient, and a minimal supply of personal protective equipment (PPE), including surgical masks and face shields, for vaccinators.
  - Each kit will include supplies needed to administer 100 doses of vaccine.
  - Jurisdictions may need to plan for additional PPE, depending on vaccination site needs.
  - For COVID-19 vaccines that require reconstitution with diluent or mixing adjuvant at the point of administration, these ancillary supply kits will include additional necessary syringes, needles, and other supplies for this purpose.
  - Sharps containers, gloves, bandages, and other supplies will not be included.
- 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.
- Vaccines will be sent directly to vaccination provider locations for administration or designated depots for secondary distribution to administration sites (e.g., chain pharmacy central distribution).
- Once vaccine products have been shipped to a provider site, the federal government will not redistribute the product.
- Jurisdictions will be allowed to redistribute vaccines while maintaining the cold chain. However, with the challenge of meeting cold chain requirements for frozen or ultra-cold vaccines, jurisdictions should be judicious in their use of redistribution and limit any redistribution to refrigerated vaccines only.
- Jurisdictions are **not** advised to purchase ultra-cold storage equipment at this time. Ultra-cold vaccine may be shipped from the manufacturer in coolers that are packed with dry ice. These coolers should be repacked with dry ice within 24 hours of receipt of shipment and repacked again within 5 days.

COVID-19 VACCINE ADMINISTRATION DATA REPORTING

- Jurisdictions will be required to report CDC-defined data elements related to vaccine administration every 24 hours.
- All vaccination providers may be required to report and maintain their COVID-19 vaccination information on CDC's VaccineFinder.
- CDC has prioritized jurisdiction onboarding to the Immunization (IZ) Gateway to allow Immunization Information Systems (IISs) to receive data directly from national providers, nontraditional vaccination providers, and other external systems, as well as to report vaccine administration data to CDC.
- Data Use Agreements (DUAs) will be required for data sharing via the IZ Gateway and other methods of vaccine administration data sharing with CDC and will be coordinated by each jurisdiction's immunization program.

COMMUNICATION

- CDC will develop communication resources for jurisdictions and tribal organizations to use for key audiences. These resources will be available on a public-facing website currently under development, but jurisdictions and tribal organizations will likely need to tailor messaging and resources specific to special populations in their communities.
- CDC will work with national organizations to disseminate key messages.
- Communication and educational materials about COVID-19 vaccination provider enrollment, COVID-19 vaccine ordering, COVID-19 vaccine storage, handling, administration (i.e. reconstitution, adjuvant use, administration techniques), etc. will be available in a variety of formats.
- 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.
- A screening tool on the CDC website will help people determine their own eligibility for COVID-19 vaccine and direct them to VaccineFinder.

COVID-19 VACCINE SAFETY

- Clinically important adverse events following any vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS).
- Adverse events will also be monitored through electronic health record- and claims-based systems (e.g. Vaccine Safety Datalink).
- Additional vaccine safety monitoring may be required under the EUA.

MARYLAND ASSUMPTIONS

- Public demand for COVID-19 vaccination will likely be high, especially when there is limited supply and if there is severe disease in the community.
- Vaccine hesitancy based on the safety and efficacy of the vaccine will be a barrier to vaccination that will need to be addressed.
- Seasonal influenza vaccination will be particularly important for all persons ≥ 6 months of age, especially front-line health care providers (HCPs), to limit influenza as another respiratory illness.

- Assuming COVID-19 will continue to spread in the community in Fall 2020 and into 2021, vaccination plans must ensure vaccine clinics will not put patients at risk for COVID-19 exposure, which in mass vaccination settings, will need to include considerations for PPE, social distancing or spacing of persons vaccinated and staff, and scheduling individual vaccination appointment times, among other approaches.
- Maryland will take full advantage of technology solutions to address COVID-19 vaccination:
  - Maryland's IIS, ImmuNet, will be used to store vaccination information and report vaccine doses to the federal "Data Lake" by way of the immunization Gateway Connect.
  - Vaccine providers must enroll and register in ImmuNet to order COVID-19 vaccine.
  - Enrolled vaccine providers will order COVID-19 from Maryland's allocation.
  - Maryland will utilize PrepMod, an online system that automates patient registration, planning, implementation, evaluation, recording, and reporting to the IIS for mass vaccination and preparedness efforts.
  - Maryland will utilize MyIR, a consumer immunization access portal, to allow the public to view/print a copy of their COVID-19 vaccine record to present to employers and schools.
  - Provider training on ImmuNet, PrepMod, and MyIR will be needed to maximize use of these solutions.
  - The current pool of resources for vaccination will be insufficient to optimize mass vaccination. Additional funding, human resources, and materials will be needed.

Overview: This plan will describe the processes for determining target/priority groups for vaccination during Phase 1 limited vaccine availability, vaccinating during later phases with wide scale vaccine availability, vaccine provider onboarding/registration, vaccine storage and handling, vaccine ordering and distribution, vaccination promotion and campaigns, and vaccine accountability/documentation. Planning for an effective response will require a collaboration among a wide variety of partners both public and private.

In preparation for the development of this plan, MDH reviewed lessons learned from previous pandemics and outbreaks, such as the 2009 H1N1 influenza pandemic as well as more recent outbreaks, such as the 2019 measles outbreak and the current ongoing increase in hepatitis A cases, through after action reports and discussions with experts overseeing outbreak investigation and response. MDH has also drawn upon years of experience conducting seasonal influenza vaccination campaigns. Lessons learned include enhancing ImmuNet to directly register vaccine providers rather than having a separate system for registration; developing queries in ImmuNet to improve data analysis and reporting; making available timely and actionable vaccination data; taking full advantage of IT solutions to promote vaccination clinic efficiency and client safety; and improving how to inform/engage the public/provider community to reduce the number of calls/questions needing immediate responses.

This plan will focus on two major phases of vaccine availability and distribution. Phase 1 will be limited vaccine availability with a focus on target/priority groups to receive vaccination (CDC Phase 1). Phase 2 will have wide scale vaccine availability with vaccinations for the general population (CDC Phase 2 & 3). This approach is taken to simplify both messaging and planning. Additionally, vaccine supply is expected to rapidly increase once distribution begins, alleviating the need to limit vaccine administration.

1. ORGANIZATIONAL STRUCTURE AND PARTNER INVOLVEMENT

Beginning in April 2020, CFI began having regular operational planning meetings for COVID-19 vaccination. By May 2020, meetings were expanded to include OP&R. In August 2020 meetings continued to expand in membership to include the following internal and external core partners: MDH Office of Communications, the Office of the Attorney General, Maryland Emergency Management Agency (MEMA), Maryland State Police (MSP), the Maryland Institute for Emergency Medical Services Systems (MIEMSS), representatives from the Local Health Departments (LHD), Public Health Emergency Planners (PHEPs), and Maryland Hospital Association (MHA). Maryland's centralized governance structure, aside from the home rule jurisdictions, allows for rapid decision making, meeting coordination, and allocation of responsibilities.

The CFI, in partnership with OP&R, has established an incident command system (ICS) to organize the COVID-19 vaccination response (Appendix 2). CFI will lead operational aspects of the planning structure and OP&R will assume planning/coordination and logistical responsibilities. Other MDH programs and agencies will be assigned roles as warranted. To assure completion of assigned tasks and responsibilities CFI will seek to hire additional staff utilizing federal COVID-19 funding to include:

- Functional Analyst: ImmuNet Support (1.0 FTE) who will be responsible for providing Help Desk support for ImmuNet and to direct calls to appropriate individuals or units, specifically for COVID-19 response
- Administrative Specialist II (2.0 FTEs) who will be responsible for reviewing and approving provider registration/profiles and reviewing and approving COVID-19 vaccines orders

As operational planning efforts developed, the need to add additional partner input was addressed. Meetings with these members are coordinated by OP&R and scheduled when needed. These partners include, but are not limited to:

1. Local Health Departments (LHDs)
2. Office of Minority Health and Health Disparities
3. Federally Qualified Health Centers (FQHCs)
4. Board of Pharmacy/Chain Pharmacists/Maryland Pharmacist Association
5. Long-Term Care/Skilled Nursing Facilities
6. National Guard
7. Primary Care Physicians
8. State Medical Society/AAP/AAFP
9. "Essential Employers"
10. Maryland Partnership for Prevention (MPP) - Maryland Immunization Coalition
11. Payer organizations, including the Maryland Medicaid program and HealthChoice Managed Care Organizations

In addition to the operational planning group, a COVID-19 vaccine technical advisory group has been established to provide input into reviewing of COVID-19 vaccine trial data generally and then applying it to priority groups. This technical group is composed of members of the existing Statewide Advisory Commission on Immunization, several research institutions, professional groups (NMA, State Medical

Society, etc.) and pharmacy representatives. The work of this group is intended to be independent and will be staffed through the Deputy Secretary for Public Health Services.

Specific partnership and outreach to Maryland's two state-recognized Native American tribes, Piscataway Conoy tribe/Piscataway Indian Nation and the Accohannock tribe, will be given the highest priority as state recognized tribes will not receive direct vaccine allocations from CDC (unlike federally recognized tribes) and may require community focused vaccination clinics. The Piscataway Conoy tribe and Piscataway Indian Nation are centered in Charles Co. and the Accohannock tribe are centered in Somerset County.

Due to the severe time constraints on this planning effort, it is unlikely that there will be time for a structured tabletop or other full-scale exercises prior to vaccine availability. Ongoing weekly discussion, input, and review with internal and external partners will continue to further refine the planning document. Discussion-based exercises may be incorporated into these meetings to work through potential COVID-19 vaccination scenarios to enhance state and local planning. We are also encouraging partners to use seasonal flu vaccination as a functional or full-scale exercise of their COVID-19 vaccination planning. All lessons learned from discussion-based and operations-based exercises will be incorporated into our planning and vaccination programs as a means of continuous quality improvement.

2. PHASED APPROACH TO VACCINATION/CRITICAL POPULATIONS

Maryland Phase 1: Limited Vaccine Availability: Target/Priority Group Determination for Vaccination (CDC Phase 1)

As mentioned above, given projected limited COVID-19 vaccine availability for late 2020/early 2021, initial COVID-19 vaccination efforts will target those at highest risk of developing complications from COVID-19 and those in critical workforce/infrastructure industries. Although subject to change, based on level of disease and state/local factors, planning for these initial doses of COVID-19 vaccine should target the following groups:

  a.   Critical, frontline healthcare personnel evaluating and caring for COVID-19 patients;
  b.   Other essential workers including public safety, education, staff in congregate living facilities; and
  c.   Persons at highest risk of developing complications from COVID-19 (ACIP high risk conditions), including persons 65 and older, staff and residents of nursing homes (SNFs), long-term care facilities (LTCFs), assisted care facilities, and clients of senior daycare facilities or similar.

Phase 1 population estimates are under development and will require further refinement through multiple means. CFI will work with MDH programs, primarily OP&R, other state/local agencies, and previously identified partners to develop estimates for groups identified by the state (core planning group and technical advisory group) and ACIP as priority for vaccination during this phase. Names, facility contact information, employee/resident population estimates for facilities and organizations that are associated with any of the target groups will be developed through surveys and existing contact lists. Ongoing communication will be established with these organizations to keep them abreast of COVID-19 vaccine developments and to prepare them for vaccinating their populations.

It is estimated that approximately 14% of Maryland residents will fall into a Phase 1 vaccination category. (Appendix 3)

Table 1: Estimated Phase 1 Target Populations

	Target Population	Estimated US population size	Estimated MD population size (2% of US pop)
Phase 1	High Risk Health Care Workers	16,119,000	322,380
	First Responders	2,603,000	41,260
	Older adults in congregate or overcrowded settings	2,158,000	43,160
	Judiciary		4,320
	People in Prisons, Jails, Detention Centers and Staff		54,460
	People with Comorbid and Underlying Conditions that put them at *Significantly* higher risk	19,500,000	390,000

Based on National Academies of Sciences, Engineering, and Medicine 2020 Framework for Equitable Allocation of COVID-19 Vaccine. Additional prioritization will be done in accordance with NASEM and ACIP recommendations and will be subject to vaccine availability. All estimates are subject to change.

In addition to facility/organization surveys, population estimates will be determined from experience gained from prior mass vaccination efforts. Lessons learned from H1N1 influenza and other vaccination campaigns revealed the need to engage the public early and often with accurate information. To accomplish this, a COVID vaccine specific preregistration effort will be deployed. Prior to the distribution of COVID-19 vaccine, Maryland residents will be asked to preregister to receive a COVID-19 vaccination and to receive news/updates on COVID-19 vaccination efforts (Appendix 4). Statewide specific preregistration communication messages will be released through a media campaign to encourage Maryland Phase 1 residents to preregister. The website URL MarylandVax.org (Figure 1), linked to Maryland's mass vaccination IIS module PrepMod, will be promoted through paid/earned/social media as the location to preregister. Preregistration through a website is considered a viable option as studies show that upwards of 90% of the U.S. adult population has access to a smart phone capable of accessing the internet.

To increase the likelihood of priority group populations getting vaccinated, Phase 1 facilities/ organizations where priority individuals work or are provided care will be contacted directly by CFI and notified to begin preregistration of their critical care staff and residents. Preregistration during Phase 1 will not be required to receive vaccination, but it will be strongly encouraged.

Figure 1: MarylandVax.org

Preregistration of individuals in PrepMod will further assist development of accurate estimates of the number of people in the Phase 1 targeted priority groups who want a vaccination. Demographic information (age, race, ethnicity, zip code, occupation, comorbidities) from preregistrants will inform the state whether or not communication messages (section 10) are reaching the targeted population (based on a review of preregistration numbers) or if more messaging is needed in specific areas of the state. Lastly, preregistration will allow MDH to create detailed prioritization categories for the targeted groups based on geographic location. Using collected addresses and zip codes, Phase 1 closed vaccination points of dispensing (PODs) can be established in targeted areas to maximize vaccination efforts.

Vaccine distribution during Phase 1 will be limited to those employers/work sites with employees that fall into the Phase 1 targeted groups and to LHDs. Once the vaccine is available and is allocated to a location, Phase 1 preregistered individuals will be instructed by email/text message to schedule an appointment for vaccination (Appendix 4) at a private/closed vaccination clinic using PrepMod. LHDs will schedule POD vaccination clinics for Phase 1 individuals, including for those that did not preregister (see section 4 for details on vaccination clinics). Specific outreach and communication messaging to the targeted/priority population will continue until Phase 1 vaccination metrics are achieved.

CDC has engaged in direct negotiations with two national retail chain pharmacies to provide COVID vaccinations to residents and/or staff at LTCFs/SNFs that request assistance. CDC, in conjunction with LTC associations and CMS, will request that facilities sign up (via NHSN for SNFs, via REDCap for LTCFs) for the on-site clinics. The chain pharmacies will receive Phase 1 COVID-19 vaccine directly from CDC to conduct the COVID vaccinations at the LTCFs/SNFs.

Phase 1 vaccine providers will be trained on how to create vaccination clinics in PrepMod, post the clinics on MarylandVax.org and how to use PrepMod during their vaccination clinic to document vaccine administration encounter information. PrepMod use will be required for all Phase 1 vaccinators as CDC requires use of an IT solution to collect and prepare vaccination data for submission to the IZ Gateway within 24 hours. PrepMod is an end-to-end clinic management system that can handle vaccine inventory, distribution, and repositioning.

In the event that two doses of COVID-19 vaccine are needed, individuals will be contacted by email/text to remind/recall them to schedule a second appointment at a closed/private clinic, a LHD POD, or at local pharmacy. Individuals will also be able to view and print a copy of their official COVID vaccination record for work or school from Maryland MyIR which downloads vaccination information from ImmuNet.

Maryland Phase 2: Wide Scale Vaccine Availability: General Public Phase (CDC Phases 2 and 3)

Determination of the beginning of vaccination Phase 2 (CDC Phases 2 and 3) will be influenced by a number of factors:
- availability of COVID-19 vaccine;
- notification by CDC and state authorities that the general public Phase can begin due to sufficient supply; and/or
- achievement of targeted metrics for vaccination of high priority Phase 1 groups.

Specific vaccination metrics from ImmuNet will be developed and reviewed by the core planning group along with the technical advisory group to assess Phase 1 vaccination progress and determine where additional effort is needed. These metrics may include:
- Percent of Phase 1 population vaccinated
- Percent and number of residents and staff at long-term care facilities vaccinated
- Determination of an equitable distribution of COVID vaccine throughout the state for the Phase 1 population
- Percent and number of Phase 1 population pre-registered
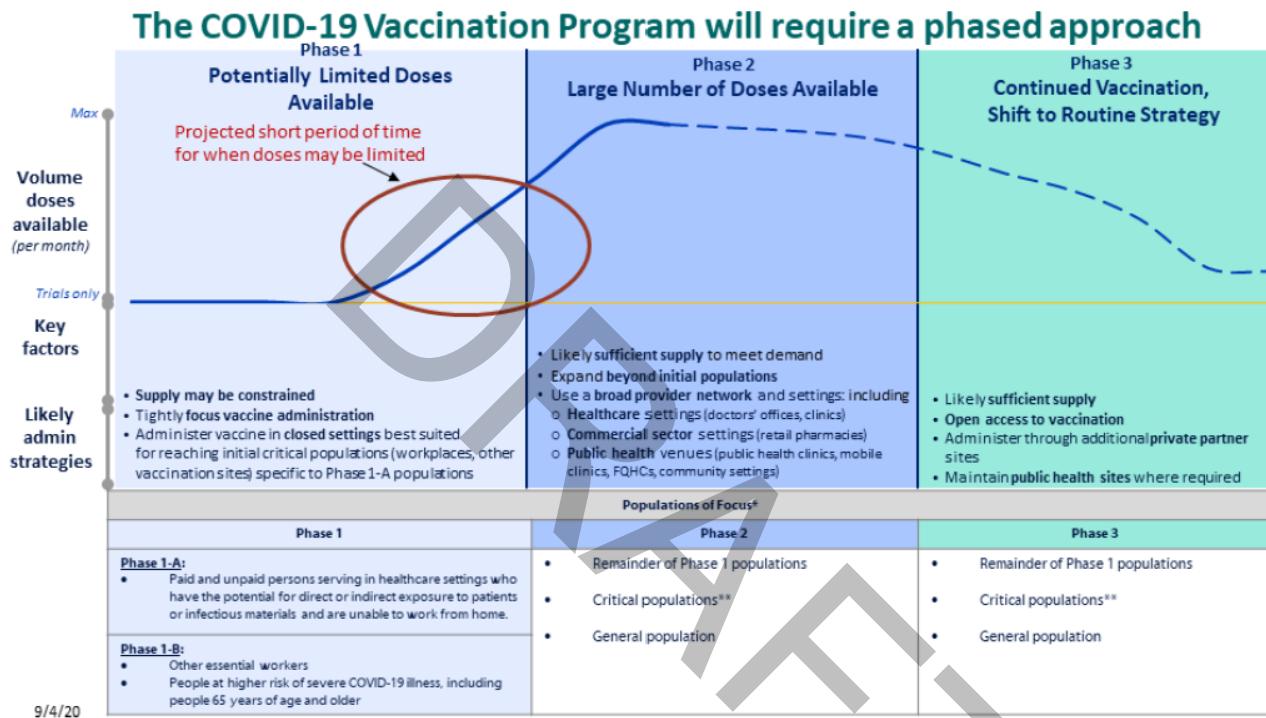
As vaccine supply increases during Phase 2, CFI will continue to promote preregistration for all Maryland residents. Because Maryland will have continuous and open preregistration for COVID-19 vaccination, receipt of information from the general public seeking vaccination will continue, including zip code, age, race, ethnicity, occupation, and health condition. Based on this information, MDH will be able to send email/text communication to select pre-registered Phase 1 individuals (based on priority category) who have not yet been vaccinated to alert them of the availability of COVID-19 vaccination clinics. Media communication will be used to reach residents who do not pre-register. The combination of actual ImmuNet vaccination data and preregistration lists will allow MDH to find potential gaps in vaccination uptake. For example, data from ImmuNet and the pre-registration list may reveal that seniors in Wicomico County have not been vaccinated and have not pre-registered in sufficient numbers (as determined by the technical advisory group). MDH would then engage in specific community outreach and would create and advertise local vaccination clinics.

As the amount of vaccine increases, the number of vaccine providers able to order COVID-19 vaccines will also increase. Vaccination and pre-registration data will also be used to determine where in the state additional vaccine providers are needed. The equitable distribution of vaccines among various providers throughout the state is a major priority for MDH. CFI has developed an enrollment process for vaccine providers that will allow high visibility on where vaccine providers are located, where additional

providers are needed, or where LHD PODs can provide a vaccination safety net. MDH is working closely with the Maryland Board of Pharmacy and Maryland Pharmacy Association to coordinate and communicate with the estimated 4,900 pharmacists trained and certified to provide vaccinations. The inclusion of these pharmacists, both chain and independent, will be added to the pool of available vaccinators during Phase 2 to help meet demand surge. These additional vaccinators will also help address any gaps in service.

Figure 2: CDC COVID-19 Phases

Communication and outreach to both preregistered individuals and the general public will continue until Phase 1 and Phase 2 vaccination metrics have been achieved or the supply of vaccine surpasses demand. Once the vaccine becomes more widely available (CDC Phase 3), earned/paid/social media communication will inform the public to seek a COVID-19 vaccination through MarylandVax.org, their doctor or local pharmacy. Continuous monitoring of vaccination metrics to ensure equitable distribution of vaccines through a broad network of vaccination providers.

3. PROVIDER RECRUITMENT AND ENROLLMENT

Quick and efficient vaccine distribution will be essential to getting Maryland residents vaccinated in a timely manner. Recruiting HCPs, LHDs, employee occupational health providers and pharmacists in Maryland to vaccinate will ensure all populations may be reached. CFI will continue to actively recruit potential vaccinators from external partners currently engaged in COVID planning. The various state medical societies and associations were contacted in May 2020 and asked to provide initial information on planning efforts for COVID vaccine distribution to their respective members (Appendix 6). This information went out to more than 36,000 clinicians throughout the state. Surveys of Maryland hospitals, LTCFs, and pharmacists have been sent to identify potential vaccinators and inform them of

the necessary steps needed to receive COVID-19 vaccine. Providers in rural areas, hospital settings, occupational health for essential employees, and those who provide care for seniors will be heavily recruited in order to serve those respective populations.

Just as all Maryland residents will be asked to preregister for a COVID vaccination, HCPs will also be asked to preregister with CFI prior to vaccine release. CFI is developing an onboarding and registration process that providers can complete that is simple, efficient, and requires minimal CFI staff resources. By onboarding and registering HCPs prior to COVID-19 vaccine availability, bottlenecks and delays will hopefully be avoided when the vaccine becomes available. Another primary aim of early provider enrollment will be to assess the provider type, location, and specialty of every HCP interested in offering COVID vaccinations. This is especially important to ensure adequate vaccinators are available for the priority Phase 1 group and to address any gaps based on geographic location.

A. Provider Onboarding - Connection to ImmuNet

Maryland HCPs interested in receiving COVID-19 vaccine will need to onboard and register in ImmuNet in order to receive and administer COVID-19 vaccine. Onboarding will allow for near real-time data exchange of COVID-19 vaccine administration data to ImmuNet for reporting to the CDC IZ Gateway within the required 24 hours (see section 7). CDC also requires dose-level accountability for all COVID-19 vaccines at all times. Another benefit to onboarding with ImmuNet is that providers will be able to query ImmuNet to find out if a patient has previously been vaccinated with COVID-19 vaccine and identify which vaccine product was used to ensure matching if a second dose is required.

It is believed that most vaccine providers are already onboarded with ImmuNet and are reporting administered vaccine doses in compliance with Health General Article §18–109, which mandates that all vaccines administered in Maryland be reported to ImmuNet. This mandate does not apply to vaccine providers who administer vaccines in a nursing facility, an assisted living program, a continuing care retirement community, or a medical day care program. A survey of more than 1,800 long-term care facilities was issued in Sept. 2020 to determine how many facilities will need to be onboarded with ImmuNet prior to the COVID-19 vaccine release. Since 2011, Maryland pharmacists licensed to vaccinate have been mandated by Health Occupations Article §12–508 to report to ImmuNet when administering a vaccination.

In October 2020 CFI will onboard additional HCPs in ImmuNet that are interested in being COVID-19 vaccine providers. Information regarding onboarding/enrolling with ImmuNet can already be found on the CFI website. The website, along with detailed instructions on how to onboard, will be sent to HCPs through the various state medical societies and associations to include:

- Maryland Chapter of the American Academy of Pediatrics
- American Academy of Family Physicians
- MedChi, the Maryland State Medical Society
- CRISP, the Maryland Health Information Exchange (HIE)
- Maryland Primary Care Physicians
- Board of Pharmacy/Maryland Pharmacy Association
- and other partners/employers/occupations

Figure 3: ImmuNet Webpage Onboarding and Reporting Section

Start Using ImmuNet Today

Most computers with high-speed internet access are adequate to use ImmuNet, which supports all browsers but Google Chrome is recommended for optimum performance.

Authorized users can access ImmuNet by enrolling here. Hard copies (here) can be downloaded for printing and distribution.

Once the Maryland Department of Health receives the enrollment, you will be contacted with your login information. In the meantime, please refer to the user guides and training videos below to learn how to use ImmuNet.

Note: Authorized users from out of state are encouraged to sign up with their own state IIS. Maryland is working towards inter-jurisdictional data exchange where you may be able to find your patient's Maryland records through your state IIS.

Report to ImmuNet All Vaccines Administered

As of October 2019, all vaccinations administered in the State of Maryland are required to be reported to ImmuNet, regardless of patient opt-out status in ImmuNet (see more info in the Patient Opt-Out section below).
Please see this page to ensure you are in compliance with the State Statute §18–109(d)(6)(I)3 Report to ImmuNet all vaccines administered (some exceptions apply).

Prospective COVID-19 vaccine providers will also be asked to complete a provider screening questionnaire, sign the CDC COVID-19 Vaccination Program Provider Agreement, and complete the provider profile.

B.   Provider Registration - Screening, CDC Agreement, Provider Profile
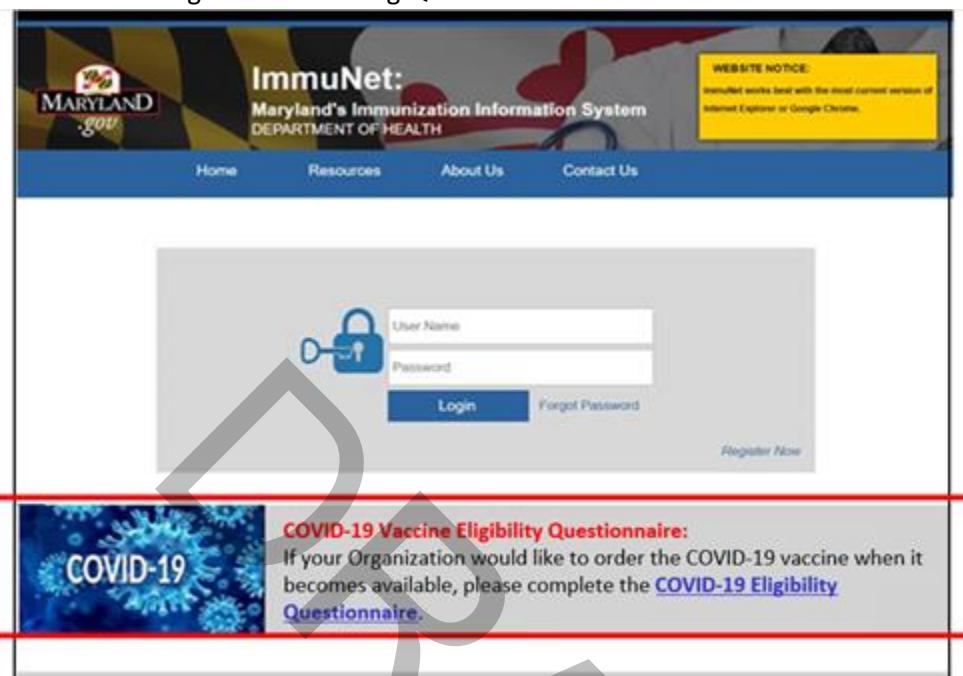
Onboarded providers will complete at two-step process to receive COVID-19 vaccine:

Step 1: Complete a provider screening questionnaire in ImmuNet to determine eligibility to order COVID-19 vaccine. The screening questionnaire was developed based on lessons learned during the H1N1 influenza campaign which revealed that an automated screening process was needed to alleviate the burden on CFI staff from having to manually review and screen every provider that requested vaccine. During H1N1 more than 2,500 providers had to be individually screened to determine their eligibility, which took hundreds of hours to complete.

The automated screening tool (Appendix 7) in ImmuNet will capture the patient population served and provider type of every prospective provider. Based on the questionnaire answers, an auto generated

response will be sent to the provider indicating whether they have been approved to complete Step 2 of the registration process.

Figure 4: Screening Questionnaire Link in ImmuNet
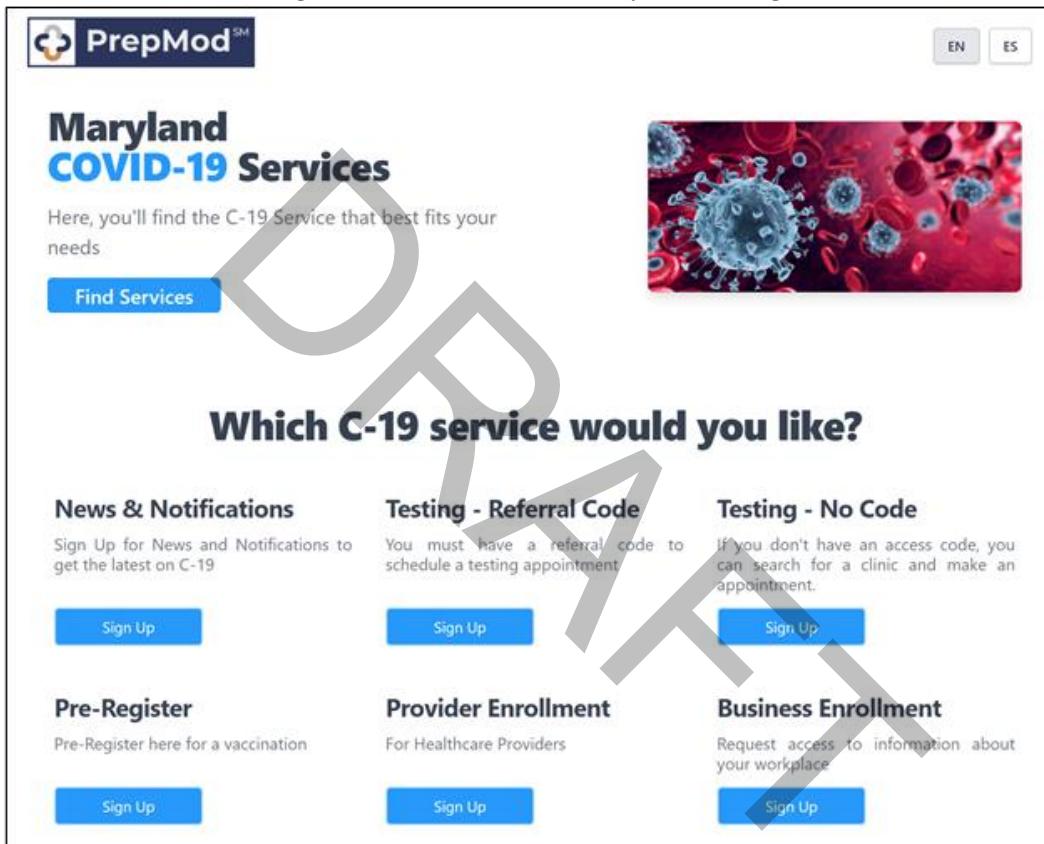
Step 2: Complete a provider profile and sign the CDC COVID-19 Vaccination Program Provider Agreement. Additional lessons learned from H1N1 indicated that the most efficient means of collecting necessary provider information is for the provider to enter it directly into ImmuNet. The provider profile will be able to automatically validate medical licenses and credentials through the Maryland Board of Physicians, and to capture the requested information from section B of the CDC agreement, as well as any Maryland specific information. (Appendix 5 and 6). The collection of this information is critical as it will be used to generate an ordering profile in CDC's VTrckS vaccine ordering system, which is used to request vaccines from the federal vaccine distributor. The final step will be for the Responsible Medical Provider and Chief Fiduciary Officer to sign the CDC COVID-19 Vaccination Program Provider Agreement. The CDC agreement will be built into ImmuNet for direct provider data entry. (Appendix 11).

C. Provider Volunteer Recruitment

Since more than five million Maryland residents will need to be vaccinated, possibly with two doses, recruiting a large number of vaccine providers is critical. Providers able to administer a COVID-19 vaccination include doctors, nurses, Maryland National Guard medical corps, licensed/trained pharmacists, and medical/nursing students. Many of these providers are expected to be willing to volunteer at a LHD POD, FQHC, or LTCF and it is important to find a way to engage volunteers to extend service capacity.

CFI will solicit information from prospective volunteers on its website, MarylandVax.org, and match them with a COVID-19 clinic in need of additional support. The Maryland Partnership for Prevention, the state's childhood/adult immunization coalition, will partner with CFI to promote this effort through social media and its coalition membership. Volunteers to assist with other clinic activities, including traffic control, patient flow and registration check-in, will also be asked to volunteer at MarylandVax.org. Contact information collected from provider registration and volunteer recruitment will be used to create a database of emails, phone numbers and fax numbers for ongoing communication.

Figure 5: COVIDReadi on MarylandVax.org

D. Provider Training

COVID-19 vaccine will be a new vaccine and will require the creation of training materials on its use, storage and handling, and administration. Vaccine storage and handling will be especially important if any of the approved vaccines require ultra-cold storage at -60℃ to -80℃. Because a large number of providers may need rapid training, CFI will use a variety of training methods:

1. Webinars - twice a month webinars conducted by the CFI Nurse Consultant and Health Educator
2. Information posted on the CFI website, MarylandVax.org and the MDH website
3. Self-guided training that allows providers to complete training at their convenience
4. Written training materials developed by CDC and CFI

Figure 6: Maryland VFC Training Webpage

It is anticipated that training will include:

- ACIP COVID-19 vaccine recommendations;
- How to use PrepMod during Phase 1 and LHD POD vaccination clinics;
- COVID-19 vaccine storage and handling (including transport requirements);
- How to administer vaccine, including reconstitution, use of adjuvants, etc.;
- How to document and report vaccine administration via ImmuNet and PrepMod;
- How to manage and report vaccine inventory via ImmuNet and PrepMod;
- How to document and report vaccine wastage/spoilage;
- Procedures for reporting adverse events to the Vaccine Adverse Event Reporting System (VAERS);
- Providing Emergency Use Authorization (EUA) fact sheets or vaccine information statements (VISs) to vaccine recipients;

● How to order and receive COVID-19 vaccine.

4. VACCINE ALLOCATION, ORDERING, DISTRIBUTION AND INVENTORY MANAGEMENT

Early quantities of COVID-19 vaccine are expected to be very limited. A standardized vaccine allocation methodology for Phase 1 providers needs to be in place and communicated to internal and external partners/organizations. The process for vaccine ordering and inventory management must also be communicated to potential vaccine providers. Vaccine distribution processes, and how the vaccine will be administered to the public, are also described in this section.

A.   COVID-19 VACCINE ALLOCATION

Phase 1: Limited Vaccine Availability

Although Phase 1 efforts will be targeted to the highest priority populations, there are likely to be more individuals in the priority Phase 1 population in need of vaccination than initial available doses. Therefore, a vaccine allocation methodology was developed to ensure an equitable distribution of initial vaccine doses and distribution to locations capable of immediate vaccine use.

Once the state has been notified that a specific amount of early COVID-19 vaccine has been allocated to Maryland, CFI and OP&R along with the State Epidemiologist, the Chief of the Center for Infectious Disease Surveillance and Outbreak Response, and the Deputy Secretary for Public Health Services will review the following data points to make initial allocation decisions:

1. Number of preregistered individuals at a given hospital or other work site where Phase 1 population groups work or reside (section 2).
2. Review of hospitals/work sites that have completed onboarding and registration with ImmuNet.
3. Review of specific disease metrics to ensure vaccine distribution takes into consideration level of disease and other state/local factors (such as number of COVID-19 patients at the hospital or positivity rate of disease in a given location).
4. Review of hospitals/work sites that can safely store and stand up a vaccination clinic within 48 hours of notification from CFI. In the event that a hospital/work site cannot stand up a vaccination clinic, a LHD may be asked to host a Phase 1 vaccination POD.

This allocation methodology will be used until vaccination Phases 2 and 3 can begin.

CDC has engaged in direct negotiations with two national retail chain pharmacies to provide COVID vaccinations to residents and/or staff at LTC/SNF facilities that request assistance. CDC in conjunction with LTC associations and CMS will request facilities sign up (via NHSN for SNF, via REDCap for LTC) for the on-site clinics. The chain pharmacies will receive Phase 1 COVID vaccine directly from CDC to conduct the COVID vaccinations at the LTC/SNF facilities. Maryland will be notified per CDC of which chain pharmacies and LTC/SNF will be working together.

Phase 2: Wide Scale Vaccine Availability

As the amount of vaccine increases in Phases 2 and 3 the amount of vaccine allocated to individual providers will be determined by responses to questions in the CDC provider agreement:
● "Approximate number of patients/clients routinely served by this location"; and
● "Influenza vaccination capacity for this location".

Vaccine providers will not be allowed to order more than the agreement responses indicate they should receive.

CDC has engaged in direct negotiations with two national retail chain pharmacies to provide COVID vaccinations to residents and/or staff at LTC/SNF facilities that request assistance. CDC, in conjunction with LTC associations and CMS, will request that facilities sign up (via NHSN for SNFs, via REDCap for LTCFs) for the on-site clinics. The chain pharmacies will receive Phase 1 COVID-19 vaccine directly from CDC to conduct the COVID vaccinations at the LTC/SNF facilities.

B.   COVID-19 VACCINE ORDERING

Phase 1: Limited Vaccine Availability Vaccine Ordering

COVID-19 vaccine will be ordered using existing infrastructure for ordering Vaccines for Children vaccines, which was also used to order H1N1 influenza vaccines. During the limited COVID-19 vaccine allocation phase, CFI will order vaccine doses on behalf of hospitals/work sites authorized to receive vaccines based on the allocation methodology detailed above. Ancillary supplies will be packaged in kits and will be automatically ordered and shipped by CDC in amounts to match vaccine orders, at no cost to vaccination providers and their patients. 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. Ancillary supply kits will not include sharps containers, gloves or bandages. Additional PPE may be needed depending on vaccination provider site. Facilities ordering outside of Maryland's allocation (i.e., commercial and federal entities with federal MOUs in place) will order directly from CDC, and CDC will be responsible for approval of those orders.
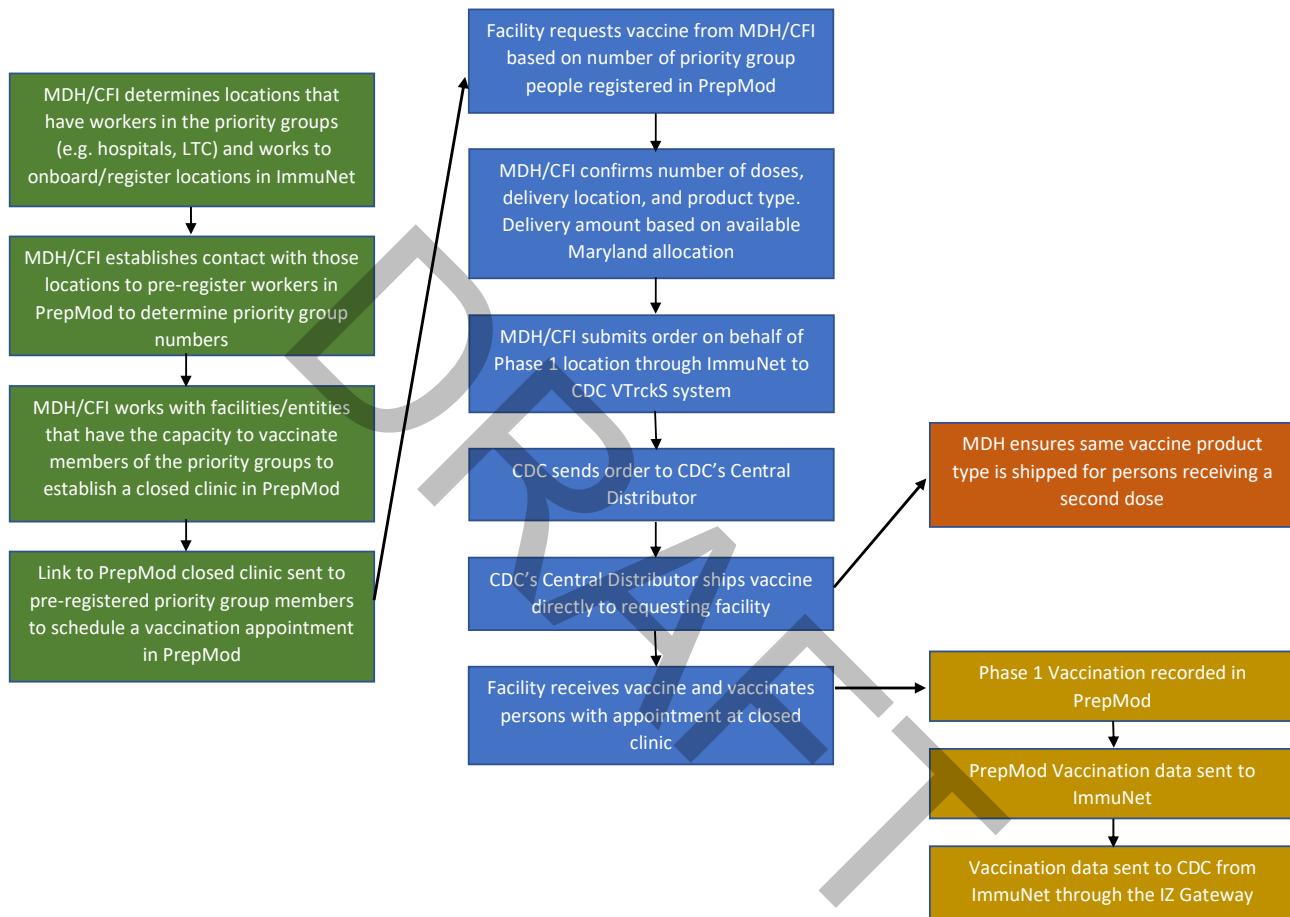
CDC will provide Maryland with regular updates on the available vaccine supply and vaccine product-specific allocations in VTrckS. CFI will review VTrckS on a daily basis to determine amounts of vaccine available for ordering. When vaccine is available, CFI will contact the hospitals/work sites approved to receive COVID-19 vaccine and instruct them to stand up a vaccination clinic within the next 48 hours. CFI will place the vaccine order in ImmuNet, which will then be uploaded to VTrckS for shipping directly to the hospital/work site location. The location of Phase 1 vaccines will be kept highly confidential in accordance with security protocols to prevent theft and publicization.

The amount of vaccines ordered will be based on the allocation methodology (including an overage of 5 percent to account for waste). The minimum order size and increment for CDC distributed vaccines will be 100 doses per order; though early in the response, some ultra-cold (-60°C to -80°C) vaccine (if

authorized for use or approved) may be shipped directly from the manufacturer in larger quantities (approximately 1,000 doses). Ultra-cold doses will only be sent to facilities that can properly store and handle the vaccine at those temperatures (Section 6). Because two doses of the same formulation of vaccine are expected to be needed for immunity, prior to the placement of a vaccine order, CFI staff will review the prior order to ensure the same formulation is shipped for second dose vaccination.
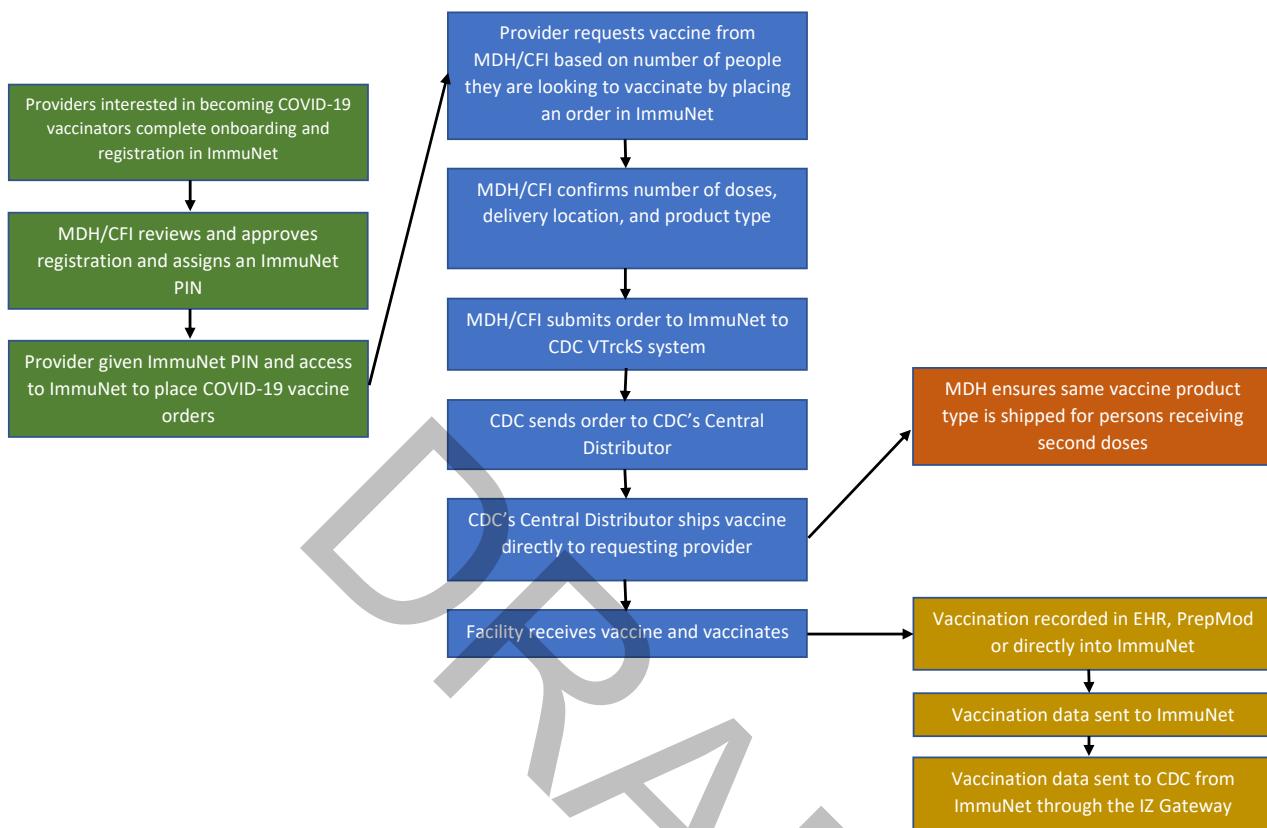
Figure 7: Phase 1 Process Flow

Phase 2 and 3: Wide Scale Vaccine Availability Vaccine Ordering

When the vaccine becomes widely available (during Phase 2 and CDC Phases 2 and 3), and the need for vaccine allocation no longer exists, the general public will be able to receive COVID-19 vaccine at their healthcare provider's office, employer worksite, LHD or local pharmacy. Vaccine providers, pre-registered individuals and the general public will be notified when Maryland enters these phases. Onboarded and registered providers (Section 3) will then be allowed to order vaccines directly through ImmuNet.

Figure 8: Phase 2 Process Flow

- Onboarded and registered providers will indicate the number of doses (minimum 100 doses) they are requesting by completing a vaccine order on the ImmuNet Specialty/Influenza vaccine page. COVID-19 vaccine ordering was added to ImmuNet to ensure efficient provider vaccine ordering and inventory data capture (Appendix 12).
- The amount of vaccine to allocate to providers during these phases will be determined by responses to questions in the CDC provider agreement:
  - "Approximate number of patients/clients routinely served by this location"
  - "Influenza vaccination capacity for this location"
- Vaccine providers will not be allowed to order more than the agreement responses indicate they should receive.
- CFI staff will review and approve COVID-19 vaccine orders and work to ensure the same product specific formulation is ordered and shipped for second dose vaccinations.
- Vaccine orders will be uploaded daily to the CDC VTrckS system for fulfillment and shipping.
- HCPs will be required to report vaccine administration data in order to receive additional vaccines (Section 7).
- Failure to report vaccine administration data will prevent any future COVID-19 vaccine shipments.

C.   COVID-19 VACCINE DISTRIBUTION

Phase 1: Limited Vaccine Availability Vaccine Distribution

COVID-19 vaccine doses will be shipped by the CDC centralized vaccine distributor, McKesson Specialty, directly to onboarded and registered providers within 48 hours of VTrckS order approval at no charge to the state or provider. Vaccine providers must ensure the vaccine delivery address and shipping hours/information submitted on their vaccine provider profile are accurate and kept up to date throughout the duration of COVID-19 vaccine shipping. To maintain the vaccine cold chain, CFI will request vaccine doses be shipped to the same location where they will be administered. According to CDC, ancillary supply kits will also ship directly to the delivery address, separate from the vaccine but timed to arrive on the same day or sooner.

CDC requires use of an IT solution for Phase 1 vaccination clinics to ensure dose level accountability and submission of vaccine administration data to CDC within the mandated 24-hour timeframe. The PrepMod online clinic management/appointment scheduling system is sufficient for this purpose. Use of PrepMod will eliminate the need for consent form manual data entry and will promote social distancing by appointment scheduling.

Hospitals, essential employer work sites and LHDs must utilize PrepMod for all Phase 1 vaccination clinics. Retail chain pharmacies receiving vaccines from the CDC allocation will not be required to use PrepMod as they will use their own corporate IT system. Phase 1 clinics will use PrepMod to perform the following functions:

1. Create a vaccination clinic at the hospital/work or LHD site location, for which Phase 1 individuals may schedule an appointment;
2. Use PrepMod on the day of the clinic to capture vaccine administration encounter data; and
3. Transmit vaccination administration data to ImmuNet for uploading to the CDC IZ Gateway within 24 hours.

Hospitals, essential employer work sites and LHDs will receive training on PrepMod prior to vaccine distribution. On the day of the vaccination clinic, onsite PrepMod technical assistance will be provided at no charge to the hospital/work site.

Once informed of delivery within 48 hours, hospitals and work sites will create a private or closed vaccination clinic with the number of available appointments based on the amount of vaccine allocated to the facility. Hospitals and work sites will then use PrepMod to send an email or text message to the pre-registered employees telling them to schedule an appointment at the clinic. Hospitals and work sites will use their own internal process to determine who receives the email or text to schedule the vaccination appointment. Depending on the amount of vaccine available, hospitals and work sites will be asked if they can vaccinate Phase 1 non-employees at their private or closed vaccination clinic. If so, CFI will send an email or text to inform pre-registered non-employees to schedule an appointment at the private or closed clinic.

Essential employee work sites that do not have the staffing to conduct their own vaccination clinic will be given the option to request temporary nursing staff. The temporary staff can be paid for by the organization or they request financial support from CFI. CFI has received a CDC grant for COVID vaccination activities, including contracting for temporary nursing staff.

CDC has engaged in direct negotiations with two national retail chain pharmacies to provide COVID vaccinations to residents and/or staff at LTC/SNF facilities that request assistance. CDC, in conjunction with LTC associations and CMS, will request that facilities sign up (via NHSN for SNFs, via REDCap for LTCFs) for the on-site clinics. The chain pharmacies will receive Phase 1 COVID-19 vaccine directly from CDC to conduct the COVID vaccinations at the LTC/SNF facilities.

LHDs may be asked to conduct Phase 1 vaccination clinics. CFI will inform LHDs how much vaccine will be ordered on their behalf. Like hospitals/work sites they will then create a private/closed Phase 1 vaccination clinic in PrepMod based on the number of expected doses. Private/closed clinics are not posted on MarylandVax.org. The LHD will then email/text pre-registered individuals in the Phase 1 group that reside in their jurisdiction to schedule an appointment at their clinic. Because not all individuals in the Phase 1 group will preregister, the LHD will have to reserve space at the clinic for non-registered individuals. It will be up to the LHD's own internal process to determine how to screen/schedule non-registered individuals.

A LHD may utilize a variety of clinic models (Appendix 13) to conduct their vaccination clinic, including:

- Indoor or outdoor POD model;
- Drive-thru;
- Drive-up/walk-up; or
- Mobile van.

To help with social distancing and decrease the need for a large indoor/outdoor clinic location, LHDs will be trained in and encouraged to take advantage of the "virtual queue" function in PrepMod. The virtual queue allows individuals with a vaccination appointment to "check in" at their scheduled appointment time and wait off site until they are notified to enter the clinic for service.

To prevent vaccine theft and publicization of arrival of the vaccine, Phase 1 clinics will have to establish security protocols to be reviewed by CFI prior to vaccine arrival. The protocol should address where the vaccine will be delivered/stored, what security will be on site during the clinic, who is responsible for the vaccine on the day of the clinic, and how unused doses will be safeguarded. Vaccine redistribution will not be allowed during the limited Phase 1 vaccine period.

Phase 2: Wide Scale Vaccine Availability Vaccine Distribution

As in Phase 1, COVID-19 vaccine doses will be shipped by the CDC centralized vaccine distributor directly to onboarded and registered providers within 48 hours of VTrckS order approval at no charge to the state. Vaccine providers must ensure the vaccine delivery address and shipping hours/information submitted on their vaccine provider profile is accurate and kept up to date throughout the duration of COVID vaccine shipping. To maintain the vaccine cold chain, CFI will request vaccine doses be shipped to the same location where they will be administered. According to CDC, ancillary supply kits will also ship directly to the delivery address, separate from the vaccine but timed to arrive on the same day or sooner.

Because vaccines are expected to become widely available, vaccine providers are not required to use PrepMod during Phase 2, unless they are conducting mass vaccination clinics. Mass vaccination campaigns, along with provider office visits and pharmacy vaccinations, are a good strategy to vaccinate the residents of Maryland over time. Various forms of mass vaccination campaigns are currently used

throughout the state for the seasonal influenza vaccine. These models will be critical to be able to vaccinate large numbers of residents with COVID-19 vaccine.

LHDs and other facilities/organizations conducting mass vaccination campaigns will be required to use PrepMod to create and post open COVID vaccination clinics on MarylandVax.org. Using PrepMod for appointment scheduling will allow the LHD to know exactly how many individuals to expect, how much vaccine will be needed, how much staffing will be needed and to promote social distancing. CDC will provide major pharmacy retail chains Phase 2 COVID vaccine directly from the federal vaccine allocation. This vaccine will then be offered to the general public.

Like in Phase 1, LHDs may utilize a variety of clinic models (Appendix 13) to conduct their vaccination clinic, including:

- Indoor or outdoor POD model;
- Drive-thru;
- Drive-up/walk-up; or
- Mobile van.

To help with social distancing and decrease the need for a large indoor/outdoor clinic location, LHDs will be trained and encouraged to take advantage of the "virtual queue" function in PrepMod. The virtual queue allows individuals with a vaccination appointment to "check in" at their scheduled appointment time and wait in their car until they are notified to enter the clinic for service.

To prevent vaccine theft and publicization of arrival of the vaccine, LHD POD clinics will have to establish security protocols to be reviewed by CFI prior to vaccine arrival. The protocol should address where the vaccine will be delivered/stored, what security will be on site during the clinic, who is responsible for the vaccine on the day of the clinic and how unused doses will be safeguarded.

Vaccine redistribution may be allowed during this phase if approved by CFI and if validated cold-chain procedures are in place in accordance with the manufacturer's instructions and CDC's guidance on COVID-19 vaccine storage and handling. These entities must sign and agree to conditions in the CDC COVID-19 Vaccine Redistribution Agreement for the sending facility/organization. Vaccines can only be redistributed to an onboarded and registered provider. CFI will be extremely judicious in allowing redistribution and limit any redistribution to refrigerated vaccines only. CFI may occasionally allow local transport of vaccines from one location to another within the state if adherence to cold chain and tracking requirements are maintained.

D.   COVID-19 VACCINE INVENTORY MANAGEMENT

CDC requires vaccine dose level accountability for all COVID-19 vaccine doses. This includes active inventory management, which entails capturing all the required FDA approved or EUA information in ImmuNet and PrepMod. Inventory management will be done for Phase 1 clinics using PrepMod which has a vaccine inventory management functionality. Phases 2 and 3 vaccine dose inventory will be collected in ImmuNet. Before a COVID vaccine order can be placed, current vaccine inventory must be collected (Appendix 12).

CFI will review submitted vaccine inventory prior to every vaccine order to ensure all prior doses have been accounted for. Providers with wasted/spoiled vaccine doses will have to report them on the state's

[Vaccine Return and Wasted form](). Providers with excessive wasted or unaccounted for vaccine will be contacted and may be suspended from further vaccine ordering.

5. VACCINE ADMINISTRATION CAPACITY

Vaccine administration capacity (VAC) is the maximum achievable vaccination throughput regardless of public demand. In order to determine the VAC, it is essential to understand the number of COVID-19 vaccination providers and their available capacity.

CDC has developed a tool called the "PanVax Tool" (PVT) to assist with estimating the VAC. Maryland has used PVT version 3.3 to estimate the VAC in the state. All values presented are estimated and may be adjusted as more information is gathered and as the pandemic evolves.

In order to determine the Maryland VAC, the following estimates and situation assumptions were added to the PVT:
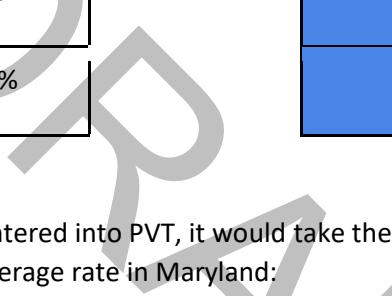
Total Maryland Population (US Census)	6,045,680
Number of doses for series completion	2
Interval between doses	4 weeks
Pandemic Vaccination Coverage Goal	80% (recommended by CDC)
Percent of Children in population (US census)	22% (under 18 years of age)

The following provider groups were used as potential COVID-19 vaccinators with their estimated number of sites in Maryland:

Provider Group	Sites	Est Weekly Avg for a single provider (from PVT)
Points of Dispensing (PODs) - LHDs	48 (2 per LHD)	1000
Urgent Care Centers	370	600
Hospitals	64	600

School Vaccination Clinics	100	500
Routine LHD Clinics	24	200
Chain/Independent Pharmacies	2250	1000
PCP Offices	1500	400

Estimated vaccine availability entered into PVT:

Month 1	5%		Month 4	20%
Month 2	10%		Month 5	20%
Month 3	20%		Month 6	25%

Based on the current information entered into PVT, it would take the following number of weeks to reach an 80 percent vaccination coverage rate in Maryland:

% of total providers participating	# of weeks to reach 80% coverage in Adults	# of weeks to reach 80% coverage in Children
100%	8	6
80%	10	8
50%	16	12

As with all modeling, estimates would change as variables are updated according to the event. Provider registration will be the primary driver of refining the modeling estimates based on actual provider information received (i.e., provider type, interest in giving COVID-19 vaccine, vaccination capacity, etc.).

6. VACCINE STORAGE AND HANDLING

COVID-19 vaccine products are temperature-sensitive and will need to be stored and handled correctly to ensure vaccine viability prior to administration to a patient. Proper storage and handling are critical to minimize vaccine loss and limit the risk of administering vaccines with reduced effectiveness. It is

expected that storage and handling requirements will vary in temperature from refrigerated (2℃ to 8℃), to frozen (-15℃ to -25℃) to ultra-cold (-60℃ to -80℃). The CDC is currently developing storage and handling guidelines for COVID-19 vaccines and will release them as an addendum to the current *Vaccine Storage and Handling Toolkit*. Upon release, this addendum will be distributed to all registered COVID-19 vaccine providers along with other specific training materials.

CFI, along with the CDC, will provide educational materials to COVID-19 vaccination providers to ensure appropriate vaccine storage and handling procedures are established and followed. Vaccination providers are responsible for maintaining vaccine quality from the time a shipment of vaccine arrives at the provider site to the time it is administered. Initial doses of vaccine are expected to require ultra-cold storage. This poses a number of challenges as few vaccine providers have the experience or necessary training to work with ultra-cold vaccines. One challenge is identifying ultra-cold vaccine storage capacity in Maryland. Maryland is developing a confidential database of facilities/organizations in the state with ultra-cold storage capabilities. Those locations will be mapped to determine the geographic spread of ultra-cold storage capacity in the state and will be called upon if any extended ultra-cold storage is needed for vaccines.

Handling of ultra-cold vaccines prior to administration is also a challenge. To ensure the safety of vaccine administrators, training and education on the safe handling of ultra-cold vaccines will need to be provided. CDC is developing these trainings and they will be made available to Maryland providers who will handle these vaccines. Maryland will offer training through webinars, an online training video and written educational materials.

A final challenge is that the storage temperature of these vaccines must be closely monitored. Most available temperature monitoring devices have the capacity to monitor routine refrigeration and frozen storage temperatures. There are a limited number of systems able to monitor ultra-cold temperatures. Further guidance from CDC is expected on how to best monitor these temperatures.

For COVID-19 vaccines that require more routine temperature monitoring, providers will need to ensure they have proper temperature monitoring equipment. Guidelines established in the *Vaccine Storage and Handling Toolkit* addendum will provide the instructions on how to best store the COVID-19 vaccine.

COVID-19 providers are required to document the type of vaccine storage unit(s) they have when they complete their provider COVID registration. Appropriate storage units will be stand alone or pharmaceutical grade units, although combination units (i.e., refrigerator and freezer in one unit) will be accepted. Dorm-style storage units will not be allowed for COVID-19 vaccine storage. Providers will be required to document storage unit temperatures at the start and end of the day. Providers will be able to use the current VFC temperature log available through CFI to document these twice daily temperatures (Appendix 14). Temperature excursions outside of the recommended temperatures must be reported to CFI according to the existing protocols found on CFI website (Figure 9). Vaccine providers that fail to adequately store COVID vaccine will be terminated from the vaccination program.

Satellite, Temporary and Off-Site Clinic Storage and Handling

Satellite, temporary or off-site clinics may be needed to ensure equitable access to COVID-19 vaccination. These locations require additional oversight and enhanced storage practices, including:

- Determining the appropriate amount of vaccine to be transported to satellite, temporary or off-site locations
- Using proper transportation methods to the satellite, temporary or off-site locations. Guidance on transportation procedures will be outlined in the CDC's *Vaccine Storage and Handling Toolkit* addendum.
- Proper storage and temperature monitoring while at the satellite, temporary or off-site location.
- At the end of the day, temperature data must be assessed prior to returning vaccine to fixed storage units to prevent administration that may have been compromised due to improper storage while off-site.
- If a temperature excursion occurs, it must be reported to the CFI on the temperature excursion webpage on the CFI website. These vaccines must be labeled "do not use" and stored at the required temperature until further determination has been made on the usability of the vaccine.

Figure 9: Temperature Excursion Reporting Page

In order to engage in vaccine redistribution, these entities gain approval from CFI, maintain cold chain procedures and sign and agree to conditions in the CDC COVID-19 Vaccine Redistribution Agreement for the sending facility/organization. Vaccine can only be redistributed to an onboarded and registered provider. CFI will be extremely judicious in allowing redistribution and will limit any redistribution to refrigerated vaccines only. CFI may occasionally allow local transport of vaccines from one location to

another within the state, if adherence to cold chain and tracking requirements are maintained. The vaccine cold chain must be maintained at all times during redistribution, which will include:

1. Documentation of the vaccine temperature prior to redistribution;
2. Transport of the vaccine in a certified temperature container (ULC vaccine cannot be redistributed);
3. Transport of the vaccine with a DDL or other temperature monitoring device approved by CFI;
4. Documentation of the vaccine temperature upon receipt at the secondary location; and
5. Placing the vaccine in a vaccine storage unit at the end of the clinic day.

7. VACCINE ADMINISTRATION DOCUMENTATION AND REPORTING

COVID-19 vaccination accountability and documentation will be necessary for determining vaccination coverage in Maryland, ensuring the elimination of disparities, providing residents with documentation of vaccination for employment/school purposes and providing updates on vaccine supply. Many requests for data are anticipated regarding vaccine use and numbers of vaccinations administered. Capturing vaccination data and presenting it on a vaccination dashboard will be critical to responding to these requests in a timely manner.

In Maryland, vaccine administration reporting has evolved over time. Pharmacists have been required to report doses administered to ImmuNet since 2011 (Health Occupations Article §12–508). In 2017, CFI mandated that VFC providers report all vaccine doses administered to ImmuNet as a requirement for enrollment in the VFC program. As of October 1, 2019, Health General §18–109 requires all vaccine doses administered in Maryland to be reported to ImmuNet, with a few exceptions. In preparation for COVID-19 vaccine reporting, CFI sent a letter on May 1, 2020 (Appendix 6) to all Maryland clinicians informing/reminding them of the requirement to report all vaccinations to ImmuNet and that reporting will be required for all providers that are interested in registering as COVID-19 vaccine providers. Since that letter was disseminated, CFI has onboarded approximately 500 new providers into ImmuNet. CFI is also working with the Maryland Primary Care Program (MDPCP) to identify additional providers that are not currently onboarded with ImmuNet to onboard them prior to COVID-19 vaccine availability.

CDC has established a list of required (Table 2) and optional (Table 3) data elements that must be collected with each COVID-19 vaccination and reported to the CDC within 24 hours of administration. CFI estimates that ImmuNet customizations will be completed in October 2020 to ensure all required and several optional data elements can be captured in ImmuNet. ImmuNet currently collects nearly 100 percent of the required elements, with the exception of race and ethnicity. Vaccine providers only report race 84 percent of the time and ethnicity 56 percent of the time to ImmuNet. During onboarding and registration, prospective providers will be informed of all required elements and submissions will be closely monitored to ensure required data is provided.

CFI will ensure that the CDC required data elements are reported to ImmuNet for each vaccine administration and transmitted to CDC. Reported data will be sent to CDC via the Immunization (IZ) Gateway "Connect" component. The IZ Gateway works to securely transmit electronic messaging of vaccination records across state IIS systems and also with other provider organizations such as the Department of Defense, Federal Bureau of Prisons and the Department of Veterans Affairs. MDH signed a data use agreement which allows connection to and data exchange with the IZ Gateway. Maryland established the "Connect" component to the IZ gateway in September 2020 and has passed the testing

requirements to allow for real-time data exchange. Data submitted to the CDC will be kept in the CDC Immunization Data Lake. The Data Lake is a cloud hosted data repository to receive, store and manage COVID-19 vaccination data for doses administered, vaccination coverage, ordering, inventory and distribution. MDH signed a second MOU with CDC allowing submission of identified patient data to the CDC Data Lake.

Table 2: CDC Required Data Elements

IIS Data Elements: Required

Required Data Element	Standard or Mass Vaccination
Administered at location: facility name/ID	Standard
Administered at location: type	Standard
Administration address (including county)	Standard
Administration date	Standard
CVX (Product)	Standard
Dose number	Standard
IIS Recipient ID	Standard
IIS vaccination event ID	Standard
Lot Number: Unit of Use and/or Unit of Sale	Standard
MVX (Manufacturer)	Standard
Recipient address*	Standard
Recipient date of birth*	Standard
Recipient name*	Standard
Recipient sex	Standard
Recipient ethnicity	Standard
Recipient race	Standard
Sending organization	Standard
Vaccine administering provider suffix	Standard
Vaccine administering site (on the body)	Standard
Vaccine expiration date	Standard
Vaccine route of administration	Standard
Vaccination series complete	Mass Vax

Table 3: CDC Optional Data Elements

IIS Data Elements: Optional

Required Data Element	Standard or Mass Vaccination
Comorbidity status (Y/N)	Mass Vax
Recipient missed vaccination appointment (Y/N)	Mass Vax
Serology results (Presence of positive result, Y/N)	Mass Vax
Vaccination refusal (Y/N)	Standard

Depending on the phase, data flow will occur in one of two ways. During Phase 1, providers will be required to use PrepMod to capture vaccine administration information. PrepMod has an established connection to ImmuNet so that any data that is collected in PrepMod will automatically be sent to ImmuNet. Once in ImmuNet, the data will be sent to CDC via the IZ Gateway Connect and stored in the CDC Data Lake. Vaccine administration data from pharmacies that contract directly with CDC will be transmitted to the CDC Data Lake by way of the pharmacists existing IT reporting system. Maryland will be able to upload Maryland resident data from the Data Lake into ImmuNet to develop an accurate assessment of vaccination coverage.

Phase 1 vaccination coverage reports will be developed and reviewed on a daily/weekly basis. Coverage report data will be shared with the media and public categorized by a variety of different metrics, which could include county, age, race, occupation, etc. Specific analysis will be done to monitor vaccine uptake among the Phase 1 targeted population and to ensure equitable vaccine distribution. Identified gaps in vaccine uptake or coverage will be addressed by increased vaccinations through LHD PODs or enhanced media/community outreach. Analysis will also occur to determine achievement of vaccination metrics to indicate Phases 2 and 3 can begin.

During Phase 2, vaccine providers will have the option of using PrepMod or their EHR/EMR to capture the required vaccination data. LHDs will utilize PrepMod for all vaccination phases. Prior to being able to receive COVID-19 vaccine, prospective vaccine providers must have successfully onboarded with ImmuNet. Onboarding allows vaccination data to be uploaded into ImmuNet through a HL7 connection with the provider's EHR/EMR that occurs in near real time. Whether submitted via PrepMod or uploaded from an EHR, vaccination data collected in Phase 2 will be sent to CDC via the IZ Gateway Connect and stored in the CDC Data Lake.

Phase 2 vaccination coverage reports will be developed and reviewed on a daily and weekly basis. Data will be shared with the media and public as in Phase 1 and similar analysis will be used to determine any gaps in coverage which will be addressed by additional clinics and/or media outreach.

8. VACCINATION SECOND DOSE REMINDERS

Most COVID-19 vaccines will require two doses separated by >21 or >28 days. COVID-19 vaccines will not be interchangeable so it will be imperative that a vaccine recipient's second dose be the same

product as the first dose. Second dose reminders will ensure compliance with vaccine dosing intervals in order to achieve optimal vaccine effectiveness.

CDC will provide COVID-19 vaccination record cards with the vaccine ancillary kits. Providers will be encouraged to use these cards, which note the dose manufacturer, lot number, date of first dose administration and second dose due date, and to give them to the vaccine recipient. Recipients should be reminded to keep the card as a record of their first dose and a reminder of when to get their second dose.

All administered doses will be reported to ImmuNet either through PrepMod or the provider EHR. Regular ImmuNet reminder/recall reports will be run to determine who is eligible to receive second doses and when. Postcard and other vaccination reminders will be used to notify individuals when a second dose is due. In addition to ImmuNet, vaccine recipients will receive an email/text message using PrepMod, if they pre-registered with PrepMod or were vaccinated at a Phase 1 clinic, indicating that they are due for a second dose and that they should go to MarylandVax.org to find a clinic where they can receive their second dose. CFI will also work with hospitals and occupational locations to ensure their system has the capacity to identify which staff members received first doses and can be reminded when second doses are due.

During Phase 2, public communication messages will promote COVID-19 vaccination completion. Paid, earned and social media messages will emphasize the need for two doses in most cases, to be fully protected and will include ways for the public to confirm their vaccination status. Maryland currently has a consumer vaccination portal, Maryland MyIR, which allows MyIR registered users to obtain their official vaccination records from ImmuNet. This portal will be used to allow consumers access to their COVID-19 vaccination record and provide certification of COVID-19 specific vaccination. MyIR can also be used to issue reminder/recall messages if two doses of COVID-19 are required. Regular ImmuNet reminder/recall reports will continue to be run to determine who is eligible to receive second doses to notify those individuals.

9. IMMUNET REQUIREMENTS AND PREPMOD

ImmuNet is the cornerstone of the COVID-19 vaccination plan. ImmuNet will be where providers register to become a COVID-19 provider, order COVID-19 vaccines, track delivery of vaccines, report doses administered and notify individuals when second doses are due. It is critical that ImmuNet functions at a high level to be able to handle the expected increased demand.

Infrastructure

CFI conducted an assessment of ImmuNet to determine the enhancements needed to ensure efficient provider registration, ordering, distribution, recording of doses administered and data reporting. The ImmuNet support vendor, Gainwell Technologies (formerly DXC Technology), has been incorporating enhancements to the system since April 2020 using federal supplemental funding. Enhancements include developing a COVID-19 provider screening and registration page, adding COVID-19 vaccine to the Specialty/Flu Vaccine Order page, and adding new functionalities for non-VFC COVID-19 vaccine providers. CFI has also ensured that ImmuNet is updated to the most recent version in order to support requested CDC data extracts.

CFI is in the process of moving ImmuNet into the AWS cloud environment. By moving to the AWS cloud, ImmuNet will be better able to handle the anticipated increased data exchange due to COVID-19 vaccination. CFI anticipates the move to AWS cloud to be completed by late 2020. A complete infrastructure review of the existing servers and hardware was done in September 2020 to ensure capacity is in place to handle provider volume prior to conversion to the AWS cloud.

Vaccination Provider Preparation

As described in *Vaccination Provider Recruitment and Enrollment* (Section 3A) providers are required to onboard with ImmuNet prior to being able to register to become a COVID-19 provider. In May 2020, CFI sent a clinician letter informing providers of the requirement to onboard with ImmuNet prior to being allowed to register for the vaccine. Since then, ImmuNet staff, along with staff from the Maryland health information exchange CRISP, have been onboarding new providers in preparation for COVID provider registration. Follow-up communication with prospective providers will include step-by-step instructions on how to onboard with ImmuNet as well as how to register to order COVID vaccine. Onboarding of providers will continue throughout the COVID-19 registration process and likely throughout the COVID-19 vaccination campaign. Non-traditional provider sites (i.e., PODs, mobile clinics) will be requested to partner with a provider or LHD that has already onboarded/registered and can use PrepMod to upload vaccination clinic data to ImmuNet within 24 hours of administration.

Data Management

As described in *Vaccine Administration Documentation and Reporting* section (Section 7), CFI is taking steps to ensure the CDC required data elements are captured in ImmuNet. To ensure ImmuNet is able to adequately exchange data with the CDC and other jurisdictions, CFI has signed the necessary DUAs and MOU to allow connection to the IZ Gateway CONNECT and SHARE. Maryland signed the DUA with the Association of Public Health Laboratories (APHL) in August 2020 to participate in IZ Gateway CONNECT. Maryland has been participating in the ONC project and already had the necessary MOU to participate in IZ Gateway SHARE and Gateway ACCESS. In September 2020, Maryland signed the required DUA with CDC to allow CDC to access ImmuNet data for national coverage analysis. By having these established connections, ImmuNet will be able to efficiently send and receive COVID-19 vaccination data and provide the most up-to-date information on vaccination in Maryland residents.

Ordering and Inventory

All COVID-19 vaccines must be requested/ordered through ImmuNet. Enhancements to ImmuNet were made to list COVID-19 vaccines on the Specialty/Flu Vaccine Order page (Appendix 12). Providers will go to this page to order COVID-19 vaccines (Section 4). To ensure vaccines are not being stockpiled by a particular provider and that they are being administered, providers will need to enter the total number of vaccines that they still have in inventory and the number of additional vaccines being requested. Doses administered by a provider can be confirmed by running an ImmuNet query of COVID-19 vaccinations by that particular provider.

 CFI will continue to manage and update the Specialty/Flu Vaccine Order page with the different COVID-19 vaccines that are currently available for order from Maryland's allocation, identified by the vaccine manufacturer name and the vaccine NDC. As vaccines become unavailable, CFI staff will make that particular NDC inactive for ordering and therefore not visible on the Specialty/Flu Vaccine Order page.

Additionally, if new or previously unavailable vaccines become available, they will be made active for ordering and will be visible on the Specialty/Flu Vaccine Order page.

Maryland will be using PrepMod as the main vaccine management system during Phase 1 and it will be used by LHDs during Phase 2. As previously mentioned, PrepMod is an online clinic management and appointment scheduling system developed in Maryland and used by Maryland local health departments to conduct mass vaccination/school-located clinics for the past four years. Use of PrepMod will eliminate the need for consent form manual data entry and promote social distancing by appointment scheduling. PrepMod will be used by COVID vaccine providers during the early/limited vaccine supply phase, in accordance with CDC guidance. CFI is currently working with the developer to add additional fields to the application in order to capture the required CDC data elements. PrepMod is also working to directly report to the IZ Gateway as an outside provider. https://multistatep4p.com

10. VACCINATION COMMUNICATIONS

Communications about COVID-19 vaccines must begin prior to vaccine availability and should continue throughout the vaccination campaign. This communication will need to be clear and effective to ensure success of the COVID-19 vaccination program.

The COVID-19 pandemic has had a disproportionate impact on people of certain races, ethnicities, ages, health status and socioeconomic status. It is essential that equity be incorporated into the implementation of a COVID-19 vaccination plan. Based on Census data, of Maryland's estimated six million residents, 31 percent are Black or African American, 11 percent are Hispanic, 0.6 percent are American Indian/Alaskan Native. Additionally, approximately 9 percent live in poverty. Those 65 years of age and older make up 15 percent of the population while those with heart disease, kidney disease, diabetes or respiratory disease (e.g., asthma, COPD, etc.) make up approximately 25 percent of the population. Communication will be essential to ensure these populations are reached as part of the vaccine program.

Survey data estimate that only 60-70 percent of the general population are willing to be vaccinated with a COVID-19 vaccine. This percentage is lower in specific population groups such as the Black or Hispanic communities, those with lower education status and those that live in rural areas. Concerns about the safety of vaccine as well as distrust in government, the medical research community and pharmaceutical companies all contribute to the hesitation in receiving the COVID-19 vaccine.

Messaging should be tailored and developed for each audience to ensure communication is effective. The MDH Office of Communications will take the lead with input from CFI. Messaging should use plain language that is easily understood. Messaging must also use non-stigmatizing, bias-free language and images.

The Office of Communications has launched an enhanced influenza vaccination awareness campaign called "Fight the Flu" to increase the number of Marylanders who get influenza vaccinations and decrease the respiratory disease burden on the healthcare system due to influenza and COVID-19. The campaign targets the general public and populations at the highest risk for influenza with outreach through paid and earned media, public service announcements, informational flyers and social media posts. The Office of Communications contracted with a media company to develop and disseminate

influenza messaging. Flyers were developed in different languages targeting both populations at highest risk for influenza and the general public. Fifteen and 30-second PSAs were developed to be aired on TV and also used on social media.

MDH will work with trusted community partners, priority group representatives, representatives of vulnerable populations and a marketing vendor to develop and disseminate COVID-19 vaccine messaging that focuses on three main areas:

- Safety and efficacy of COVID-19 vaccine: With the rapid development and licensing of COVID-19 vaccines, there will be concerns as to the safety and efficacy of the vaccine. Messaging will need to instill confidence in the vaccine and describe the process for reporting vaccine adverse events. Objectives for this area will include educating the public about the development of vaccines, the approval process for vaccines, the process for monitoring safety of vaccines, the process for determining a vaccine's efficacy, describing the difference between FDA emergency use authorization and FDA approval/licensure, and addressing vaccine hesitancy. Communication for this area will begin prior to the vaccine being available and continue throughout the vaccination campaign.
- Phase 1 Priority group vaccination: Messaging regarding vaccination of the priority groups during Phase 1 will focus on the determination of the priority groups and why they were chosen, how to report an adverse event, and how vaccination of these groups will occur. Communication for this area will begin prior to the vaccine being available and will continue until Phase 2 begins.
- Phase 2 General populations vaccination: Messaging regarding vaccination during Phase 2 will include where the vaccine is available, how to register on Marylandvax.org, how to report an adverse event, and how to attend a vaccination clinic safely. Communication for this area will begin toward the end of Phase 1 and will continue throughout the rest of the vaccination campaign.

The Office of Communications will respond to any media inquiries about the COVID-19 vaccination with input from representatives of the various agencies within MDH, such as the CFI, OP&R, the Infectious Disease Bureau and the Environmental Health Bureau.

11. REGULATORY CONSIDERATIONS FOR COVID-19 VACCINATION

Initial COVID-19 vaccine supply during Phase 1 may be authorized for use under an Emergency Use Authorization (EUA) issued by the FDA or approved as licensed vaccines.

<u>EUA Fact Sheets</u>

EUA authority allows FDA to authorize (a) the use of an unapproved medical product (e.g., drug, vaccine or diagnostic device) or (b) the unapproved use of an approved medical product during an emergency based on certain criteria. The EUA will outline how the COVID-19 vaccine should be used and any conditions that must be met to use the vaccine. These conditions can include distribution requirements, reporting requirements and safety and monitoring requirements. The EUA will be authorized for a specific time period to meet response needs.

A product-specific *EUA fact sheet for COVID-19 vaccination providers* will be made available that will include information on the specific vaccine product and instructions for its use. A separate *EUA fact sheet for vaccine recipients* will also be developed.

Vaccine Information Statements (VIS)

VISs are required only if a vaccine is added to the federal Vaccine Injury Table. Plans for developing a VIS for COVID-19 vaccine are not known at this time but will be communicated as information becomes available.

The EUA Fact Sheet or the VIS will be added into the PrepMod system and available on MarylandVax.org to provide information to vaccine recipients prior to vaccination. The EUA Fact Sheet or VIS will also be available at clinics that do not use the PrepMod system. Copies of each will be made available on the MDH website.

12. VACCINE SAFETY MONITORING

Vaccine safety monitoring will be essential to maintain confidence in the vaccine. An "adverse event following immunization" is an adverse health problem or condition that happens after vaccination. An adverse event might be truly caused by the vaccine or it might be purely coincidental and not related to vaccination. CDC continuously monitors the safety of vaccines given to children and adults in the United States. Three main systems are used to monitor the safety of vaccines: Vaccine Adverse Event Reporting System (VAERS), Vaccine Safety Datalink (VSD) and the Clinical Immunization Safety Assessment Project.

Per the *CDC COVID-19 Vaccination Program Provider Agreement* that providers will sign when they register to order and receive COVID-19 vaccines, vaccination providers are required to report adverse events following COVID-19 vaccination and should report clinically important adverse events even if they are not sure if the vaccination caused the event. Vaccine manufacturers are also required to report to VAERS all adverse events that come to their attention.

MDH will issue communications to describe the process for reporting any adverse events related to receiving COVID-19 vaccination. MDH will direct providers and vaccine recipients to report any adverse events to the VAERS. Instructions will include the VAERS website to submit an online report and who should report adverse events.

MDH will also use existing biosurveillance systems to monitor potential vaccine-related adverse events and follow up with providers to ascertain if the exposure is limited to an individual or related to a particular vaccine/vaccine lot.

13. VACCINATION PROGRAM MONITORING

Dashboards
Monitoring of the COVID-19 vaccination program will be critical for a successful outcome. CDC will be making COVID-19 vaccination dashboards available to the public: *The Weekly Flu Vaccination Dashboard* and *The COVID-19 Vaccination Response Dashboard* will use data related to flu and COVID vaccination that are collected from various sources.

MDH will also have Maryland-specific dashboards based on information collected in ImmuNet. CFI is currently working with the Surveillance division to develop flu dashboards that will be posted on the MDH website. These dashboards will also serve as the basis for the MDH COVID-vaccination dashboards. CFI staff will ensure that the MDH COVID-19 vaccination dashboard is updated daily to include, but is not limited, to the following information:

- Total number of COVID-19 vaccinations administered
- Number of persons vaccinated by age group
- Number of persons vaccinated by ZIP code
- Number of persons vaccinated by county
- Number of persons vaccinated by gender
- Number of persons vaccinated by race/ethnicity
- Vaccination coverage rates by county
- Remaining inventory of COVID-19 vaccine

APPENDIX 1

OPERATION WARP SPEED
VACCINE DISTRIBUTION PROCESS

IN SUPPORTING THE DISTRIBUTION & ADMINISTRATION OF COVID-19 VACCINES, OWS HAS FOUR KEY GOALS, TENETS, AND ARCHITECTURE

Ensure safety and effectiveness of COVID-19 vaccines

Reduce morbidity and mortality of COVID-19 disease through effective and efficient distribution of COVID-19 vaccines

Support rapid vaccine distribution based on CDC guidance for states immunizations services

Assist with the return to pre-pandemic quality of life

DISTRIBUTION AND ADMINISTRATION OF A COVID-19 VACCINE
FOUR KEY TENETS

CONTROL/VISIBILITY
Where vaccines and secondary item kits are at all times in the process of distribution and ensuring the vaccines go to prioritized groups as determined by policy

COVERAGE
Deliver vaccines beyond the normal brick and mortar facilities, including potential mobile or on-site delivery of vaccine to long-term healthcare facilities and other hard to reach populations

UPTAKE
How many vaccines were administered per location per day to match supply with demand

TRACEABILITY
Confirm which of the approved vaccines were administered:
- Regardless of location (private/public)
- Reminder to return for second dose
- Administer the correct second dose

TRIALS

MANUFACTURING

FDA
Based on data from clinical trials, vaccine candidate is submitted for Emergency Use Authorization (EUA) or Biologics License Application (BLA)
- Reviews EUA/BLA application
- Approves EUA/BLA application
- Oversees ongoing reporting
- Pharmacovigilance

MANUFACTURER
Vaccine is being manufactured concurrent with clinical trials, and upon EUA/BLA and CDC recommendation, vaccine is ready to ship

OWS & CDC
Allocation of initial/limited doses will be based on CDC prioritization models
- Independent advisory panel (Advisory Committee on Immunization Practices with input from Nat'l Academies of Science) informs CDC prioritization
- Initial/limited doses will be allocated for specific groups
  o Oversees distribution of vaccine
  o Tracks product that is delivered/administered

ADMINISTRATION SITES
Vaccines, upon EUA/BLA, are ready to ship to:
- Pharmacies
- Nursing homes
- Public Clinics
- Hospitals
- Doctor's offices and Mobile Clinics
- Military Treatment Facilities

DISTRIBUTION FACILITIES
Vaccines & associated ancillary kits (syringes, needles, and alcohol swabs) will be shipped concurrently to distribution depots and facilities

DISTRIBUTOR
- Maximize use of existing pharmaceutical distribution infrastructure
- Central Distributor established for kitting & distribution operations
- IT infrastructure supports ordering, distribution, administration, and tracking end-to-end

PHARMACOVIGILANCE (FDA & CDC)
24 month post trial monitoring for adverse effects/additional safety feature

APPENDIX 2
COVID-19 VACCINATION INCIDENT COMMAND

COVID-19 Vaccination Incident Command Structure

```
┌──────────────────────┐      ┌──────────────────────┐      ┌──────────────────────┐
│ SARS-CoV-2 Vaccine   │------│  Incident Commander  │------│ SARS-CoV-2 Vaccine   │
│ Technical Advisory   │      │                      │      │ Stakeholder Group    │
│ Group                │      │                      │      │                      │
└──────────────────────┘      └──────────────────────┘      └──────────────────────┘
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- **Communications**
- **Legal**

- **Planning**
  - Documentation
  - Evaluation
  - Core Planning Group
    - EMS
    - Hospitals
    - Law Enforcement
    - EMA
    - LHDs
    - Schools/Universities
  - Vulnerable Population/Outreach
    - MHHD
    - Aging
    - Behavioral Health
    - Home Care
    - DDA/MDoD
    - LTCs
    - Corrections
    - Human Services
    - MD Tribal Communities
    - MIA

- **Operations**
  - Surveillance/Epidemiology
  - Distribution
    - Registration
    - Ordering
    - Security
  - Dispensing
  - Open PODs:
    - LHDs
    - PCPs
    - FQHCs
    - Pharmacies
  - Closed PODs:
    - Continuity of Government
    - Hospitals
    - EMS
  - Scheduling/Training
  - Tracking/ Data Reporting

- **Logistics**
  - Volunteer Management
  - Resource Management
    - PPE
    - Ancillaries
    - Cold Chain
    - Transport

- **Finance/Administration**
  - Procurement
  - Fiscal Processing

APPENDIX 3
VACCINATION PRIORITY GROUP ESTIMATES - MARYLAND

Based on National Academies of Sciences, Engineering, and Medicine 2020. Framework for Equitable Allocation of COVID-19 Vaccine. Additional prioritization will be done in accordance with NASEM and ACIP recommendations and based on vaccine availability. All estimates are subject to change.

	Target Population	Category	Estimated US population size	Estimated MD population size (2% of US pop)
Phase 1	High Risk Health Care Workers	Health Care Practitioners and Technical Staff	6,728,000	134,560
		Health Care Support Staff	3,160,000	63,200
		Full TIme Nursing Home Employees	1,500,000	30,000
		Health Care Practitioners in Skilled Nursing	432,000	8,640
		Home Health Care Workers	3,162,000	63,240
		Public Health	291,000	5,820
		Pharmacists and Pharmacy Staff	621,000	12,420
		Dentists	200,000	4,000
		Morticians, Undertakers, Funeral Directors	25,000	500
	First Responders	EMS Personnel	262,000	5,240
		Law Enforcement	701,000	14,020
		Firefighters	1,100,000	22,000
	Older adults in congregate or overcrowded settings	Nursing Home Residents	1,347,000	26,940
		Residential Care Facility Residents	811,000	16,220
	Judiciary	Judges		320
		Judiciary Support Staff		4,000
	People in Prisons, Jails, Detention Centers and Staff	Incarcerated/Detained Individuals	2,300,000	46,000
		Correctional Officers, Jailers, Support Staff	423,000	8,460

	People with Comorbid and Underlying Conditions that put them at *Significantly* higher risk	Chronic Kidney Disease	747,000	14,940
		COPD	22,576,800	451,536
		Organ Transplant	819,930	16,399
		Obesity (BMI≥30)	101,104,800	2,022,096
		Serious Heart Conditions	*22,249,600*	*444,992*
		Diabetes Type 2	37,300,800	746,016
		Comorbidity with Above Conditions	*19,500,000*	*390,000*
Phase 2	K1-12 Teachers/ School Staff/ Child Care Workers	Elementary and Secondary School Teachers and Staff	8,605,000	172,100
		ChildCare Service Providers	463,000	9,260
	Critical Workers in High Risk Settings - Workers in Industries Essential to the Functioning of Society and *Substantially* Higher Risk of Exposure	Food and Beverage Production	1,700,000	34,000
		Cashiers and Food Store Workers	865,000	17,300
		Workers in the Utilities Sector	539,000	10,780
		Postal Workers	497,000	9,940
		Delivery Workers	1,506,000	30,120
		Passenger Vehicle Drivers	1,077,000	21,540
		Construction Workers	7,214,000	144,280
		Public Transit Workers	179,000	3,580
	People with Comorbid and Underlying Conditions that put them at *Moderately* higher risk	Asthma	19,200,000	384,000
		Cystic Fibrosis	29,887	598
		HIV/AIDS	1,553,029	31,061
		Liver Disease	4,500,000	90,000
	People in Homeless Shelters or Group Homes and Staff	Homeless Shelters	575,000	11,500
		Group Homes	469,000	9,380

	All Other Older Adults	People 65 and older	49,200,000	984,000
Phase 3	Young Adults	People aged 18-30 minus potential other categories	46,500,000	930,000
	Children	People aged 0 to 19 years of age	80,000,000	1,600,000
	Workers in Industries Important to the Functioning of Society and *Moderately* Higher RIsk of Exposure	College and University Faculty and Staff	3,089,000	61,780
		Factory Workers	8,400,000	168,000
		Restaurant Wait Staff	2,600,000	52,000
		Hotel Cleaning and Management Staff	1,200,000	24,000
		Bank Tellers	442,000	8,840
	Other Adults	People aged 30-65 without an underlying condition and not addressed in previous stages	TBD	TBD

Welcome to Team COVIDReadi!

Make a difference and help your community getting back on its feet.

① CONTACT INFORMATION

First Name
Ben

Middle Name (optional)
Harris

Last Name
❌

Please add your last name.

Phone Number
(111) 111 - 1111

Date of Birth
DD / MM / YYYY

Email
yourname@internet.com
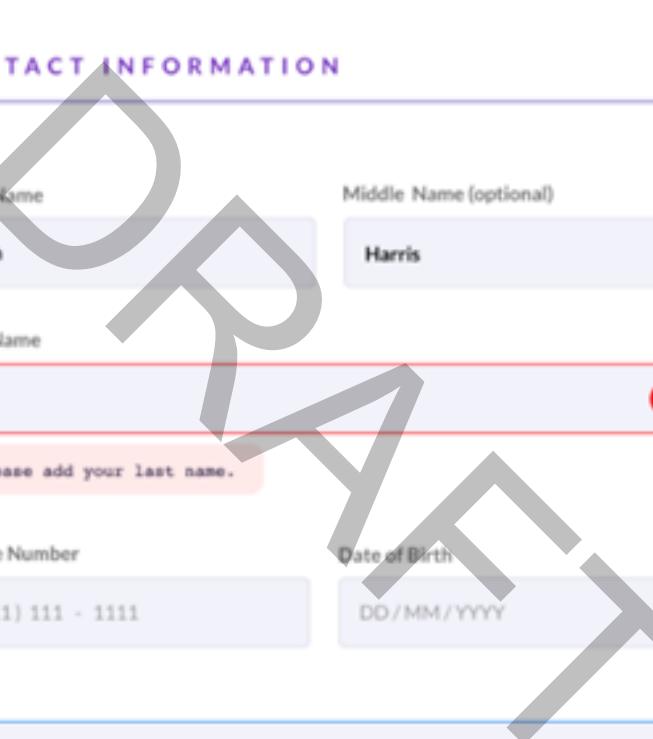
Address
21 Downing Street

Apartment/Suite # (optional)

City
New York

State
New York

Zip Code
10002

❷ HOUSEHOLD INFORMATION

Gender

(●) Male   Female

Race/Ethnicity

Spanish

Who is in your household (including yourself)?

ADULTS   ⊖ 0 ⊕

CHILDREN   ⊖ 5 ⊕

SENIORS (65 years+)   ⊖ 1 ⊕

Do you or anyone in your household have a chronic health conditions?

(●) Yes   No

❸ PREFERENCES

Do you have a preference of where you would like to be vaccinated ?
You can select more than one.

| ✓ Doctor's Office | Hospital | ✓ School | ✓ Local Health Department | No Preferences |

③ PREFERENCES

Do you have a preference of where you would like to be vaccinated ?
You can select more than one.

| Doctor's Office ✓ | Hospital | School ✓ | Local Health Department ✓ | No Preferences |

Once available, how soon would you like to receive the vaccine?
You can only select one option.

⊙ As soon as the vaccine is available!   I'd prefer to wait a few weeks

I'd prefer to wait multiple weeks to a few months

I'd like to pre-register, but am not interested in vaccination at this time

I'm not sure yet

④ SIGNATURE

Draw your signature in the box

⊗ Clear

or type it in

Register

APPENDIX 5
PRIORITY GROUPS BY COUNTY

TBD

DRAFT

APPENDIX 6
PROVIDER ONBOARDING LETTER

Maryland
DEPARTMENT OF HEALTH

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Robert R. Neall, Secretary

May 1, 2020

Dear Colleague:

As we begin to plan and prepare for potential COVID-19 vaccinations, this letter is to provide you with important information related to COVID-19 vaccines and ImmuNet, Maryland's Immunization Information System. As you might know, ImmuNet is a secure web-based registry operated by the Maryland Department of Health (MDH). ImmuNet information is confidential, HIPAA compliant and available only to authorized users including Maryland health care providers.

1. **COVID19 Vaccine Request and Reporting**

   As we are still many months away from a potential COVID-19 vaccine for the general population, HHS and CDC are currently planning for COVID-19 vaccine ordering and distribution. During the H1N1 influenza outbreak in 2009, H1N1 vaccine was ordered and distributed through the same public health infrastructure used to order/distribute Vaccines for Children (VFC) vaccine. While unknown at this time, planning is underway by MDH to utilize the current VFC vaccine ordering/distribution infrastructure for COVID-19 vaccine.

   Currently, VFC vaccine is ordered and distributed utilizing ImmuNet. If your practice is interested in potentially providing COVID-19 vaccine, it is essential that your practice is connected to ImmuNet prior to vaccine availability. We are looking to be proactive and connect/onboard sites now so that there is no delay in distributing COVID-19 vaccine once available. Please see bullet #2 below on how to onboard with ImmuNet.

   In order for your practice to be ready to receive COVID-19 vaccine, your practice must 1) be onboarded with ImmuNet and report routine vaccinations administered and then 2) register with the Center for Immunization through ImmuNet to receive COVID-19 vaccine. **Information on registering to receive COVID-19 vaccine (#2) will be issued at a later date.**

2. **Vaccination Reporting Requirement as of October 1, 2019**

   Since October 1, 2019 Maryland statute Health General §18–109 mandates that all vaccinations administered in the State of Maryland be reported to ImmuNet, regardless

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of patient opt-out status in ImmuNet. This will include administered COVID-19 vaccines. COVID vaccine administration data from ImmuNet will be used to determine vaccine coverage rates throughout the state and ensure high-risk populations are being successfully vaccinated.

The ImmuNet website, www.health.maryland.gov/immunet (under the link "Report to ImmuNet"), has been updated to guide vaccine providers with the mandatory reporting process.

The MDH Center for Immunization continues to partner with CRISP to onboard vaccine providers who are not already reporting to ImmuNet. **Vaccine providers are encouraged to review the "Report to ImmuNet" website to determine what steps are needed to connect/onboard with ImmuNet to prepare to receive COVID-19 vaccine.** The "Report to ImmuNet" website has details on reporting and how to contact the ImmuNet Help Desk for additional assistance.

If you have any questions, please contact the ImmuNet program at mdh.mdimmunet@maryland.gov. As always, we appreciate your commitment to vaccinating Maryland residents and helping keep Maryland vaccination coverage rates high.

Sincerely,

Kurt Seetoo, MPH
Chief, Center for Immunization

David Blythe, MD, MPH
Director, Infectious Disease
Epidemiology and Outbreak
Response Bureau

2

APPENDIX 7
COVID-19 PROVIDER SCREENING TOOL

STG Region — Maryland.gov | Phone Directory | State Agencies | Online Services

MARYLAND.gov

ImmuNet:
Maryland's Immunization Information System
DEPARTMENT OF HEALTH

WEBSITE NOTICE:
Immunet works best with the most current version of Internet Explorer or Google Chrome.

Home   Resources   About Us   Contact Us

ImmuNet COVID-19 Vaccine Provider Eligibility Questionnaire

Maryland's Immunization Information System (ImmuNet) is a secure web-based registry operated by the Center for Immunization at the Maryland Department of Health (MDH). ImmuNet information is confidential, HIPAA and FERPA compliant, and available only to authorized users, and will not be released to third parties without written consent.

If you are an authorized user interested in administering the COVID-19 vaccine, please complete this questionnaire. Organizations with multiple locations should fill in a questionnaire for each location.

Does you organization routinely administer vaccines? *

- Yes
- No, but able to vaccinate during emergencies
- No

ORGANIZATION INFORMATION

Organization Name *

Organization Group NPI (National Provider Identifier)

Organization Address *

Address Line 1

Address Line 2

City   State   ⌄   Zip Code

IMPORTANT NOTE: If you administer COVID-19 vaccines you will be required to report all administered doses to ImmuNet.

Is your organization currently reporting administered doses to ImmuNet? *

- Yes, please provide your Org ID. [Organization ID] *   No   Unsure

Do you participate in the Vaccines For Children (VFC) Program? *

- Yes, please provide your VFC PIN. [VFC PIN] *
- No, but would like to participate.
- No, only interested in ordering COVID-19 vaccine.

Population your organization serves (select all that apply): *

- Newborn/Infant   ☐ Adolescents   ☐ Adults
- Pediatrics   ☐ Pregnant Women   ☐ Seniors (65+)

Does your organization see patients who are considered Medically High Risk (select all that apply).

- ☐ Asthma   ☐ Genetic Disorders   ☐ HIV/AIDS   ☐ Immunocompromised
- ☐ Cancer   ☐ Diabetes   ☐ Heart Disease ☐ Transplant

Organization Contact Information *

Contact Name

Title/Department

Phone   **Email Address**
( )
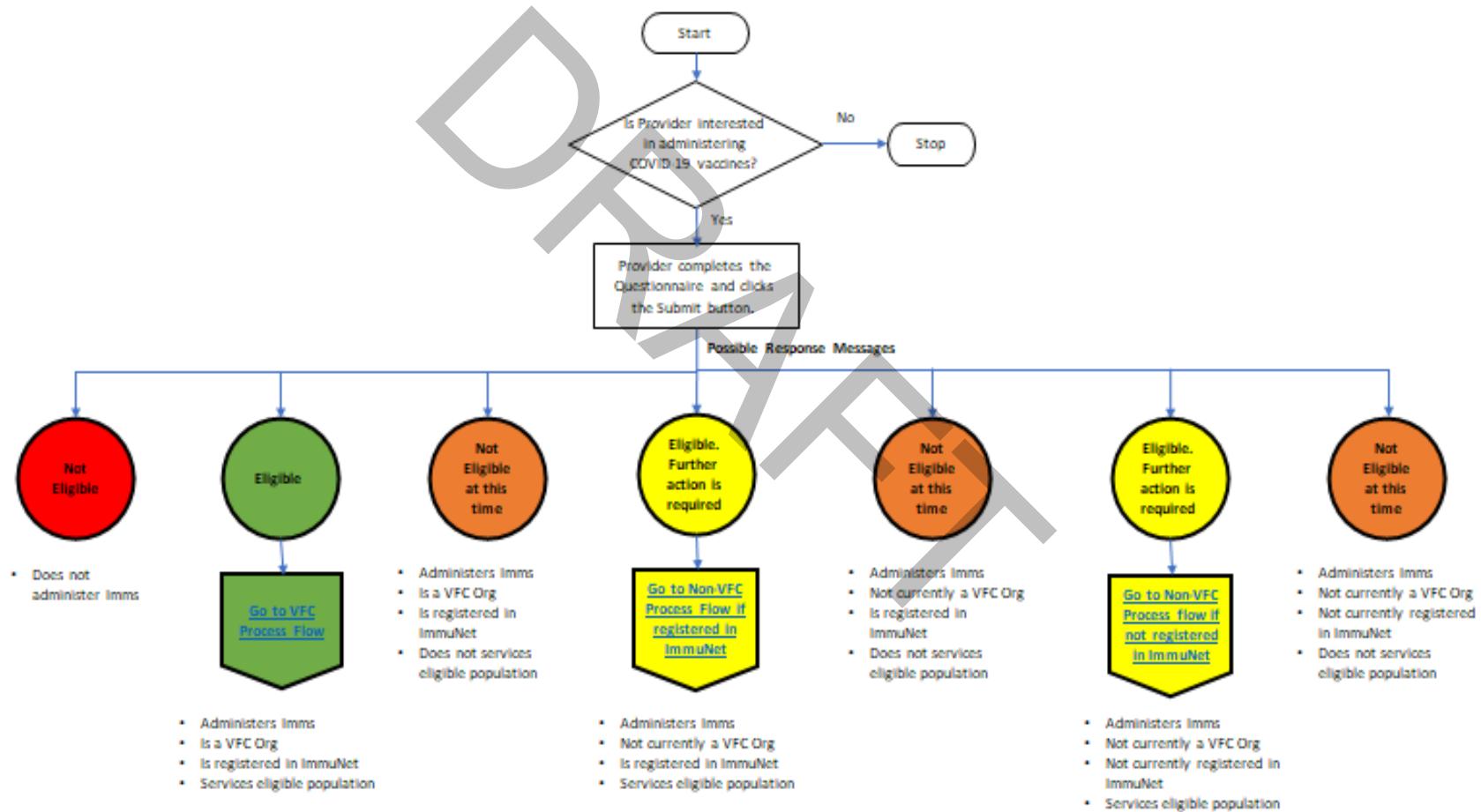
Date
06/06/2020

[Submit]

APPENDIX 8
PROVIDER SCREENING TOOL RESPONSES

COVID-19 Eligibility Screening Questionnaire Process & Possible Response Messages

APPENDIX 9
COVID-19 NON-VFC PROVIDER REGISTRATION SCREEN SHOT (DRAFT)

(SECTIONS EXPAND TO COMPLETE)

Edit Non-VFC Profile

Non-VFC Profile

Provider Pin:

Organization Type: Hospital

Provider Specialty: Birthing

Initiating Organization: Amanda Org 4

Initiating User: Amanda kitterman

Save

Cancel

Provider Practice/Facility Information ▼

Delivery Contact Information ▼

Responsible Medical Provider Information ▼

Additional Medical Providers within the Practice ▼
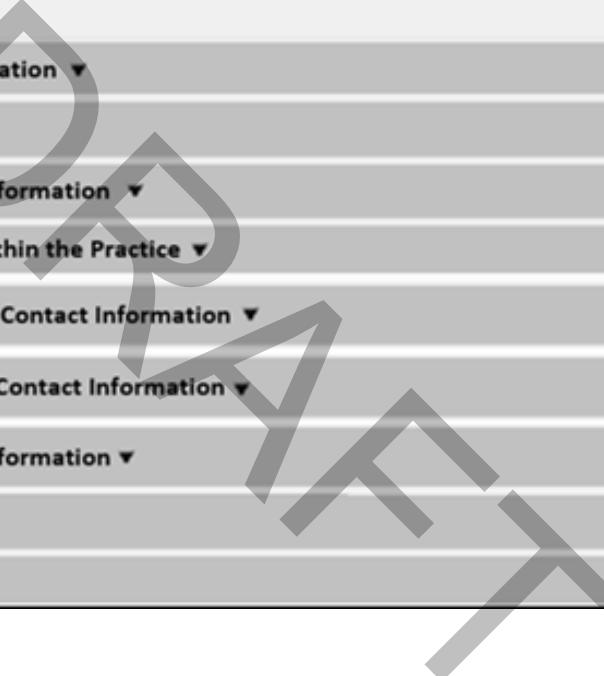
Practice Vaccine Supply Primary Contact Information ▼

Practice Vaccine Supply Backup Contact Information ▼

Vaccine Storage and Handling Information ▼

Provider Population ▼

Vaccine Agreement(s) ▼

APPENDIX 10
COVID-19 VFC PROVIDER REGISTRATION SCREEN SHOT (DRAFT)

(SECTIONS EXPAND TO COMPLETE)

APPENDIX 11
CDC COVID-19 PROVIDER AGREEMENT
CDC COVID-19 Vaccination Program Provider Agreement

	AGREEMENT REQUIREMENTS
	I understand this is an agreement between Organization and CDC. This program is a part of collaboration under the relevant state, local, or territorial immunization's cooperative agreement with CDC. To receive one or more of the publicly funded COVID-19 vaccines (COVID-19 Vaccine), constituent products, and ancillary supplies at no cost, Organization agrees that it will adhere to the following requirements:
1.	Organization must administer COVID-19 Vaccine in accordance with all requirements and recommendations of CDC and CDC's Advisory Committee on Immunization Practices (ACIP).[1]
2.	Within 24 hours of administering a dose of COVID-19 Vaccine and adjuvant (if applicable), Organization must record in the vaccine recipient's record and report required information to the relevant state, local, or territorial public health authority. Details of required information (collectively, Vaccine-Administration Data) for reporting can be found on CDC's website.[2] Organization must submit Vaccine-Administration Data through either (1) the immunization information system (IIS) of the state and local or territorial jurisdiction or (2) another system designated by CDC according to CDC documentation and data requirements.[2] Organization must preserve the record for at least 3 years following vaccination, or longer if required by state, local, or territorial law. Such records must be made available to any federal, state, local, or territorial public health department to the extent authorized by law.
3.	Organization must not sell or seek reimbursement for COVID-19 Vaccine and any adjuvant, syringes, needles, or other constituent products and ancillary supplies that the federal government provides without cost to Organization.
4.	Organization must administer COVID-19 Vaccine regardless of the vaccine recipient's ability to pay COVID-19 Vaccine administration fees.
5.	Before administering COVID-19 Vaccine, Organization must provide an approved Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative.
6.	Organization's COVID-19 vaccination services must be conducted in compliance with CDC's Guidance for Immunization Services During the COVID-19 Pandemic for safe delivery of vaccines.[3]
7.	Organization must comply with CDC requirements for COVID-19 Vaccine management. Those requirements include the following: a) Organization must store and handle COVID-19 Vaccine under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with the manufacturer's package insert and CDC guidance in CDC's Vaccine Storage and Handling Toolkit[4], which will be updated to include specific information related to COVID-19 Vaccine; b) Organization must monitor vaccine-storage-unit temperatures at all times using equipment and practices that comply with guidance located in CDC's Vaccine Storage and Handling Toolkit[4]; c) Organization must comply with each relevant jurisdiction's immunization program guidance for dealing with temperature excursions;

This agreement expressly incorporates all recommendations, requirements, and other guidance that this agreement specifically identifies through footnoted weblinks. Organization must monitor such identified guidance for updates. Organization must comply with such updates.

[1] https://www.cdc.gov/vaccines/hcp/acip-recs/index.html
[2] https://www.cdc.gov/vaccines/programs/iis/index.html
[3] https://www.cdc.gov/vaccines/pandemic-guidance/index.html
[4] https://www.cdc.gov/vaccines/hcp/admin/storage-handling.html

CDC COVID-19 Vaccination Program Provider Agreement

	d) Organization must monitor and comply with COVID-19 Vaccine expiration dates; and e) Organization must preserve all records related to COVID-19 Vaccine management for a minimum of 3 years, or longer if required by state, local, or territorial law.
8.	Organization must report the number of doses of COVID-19 Vaccine and adjuvants that were unused, spoiled, expired, or wasted as required by the relevant jurisdiction.
9.	Organization must comply with all federal instructions and timelines for disposing COVID-19 vaccine and adjuvant, including unused doses.[5]
10.	Organization must report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS).[6]
11.	Organization must provide a completed COVID-19 vaccination record card to every COVID-19 Vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative. Each COVID-19 Vaccine shipment will include COVID-19 vaccination record cards.
12.	a) Organization must comply with all applicable requirements as set forth by the U.S. Food and Drug Administration, including but not limited to requirements in any EUA that covers COVID-19 Vaccine. b) Organization must administer COVID-19 Vaccine in compliance with all applicable state and territorial vaccination laws.

By signing this form, I certify that all relevant officers, directors, employees, and agents of Organization involved in handling COVID-19 Vaccine understand and will comply with the agreement requirements listed above and that the information provided in sections A and B is true.

The above requirements are material conditions of payment for COVID-19 Vaccine-administration claims submitted by Organization to any federal healthcare benefit program, including but not limited to Medicare and Medicaid, or submitted to any HHS-sponsored COVID-19 relief program, including the Health Resources & Services Administration COVID-19 Uninsured Program. Reimbursement for administering COVID-19 Vaccine is not available under any federal healthcare program if Organization fails to comply with these requirements with respect to the administered COVID-19 Vaccine dose. Each time Organization submits a reimbursement claim for COVID-19 Vaccine administration to any federal healthcare program, Organization expressly certifies that it has complied with these requirements with respect to that administered dose.

Non-compliance with the terms of Agreement may result in suspension or termination from the CDC COVID-19 Vaccination Program and criminal and civil penalties under federal law, including but not limited to the False Claims Act, 31 U.S.C. § 3729 *et seq.*, and other related federal laws, 18 U.S.C. §§ 1001, 1035, 1347, 1349.

By entering Agreement, Organization does not become a government contractor under the Federal Acquisition Regulation.

Coverage under the Public Readiness and Emergency Preparedness (PREP) Act extends to Organization if it complies with the PREP Act and the PREP Act Declaration of the Secretary of Health and Human Services.[7]

---

[5] The disposal process for remaining unused COVID-19 Vaccine and adjuvant may be different from the process for other vaccines; unused vaccines must remain under storage and handling conditions noted in Item 7 until CDC provides disposal instructions; website URL will be made available.

[6] https://vaers.hhs.gov/reportevent.html

[7] *See* Pub. L. No. 109-148, Public Health Service Act §§ 319F-3 and 319F-4, 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e; 85 Fed. Reg. 15,198, 15,202 (March 17, 2020).

CDC COVID-19 Vaccination Program Provider Agreement

Chief Medical Officer (or Equivalent)

Last name	First name	Middle initial
Signature:		Date:

Chief Executive Officer (or Chief Fiduciary)

Last name	First name	Middle initial
Signature:		Date:

For official use only:
VTrckS ID for this Organization, if applicable: _____

Vaccines for Children (VFC) PIN, if applicable: _____   Other PIN (e.g., state, 317): _____

IIS ID, if applicable: _____

Unique COVID-19 Organization ID (Section A)*: _____

*The jurisdiction's immunization program is required to create a unique COVID-19 ID for the organization named in Section A that includes the awardee jurisdiction abbreviation (e.g., an organization located in Georgia could be assigned "GA123456A"). This ID is needed for CDC to match Organizations (Section A) with one or more Locations (Section B). These unique identifiers are required even if there is only one location associated with an organization.

APPENDIX 12

SPECIALTY/FLU VACCINE ORDER PAGE (DRAFT)

Order Specialty/Flu Vaccines

Grantee Code: MDA   **Provider Pin:** 4545

Organization Name: ACCOUNTABILITY

Inventory Date: 08/11/2020

[Confirm Order]

[Cancel]

Is this a priority Order? ○ yes ● no   **If yes, select Priority Reason:** [⌄]

Inventory entry instructions:
Please enter the number of VFC doses remaining in your organization's inventory as of today's date. Enter remaining inventory in the 'Doses on Hand (#)' column. If your organization has used all doses or has no doses for the trade name, enter a zero.

Order entry instructions:
Please enter a 'Doses Requested (#)' for each line. The Order Quantity can be zero, or equal to, or a multiple of the Package Quantity.

Exception: The Single Dose section allows a Doses Requested of 1 dose.

Specialty Trade Name/Mfr/Description	NDC	Doses on Hand (#)	Ordering Intention	Funding Type	Package Quantity	Doses Requested (#)
COVID-19 Moderna 1 Dose Syringe	00000-9999-01		PED		10	0
COVID-19 Inovio 1 Dose Syringe	99999-0000-01		PED	State	10	0

* Justification Statement:

Please enter Justification Statement, why this order is needed.
Click Confirm Order, once you have completed inventory, order, and Justification entries.
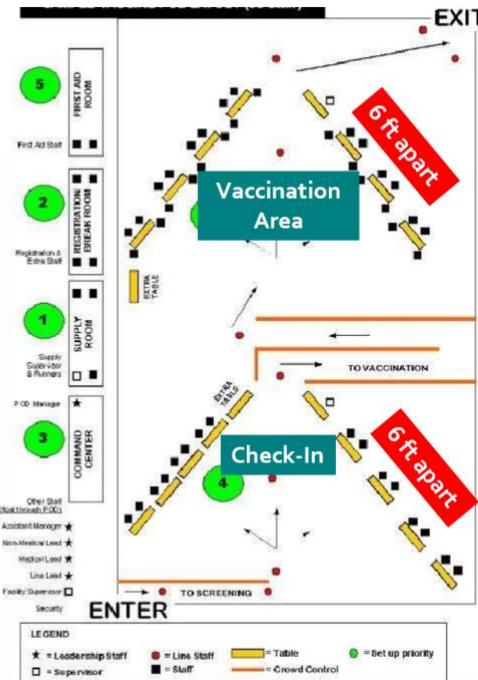
Clinic Models: POD

Requirements

· Indoor or outdoor large space

· Well-ventilated (if indoors)

· Ideally, separate entrance and exit

· Patients and staff wear appropriate PPE

· Tables 6 feet apart
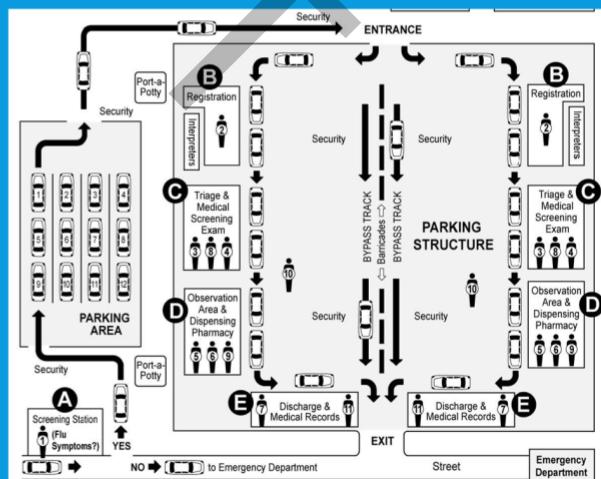
Venues: Gymnasium, Convention Center, Athletic Field, Ballroom

Clinic Models: Drive-Thru

Requirements
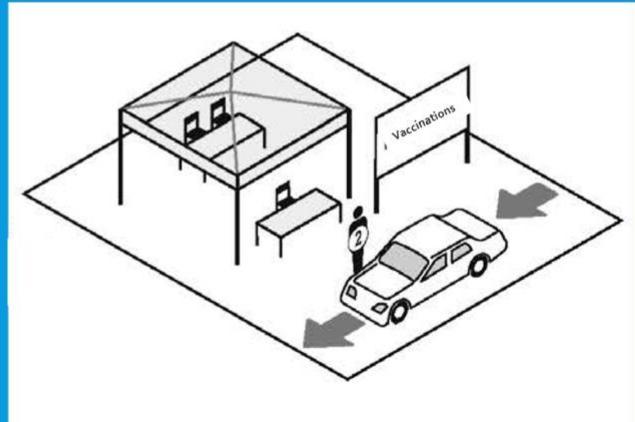
· Large Open Space

· Tents

· Large Parking Lot

· Traffic Control

· Post-Vaccination Waiting Area (if driver is vaccinated)

Clinic Models: Drive-Up/Walk-Up

Requirements

· Medium to Large Parking Lot

· Tent

· Minimal Traffic Control

· Post-Vaccination Waiting Area
  (if driver is vaccinated)

Venues: Schools, Shopping Centers, Athletic Fields

Clinic Models: Mobile Unit

Requirements

· Large Parking Lot

· Tent

· Minimal Traffic Control

· Post-Vaccination Waiting Area
  vaccinated)

Venues: Shopping Centers, Providers' Offices, Schools, Libraries

Temperature Log for Refrigerator – Fahrenheit

F° DAYS 1–15

Month/Year _____ VFC PIN or other ID #_____ Page 1 of 3

Facility Name_____

Monitor temperatures closely!
1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. Record temps twice each workday.
3. Record the min/max temps once each workday – preferably in the morning.
4. Put an "X" in the row that corresponds to the refrigerator's temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Take action if temp is out of range – too warm (above 46°F) or too cold (below 36°F).
1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of Month	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15	
Staff Initials																														
Exact Time	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Min/Max Temp (since previous reading)																														

Danger! Temperatures above 46°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!

TEMPERATURES
46°F
45°F
44°F
43°F
42°F
41°F

Aim for 40° → 40°F

ACCEPTABLE
39°F
38°F
37°F
36°F

Danger! Temperatures below 36°F are too cold! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!

ACTION
Write any out-of-range temps (above 46°F or below 36°F) here:
Room Temperature

Week 1 DDL Download Signoff – Signature_____ Date_____ Any New Alarms? NO / YES
Week 2 DDL Download Signoff – Signature_____ Date_____ Any New Alarms? NO / YES
Week 3 DDL Download Signoff – Signature_____ Date_____ Any New Alarms? NO / YES
Week 4 DDL Download Signoff – Signature_____ Date_____ Any New Alarms? NO / YES
Week 5 DDL Download Signoff – Signature_____ Date_____ Any New Alarms? NO / YES

(If yes, be sure to save supporting documents with temperature logs.)