

COVID-19 Vaccination Playbook

DELAWARE

DELAWARE COVID-19 Vaccination Planning Team
7 JANUARY 2021

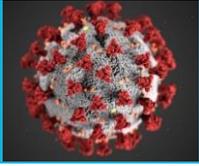


Table of Contents

Record of Changes 3

Introduction 4

Section 1: COVID-9 Vaccination Preparedness Planning 5

Section 2: COVID-19 Organizational Structure and Partner Involvement 8

Section 3: Phased Approach to COVID-19 Vaccination..... 13

Section 4: Critical Populations 18

Section 5: COVID-19 Provider Recruitment and Enrollment 23

Section 6: COVID-19 Vaccine Administration Capacity..... 30

Section 7: COVID-19 Vaccine Allocation, Ordering, Distribution, and Inventory Management..... 31

Section 8: COVID-19 Vaccine Storage and Handling..... 34

Section 9: COVID-19 Vaccine Administration Documentation and Reporting 36

Section 10: COVID-19 Vaccination Second-Dose Reminders..... 38

Section 11: COVID-19 Requirements for IISs or Other External Systems 39

Section 12: COVID-19 Vaccination Program Communication..... 42

Section 13: Regulatory Considerations for COVID-19 Vaccination 44

Section 14: COVID-19 Vaccine Safety Monitoring 45

Section 15: COVID-19 Vaccination Program Monitoring 46

Appendix A-Vaccine Transport 49

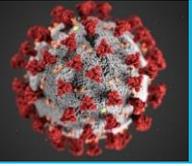
Appendix B-Vaccine Transfer Log 50

Appendix C: DPH Org Chart..... 51

Appendix D: SHOC Org Chart 52

Appendix E: CDC COVID-19 Vaccination Playbook Supplement #1 53

Appendix F: Delaware COVID-19 Vaccine Allocation Framework 57



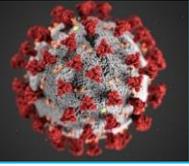
Introduction

Delaware, located on the eastern Atlantic coast of the United States, occupies part of the Delmarva Peninsula between Delaware Bay and Chesapeake Bay, and was one of the thirteen original states. Delaware is divided into three counties: New Castle, Kent, and Sussex. Historically, industrialized New Castle County has contrasted with the other two counties, which have been predominantly agricultural areas. Today approximately 60% of the population live in New Castle County, the northernmost county. Wilmington, the state's largest city, with more than 70,000 people, is in New Castle County. Dover, located in Kent County in the center of the state, is the capital of Delaware.

According to the 2019 Delaware Population Consortium, the population of Delaware is 972,332. This represented an increase of 8.3% percent over the 2010 census figure of 897,934. Delaware's beaches and boardwalks make the state a popular tourist destination during the summer months. The southern portion of the state, particularly the coastline in Sussex County, sees an increase in their summer population. In addition to the tourists that visit the coastline, Delaware is host to thousands of foreign students employed by local businesses to assist with the economic boost associated with the tourism influx. These students' staff restaurants, retail stores, and other associated businesses in and around the most heavily affected tourist destinations.

During this current COVID-19 pandemic effective allocation and administration of a future vaccine will play a vital role in reducing COVID-19 effects on Delaware's health, society, and economy. Although the overarching aim of Delaware's Division of Public Health's vaccination program is to vaccinate all persons in Delaware who choose to be vaccinated, the initial vaccine supply will be insufficient to meet this goal.

The Delaware Department of Health and Social Services (DHSS), Division of Public Health (DPH) is a unique organization in terms of the responsibility, size, and scope of operations. While most states have municipal or county health departments in addition to a state health department, DPH serves as the public health entity for both state and local initiatives.



Section 1: COVID-9 Vaccination Preparedness Planning

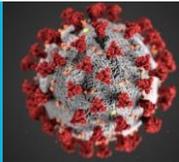
Instructions:

- A. Describe your early COVID-19 vaccination program planning activities, including lessons learned and improvements made from the 2009 H1N1 vaccination campaign, seasonal influenza campaigns, and other responses to identify gaps in preparedness.*

Since the COVID-19 outbreak, the DPH Immunization Program has been working internally to improve our processes if the vaccines were to be facilitated through the program. During normal operations, each position in the program had a singular purpose, but with an advancing vaccine response forthcoming, the Immunization Program needed to make some changes. One such change was the personnel structure. With the increased need of dose level accountability, several personnel have been cross trained to assist with vaccine inventory, ordering and storage and handling of the vaccine. Our two CDC Public Health Advisors and the two health program representatives will be educated on the intricacies of maintaining dose level accountability into the Immunization Information System (IIS), which is referred to as DelVAX. During DPH's last CDC site visit in 2019, additional staff were recommended by the CDC and were budgeted in the 2020 cooperative agreement to assist with vaccine management and to increase our storage and handling presence out in the community.

With the messaging from the CDC remaining consistent about how the vaccine was going to be handled, it gave the Immunization Program time to work on a process that has been slow to achieve, which is to decrease the time it takes to report immunization data to the IIS from a community clinic or Point of Dispensing (POD) exercise. The program has worked with the CDC and the IIS vendor, Envision Technologies, to create a system to where administered immunization data can be reported directly from a clinic site. This process was not part of the COVID-19 response, but it aligned with current response activities. This new process will allow real time submission into the IIS if a Wi-Fi connection is available. If not, the administered data can be uploaded to the IIS at the end of the clinic day

DPH has held weekly internal meetings since the release of the COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations – one for the DPH COVID-19 Vaccination Task Force which comprises of many members from the Influenza Advisory Committee and one for DPH leadership, within which many members are part of the COVID-19 Vaccination Task Force to ensure coordination between the two main groups. DPH has also met with certain stakeholders to provide a preliminary approach to COVID-19 vaccine distribution while waiting for further guidance from the federal level given their anticipated involvement during the initial delivery of vaccine. These stakeholders include the Delaware Public Health and Medical Ethics Advisory Group, Delaware Healthcare Association, Healthcare Associated Infection Advisory Committee, Post-Acute Care Task Force, and the Delaware Healthcare Preparedness Coalition.



- B. Include the number/dates of and qualitative information on planned workshops or tabletop, functional, or full-scale exercises that will be held prior to COVID-19 vaccine availability. Explain how continuous quality improvement occurs/will occur during the exercises and implementation of the COVID-19 Vaccination Program.*

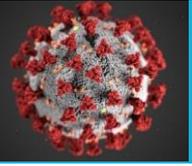
Dose level accountability was an issue of concern during the H1N1 campaign, where many doses went to sites that were not enrolled as vaccinating providers and these doses could not be tracked by the Immunization Program. With the increased attention to dose level accountability, through the creation of a new CDC Vaccine Tracking System (VTrckS), a dose of vaccine can be traced from the time it leaves the CDC Vaccine Depot, arrives at a provider site, and then is reported to the IIS as a dose that was administered. DelVAX has the ability of accepting either the Unit of Use or Unit of Sale information submissions using Health Level 7 (HL7) protocol messages to allow for flexibility in dose level accountability.

Reporting of immunizations has been a manual process of reporting by paper to the Immunization Program for several years. With the Centers for Medicare and Medicaid Services (CMS) Meaningful Use initiative, it gave providers an opportunity to connect their Electronic Medical Record (EMR) to the IIS. While this has been a successful project, it has not been a quick one, with an average time of 34 days required to onboard providers using HL7 messaging. Even with this short amount of time, Delaware still has several providers still reporting manually. The Immunization Program continues to reach out to onboard providers, with an estimated completion date of December 31, 2020.

Increased participation will involve the COVID-19 vaccine enrollment process, outreach to providers, and development of an online training program, and these initiatives are in currently in place to support the transition process, which is anticipated to be ongoing as we evolve to complete electronic reporting after COVID-19. The program also has worked with the CDC and the IIS vendor, Envision Technologies, to create a system to where administered immunization data can be reported directly from a clinic site. State Service Centers that house the public health clinics wanted to get the responses from the questions prior to vaccination, and this new enhancement will allow DPH to do that.

DPH plans to develop the Delaware COVID-19 Vaccination Task Force to engage additional internal and external partnerships in the operational and logistical processes specific for vaccine distribution, with its first meeting on October 23, 2020. Additional subcommittees and groups would be developed as the need arises, including the insertion of vaccine distribution discussions in established COVID-19 working groups involving health systems, long-term care, corrections, mental health, community groups, faith-based organizations, commercial pharmacies, other governmental agencies, schools and institutes of higher education, professional organizations, and businesses. Many of these groups already have COVID-19 vaccination as a standing agenda item, so these discussions will continue to evolve as more information is available for planning.

A tabletop exercise for DPH is planned for October 29, 2020 to focus on internal processes. Another exercise for the Delaware COVID-19 Vaccination Task Force will be scheduled after the introductory meeting on October 23, 2020 and will be focused more on vaccine operations involving these

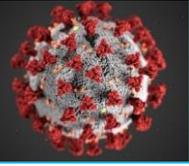


stakeholders such as professional medical organizations, health systems, FQHCs, third-party payers, health care associations, community groups, and other governmental agencies.

Regular weekly facilitated discussions with DPH leadership will be conducted to review updates to the Vaccine Allocation Framework and strategies to engage stakeholders in the vaccine administration process.

C. Explain how continuous quality improvement occurs/will occur during the exercises and implementation of the COVID-19 Vaccination Program

The Delaware COVID-19 Vaccination Program Committee is a diverse and well-rounded group, with every organization committed to providing vaccine for immunization in the most efficient manner. The key objective to this initiative is that processes in the COVID-19 vaccination program be fluid and adaptable to be able to fit every situation as changes occur. With a scheduled tabletop exercise scheduled for October 29, 2020 to review and walk through some of the objectives, specifically when it comes to critical populations and vaccine allocation. Further exercises will be planned as extensively as needed in order to achieve the best outcome. Many different scenarios, including those involving operational, logistical, political, and technological/informatic challenges, must be tested and approved to develop processes before implementation in order to achieve desired goals. Once implementation begins, each process should be screened for validity and be modified as situations warrant. Continuously retesting processes during implementation will allow for the phasing out of issues as they arise, ensuring that processes meet the objective. Process will be reviewed and discussed during the weekly vaccine planning committee meetings to ensure that every step that needs to be corrected is identified and presented to the committee for resolution.



Section 2: COVID-19 Organizational Structure and Partner Involvement

A. Describe your organizational structure.

Using the current DPH organizational chart (Appendix C), the Office of the Medical Director (OMD) is taking the lead for the vaccination effort, with the Immunizations Program and Emergency Medical Services and Preparedness Section (EMSPS) supporting the required processes and reporting up to OMD through the structure. The DPH's State Health Operations Center (SHOC) also has the organization structure (Appendix D) to show the responsible agencies responsible for different areas when activated for the vaccine response.

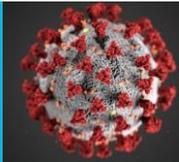
B. Describe how your jurisdiction will plan for, develop, and assemble an internal COVID-19 Vaccination Program planning and coordination team that includes persons with a wide array of expertise as well as backup representatives to ensure coverage.

DPH has held weekly internal meetings since the release of the COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations – one for the DPH COVID-19 Vaccination Task Force which comprises of many members from the Influenza Advisory Committee and one for DPH leadership, within which many members are part of the COVID-19 Vaccination Task Force to ensure coordination between the two main groups. DPH has also met with certain stakeholders to provide a preliminary approach to COVID-19 vaccine distribution while waiting for further guidance from the federal level given their anticipated involvement during the initial delivery of vaccine. These stakeholders include the Delaware Public Health and Medical Ethics Advisory Group, Delaware Healthcare Association, Healthcare Associated Infection Advisory Committee, Post-Acute Care Task Force, and the Delaware Healthcare Preparedness Coalition.

The current team for influenza vaccine planning encompasses expertise in mass vaccination and pandemic planning/response (OMD, Immunizations, EMSPS, Community Health, etc.) so that this team is the appropriate conduit to expand into COVID-19 vaccination. Also, key members of the Pandemic Task Force and H1N1 response will be involved, which include:

- DPH Office of Communications
- OMD
 - Immunization Program
 - Office of Infectious Disease Epidemiology (OIDE)
 - Office of the State Epidemiologist
- EMSPS
- Delaware Attorney General's Office
- Office of the Governor Constituent Affairs

As mentioned above, an internal public health leadership call has been occurring weekly and as of October 23rd, additional external partners will be added.



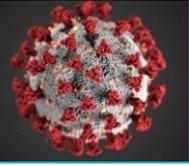
- C. Describe how your jurisdiction will plan for, develop, and assemble a broader committee of key internal leaders and external partners to assist with implementing the program, reaching critical populations, and developing crisis and risk communication messaging.*

Partnerships created during COVID-19 response specifically for testing – testing collaboratives, Pandemic Resurgence Advisory Committee, etc. – will also be engaged in vaccination initiatives as the objectives are similar, especially regarding access by vulnerable populations. Partnership include DPH, Delaware Emergency Management Agency, other state agencies, health care systems, Federally Qualified Health Centers (FQHCs), governmental representatives, academic universities, professional organizations, community organizations, etc. Also, existing partnerships related to immunizations and influenza, such as the Healthcare Associated Infection Advisory Committee and the Immunization Coalition of Delaware, provide subject matter expertise in clinical and operational aspects of vaccination distribution. The Delaware Public Health and Medical Ethics Advisory Group (Ethics Group) was involved in the review of the priority groups for H1N1 vaccination and will be included for COVID-19 to allow for transparency and standardization of the phased approach, with its first meeting regarding COVID-19 vaccination scheduled on November 2, 2020 in anticipation of finalized guidance from federal partners on approach to allocation.

DPH plans to develop the Delaware COVID-19 Vaccination Task Force to engage additional internal and external partnerships in the operational and logistical processes specific for vaccine distribution, with its first meeting on October 23, 2020. Additional subcommittees and groups would be developed as the need arises, including the insertion of vaccine distribution discussions in established COVID-19 working groups involving health systems, long-term care, corrections, mental health, community groups, faith-based organizations, commercial pharmacies, other governmental agencies, schools and institutes of higher education, professional organizations, and businesses.

- D. Identify and list members and relevant expertise of the internal team and the internal/external committee.*

Experts will include, but are not limited to, those from health systems, medical community, community-based organizations, correctional facilities, homeless shelters, faith-based leaders, FQHC's, Governor's Office, Legislators, academic institutions, health care associations, professional organizations, commercial pharmacies, etc., for which many are currently involved in COVID-19 testing strategies, with goals to include others as appropriate. Many of these stakeholders have been invited to participate in the COVID-19 Vaccination Task Force given experience with the current COVID-19 pandemic, the previous novel H1N1 influenza pandemic, public health, mass vaccination, crisis standard of care, community health and vulnerable population needs, delivery of health care, and communications, with others already participating in other groups involved in COVID-19 planning and response that can become



subcommittees to support the overall COVID-19 Vaccination Program. The introductory meeting for the COVID-19 Vaccination Task Force is scheduled on 10/23.

E. *Describe how your jurisdiction will coordinate efforts between state, local, and territorial authorities.*

Collaboration has been on-going between state and federal authorities through the HHS Region III (mid-Atlantic State Health Officers), specifically the Region III Vaccine Task Force, and various weekly to monthly calls with partners such as CDC, HHS, ASTHO, etc. The DPH Medical Director has been assigned as the designated state lead for vaccine distribution planning, with scheduled calls with federal and national partners (CDC, HHS, ASTHO, etc.) on a weekly to monthly basis based on the call. Since DPH is the only designated health department in Delaware, it is responsible for local public health activities as well and will continue to work in that same capacity with local partners. One advantage to this structure is that DPH does not need to coordinate with a local public health entity to reach the community level, and DPH has been successful in maintaining those relationships and communication channels with individual communities.

F. *Describe how your jurisdiction will engage and coordinate efforts with leadership from tribal communities, tribal health organizations, and urban Indian organizations.*

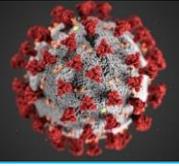
Representation from the state-recognized Lenape Indian Tribe of Delaware and Nanticoke Indian Tribe has been included in the DPH COVID-19 Vaccination Task Force, and further outreach to these communities continue to enhance engagement. The Immunization Program Manager has reached out to both tribal communities, hoping to discuss current COVID activity, and the need to immunize their population. These tribes are small and integrated into the communities. They are not federally recognized and therefore do not have access to Indian Health Services.

While engaging with tribal leaders, each tribal nation has the sovereign authority to provide for the welfare of its people and, therefore, has the authority to:

- Choose among the jurisdiction or Indian Health Service (IHS) options for accessing vaccine.
- Determine the population(s) it chooses to serve.
- Choose how vaccines are distributed to its community.
- Establish phased groups when there is a limited supply of COVID-19 vaccine or other accompanying resources.

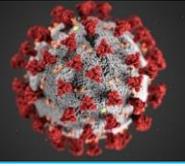
G. *List key partners for critical populations that you plan to engage and briefly describe how you plan to engage them, including but not limited to:*

- Pharmacies – Walgreens, CVS, Rite Aid



- Correctional facilities/vendors – Delaware Department of Corrections
- Homeless shelters – DHSS Division of State Service Centers (Hotels) and Housing Alliance are communicated with at least monthly via meetings and phone conversations
- Community-based organizations – National Coalition of 100 Black Women
- Faith-based leaders – similar organizations for testing opportunities
- FQHCs – Westside Family Health, LA Red Health Center, Henrietta Johnson Medical Center
- Health systems – Delaware Healthcare Preparedness Coalition facility members and their internal SME's for vaccination efforts
- EMS/Police/Fire – Engaging with county paramedic agencies to become Closed PODs for first responder agencies.
- Delaware Public Health and Medical Ethics Advisory Group – recommendations on phased groups for vaccine

DPH has a list of contacts for these partners and will either invite them to our discussions or offer to participate in their meetings to share information and expertise.



Section 3: Phased Approach to COVID-19 Vaccination

Instructions:

- A.** Describe how your jurisdiction will structure the COVID-19 Vaccination Program around the three phases of vaccine administration:

Phase 1: Potentially Limited Doses Available

Phase 2: Large Number of Doses Available, Supply Likely to Meet Demand

Phase 3: Likely Sufficient Supply, Slowing Demand

The SHOC understands there may be significant challenges with vaccine distribution especially in phase 1 in which there may be a limited number of doses available. The state will follow the CDC recommended¹ phase groups listing for distribution. In preparation the state has been in discussion with strategic partners (especially hospitals, first responders etc.) regarding the need to identify those individuals that need and want to be vaccinated.

DPH will determine the specific amount of vaccine that will be allocated to each phase group based on the anticipated weekly vaccine allocations offered to the state by the federal government, the organizations participating as enrolled providers in DelVAX, and the ability of the enrolled provider to speedily vaccinate the designated phase group.

Section 3.1: Vaccine Allocation Framework

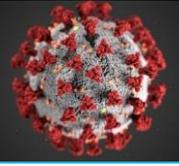
1.0 Purpose

- 1.1. DPH will maintain a comprehensive and dynamic Vaccine Allocation Framework (see Appendix F) that outlines the phased approach to vaccine allocation for high-risk and subsequent groups.
- 1.2. The Vaccine Allocation Framework is updated regularly for the following reasons:
 - 1.2.1. Updates from the CDC ACIP on recommendations for phase groups and sub-groups.
 - 1.2.2. Updates from the vaccine manufacturers on allocations projected to be delivered to Delaware in the upcoming weeks.

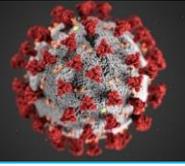
2.0 Vaccine/Medication Groups

- 2.1. DPH, with recommendations from the Ethics Group, will review the CDC list of phased population groups and recommend the ethical allocation of vaccine(s).

¹ The CDC recommendations come from the Advisory Committee on Immunization Practices (ACIP). DPH will present the ACIP phase 1 recommendations to the Delaware Public Health and Medical Ethics Advisory Group for consideration. The Ethics Group may recommend approval as is or with suggested modifications.



- 2.2. High-risk workforce groups will include, but are not limited to the following:
 - 2.2.1. Paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials and are unable to work from home.
 - 2.2.2. Health care workers
 - 2.2.3. Public Safety/Emergency Services including, but not limited to the following:
 - A. Law Enforcement (LE)
 - B. Emergency Medical Services (EMS)
 - C. Fire/Rescue Departments (FD)
 - D. Corrections
 - E. National Guard (NG)
 - F. Other
 - 2.2.4. Public Health and Community Health support workers
 - 2.2.5. Critical Infrastructure workers including, but not limited to:
 - A. Manufacturing operations deemed essential
 - B. Supply chain (warehousing and shipping)
 - C. Food supply chain
 - D. Utilities and other services
 - 2.2.6. Essential workers (as defined by Delaware State of Emergency declarations, Public Health Emergency declarations, etc.)
 - A. Manufacturing
 - B. Public facing employees such as grocery stores, banks, etc.
 - C. Food Service
 - D. Retail
 - E. Others
- 2.3. High-risk population groups will include, but are not limited to the following:
 - 2.3.1. Population(s) most at risk for the following:
 - A. Susceptibility
 - B. Spreading
 - C. Hospitalization
 - D. Mortality
 - 2.3.2. Congregate facilities
 - A. Long Term Care/Rehabilitation
 - B. Prisons
 - C. Schools, including colleges and universities



D. Other facilities

2.3.3. Populations most at risk for severe illness or death

A. Age groups (over age 65)

B. Health disparities

1. Densely populated areas
2. Multi-generation households
3. Health care access limited
4. Co-morbidities
 - a. Medical
 - b. Mental Health
 - c. Substance Use disorders
5. Lack of insurance
6. Language and cultural barriers
7. Fixed income
8. Homeless population

3.0 Allocation Decision-making

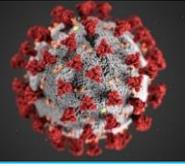
3.1. Each pandemic has specific levels of risk based on transmissibility, clinical severity, co-morbid and socioeconomic factors.

3.2. The Ethics Group will provide guidance for vaccine(s)/medication allocation based on the following framework:

3.2.1. Ethical Principles²

- A. Maximize benefits and minimize harms — Respect and care for people using the best available data to promote public health and minimize death and severe illness.
- B. Mitigate health inequities — Reduce health disparities in the burden of COVID-19 disease and death, and make sure everyone has the opportunity to be as healthy as possible.
- C. Promote justice — Treat affected groups, populations, and communities fairly. Remove unfair, unjust, and avoidable barriers to COVID-19 vaccination.

² Johns Hopkins Bloomberg School of Public Health, Center for Health Security (2020). *Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States*. Retrieved from: https://www.centerforhealthsecurity.org/our-work/pubs_archive/pubs-pdfs/2020/200819-vaccine-allocation.pdf



- D. Promote transparency — Make a decision that is clear, understandable, and open for review. Allow and seek public participation in the creation and review of the decision processes.

3.2.2. Situations and Assumptions

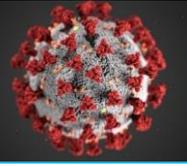
- A. The COVID-19 vaccine allocation phased groups for Delaware were developed based on ethical decision-making only; logistics were not a consideration.
- B. The initial allocation of COVID-19 Vaccine to the State of Delaware will not be adequate to protect all the Phase 1 groups³.
- C. The initial allocation of vaccine must be distributed and administered in a very short period due to storage and utilization requirements and urgency to reduce transmission during the pandemic.
- D. Operational decision-making is used to consider the physical ability to vaccinate within the Phase 1 sub-groups in order to efficiently utilize the anticipated vaccine supply with the resources available and within the limited timeframe.
- E. The vaccine delivery timeline will drive the allocation of resources among the phases; overlap of phased groups is likely (see Figure 2).
- F. Flexibility is permitted to adjust phased groups based on current trends and public health needs.

3.2.3. The Ethics Group will develop recommendations for vaccine(s)/medication allocation based the above framework, to include phase group and sub-groups as needed. The recommendations will be provided through the Public Health Medical Director to DPH leadership.

3.3. SHOC and/or DPH will implement specific actions outlined in the *Delaware Pandemic Influenza Plan*, the *Delaware Division of Public Health Mass Distribution of Medications/Vaccines Standard Operating Guideline*, and other applicable plans, procedures, and guidelines to achieve widest distribution of available vaccines. The Vaccine Allocation Framework (Appendix F) includes proposed strategies and potential timelines for vaccine administration efforts to the phase groups.

3.4. Final decisions are being made about use of initially available supplies of COVID-19 vaccines. These decisions will be partially informed by the proven efficacy of the

³ Johns Hopkins Bloomberg School of Public Health, Center for Health Security (2020). *Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States*. Retrieved from: https://www.centerforhealthsecurity.org/our-work/pubs_archive/pubs-pdfs/2020/200819-vaccine-allocation.pdf



vaccines coming out of Phase 3 trials, but populations of focus for initial COVID-19 vaccination include those listed in the Vaccine Allocation Framework (Appendix F).

3.5. All planning will be conducted within the context of the three phases:

3.5.1. Phase 1: Potentially limited supply of COVID-19 vaccine doses available

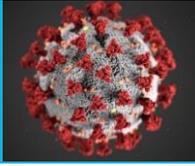
- A. Concentrate efforts on reaching the initial populations of focus for COVID-19 vaccination listed above, including those who may be part of other critical populations that might require additional vaccination efforts to ensure access to vaccine. Ensure vaccination locations selected can reach populations, manage cold chain requirements, and meet reporting requirements for vaccine supply and uptake.

3.5.2. Phase 2: Large number of vaccine doses available

- A. Focus on ensuring access to vaccine for all critical populations who were not vaccinated in Phase 1, as well as for the general population; expand provider network.

3.5.3. Phase 3: Sufficient supply of vaccine doses for entire population (surplus of doses)

- A. Focus on ensuring equitable vaccination access across the entire population. Monitor vaccine uptake and coverage; reassess strategy to increase uptake in populations or communities with low coverage.

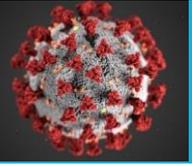


Section 4: Critical Populations

Instructions:

ACIP, the National Institutes of Health, and the National Academies of Sciences, Engineering, and Medicine (NAEM) are working to determine populations of focus for COVID-19 vaccination and ensure equity in access to COVID-19 vaccination availability across the United States. CDC has established an ACIP work group to review evidence on COVID-19 epidemiology and burden as well as COVID-19 vaccine safety, vaccine efficacy, evidence quality, and implementation issues to inform recommendations for COVID-19 vaccination policy. A key policy goal is to determine critical populations for COVID-19 vaccination, including those groups identified to receive the first available doses of COVID-19 vaccine when supply is expected to be limited. After a short period of potentially limited vaccine supply, supply will likely increase quickly, allowing vaccination efforts to be expanded to include additional critical populations as well as the general public. Delaware will develop plans to ensure equitable access to vaccination for each of the critical populations identified in the Vaccine Allocation Framework.

In the event that Delaware's allocation during Phase 1 is insufficient to vaccinate all those included in the initial populations of focus, it is important to identify and estimate the subset groups (i.e., Phase 1a, Phase 1b) within these initial populations of focus to determine who will receive the first available doses of COVID-19 vaccine. Delaware will review current ACIP work group considerations for assistance in identifying, prioritizing, and estimating Phase 1 sub-population groups. Considerations for Phase 1 subset groups may include paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials; people who play a key role in keeping essential functions of society running and cannot socially distance in the workplace (e.g., emergency and law enforcement personnel, food packaging and distribution workers, teachers/school staff, childcare providers); adults with high-risk medical conditions who possess risk factors for severe COVID-19 illness; and people 65 years of age or older (including those living in LTCFs). There may be insufficient COVID-19 vaccine supply initially to vaccinate all those who fall into sub-population groups, so Delaware will plan for additional subsets within that group (see CISA guidance for categories of health care personnel). Phase 2 planning may also benefit from identifying subsets of population groups if there is high demand for vaccine. The U.S. Department of Labor's Occupational Safety and Health Administration has information on classifying workers at risk (low to very high based on position within an organization) for exposure to SARS-CoV-2. This information could prove helpful in determining subsets of critical populations for vaccination. Also, Delaware will consider enumeration by place of employment rather than residence, as accounting for workers by place of employment will help to minimize underestimation of these critical populations. The convenience of receiving vaccination at the place of employment may also result in increased vaccination coverage.



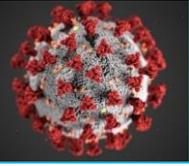
A. Describe how your jurisdiction plans to: 1) identify, 2) estimate numbers of, and 3) locate (e.g., via mapping) critical populations. Critical population groups may include:

- *Health care personnel*
- *Other essential workers*
- *Long-term care facility residents (e.g., nursing home and assisted living facility residents)*
- *People with [underlying medical conditions](#) that are risk factors for severe COVID-19 illness*
- *People 65 years of age and older*
- *People from racial and ethnic minority groups*
- *People from tribal communities*
- *People who are incarcerated/detained in correctional facilities*
- *People experiencing homelessness/living in shelters*
- *People attending colleges/universities*
- *People living and working in other congregate settings*
- *People living in rural communities*
- *People with disabilities*
- *People who are under- or uninsured*

Several divisions, sections, and programs across the state, and specifically within the Delaware Department of Health and Social Services, will be able to assist the state in identifying, estimating numbers of, and locating critical populations. The DHSS Division of Healthcare Quality oversees long-term care and assisted living facilities. The DPH's Community Health Services will use trusted members of populations in vulnerable communities to connect with this group. The Medical Director with the Department of Corrections can provide information on correctional facilities. The Division of Developmental Disabilities Services and Division of Services for Aging and Adults with Physical Disabilities maintain information on these population. The Division of Medicaid & Medical Assistance, as well as several programs within DPH, provides assistance to those who are under- or uninsured. The state will connect with programs and sections that serve specific populations, such as those mentioned above, to better understand these populations.

The internal workgroup is connecting with statewide divisions, sections, and programs to identify, estimate numbers of, and locate critical populations. DPH's Community Health Services has existing partnerships with several of the populations described above, such as people from racial and ethnic minority groups, and can assist in identification, estimating numbers of, and locating critical populations.

Identifying, estimating numbers of, and locating critical populations are critical to determining the resources needed during the early phases of vaccination, including the number of vaccine doses, and the approach to vaccine administration. The resources and approach to administration will evolve as the vaccine supply expands.



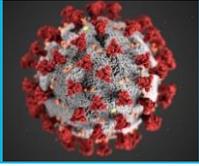
Broadly speaking, epidemiologists with DPH currently leverage various data sources, such as My Healthy Community, to identify, estimate numbers of, and locate critical populations and subpopulations. Epidemiological data sources provide demographic information such as age, sex, race, and ethnicity, which will allow for identification of critical populations. Epidemiologists have been collecting surveillance data and conducting case investigations since March 2020; this data provides a wealth of information about the demographics of COVID-19 cases in the state and may provide insights into critical populations that can be served by the COVID-19 vaccine.

Since July 2020, DPH has onboarded 16 new epidemiologists, data analysts, and public health professionals to assist with conducting out the state's COVID response. The current COVID epidemiology team includes a data team comprised of three epidemiologists and two data analysts and is overseen by the State's Deputy Epidemiologist. The data team meets twice weekly to review data-related activities, such as analyzing testing event data. Additionally, the data team disseminates daily outbreak detection reports which drill down into specific locations and populations that may be at risk for COVID-19. The State Deputy Epidemiologist provides a daily update to state public health leadership on the number of new cases overall and by demographic group and geographic region. Thus, the results produced by the data team help create a better understanding of the state's critical populations and will be used to inform vaccine allocation/distribution efforts in the coming months.

B. *Describe how your jurisdiction will define and estimate numbers of persons in the critical infrastructure workforce, which will vary by jurisdiction.*

DPH will utilize connections with health systems, EMS agencies, and employers of other essential personnel to estimate the number of persons in the critical infrastructure workforce, including identifying subgroups of individuals at greater risk for COVID-19. DPH will solicit input from employers to determine who is included in the critical infrastructure workforce.

Throughout the remainder of the calendar year and into 2021, as the vaccine becomes available for distribution to certain populations, DPH will engage in the aforementioned activities to estimate the number of persons in the critical infrastructure workforce and incorporate this group with critical populations into the prioritization process. DPH has already sent out an online survey through the Medical Society of Delaware (see Section 5 below for greater detail) to assist with provider recruitment and enrollment. Information gathered in the survey includes the number of staff at numerous health care organizations and practices across the state, therefore providing insight on the number of people in the critical infrastructure workforce as it relates to health care. DPH is in a unique position as it is the centralized health department (i.e., one department for the whole state as opposed to county or local health departments), and therefore has more streamlined channels of communication with partners across the state. Decisions about dissemination of information and coordination of immunization-related activities occur at the state level, which allows for a timelier and coordinated response as there are fewer avenues of communication to maintain.



Delaware hospitals are in the process of determining estimates for prioritization groups by a) number of direct patient care, b) support for direct patient care, C) essential employees that cannot work from home and may come in contact with COVID patients, and d) others. Estimates for first responders (EMS/Fire/Police/Dispatch) have been completed. DPH is currently in the process of contracting with a vendor to assist with estimating vulnerable population numbers, with expectation to have these data available prior to vaccine availability anticipated to be in November.

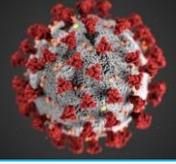
C. *Describe how your jurisdiction will determine additional subset groups of critical populations if there is insufficient vaccine supply.*

The SHOC will provide recommendations for vaccine allocation in subset groups of critical populations if there is insufficient vaccine supply. Given that there is likely to be substantial overlap between subgroups critical populations identified above, targeted efforts may focus on specific populations most at-risk. DPH will also communicate with community leaders across the state to identify subset groups of critical populations based on COVID-19 prevalence and the status of the virus among these groups. DPH staff, including leadership and epidemiologists, maintain communication with employers of members of groups in Phase 1, such as health care systems, schools, and food packaging and distribution plants. Over the next several weeks, the state will work with employers to estimate the number and composition of subset groups of critical populations based on vaccine availability. DPH has already collected some of this information with the survey mentioned above and described in greater detail below (Section 5). Key metrics of COVID-19 in the state at the time that the vaccine becomes available, such as prevalence, positivity rate, and demographics of those infected, will also help identify additional subset groups of critical populations.

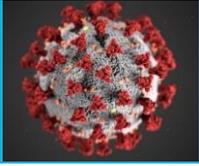
The DPH Ethics Group will be activated to provide recommendations to the DPH Director when vaccine is in insufficient supply to administer to all members within an identified population group. The Ethics Group will also take into consideration the current ACIP workgroup recommendations, in order to make decisions about additional subset groups of critical populations. The state will solicit input from employers of critical populations (such as health care workers) about specific subgroups that are most at risk for COVID-19 within the overall critical population.

D. *Describe how your jurisdiction will establish points of contact (POCs) and communication methods for organizations, employers, or communities (as appropriate) within the critical population groups.*

Community Health Services and the EMS/PS Vulnerable Populations Coordinator will leverage existing relationships with community leaders who advocate for their communities, which may include individuals at increased risk for COVID-19. The State has created many partnerships with community members and leaders prior to and during COVID-19 and will use these partnerships to identify points of contact (whether the current ones or new ones based on needs and



expertise) within the critical population groups. Leadership and staff within Community Health Services can use their connections with community members to establish communication methods within critical population groups as appropriate.



Section 5: COVID-19 Provider Recruitment and Enrollment

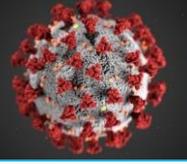
Instructions:

- A.** *Describe how your jurisdiction is currently recruiting or will recruit and enroll COVID-19 vaccination providers and the types of settings to be utilized in the COVID-19 Vaccination Program for each of the previously described phases of vaccine availability, including the process to verify that providers are credentialed with active, valid licenses to possess and administer vaccine.*

DPH has reached out to potential COVID-19 vaccination providers and targeted the appropriate settings so that COVID-19 vaccination services are accessible to the initial populations of focus when the first COVID-19 vaccine doses arrive. Providers and settings that maximize the number of people who can be vaccinated should be prioritized for enrollment; however, jurisdictions should ensure social distancing and other infection control procedures can be maintained in selected settings (see CDC guidance on vaccination during a pandemic). All providers/settings, especially those enrolled for Phase 1, must be able to meet the reporting requirements discussed in Section 9: COVID-19 Vaccine Administration Documentation and Reporting and Section 11: COVID-19 Requirements for Immunization Information Systems or Other External Systems. Jurisdictions should consider partnering with the private sector and with local hospitals or health systems to provide COVID-19 vaccination in the closest proximity possible to the initial populations of focus. Delaware will recruit additional COVID-19 vaccination providers to expand equitable access to COVID-19 vaccination when vaccine supply increases and will consider engaging both traditional and nontraditional vaccination providers and settings.

To recruit interested providers, an online survey link was sent through the Medical Society of Delaware newsletter, Delaware Health Alert Network (DHAN), the email addresses of long-term care facility (LTCF) contacts, and kidney/dialysis centers in Delaware. The survey responses are used to determine interest and capacity to administer COVID-19 vaccine to patients and staff. Once the provider has received and agreed to completing the COVID-19 vaccinator checklist, they will be eligible for enrollment. The survey was released on September 1, 2020 without a deadline. The program will continue to monitor responses and enroll potential providers on a rolling basis. As of October 13, 2020, 190 responses were collected with 130 respondents expressing interest in administering COVID-19 to either patients, staff, or both.

Once the vaccination provider has been identified through the recruitment process, Phase 1 providers will be sent the enrollment form to be filled out and returned and loaded into VTckS before November 1, 2020. Phase 2 and Phase 3 providers will receive an email containing a link to COVID-19 enrollment documents within the DelVAX, which is still under construction by the DelVAX vendor, Envision Technologies. Both the Provider Agreement and Provider Profile information are in DelVAX as a PDF and can be downloaded for signature of the chief medical officer and chief executive officer. The enrollment template in DelVAX is built to require an Immunization Program User (user from the program approving the enrollment) to confirm the medical license. The medical license will be verified by the program user utilizing the Delaware



Division of Professional Regulation License Look-Up webpage

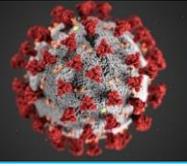
https://delpros.delaware.gov/oh_verifylicense. The information on this website will verify that the license is valid and supplies the issue and expiration date.

Utilizing the online survey, interested providers will be screened to verify their specialty (i.e., Geriatric, Family medicine, LTCF, etc.), approved vaccine storage units and staffing capacity to ensure proper vaccination of patients. Additionally, the provider will be screened to ensure their patient demographics meet one of the three criteria: people at increased risk for severe COVID-19 illness; people at increased risk of acquiring or transmitting COVID; or people with limited access to routine vaccination services.

B. *Describe how your jurisdiction will determine the provider types and settings that will administer the first available COVID-19 vaccine doses to the critical population groups listed in Section 4.*

DPH is currently collaborating with EMS agencies in the three counties on initiatives to administer vaccine in closed POD-type settings for established critical populations. The DPH Office of EMS (OEMS) is preparing to have adequate infrastructure and supplies to simultaneously hold three PODs at once. See Section 4C. DPH has established Closed POD agreements with hospitals, health care systems and 1st responder agencies to positively affect the administration of vaccine to critical work force populations. Hospitals have demonstrated with 2019 flu vaccine efforts that they can vaccinate approximately 75% of their workforce within three (3) days.

Outlined below are the federal entities (and their respective populations) that will receive a direct allocation of COVID-19 vaccine.

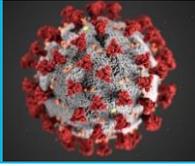


Federal Entity	Population Served
Bureau of Prisons (BoP)	<ul style="list-style-type: none"> All BoP-managed facilities: facility staff and inmates Private contracted facilities and contracted residential reentry centers (RRCs) not included
Department of Defense (DoD)	<ul style="list-style-type: none"> Active duty personnel and their dependents Retirees (does not include their dependents) U.S. Coast Guard (does not include their dependents) DoD civilian and contractor employees (those who regularly receive care through DoD as well as those who don't) To be determined: Reserves and National Guard (including those not activated)
Department of State (DoS)	<ul style="list-style-type: none"> All personnel under Chief of Mission eligible to receive care through DoS Stateside civil service employees
Indian Health Service (IHS)	<ul style="list-style-type: none"> Tribal nations selecting IHS for vaccine allocation (see page 12: Tribal Nations and Tribal Communities) Potentially includes IHS/Tribal/Urban facility staff and individuals served
Veterans Health Administration (VHA)	<ul style="list-style-type: none"> VA staff (including volunteers and trainees) and veterans regularly receiving care at VHA facilities (State Veterans Homes not included)

- C. Describe how provider enrollment data will be collected and compiled to be reported electronically to CDC twice weekly, using a CDC-provided Comma Separated Values (CSV) or JavaScript (JSON) template via a SAMS-authenticated mechanism.

To receive/administer COVID-19 vaccine, constituent products, and ancillary supplies, vaccination provider facilities/organizations must enroll in DelVAX. Enrolled COVID-19 vaccination providers must be credentialed/licensed in the jurisdiction where vaccination takes place, and sign and agree to the conditions in the CDC COVID-19 Vaccination Program Provider Agreement.

The vaccinating providers will enter their enrollment data and upload this information directly into DelVAX. Once this information is reviewed and approved, it will be downloaded directly to CDC using IIS. The DelVAX vendor, Envision Technologies, is currently working to finalize the enrollment template. Once finalized, Envision Technologies will develop a data extraction tool that will submit data directly to CVRS. A reporting template from CDC has been provided to Envision Technologies in order to create this functionality within DelVAX, with an expectation of this functionality being added to DelVAX by November 7, 2020.



A vaccine coordinator is the POC for receiving vaccine shipments, monitoring storage unit temperatures, managing vaccine inventory, etc. The Immunization Program will encourage enrolled facilities/organizations to designate a vaccine coordinator role at each location as well as a back-up vaccine coordinator. To support more efficient distribution of vaccine, locations should offer full day receiving hours to the extent possible. When that is not possible, COVID-19 vaccination providers must be available to receive vaccine shipments during a 4-hour window on a weekday other than Monday

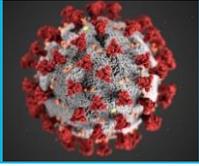
- D.** *Describe the process your jurisdiction will use to verify that providers are credentialed with active, valid licenses to possess and administer vaccine.*

The Immunization Program will use the information reported on the CDC COVID-19 Vaccination Program Provider Profile Information Form to verify that the medical license number(s) are active and valid to both possess and administer vaccines by checking this information with the Delaware Division of Professional Regulation License Look-Up webpage https://delpros.delaware.gov/oh_verifylicense. A printable version of the verification is available and can be saved with the provider enrollment information. If any of these providers licenses are found to be invalid or if the provider is unable to possess or administer vaccines the Chief Medical Officer and/or the CEO will be notified that the identified provider will not be able to administer and/or receive vaccine until the license information can be updated or resolved. Pharmacist licenses on enrollment forms will be verified through information provided by the Division of Professional Regulation.

- E.** *Describe how your jurisdiction will provide and track training for enrolled providers and list training topics.*

Providers will be notified of all required trainings through correspondence with the primary vaccine coordinators identified at every enrolled CDC COVID-19 vaccine provider site. Prior to the enrollment process, providers that do not report administered doses electronically via HL7 or flat file will have to complete training for direct data entry into DelVAX. There is currently a Training Material module built into DelVAX which contains training guidance (Quick Reference Guides) for vaccine ordering and inventory management, CDC's *You Call the Shots*, and a Reports Training section that contains training information on using the reminder/recall functions within DelVAX. Training documents for the provider enrollment process are currently being developed. The *You Call the Shots* training materials will be updated to address specific COVID-19 vaccination once CDC makes this information available. The Immunization Program will require the providers to submit their training certificates from CDC *You Call the Shots* training to the program office. Completion of all other required provider trainings will be self-reported from the vaccinating providers by utilizing and submitting a completed Provider Training form to the program. This data will be entered into an Access or Excel database so it can be monitored.

CDC is developing and updating a variety of clinical educational and training resources for health care professionals related to COVID-19 vaccine(s). Some of these materials will soon be available

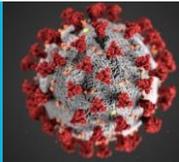


to assist with planning for vaccine implementation. Other materials will become available as regulatory authorization or approval from FDA for each vaccine candidate is acquired. Each manufacturer is also developing educational and training resources for its individual vaccine candidate. The list may change or be updated as appropriate (see table below).

PRODUCT	NEW/UPDATE	ADDITIONAL INFORMATION
<i>Vaccine Storage and Handling Toolkit</i>	Update	An addendum with general COVID-19 vaccine storage, handling and transport information will be added, and the addendum will be updated as COVID-19 vaccine products are approved. A fully updated toolkit, incorporating COVID-19 information into the actual toolkit will not be issued until 2022.
COVID-19 training module	New	Under development is a web-based module. Topics will include storage/handling, vaccine indications, contraindications/precautions, administration, and documentation. It will not have CE and will be amended as new COVID-19 vaccine products are introduced.
Vaccine product summary sheets	New	Fact sheets with storage, handling, preparation, indications, contraindications/precautions, and administration will be developed for each vaccine
Additional immunization guidance materials	New	More extensive information related to storage, handling, preparation, administration, shipping, packaging, and transport will be provided as necessary (not all vaccines will need additional guidance)
Comprehensive table of vaccine products	New	A table of COVID-19 vaccine products with key information will be updated as vaccines are approved.
Beyond use dates and expiration date tracking tools	New	A resource will be provided to track BUD and expiration dates, for use early in vaccine distribution process.
ACIP recommendation summary information	New	Conduct webinar, slide deck for use by awardees and other partners
<i>You Call the Shots</i> web-based Training	Update	Updates to the <i>You Call the Shots</i> Vaccine Administration and Storage and Handling modules to refer users to appropriate COVID-19 vaccine websites. Information will be updated more extensively in early 2021 based on continuing education timelines.
Healthcare personnel FAQs	New	Web-based FAQ document
Providing vaccinations Safely during a pandemic	Update	CDC has developed this website to provide guidance about safely providing vaccines during COVID 19. The website will be updated as appropriate.

F. Describe how your jurisdiction will approve planned redistribution of COVID-19 vaccine (e.g., health systems or commercial partners with depots, smaller vaccination providers needing less than the minimum order requirement).

All COVID-19 vaccine transfers will be coordinated through the Immunization Program utilizing a process similar to the transfer of publicly funded vaccines guidance and will be provided to all



vaccinating provider sites regarding the procedures and requirements for redistribution of COVID-19 vaccines. This guidance will adhere to the Vaccine Transport section of the CDC Vaccine Storage and Handling Toolkit (see Appendix A). Once the provider contacts the Immunization Program via email or phone requesting to redistribute vaccine, the provider will be emailed a Vaccine Transfer Form (See Appendix B) to complete and return to the Immunization Program.

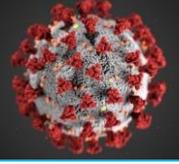
- G.** *Describe how your jurisdiction will ensure there is equitable access to COVID-19 vaccination services throughout all areas within your jurisdiction.*

The DPH Ethics Group will be consulted, along with the Health Equity Bureau to assess availability of vaccine to provide for equitable access for the available vaccine. The Vaccine Allocation Framework (Appendix F) is regularly updated and publicly shared in this document which will be placed on the DPH webpage.

- H.** *Describe how your jurisdiction plans to recruit and enroll pharmacies not served directly by CDC and their role in your COVID-19 Vaccination Program plans.*

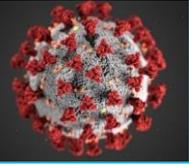
CDC will collaborate with CVS and Walgreens to provide on-site vaccination clinics for LTCF residents. CDC is working closely with LTCFs, jurisdictions, CMS, professional trade organizations that serve LTCFs and assisted living facilities, and pharmacy partners to inform facilities of their options to receive COVID-19 vaccine. Depending on when LTCF staff is prioritized to receive vaccine, they will be covered under this plan (if prioritized at the same time as residents) or covered under Delaware's plan for vaccinating health care workers/essential populations (if prioritized before residents). If staff is prioritized before residents, any staff not already vaccinated may be vaccinated through the on-site clinics offered by pharmacy partners.

To vaccinate a broader population group in Phase 2, vaccine will be allocated and distributed directly from the federal government to select pharmacy partners. Direct allocation opportunities will be provided to retail chain pharmacies and networks of independent and community pharmacies (those with a minimum of 200 stores). All partners must sign a pharmacy provider agreement with the federal government. As part of such agreement, before receiving COVID-19 vaccine, the partner must propose, in writing, its minimum capacity for vaccine administration, including a) the number and location of facilities that will administer COVID-19 vaccine, b) the estimated number of COVID-19 vaccine doses that each facility will be able to administer within defined periods, and c) estimated cold chain storage capacity. On a daily basis, pharmacy partners must report to CDC via designated methods the number of doses of COVID-19 vaccine a) ordered by store location; and b) on hand in each store reported through VaccineFinder. Pharmacy providers will also be required to report CDC-defined data elements related to vaccine administration to DelVAX. CDC will provide information on these data elements and reporting methods if stores are not able to directly provide data to DelVAX. Partnerships with pharmacies will need to be synchronized with jurisdictions to improve vaccination coverage and ensure transparency across the COVID-19 Vaccination Program.



Pharmacies are consistently enrolled in DelVAX. Designated staff identify smaller pharmacies and train those sites for enrollment in DelVAX. The Delaware Board of Pharmacy is a partner the program will use to ensure all pharmacies have had an opportunity to enroll in DelVAX. Presently, there are less than five small pharmacies that are not enrolled in DelVAX. DPH does not anticipate using these pharmacies during phase 1.

Additionally, Delaware pharmacies are actively contacting the Immunization Program to express interest in becoming a COVID-19 vaccination partner. Pharmacy contact information is being collected and will be used once more COVID-19 vaccine information becomes available. An onboarding process will be established, which will include license verification through the Bureau of Professional Regulation.



Section 6: COVID-19 Vaccine Administration Capacity

Instructions:

- A. Describe how your jurisdiction has or will estimate vaccine administration capacity based on hypothetical planning scenarios provided previously.*
- B. Describe how your jurisdiction will use this information to inform provider recruitment plans.*

The DPH will utilize the Pandemic Vaccination Campaign Planning Tool to help determine the vaccination capacity for the COVID-19 vaccine response for the State of Delaware. The results of the tool should help to target where the vaccine can be most effectively used. The results from this tool will be used for a discussion in the COVID vaccination planning group to determine the best course in providing COVID-19 vaccinations in every phase of the response. If effective, DPH should be able to ascertain the time it will take to vaccinate the adult population in the State of Delaware.

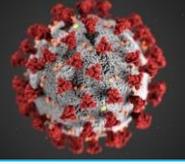
DPH will reach out to the health systems during the week of October 12th, 2020, to discuss vaccine planning and allocation. Further outreach to other agencies will be accomplished as progress is reported to the Vaccine Planning Committee. CDC has also developed a tool to assist with estimating vaccination capacity. The newest version of this tool, the PanVax Tool for Pandemic Vaccination Planning (version 3.3), is available on the CDC website.

The Immunization Program will enter the information into the planning tool once a consensus is reached on the following areas:

1. Population to be vaccinated
2. Provider vaccination groups
3. Provider group vaccination scenarios
4. Vaccine availability
5. Vaccine allocation
6. Monthly vaccine availability

Once the data is entered and agreed upon, the vaccination planning group can use the information to determine the strengths and shortfalls in providers groups starting in Phase 1 of the response. Knowing the capacity of the provider groups is key, especially in determining to what extent that other provider groups (Example: pharmacies supporting community clinics) can supplement to fill in the gaps to optimize vaccine availability and allocation. This is especially important in Phase1 of the response, as the goal is to vaccinate this population as quickly as possible using the vaccine that is available.

Once the state enters Phases 2 & 3, and vaccine becomes more readily available, the vaccination planning group can use the data from the planning tool, data from the CDC program Tiberius, and data from the Data Lake to forecast coverage rates, completion dates for differing age groups and have the ability to target areas of need.



Section 7: COVID-19 Vaccine Allocation, Ordering, Distribution, and Inventory Management

Instructions:

- A.** *Describe your jurisdiction's plans for allocating/assigning allotments of vaccine throughout the jurisdiction using information from Sections 4, 5, and 6. Include allocation methods for populations of focus in early and limited supply scenarios as well as the variables used to determine allocation.*

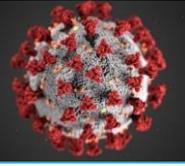
Once guidance regarding the Ethics Groups recommendations concerning vaccine allocation has been reached, DPH leadership will meet to discuss the decisions of the group, and how much vaccine will be distributed to the applicable populations. With the meeting of ACIP on October 28, 2020, the Ethics Group will be meeting on November 2, 2020 to review any guidance or statements regarding prioritization groups and vaccine allocation from the ACIP meeting.

Ancillary supplies will be packaged in kits and will be automatically ordered in amounts to match vaccine orders in VTrckS. For centrally distributed vaccines, each kit will contain supplies to administer 100 doses of vaccine, including needles (#105), syringes (#105), alcohol prep pads (#210), surgical masks (#4), face shields (#2), and COVID-19 vaccination record cards for vaccine recipients (#100). If a COVID-19 vaccine that requires mixing with diluent is ordered and shipped from CDC's centralized distributor, a mixing kit that includes the necessary needles, syringes, and alcohol prep pads will also be automatically added to the order. Ancillary supply kits will not include sharps containers, gloves, and bandages. Additional personal protective equipment (PPE) may be needed depending on vaccination provider site needs.

- B.** *Describe your jurisdiction's plan for assessing the cold chain capability of individual providers and how you will incorporate the results of these assessments into your plans for allocating/assigning allotments of COVID-19 vaccine and approving orders.*

As part of the enrollment process, specific information regarding vaccine storage capabilities and equipment will be collected. DelVAX has an asset management functionality that will be utilized for those providers capable of uploading temperature monitoring data via a .csv file. The goal is to maintain similar procedures that already exist and are familiar to providers (e.g., protocols from the Vaccine for Children (VFC) Program.

Information collected during enrollment will include type of storage unit (pharmacy grade, household, commercial, etc.); temperature capabilities of the storage units; temperature monitoring equipment (hospital based system, continuous temperature monitoring, etc.); capacity; and appropriate equipment and training to transfer vaccine if necessary.



- C. *Describe your jurisdiction's procedures for ordering COVID-19 vaccine, including entering/updating provider information in VTrckS and any other jurisdictional systems (e.g., IIS) used for provider ordering. Describe how you will incorporate the allocation process described in step A in provider order approval.*

Entering/ Updating Provider Information in VTrckS and DelVAX:

- Providers will be created in VTrckS and DelVAX utilizing information obtained from the COVID-19 Vaccine Provider Enrollment Initiation form.
- Once providers are established in VTrckS, provider information will be updated by ExIS file upload from the DelVAX Master Date File (twice daily).

Allocations:

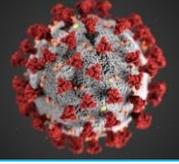
- Allocations will be managed in a process similar to the influenza vaccine allocations. Provider orders are submitted and entered onto an order template (excel spreadsheet).
- Doses requested or allocated are totaled. If all doses can be ordered, all orders are processed utilizing the template via VTrckS order upload.
- If only a percentage can be processed due to limited allocation, that percentage is established for the doses needed, keeping in mind the minimum dose requirement.
- Balances are determined and the spreadsheet is maintained as a master file in order to send balances once the allocation is updated.

To support more efficient distribution of vaccine, locations should offer full-day receiving hours to the extent possible. When that is not possible, locations identified to receive vaccine and ancillary supply shipments must be available during a 4-hour window on a weekday other than Monday to receive those shipments. COVID-19 vaccination providers will be required to report COVID-19 vaccine inventory daily using VaccineFinder. Once providers are enrolled in VTrckS, they will be preregistered for a VaccineFinder account and provided instructions via email on how to submit daily supply information.

- D. *Describe how your jurisdiction will coordinate any unplanned repositioning (i.e., transfer) of vaccine.*

The Immunization Program staff trained and experienced in vaccine transfers will utilize an approved process for transferring vaccine. Immunization Program staff responsible for transferring vaccine will be trained on storage and handling of ultra-cold COVID vaccine utilizing revised guidance from CDC.

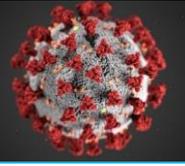
- Specific providers may be authorized by the Immunization Program to transfer vaccine from one location to another within their organization.
- All transfers are coordinated and approved by the Immunization Program staff.
- Vaccine transfers are entered in DelVAX under the Inventory Management module.
- Vaccine Transfer reports may be accessed using DelVAX's Inventory Transfer Inquiry.



- Entities must sign and agree to conditions in the *CDC COVID-19 Vaccine Redistribution Agreement* for the sending facility/organization and have a fully completed and signed *CDC COVID-19 Vaccination Provider Profile* for each receiving location.

E. *Describe jurisdictional plans for monitoring COVID-19 vaccine wastage and inventory levels.*

COVID-19 vaccine wastage and inventory levels will be monitored utilizing VTrckS allocation reports daily and requiring vaccine wastage reporting via DelVAX. DelVAX COVID-19 vaccine inventory reconciliation will be required weekly and the DelVAX Inventory Management reports will be utilized by Immunization Program staff to monitor inventory levels.

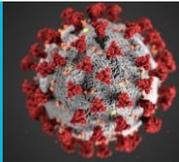


Section 8: COVID-19 Vaccine Storage and Handling

Instructions:

A. Describe how your jurisdiction plans to ensure adherence to COVID-19 vaccine storage and handling requirements, including cold and ultracold chain requirements, at all levels:

- *Individual provider locations*
 - i. As part of the enrollment process, specific information regarding vaccine storage capabilities and equipment will be collected.
 - ii. Information collected during enrollment will include type of storage unit (pharmacy grade, household, commercial, etc.); temperature capabilities of the storage units; temperature monitoring equipment (hospital based system, continuous temperature monitoring, etc.); capacity; and appropriate equipment and training to transfer vaccine if necessary. Hospital Systems will be contacted about ultra-cold temperature capacity.
- *Satellite, temporary, or off-site settings*
 - i. Any satellite or temporary site location will have the appropriate vaccine storage unit for the type of vaccine that is being administered. Digital data logging equipment will be with the storage unit to track the temperature of the vaccine at these locations.
 - ii. The Immunization Program will provide trainings on vaccine storage and handling and for all personnel responsible for the management of the vaccine before these temporary vaccination sites are conducted. A manual with the CDC Storage and Handling Toolkit information and temperature excursion information will be provided to the team leads of these clinics.
- *Planned redistribution from depots to individual locations and from larger to smaller locations*
 - i. The DPH warehouse will have the appropriate vaccine storage unit for the type of vaccine that is being stored and administered. Digital data logging equipment will be with the storage unit to track the temperature of the vaccine at these locations.
 - ii. All personnel responsible for the management of the vaccine will have the appropriate training on vaccine storage and handling from program and CDC resources.
 - iii. Local transport of vaccine from one location to another within the jurisdiction may be necessary but should only occur only on a limited basis. Only enrolled providers with an approved Redistribution Agreement will be permitted to redistribute COVID-18 vaccine. An approved Redistribution Agreement must include standard operating procedures describing the process for validating cold-chain procedures in accordance with the manufacturer's instructions and CDC's guidance on COVID-19 vaccine storage and handling.
- *Unplanned repositioning among provider locations*



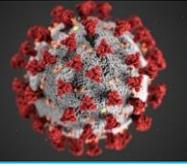
- i. Any surplus vaccine among provider locations, except for approved redistribution providers, will be transported back to the DPH warehouse in the appropriate transport equipment by Immunization Program personnel.

B. *Describe how your jurisdiction will assess provider/redistribution depot COVID-19 vaccine storage and temperature monitoring capabilities.*

Primarily, the redistribution will be managed and conducted by the Immunization Program staff who are trained and experienced in vaccine transfers. The staff will utilize the current state-approved process for transferring vaccine. In some case, specific providers may be authorized by the Immunization Program to transfer vaccines from one location to another within their organization. These provider transfers must be approved and coordinated by the Immunization Program staff prior to transporting any vaccine. Those providers that are approved to transport vaccines, have demonstrated to the program that they have the proper vaccine transport unit and temperature monitoring devices to redistribute the vaccines and the knowledge of packing out the vaccines as described in the CDC Vaccine Management Toolkit.

SHOC is surveying large hospital groups to determine if they can store the vaccines at the ultra-cold temperatures. If so, the plan would be to direct ship to these sites to avoid the need to redistribute. It is not recommended to transport vaccines that need ultra-cold chain temperatures to maintain viability; however, vaccine can be kept for 5 days (120 hours) between 2°C and 8°C to allow for off-site vaccine administration. If the shipping container is used for vaccine storage, the manufacturer recommends only opening the shipping container twice a day. Vaccine stored in a refrigerator should be used first before additional vials are removed from frozen storage as vaccine cannot be refrozen once thawed. Vaccine should also be shielded from light. Vaccines vials should have beyond-use dates (BUDs) documented prior to transport of vaccine.

Every vaccine storage unit/container must have a temperature monitoring device. CDC recommends digital data loggers (DDLs). One vaccine product is stored at ultra-cold temperatures and will require a DDL that can register these temperatures. CDC is currently exploring options to support acquisition of DDLs for use with ultra-cold vaccines. However, jurisdictions should continue to identify options to obtain DDLs for use with ultra-cold vaccines, in addition to the DDLs needed for storage of refrigerated and frozen (-20°C) vaccines. DDLs using a buffered temperature probe provide the most accurate measurement of vaccine temperatures. However, many manufacturers use pure propylene glycol (freezing point -59°C) or a glycol mixture with a warmer freezing point in their probes. For accurate temperature monitoring of ultra-cold vaccines, it is essential that an air-probe or a probe designed specifically for ultra-cold temperatures is used with the DDL.



Section 9: COVID-19 Vaccine Administration Documentation and Reporting

Instructions:

- A.** *Describe the system your jurisdiction will use to collect COVID-19 vaccine doses administered data from providers.*

Delaware will use DelVAX.

- B.** *Describe how your jurisdiction will submit COVID-19 vaccine administration data via the Immunization (IZ) Gateway.*

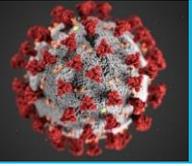
DPH has approved and submitted the CONNECT DUA. DPH has received a confirmation email that the onboarding for the IZGateway Connect is complete for Delaware. In a recent conference call with DPH's IIS vendor, Envision Technology Partners, DPH was informed that vaccine administration data would no longer be reported via Connect to CDC but via a flat file (CVRS Covid-19 Vaccine Reporting Specifications) to the CDC Data Clearinghouse. This is according to information the IIS vendors have received from CDC. Delaware's IIS vendor is committed to providing this extract flat file for Delaware. Having just received the layout and required data elements, Delaware's IIS vendor is currently working to create a process that will collect all the required data elements, create an exportable file that can be loaded into CDC's Data Clearinghouse. Delaware expects to be able to load a test file to the CDC by November 16, 2020, and a production file by November 25, 2020. CDC has offered technical support as needed.

- C.** *Describe how your jurisdiction will ensure each COVID-19 vaccination provider is ready and able (e.g., staff is trained, internet connection and equipment are adequate) to report the required COVID-19 vaccine administration data elements to the IIS or other external system every 24 hours.*

Providers who are currently onboarded with DelVAX to submit vaccine administration data via their EMR/EHR system will continue to report in this manner. Those providers who have not onboarded with DelVAX will be required to perform direct data entry of doses administered. Training for provider staff will be provided.

- D.** *Describe the steps your jurisdiction will take to ensure real-time documentation and reporting of COVID-19 vaccine administration data from satellite, temporary, or off-site clinic settings.*

Delaware has purchased and is implementing a mobile application that is ready for implementation. This will allow patient registration, vaccination reporting and inventory management that can be used at satellite, temporary, or off-site clinic settings.



- E.** *Describe how your jurisdiction will monitor provider-level data to ensure each dose of COVID-19 vaccine administered is fully documented and reported every 24 hours as well as steps to be taken when providers do not comply with documentation and reporting requirements.*

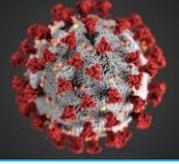
Where possible, providers will be set up as Type III full inventory providers where doses will be decremented from inventory, dose by dose, as the administration is being recorded. Those sites not set up as full inventory (i.e., VFC providers are aggregate reported currently and will need to remain aggregate even if receiving COVID-19 vaccine), the Immunization Program will be utilizing DelVAX reports (i.e., doses administered, Patients Detail with Services, inventory reconciliation, etc.) to monitor vaccine inventory and reporting.

- F.** *Describe how your jurisdiction will generate and use COVID-19 vaccination coverage reports.*

DelVAX contains many “canned” reports that can be utilized by DPH to monitor and evaluate COVID-19 vaccination distribution, storage/handling, administration, and reporting. Some example reports available are:

- Reminder/Recall
- Patients with Vaccine Refusals
- Doses Administered
- Immunization Rates
- Vaccine Shipments/order status/returns inquiry/return status.

DPH also has the availability to have ad-hoc reports created as needed by Delaware’s IIS vendor through the vendor contract



Section 10: COVID-19 Vaccination Second-Dose Reminders

Instructions:

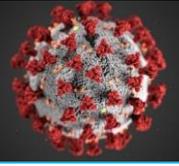
- A.** *Describe all methods your jurisdiction will use to remind COVID-19 vaccine recipients of the need for a second dose, including planned redundancy of reminder methods.*

There will be three methods of second-dose reminders for COVID-19 vaccine recipients. First, providers will receive instruction/training regarding the importance of documenting accurate information on vaccine record cards provided to patients receiving the COVID-19 vaccine.

Second, the state IIS registry, DelVAX, has reminder/recall functionality, which providers may use to send reminder letters to their patients with valid addresses in DelVAX.

Finally, the program plans to contract second-dose reminders with a vendor that can automate reminders via phone call or SMS from patient contact information collected from DelVAX. At this time, Immunization Program staff are entering into a contract with OneCallNow for implementation of patient second-dose reminders.

Training will be provided to vaccinators to ensure they are entering complete address information and accurate phone numbers into patient demographic sections of their EMR and/or DelVAX. The Immunization Program will encourage pharmacies and provider offices that have their own reminder recall systems to utilize this functionality to recall patients for their second dose.



Section 11: COVID-19 Requirements for IISs or Other External Systems

Instructions:

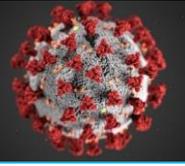
- A.** Describe your jurisdiction's solution for documenting vaccine administration in temporary or high-volume vaccination settings (e.g., CDC mobile app, IIS or module that interfaces with the IIS, or other jurisdiction-based solution). Include planned contingencies for network outages or other access issues.

DelVAX has a mobile component that will be used for offsite locations, this solution does not require internet access, the data is loaded to the iPads and will be uploaded to DelVAX once they return to the office. Back-up would be a manual process to be entered once they return to the office. Additional training is under way for DPH personnel for its use.

- B.** List the variables your jurisdiction's IIS or other system will be able to capture for persons who will receive COVID-19 vaccine, including but not limited to age, race/ethnicity, chronic medical conditions, occupation, membership in other critical population groups.

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

*Identifiable Data Elements



These data elements are collected in DelVAX. DPH is consulting with the IIS vendor to assess if these elements can be included in HL7 messages.

C. *Describe your jurisdiction's current capacity for data exchange, storage, and reporting as well as any planned improvements (including timelines) to accommodate the COVID-19 Vaccination Program.*

DelVAX system infrastructure is hosted outside of the state using cloud-based technology and has storage and back up support. Through our vendor as a participant in the CDC program IZ Gateway we have the capacity to exchange data with neighboring states and jurisdictions. Delaware is prepared to produce the reporting requirement to the CDC.

The enhancements below are scheduled to be completed by January 1, 2021, but, although helpful, these enhancements are not integral to the plans for data exchange, storage, and reporting of COVID-19 vaccine:

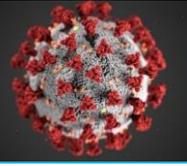
- A streamlined provider registration process to fast track pandemic providers so they can leverage DelVAX to gather patient and COVID-19 vaccinations
- A consumer facing portal that allows Delaware to access and print their own and their children's COVID-19 immunization records
- An expanded DelVAX Vaccination Reminder/Recall capability to target contact of COVID-19 high-risk patients
- Implement the use of address verification software (SmartyStreets) for data at rest that will enhance reminder recall capacity in DelVAX.

D. *Describe plans to rapidly enroll and onboard to the IIS those vaccination provider facilities and settings expected to serve health care personnel (e.g., paid and unpaid personnel working in health care settings, including vaccinators, pharmacy staff, and ancillary staff) and other essential workers.*

DPH will be using the Provider Management module within DelVAX to enroll practices for COVID-19 vaccinations. Delaware's IIS vendor is working to create an exportable provider enrollment file that will be uploaded into CDC's Immunization Data Lake twice weekly and should be ready for use by November 7, 2020. DPH is prepared to have providers complete paper enrollment forms and to manually create the twice weekly provider enrollment file to send to CDC if the vendor is unable to meet the deadline.

E. *Describe your jurisdiction's current status and plans to onboard to the IZ Gateway **Connect** and **Share** components.*

Delaware is already a participant in IZ Gateway Share and the DUA has been signed for Connect.



F. *Describe the status of establishing:*

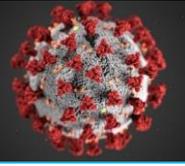
1. Data use agreement with the Association of Public Health Laboratories to participate in the IZ Gateway - Work is in progress to sign agreement.
2. Data use agreement with CDC for national coverage analyses has been signed.
3. Memorandum of Understanding to share data with other jurisdictions via the IZ Gateway Share component – The MOU is signed by Delaware and is exchanging data with the City of Philadelphia and the State of Maryland. Other bordering states (New Jersey, Pennsylvania, Virginia, and Washington D.C.) will be asked to participate in the future.

G. *Describe planned backup solutions for offline use if internet connectivity is lost or not possible.*

DelVAX has a mobile component that will be used for offsite locations, this solution does not require internet access, the data is loaded to the iPads and will be uploaded to DelVAX once they return to the office. Plans are to “test” the mobile component at community influenza clinics in October 2020.

H. *Describe how your jurisdiction will monitor data quality and the steps to be taken to ensure data are available, complete, timely, valid, accurate, consistent, and unique.*

Utilizing tools in DelVAX we can monitor data quality using the Traffic Analysis tool to review incoming messages, message log tool which shows warnings and errors in the messages, and reports.



Section 12: COVID-19 Vaccination Program Communication

Instructions:

A. Describe your jurisdiction's COVID-19 vaccination communication plan, including key audiences, communication channels, and partner activation for each of the three phases of the COVID-19 Vaccination Program.

1. Key audiences, many of whom have established partnerships prior to and during COVID-19:

- First responders (health care workers, police, EMS, fire)
- Older individuals (i.e., LTCFs, senior centers, 55+ communities and towns/municipalities with older populations)
- Other vulnerable populations (immunocompromised, chronic, or underlying medical conditions – cancer, diabetes, stroke, lung/heart/kidney disease)
- Diverse populations (African American communities, Hispanic/Latino, etc.)
- Uninsured/underinsured Delawareans
- Legislators
- Employers (including state, county, and municipal governments)
- Community partners and stakeholders

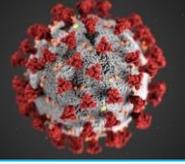
2. Communication channels:

DPH is working closely with AB&C, a marketing and communications firm, to develop and subsequently implement clear and concise messaging regarding the COVID vaccine. Messages will be tailored to key audiences to ensure they are understood and accepted by members of various populations and communities. Messaging during COVID-19 has been translated into Spanish and Haitian-Creole given the population composition in Delaware. The planned communication channels will include:

- Social media (Facebook, Twitter, Instagram)
- Press briefings
- Press releases
- Radio
- Publications utilized by Delaware's Hispanic community
- Billboards
- Other digital media: Pandora, Spotify, ad theorent display network, Taboola Native Display
- E-blasts
- DE Health Alert Network
- Community influencers

3. Partner activation - DPH will ask for assistance with outreach from:

- Schools, school nurses, parents, children



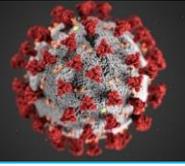
- College/university health centers
- FQHCs
- State/county chambers
- Faith-based partners
- Non-profit associations
- Legislators
- Employers – private, state, county and municipal
- Delaware Healthcare Association and its member Hospital systems
- Local pharmacies: CVS, Rite-Aid, and Walgreens
- Medical Society of DE and medical practices
- Black, Latino and Haitian Creole community organizations
- Tribal nations
- Immunization Coalition

B. *Describe your jurisdiction’s expedited procedures for risk/crisis/emergency communication, including timely message development as well as delivery methods as new information becomes available.*

In the event of emergency communications, the DPH Office of Communications (OComms) will closely follow the Continuity of Operations Plan as well as the Crisis and Risk Communications Annex. OComms will work in tandem with the DHSS Communications Office, the Delaware Emergency Management Agency, the Governor’s Office, and any other agency to ensure fast and accurate information is presented to the public. This will include but is not limited to updating scripts for the COVID-19 Call Center, drafting, and sending press releases, drafting and posting social media, and handling inquiries from the media when subsequent questions are asked of DPH.

To deliver an evolving message, OComms will rely heavily on social media as well as the local press to distribute its information in press release form to as wide an audience as possible, as well as utilize relationships with faith-based and community partners which have been enhanced during the COVID-19 response. The Crisis and Risk Communications Annex contains draft press releases for various scenarios, including vaccine distribution and distribution events.

OComms will also work closely with public information officers at local schools, hospitals, LTCFs, FQHCs, and shelters to ensure the information is disbursed to as wide an audience as possible. OComms will also continue to communicate information with community groups such as faith-based organizations, tribal organizations, and African American and Latino populations.

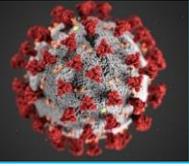


Section 13: Regulatory Considerations for COVID-19 Vaccination

Instructions:

- A. *Describe how your jurisdiction will ensure enrolled COVID-19 vaccination providers are aware of, know where to locate, and understand the information in any Emergency Use Authorization (EUA) fact sheets for providers and vaccine recipients or vaccine information statements (VISs), as applicable.*
- B. *EUA/VIS fact sheets will be made available on the DPH COVID-19 webpage as soon as that information is made available by the Food and Drug Administration (FDA) and the CDC. Practitioners will be able to make inquiries to DPH through the Call Center for any questions related to the EUA/VIS. Describe how your jurisdiction will instruct enrolled COVID-19 vaccination providers to provide Emergency Use Authorization (EUA) fact sheets or vaccine information statements (VISs), as applicable, to each vaccine recipient prior to vaccine administration.*

DPH will provide the EUA/VIS to all enrolled providers receiving vaccine from the DPH warehouse. Enrolled providers will be required to provide the EUA/VIS to all recipients of the vaccine prior to administration. EUA/VIS fact sheets will be made available on the DPH COVID-19 webpage as soon as that information is made available by the Food and Drug Administration (FDA) and the CDC.



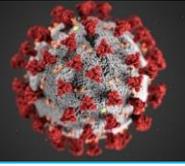
Section 14: COVID-19 Vaccine Safety Monitoring

Instructions:

- A. *Describe how your jurisdiction will ensure enrolled COVID-19 vaccination providers understand the requirement and process for reporting adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS).*

The Immunizations Program will provide information on the state COVID-19 webpage on the options on how to report Vaccine Adverse Events, which is standard practice for Delaware vaccine providers. They are required to report to VAERS any additional adverse events and/or adhere to any revised safety reporting requirements per FDA’s conditions of authorized vaccine use posted on FDA’s website throughout the duration of the EUA, as applicable. Vaccination providers should also report any additional clinically significant adverse events following COVID-19 vaccination to VAERS, even if they are not sure if the vaccination caused the event. DPH will ensure that enrolled COVID-19 vaccination providers understand the procedures for reporting adverse events to VAERS. More information on submitting a VAERS report electronically can be found at <https://vaers.hhs.gov/reportevent.html>.

CDC will implement v-safe, a new smartphone-based tool that uses text messaging and web surveys to check in with vaccinated individuals for adverse events after a COVID-19 vaccination. V-safe will also provide second-dose reminders (if needed) and live telephone follow up by CDC if vaccinated individuals report a medically significant event during a v-safe check-in. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. Medically significant events will be identified if the vaccinated individual reports that they missed work, were unable to complete normal daily activities, or had to seek care from a health provider or health care professional. The information will be used to analyze common side effects (soreness in the arm, muscle aches, etc.) and to detect unexpected, serious health problems if they occur.



Section 15: COVID-19 Vaccination Program Monitoring

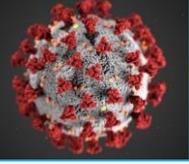
Instructions:

A. Describe your jurisdiction's methods and procedures for monitoring progress in COVID-19 Vaccination Program implementation, including:

1. Provider enrollment
 - Compare provide enrollment data in DelVAX versus recruitment outreach efforts.
2. Access to COVID-19 vaccination services by population in all phases of implementation
 - Surveillance through the Immunization Program and OIDE with My Healthy Community website for public reporting
3. DelVAX or other designated system performance
 - Monitor DelVAX performance via reports from vendor to determine performance shortfalls.
4. Data reporting to CDC
 - Monitor immunization reporting to IZ Gateway using established DelVAX reports.
5. Provider-level data reporting
 - Using established DelVAX reports, provide data on reporting for inclusion to My Healthy Community website.
6. Vaccine ordering and distribution
 - Using established VTrckS data downloaded to incorporate into the My Healthy Community website or use the CDC's Tiberius program to incorporate data.
7. First- and second-dose COVID-19 vaccination coverage
 - Using established DelVAX Coverage Rate Reports to monitor progress. Further enhancements may be needed to review demographic coverage rates.
 - Routine meeting with stakeholders to cover data reporting, DelVAX performance, provider surveys and epidemiological surveillance.

B. Describe your jurisdiction's methods and procedures for monitoring resources, including:

1. Budget
 - Immunization Program manages grant budget using Office of Management and Budget established fiscal process. EMSPS monitors the Epidemiology and Laboratory Capacity grant budget fiscal process.
2. Staffing
 - SHOC in coordination with vaccine planning group will manage staffing for preparedness events and SHOC staffing.
3. Supplies



- Similar process will be used by SHOC that is currently underway with COVID-19 testing resources.

C. *Describe your jurisdiction's methods and procedures for monitoring communication, including:*

1. Message delivery

- OComms serves as the public information hub for any response activity when the SHOC is activated.

2. Reception of communication messages and materials among target audiences throughout jurisdiction

- OComms disseminates the information for public consumption for any response activity when the SHOC is activated. OComms has website analytics to monitor and evaluate access to information and determine effectiveness of messaging through websites and social media.

D. *Describe your jurisdiction's methods and procedures for monitoring local-level situational awareness (i.e., strategies, activities, progress, etc.).*

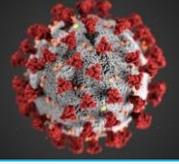
1. A similar process will be used that is underway with COVID testing with regular review of the data from DeIVAX and epidemiological surveillance. DPH will review data viewed on the My Healthy Community website to determine progress, with the.

E. *Describe the COVID-19 Vaccination Program metrics (e.g., vaccination provider enrollment, doses distributed, doses administered, vaccination coverage), if any, that will be posted on your jurisdiction's public-facing website, including the exact web location of placement.*

COVID-19 Vaccination Program metrics will be able to be tracked on the [My Healthy Community](#) website and will mimic testing data, similar to [flu.delaware.gov](#) and [COVID-19](#) websites, with plans to include the following information based on available data and technological capabilities:

- Vaccination sites
- Vaccination provider enrollment
- Doses distributed
- Doses administered
- Vaccination coverage capturing race/ethnicity
- Percent infection in vaccinated population

Two dashboards will be available by CDC to provide situational awareness for jurisdictions and the general public throughout the COVID-19 vaccination response. CDC's Weekly Flu Vaccination Dashboard will include weekly estimates of influenza vaccination for adults, children, and pregnant women using existing (National Immunization Survey [NIS]-Flu) data sources. Data and estimates from additional sources will be added, as available. An additional dashboard, the CDC's Tiberius platform, is a COVID-19 vaccine distribution planning, tracking, modeling, and



analysis application that provides flexible, real-time, data-backed processes so users of all types can make data-driven decisions. Tiberius will integrate data sources from federal agencies, state and local partners, private-sector partners, and other data providers to create a comprehensive common operating picture for the COVID-19 vaccine planning, distribution, and administration effort that DPH can use to support the COVID-19 vaccine response.

Appendix A-Vaccine Transport

SECTION SIX: Vaccine Transport

Transport, as described in this section, involves the movement of vaccine between providers or other locations over a shorter distance and time frame and is appropriate for events such as an emergency, off-site clinic, or to ensure vaccines that are about to expire can be used rather than wasted.

Vaccine Transport Situations

Vaccine transport to off-site or satellite facilities is different from both shipping and emergency transport. Shipping usually involves a professional carrier and a longer distance and time frame for moving vaccines between locations. Emergency transport usually involves relocating vaccines to protect them when a facility's ability to store vaccines is compromised (e.g., because of power loss). Depending on the situation, some transport recommendations may be the same, but there are also some differences.

Vaccine Transport

Vaccines from your supply should not be routinely transported. In instances where the transport of vaccine from your supply is necessary, take appropriate precautions to protect your supply. Vaccines should only be transported using appropriate packing materials that provide the maximum protection.



Protecting your vaccine supply

- » Vaccine that will be used at an off-site or satellite facility should be delivered directly to that facility.
- » If delivery to the specific site is not possible, then vaccine can be transported in a stable storage unit and monitored with a TMD. If the facility doesn't have the capacity to refrigerate the vaccines, then a portable vaccine storage unit or qualified container and packout may be used with a DDL.
- » Develop an emergency plan or SOPs for transporting vaccines and include procedures and protocols for packing and transport.

Partially used vials cannot be transferred between providers OR across state lines.*

- ✔ The total time for transport alone or transport plus clinic workday should be a maximum of 8 hours (e.g., if transport to an off-site clinic is 1 hour each way, the clinic may run for up to 6 hours).
- ✔ Transport diluents with their corresponding vaccines to ensure there are always equal amounts of vaccines and diluents for reconstitution.
- ✔ Your facility should have a sufficient supply of materials needed for vaccine transport of your largest annual inventory. Appropriate materials include:
 - Portable vaccine refrigerator/freezer units (preferred option)
 - Qualified containers and packouts
 - Hard-sided insulated containers or Styrofoam™ (Use in conjunction with the [Packing Vaccines for Transport during Emergencies](#)* tool. This system is only to be used in an emergency.)
 - Coolant materials such as phase change materials (PCMs) or frozen water bottles that can be conditioned to 4° C to 5° C
 - Insulating materials such as bubble wrap and corrugated cardboard—enough to form two layers per container
 - TMDs for each container

Soft-sided containers specifically engineered for vaccine transport are acceptable. Do not use commercially available soft-sided food or beverage coolers because most are poorly insulated and likely to be affected by room or outdoor temperatures.

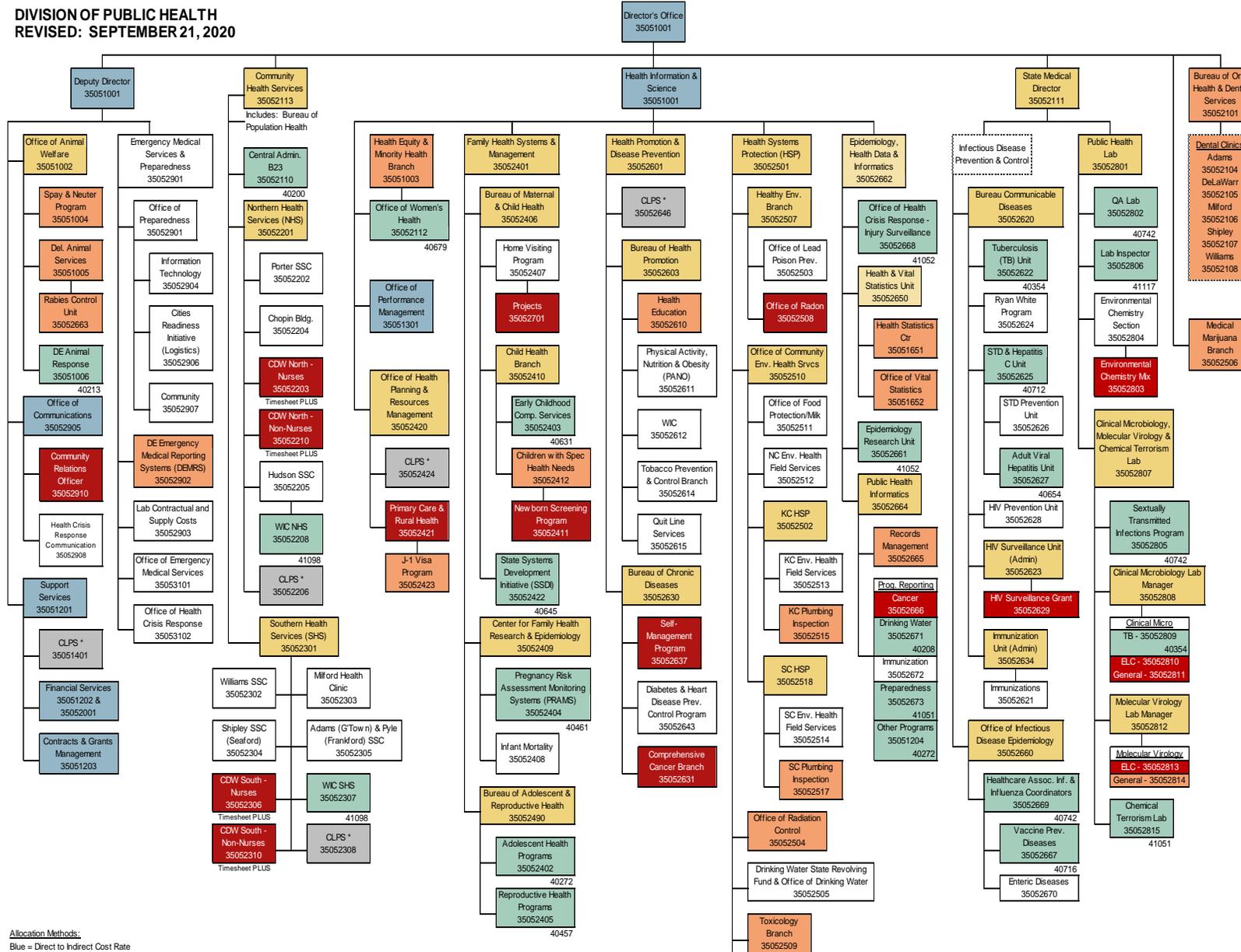
The same shipping materials the vaccines were initially shipped in should rarely, if ever, be used as they are not meant for reuse. This could put the cold chain and, ultimately, the viability of the vaccine, at risk.

* Contact your immunization program for details about specific state or local regulations impacting this activity.

* [Packing Vaccines for Transport during Emergencies: www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf](http://www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf)

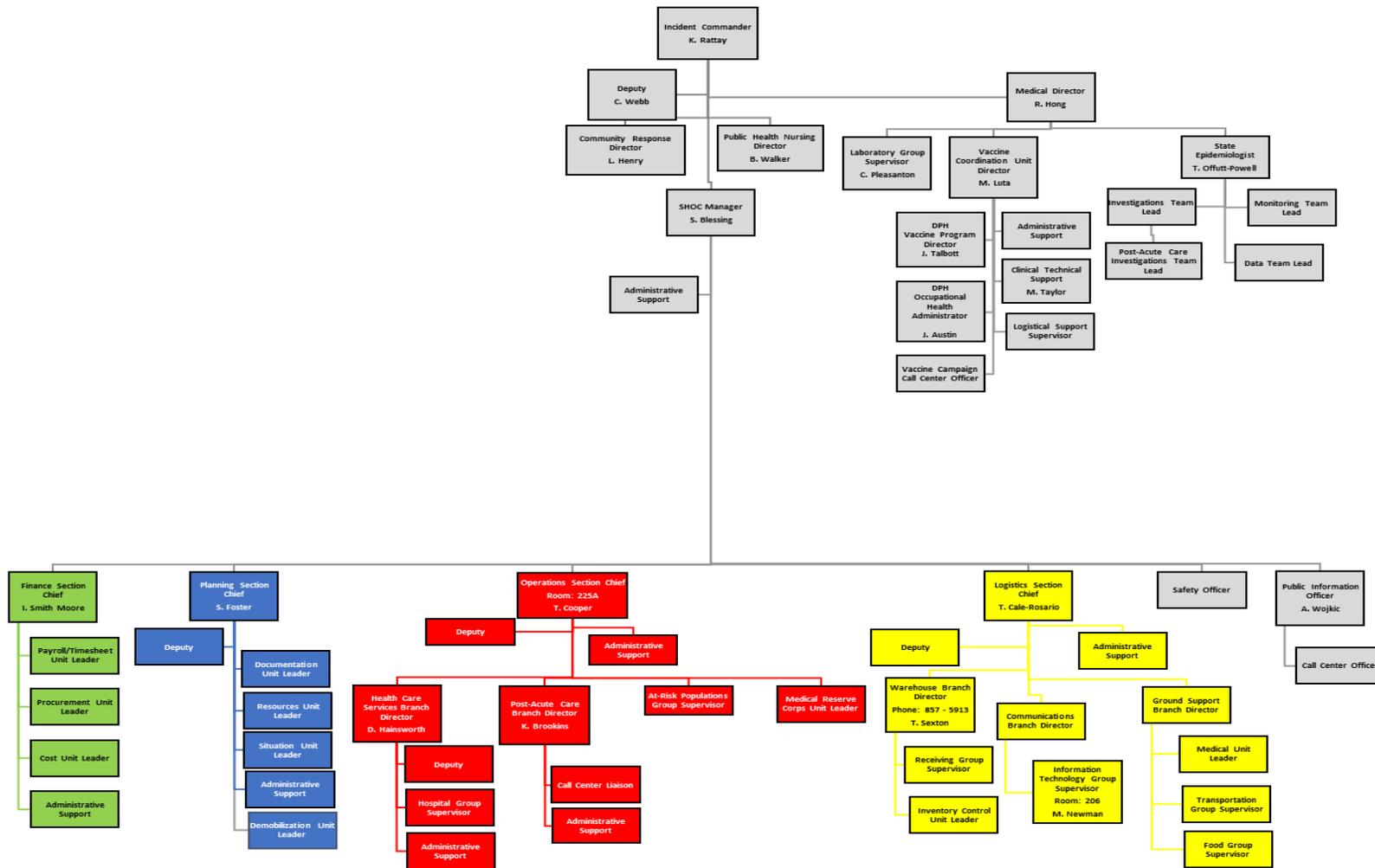
Appendix C: DPH Org Chart

DIVISION OF PUBLIC HEALTH
REVISED: SEPTEMBER 21, 2020



Allocation Methods:
Blue = Direct to Indirect Cost Rate

Appendix D: SHOC Org Chart



Appendix E: CDC COVID-19 Vaccination Playbook Supplement #1

Distribution Plan Update

November 20, 2020

CDC is working with other federal partners of [Operation Warp Speed](#) (OWS) to plan and implement a COVID-19 Vaccination Program. OWS's goal is to produce and deliver 300 million doses of safe and effective vaccines, with the initial doses available before the end of 2020. The following high-level distribution update is provided to aid jurisdictions to further refine their implementation plans. This approach for centralized vaccine ordering and distribution will be executed in phases by CDC in collaboration with jurisdictions, tribes, federal agencies receiving a direct allocation of vaccine, and commercial partners.

The information below covers four key topics:

1. Allocation
2. Ordering
3. Receipt, storage, and handling
4. Operational norms

The information within these sections will continue to evolve as new information becomes available.

Allocation:

COVID-19 vaccine will be allocated according to the following principles:

- Allocations will be calculated pro-rata based on the size of the jurisdiction's population and the quantity of ready-to-ship doses from manufacturer(s).
- Allocation amounts will be communicated to jurisdictions weekly. These allocations will be immediately available for ordering.
- If a jurisdiction does not order the full allocation, the remainder will roll over for future ordering. Unused allocations will not be reallocated to other jurisdictions.

For the two initial vaccine candidates, two doses will be required, and the same product must be used for both doses. Two-dose vaccine allocations will be managed in the following way:

- In coordination with vaccine manufacturers, CDC will reserve and store inventory of second-dose product to include in future allocations for ordering at the appropriate time (e.g., 2 weeks after first doses are ordered for a product requiring the second dose on Day 21).
- CDC does not expect jurisdictions or federal and commercial partners to maintain physical inventory of second-dose product (i.e., jurisdictions will not be expected to store product for 21–28 days to prepare for second-dose administration).

Ordering:

The COVID-19 Vaccination Program will utilize CDC's VTrckS system.

1. Each jurisdiction, federal agency, and commercial partner will receive allocations (order caps) weekly in VTrckS.

2. Jurisdictions, federal agencies, and commercial partners will submit orders for vaccination provider sites. These orders will be processed against the allocation (order cap).
 - a. Federal and commercial partners may pull order files from the Vaccine Provider Ordering Portal (VPOP) to upload into VTrckS.
3. Orders will be scheduled for delivery Monday through Friday.

Direct-Ship Vaccine (Vaccine A):

Jurisdictions are asked to identify locations to receive early shipments of this vaccine once the Food and Drug Administration (FDA) issues an Emergency Use Authorization (EUA) but before the Advisory Committee on Immunization Practices (ACIP) meets and makes recommendations for use and the recommendations are approved. This will ensure that product is available at the jurisdictional level and jurisdictions are ready to support vaccine administration after ACIP recommendations are issued and approved.

- A. The minimum order volume for Vaccine A is 975 doses.
- B. Each jurisdiction is asked to identify delivery sites to receive initial shipments of product. Jurisdictions can decide what quantity to order for each initial site (in 975-dose increments), based on what is feasible to administer.
 - Jurisdictions are encouraged to finalize site locations as soon as possible. Jurisdictions will be asked to confirm these sites once an EUA has been authorized.
- C. After ACIP recommendations have been approved, additional sites will be able to place orders against their jurisdiction's allocation. Vaccine will be delivered within 24–48 hours of order placement.
- D. Along with vaccine, each site will receive ancillary kits and an initial dry ice resupply:
 - Ancillary supply kits will include diluent and administration materials (including appropriate needles, syringes, alcohol swabs, and limited PPE). Ancillary supply kits will be automatically added to vaccine orders and do not require additional action or separate orders from jurisdictions/sites. CDC will provide details on dimensions of ancillary supply kits once the information is confirmed.
 - OWS will provide an initial dry ice resupply to facilitate storage in coordination with each vaccine shipment. Jurisdictions will have the option to allow sites to opt out of the

Final decisions about prioritization of populations will not be made until closer to implementation; jurisdictions should have multiple scenarios prepared for local distribution and administration.

initial dry ice resupply if desired. Sites will receive this initial dry ice resupply in coordination with receipt of the product, as they will need to replenish the dry ice upon product receipt. Further details about shipping and receipt of dry ice will be forthcoming.

Receipt, Storage, and Handling:

CDC is updating its *Vaccine Storage and Handling Toolkit*, to include a COVID-19 Vaccine Addendum, which will provide guidance on each vaccine product. CDC will also provide additional product-specific materials, including storage, handling and administration job aids. CDC will provide these resources as soon as possible.

The Vaccine Storage and Handling Toolkit can be found at:

<https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>. General Additional web pages with clinical guidance will be added as COVID-19 vaccine products become available.

Vaccine A:

Thermal shipping containers with Vaccine A will arrive with a GPS-enabled temperature monitoring device that will monitor temperature excursions in transit as well as at the vaccination provider site, if used.

If a jurisdiction/site plans to store product in an ultra-low temperature (ULT) freezer, the jurisdiction/site must remove vaccine trays from the thermal shipping container before moving them to the freezer. The jurisdiction/site must then monitor the temperature inside the ULT freezer using standard protocol to ensure temperature excursions are identified quickly. Once the vaccine is removed from the thermal shipping container and put in the ULT freezer, the temperature monitoring device accompanying the vaccine can no longer be used; a digital data logger (DDL), or other appropriate monitoring method, will be needed.

A jurisdiction/site may also use the thermal shipping container for temporary storage of the vaccine. Instructions will be provided for monitoring vaccine temperatures in the thermal shipping container using the device that is available on the shipper (details will be forthcoming). In addition, storage and handling instructions for vaccine stored in the thermal shipper will be made available by the manufacturer and in CDC's storage and handling tool kit. Please also see Vaccine A information in this CDC Playbook.

Operational Norms:

Jurisdictions should operate under the following assumptions and account for the following variables:

- Vaccine will be authorized by FDA (EUA).
- ACIP will make recommendations for vaccine use, including populations for phased allocation of initial doses.
- Vaccine is expected to be recommended in a phased approach by ACIP until supplies allow for broader administration.
- Jurisdiction and federal agency plans will need to be updated regularly as additional information becomes available and implemented in a timely manner.

Planning Appendix: The following materials are being provided to inform planning activities.

Chart 1: Vaccine A storage and handling guide

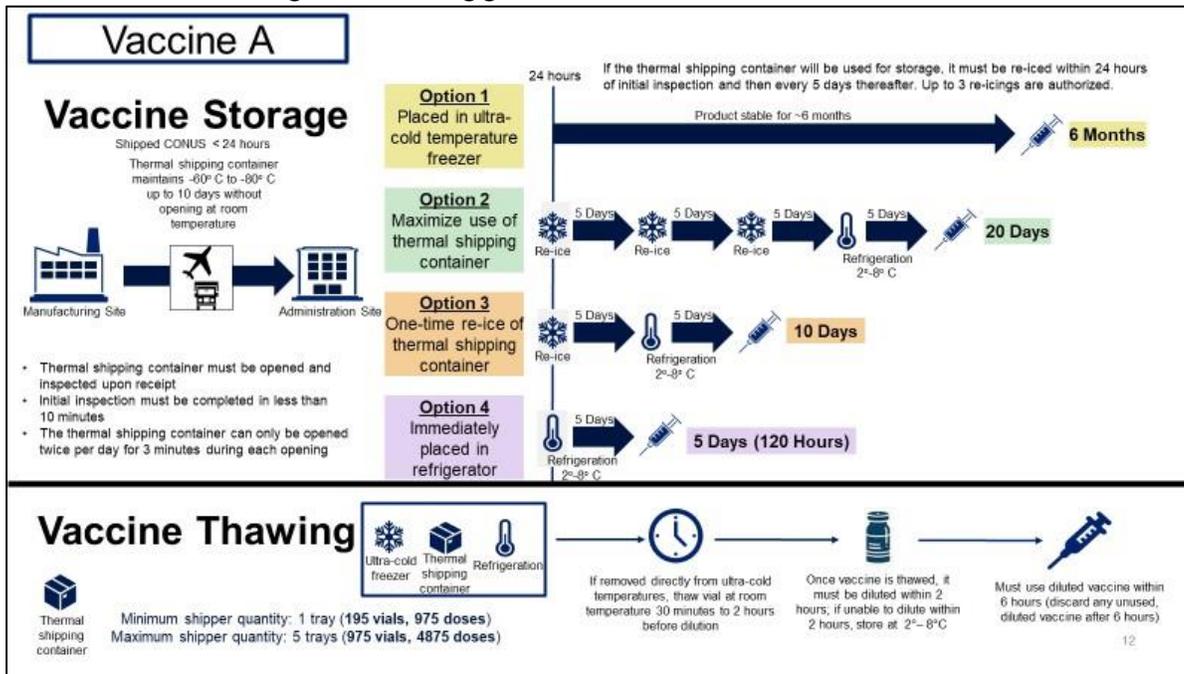


Chart 2: Vaccine A vaccination provider site archetypes for shipment timing and site planning

Vaccination provider site	Ordering assumptions			Operating assumptions				
	Order size	Storage conditions	Patient flow	Number of immunizers	Patients per immunizer	Hours per day	Vaccines per day	Shipment model
A – large outpatient center (mass vx)	1 tray (975 doses)	Thermal box with dry ice, 2-8C fridge, for product estimated at site (5 days)	~500/day	10 immunizers	6 patients/hour (~10 min/Vx)	8 hours	480 vaccinations	1 tray; 2-3 times per week
B – hospital or outpatient center	1 tray (975 doses)	Ultra-cold freezer, Thermal box with dry ice, 2-8C fridge, for product estimated at site (5 days)	Variable	4 immunizers	6 patients/hour (~10 min/Vx)	8 hours	192 vaccinations	1 tray; every week
C – large hospital with affiliated outpatient center	5 trays (4,875 doses)	Ultra-cold freezer, Thermal box with dry ice, 2-8C fridge, for product estimated at site (5 days)	Variable	7 immunizers (hospital outpatient clinic)	6 patients/hour (~10 min/Vx)	8 hours	340 vaccinations	1 tray; 1-2 times a week
D – outdoor parking lot vaccination hub at large retail pharmacy	1 tray (975 doses)	2-8C fridge, for product estimated at site (5 days)	~200/day	5 immunizers	6 patients/hour (~10 min/Vx)	N/A	240 vaccinations	1 tray; every week
E – mobile vaccination in targeted geographic areas	5 trays (4,875 doses)	2-8C fridge, for product estimated in mobile unit (5 days)	Variable	3 immunizers	6 patients/hour (~10 min/Vx)	Not specified	150 vaccinations	1 tray; every week

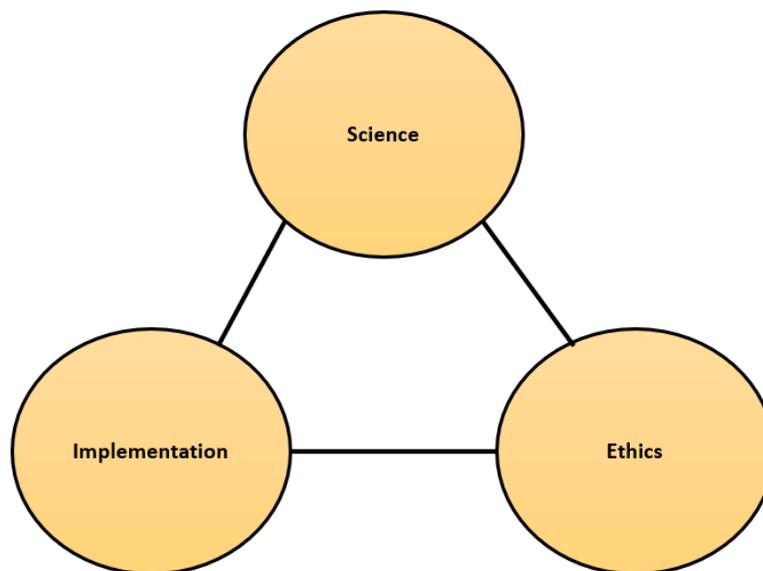
Appendix F: Delaware COVID-19 Vaccine Allocation Framework

Delaware COVID-19 Vaccine Allocation Framework

The Delaware Division of Public Health has adopted an ethical framework that guides decision-making for administration of the vaccines that are expected to be limited for the first several weeks. Vaccine administration to the public expands through the phases as vaccine becomes more available.

Overarching Goal: To vaccinate as many people who choose to be vaccinated as possible in a time-sensitive manner as a critical mitigation strategy in the COVID-19 pandemic response.

Advisory Communities on Immunization Practices (ACIP) Allocation Framework of COVID-19 Vaccine⁴



Balancing Goals: Prevention of Morbidity & Mortality and Preservation of Societal Functioning

Phase 1 Operational Goals⁵

- Decrease death and serious disease as much as possible
- Preserve functioning of society
- Reduce the extra burden the disease is having on people already facing disparities
- Increase the chance for everyone to enjoy health and well-being

⁴ Chamberland, M.E. Ethical Principles for Phased Allocation of COVID-19 Vaccines. (October 30, 2020). Retrieved from <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-10/COVID-Chamberland.pdf>

⁵ How CDC is Making COVID-19 Vaccine Recommendations. (November 25, 2020). Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations-process.html>

Ethical Principles⁶

- **Maximize benefits and minimize harms** — Respect and care for people using the best available data to promote public health and minimize death and severe illness.
- **Mitigate health inequities** — Reduce health disparities in the burden of COVID-19 disease and death, and make sure everyone has the opportunity to be as healthy as possible.
- **Promote justice** — Treat affected groups, populations, and communities fairly. Remove unfair, unjust, and avoidable barriers to COVID-19 vaccination.
- **Promote transparency** — Make a decision that is clear, understandable, and open for review. Allow and seek public participation in the creation and review of the decision processes.

Other Considerations

- National/statewide trends and data (at-risk groups)
- Operational considerations (staff levels, critical services/infrastructure, available supply, etc.)
- Logistics (vaccination staff/resources, storage, venue support requirements)
- Time sensitivity (ability to vaccinate large groups within the timeframe)

Situations and Assumptions

- The COVID-19 vaccine allocation phased groups for Delaware were developed based on ethical decision-making only; logistics were not a consideration.
- The initial allocation of COVID-19 Vaccine to the State of Delaware will not be adequate to protect all the Phase 1 groups⁷.
- The initial allocation of vaccine must be distributed and administered in a very short period due to storage and utilization requirements and urgency to reduce transmission during the pandemic.
- Operational decision-making is used to consider the physical ability to vaccinate within the Phase 1 sub-groups in order to efficiently utilize the anticipated vaccine supply with the resources available and within the limited timeframe.
- The vaccine delivery timeline will drive the allocation of resources among the phases; overlap of phased groups is likely (see Figure 2).
- Flexibility is permitted to adjust phased groups based on current trends and public health needs.

⁶ Johns Hopkins Bloomberg School of Public Health, Center for Health Security (2020). *Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States*. Retrieved from: https://www.centerforhealthsecurity.org/our-work/pubs_archive/pubs-pdfs/2020/200819-vaccine-allocation.pdf

⁷ Johns Hopkins Bloomberg School of Public Health, Center for Health Security (2020). *Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States*. Retrieved from: https://www.centerforhealthsecurity.org/our-work/pubs_archive/pubs-pdfs/2020/200819-vaccine-allocation.pdf

Figure 1: Delaware COVID-19 Vaccine Allocation Framework

Phase 1a and 1b have been recommended, the remaining phases are proposed phase allocation pending federal and state recommendations.

Phase 1 - Higher risk for acquiring or experiencing severe COVID-19				
Group	Definition	Examples	Primary Strategies	Anticipated Vaccine Availability
Phase 1a	Residents of long-term care facilities (LTCFs)	<ul style="list-style-type: none"> • Skilled Nursing Facilities • Assisted Living Facilities 	Pharmacy Partnership for Long-term Care (LTC) Program	Week 0 (constrained supply)
	Health care personnel (HCP) ^{8,9,10} (including “direct care providers”)	<ul style="list-style-type: none"> • Hospitals • Long-Term Care Facilities • Ambulatory Sites (e.g., FQHC’s, Urgent Care) • Home Health • Pharmacies • First Responders with direct patient care • Public Health • Direct care providers (e.g., direct service providers, personal attendant services) 	Existing or new vaccine administration providers within health facilities or designated vaccination sites LTC Pharmacy Partnership for staff	

⁸ The Advisory Committee on Immunization Practices’ Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine - United States, 2020. US Department of Health and Human Services, Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, December 11, 2020 / Vol. 69 / No. 49 1857. Accessed December 17, 2020.

⁹ HCP refers to all paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These HCP may include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, home health care personnel, physicians, technicians, therapists, phlebotomists, pharmacists, students and trainees, contractual staff not employed by the health care facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the health care setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

¹⁰ Guidance on the Essential Critical Infrastructure Workforce: Ensuring Community and National Resilience in COVID-19 Response, U.S. Department of Homeland Security, Cybersecurity & Infrastructure Security Agency. 2020.

https://www.cisa.gov/sites/default/files/publications/ECIW_4.0_Guidance_on_Essential_Critical_Infrastructure_Workers_Final3_508_0.pdf. Accessed December 16, 2020.

Phase 1b - Higher risk for acquiring or experiencing severe COVID-19

Group	Definition	Examples	Strategy	Anticipated Vaccine Availability
Phase 1b ^{11,12}	Persons 65 years and older ¹³		Vaccine administration through existing outpatient or pharmacy networks or traditional delivery systems through available channels	Week 4 (constrained supply)
	Frontline essential workers	<ul style="list-style-type: none"> • Other First Responders (firefighters, police) • Education (teachers, support staff, daycare) • Food and Agriculture • Manufacturing • Corrections workers • U.S. Postal service workers • Public transit workers • Grocery store workers 	Existing or new vaccine administration providers within essential critical infrastructure organizations	

¹¹ Recommendation by the Delaware Public Health and Ethics Advisory Group to adopt the Advisory Committee on Immunization Practices Phase 1b allocation for COVID-19 vaccines on 12/22/2020.

¹² Advisory Committee on Immunization Practices, COVID-19 Work Group, Phased Allocation of COVID-19 Vaccines, Dooling, December 20, 2020.

¹³ Age adjusted by DPH on December 28, 2020.

Proposed Remaining Phase 1 - Higher risk for acquiring or experiencing severe COVID-19

Group	Definition	Examples	Strategy	Anticipated Vaccine Availability
Remaining Phase 1	<p>Persons 16-64 years with high-risk medical conditions¹⁴</p> <p>High-risk congregate settings</p>	<ul style="list-style-type: none"> • High-risk medical or other chronic conditions: Obesity, Severe Obesity, Diabetes, COPD, Heart Condition, Chronic Kidney, Cancer, Smoking, Solid Organ Transplant, Sickle Cell Disease, Intellectual/Developmental Disabilities, Severe and persistent mental/behavioral health conditions • High-risk congregate settings including Homeless Shelters, Group Homes, and Corrections 	<p>Vaccine administration through existing outpatient or pharmacy networks or traditional delivery systems through available channels</p> <p>New vaccine administration providers within congregate settings</p>	<p>Week 11 (constrained supply)</p>
	Other Essential Workers ¹⁵	<ul style="list-style-type: none"> • Transportation and logistics • Food Service • Shelter and Housing (construction) • Finance • IT and Communications • Energy • Media • Legal • Public Safety (Engineers) • Water and Wastewater 	Existing or new vaccine administration providers within essential critical infrastructure organizations.	

¹⁴ Advisory Committee on Immunization Practices, COVID-19 Work Group, Phased Allocation of COVID-19 Vaccines, Dooling, December 20, 2020.

¹⁵ Advisory Committee on Immunization Practices, COVID-19 Work Group, Phased Allocation of COVID-19 Vaccines, Dooling, December 20, 2020.

Proposed Phase 2 - Moderate risk for acquiring or experiencing severe COVID-19

Group	Definition	Examples	Strategy	Anticipated Vaccine Availability
Phase 2	Persons 50-64 years ¹⁶ Persons 16-49 years with moderate-risk medical conditions ¹⁷ Other congregate settings	<ul style="list-style-type: none"> • Moderate-risk medical or other chronic conditions: Asthma (moderate-to-severe), Cerebrovascular disease, Cystic fibrosis, Hypertension, Immunocompromised state, Neurologic conditions, Liver disease, Overweight, Pulmonary fibrosis, Thalassemia • Other congregate settings not receiving vaccine in Phase 1 	<p>Vaccine administration through existing outpatient or pharmacy networks or traditional delivery systems through available channels</p> <p>New vaccine administration providers within congregate settings</p>	Week 16 (likely sufficient supply)
	Essential workers not receiving vaccine in Phase 1	<ul style="list-style-type: none"> • Workers unable to work from home at all times 	Existing or new vaccine administration providers within essential critical infrastructure organizations	

¹⁶ Advisory Committee on Immunization Practices, COVID-19 Work Group, Phased Allocation of COVID-19 Vaccines, Dooling, December 20, 2020.

¹⁷ Advisory Committee on Immunization Practices, COVID-19 Work Group, Phased Allocation of COVID-19 Vaccines, Dooling, December 20, 2020.

Proposed Phase 3 - Community risk for acquiring or experiencing severe COVID-19

Group	Definition	Examples	Strategy	Anticipated Vaccine Availability
Phase 3	Persons 16-49 years		Traditional delivery systems through available channels	Week 21 (sufficient supply to meet demand)
	Essential workers not receiving vaccine in Phase 2	<ul style="list-style-type: none"> Workers able to work from home 	Existing or new vaccine administration providers within essential critical infrastructure organizations	

Proposed Phase 4 - Anyone who did not have access to vaccines in prior phases

Group	Definition	Examples	Strategy	Anticipated Vaccine Availability
Phase 4	Anyone who did not have access to vaccines in prior phases		Traditional delivery systems through available channels	≥ Week 22

Figure 2: Proposed Vaccine Allocation Phase Sequence and Duration^{18,19}

Week 1-4	Week 5-8	Week 9-12	Week 13-16	Week 17-20	Week 21-24	Week 25-28	Week 29-32
Mid December – Mid January	Mid/late January – Mid/late February	Mid/late February – Mid/late March	March - April	Mid/late April – Mid/late May	Mid/late May – Mid/late June	June	July
					Phase 4 <ul style="list-style-type: none"> Anyone who did not have access to vaccines in prior phases 		
					Phase 3 <ul style="list-style-type: none"> 16-49 years Essential workers not receiving vaccine in Phase 2 		
				Phase 2 <ul style="list-style-type: none"> 50-64 years 16-49 years with moderate-risk medical conditions Other congregate settings Essential workers not receiving vaccine in Phase 1 			
			Remaining Phase 1 <ul style="list-style-type: none"> 16-64 years with high-risk medical conditions High-risk congregate settings Other essential workers 				
	Phase 1b <ul style="list-style-type: none"> 65 years and older Frontline essential workers 						
Phase 1a <ul style="list-style-type: none"> Residents of LTCFs HCP 							

¹⁸ Dooling, K. Phased Allocation of COVID-19 Vaccine. (November 23, 2020). Retrieved from <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-11/COVID-04-Dooling.pdf>

¹⁹ Delaware Public Health and Medical Ethics Advisory Group Meeting. (November 4, 2020). Section IV.

Operational Considerations for Sub-Groups within Phases:

1. Positive test within 90 days – The best characterized cases of re-infections to date have occurred at least 90 days after the first illness episode’s onset. An increasing number of published studies suggest that >90% of recovered COVID-19 patients develop anti-SARS-CoV-2 antibodies²⁰. Additional studies also demonstrate antibody response, including after mild or asymptomatic infection, can be durable for 3 months or more. This evidence must be interpreted cautiously as anti-SARS-CoV-2 antibodies have not been definitively correlated with protection of humans from infection.
2. Sole Source or Critically Limited Service – If limited staff are available to provide a particular critical service, consider more timely vaccination for these staff to maintain services.
3. Vaccine Side Effects – Although most side effects after vaccination are mild, side effects may lead to absenteeism from work. Planning for work absenteeism should be considered in the vaccination of staff at a workplace.
4. Multiple Phase Criteria – Individuals that meet multiple phase criteria may be determined to be of higher risk than any one phased group and should be considered for more timely vaccination.

Vaccine Phase 1 Operational Decision-making Steps ²¹	
Step 1	Confirm Phased Groups based on most recent National/state trends and data
Step 2	Identify vaccine supply availability and timeframe for distribution and vaccinations
Step 3	Identify storage requirements (temperature controls and storage requirements)
Step 4	Schedule Phase 1 Groups and develop proposed allocation strategy based on existing data; compare against most recent National/trend data to confirm
Step 5	Ensure adequate state resource availability to meet allocation strategy requirements and timeframe
Step 6	Communicate requirements for storage and vaccination timelines to proposed groups schedules; confirm vaccination amounts and compliance with all requirements
Step 7	Identify the anticipated distribution schedule and confirm with selected groups
Step 8	Allocation strategy implementation

²⁰ Ibarrodo, J.F., et al. Rapid decay of anti-SARS-CoV2 antibodies in persons with mild Covid-19. (2020). *New England Journal of Medicine*; 83:1085-1087

DOI: 10.1056/NEJMc2025179. Retrieved from: <https://www.nejm.org/doi/full/10.1056/nejmc2025179>

²¹ Adapted from the Delaware Division of Public Health Crisis Standards of Care Concept of Operations. (2020).