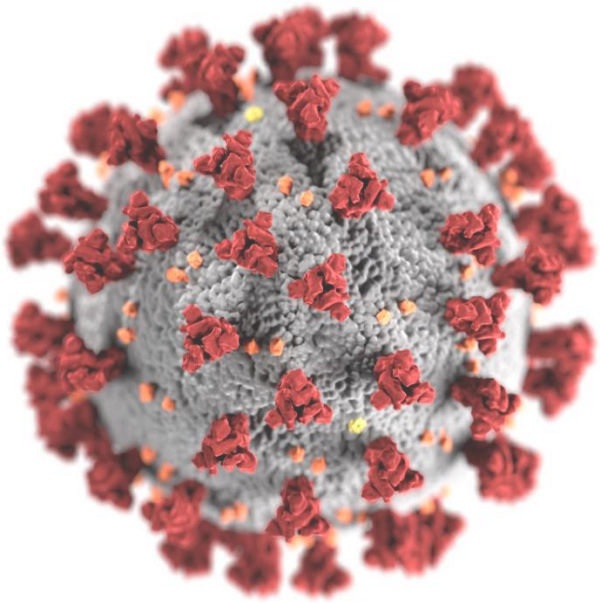
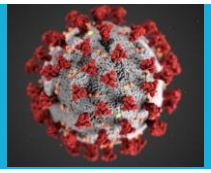


COVID-19 Interim Vaccination Plan

Pennsylvania

PA COVID-19 Vaccine Task Force/PA Department of Health
DECEMBER 11, 2020 | VERSION 3.0



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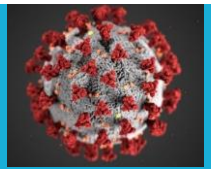


Section 1: COVID-9 Vaccination Preparedness Planning

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.*

This Interim plan is provided as guidance for distribution and administration of the COVID-19 vaccine throughout 66 of the 67 counties in the Commonwealth of Pennsylvania by the Pennsylvania Department of Health (DOH) and its public and private partners. Philadelphia County receives independent federal funding and is establishing its own COVID-19 vaccination administration plan.

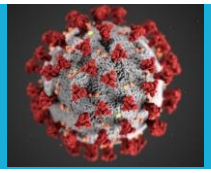
Prior to the *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations*, the COVID-19 Vaccine Planning Workgroup drafted a COVID-19 Vaccine plan from the 2009 H1N1 plan. Based on the playbook and the draft plan, planning gaps have been identified and a spreadsheet was developed to track the completion of the plan's gaps. This interim plan will continue to be updated as more information is made available and plans are further developed.

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.*

The goal of the interim COVID-19 vaccination plan is to provide a transparent strategy to vaccinate all Pennsylvanians who want to be vaccinated so that Pennsylvanians can return to everyday activities as quickly and safely as possible. In order to meet this goal, DOH will utilize multiple methods dependent on the availability of vaccine doses. One of the methods DOH plans on using when there are large numbers of vaccine doses available is County Mass Vaccination Clinics (MVCs). MVCs will account for social distancing and adhere to a systematic flow, as seen in Appendix 1.

When there are large numbers of vaccine doses available, DOH will utilize COVID-19 MVCs to provide vaccines to the general population in a coordinated, orderly and efficient manner to help slow or stop the spread of COVID-19 within the community. These mass vaccination clinics will implement the standard Incident Command System as seen in the MVC Staffing Organizational Chart (Appendix 2).

The Public Health Preparedness Coordinators (PHPCs), in collaboration with the Emergency Management Agencies (EMAs), have identified one MVC in each county. Locations will be



identified in collaboration with the District Health Offices, PHPCs, County EMAs and other stakeholders.

In preparation for COVID-19 Vaccine, DOH will be utilizing influenza Mass Vaccination clinics (MVCs) to test its COVID-19 Plans, including its MVC registration and scheduling software (PrepMod), once available. DOH understands the importance of testing counties of varied sizes and, as such, has identified four influenza MVCs in the following counties on the following dates :

Blair County (first responders only) – October 10, 2020
Carbon County – 10/24/2020 October 24, 2020
Delaware County – 10/7/2020 & 10/8/2020 October 7, 2020 & October 8, 2020
Sullivan County – 10/17/2020 October 17, 2020

Once the MVCs are completed, DOH will conduct an evaluation as well as prepare an After-Action Report within 14 days of MVC completion. The After-Action Report will address the following:

- Problems and successes during the operation;
- Analysis of the effectiveness of the response organization's components; and
- Description and definition of a plan of action for implementation of improvements.

The Incident Command System (ICS) approach to the use of After-Action Reports emphasizes the improvement of emergency management at all levels. All staff is encouraged to provide feedback during the After-Action Report process. DOH will use the After-Action Reports to identify gaps and deficiencies in its plan.

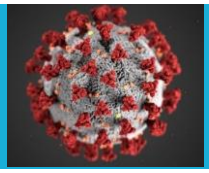
To further DOH's outreach, it is planning on using mobile vaccination units in underserved communities. These mobile units will be used to provide direct access to vaccines to populations that may otherwise be excluded. DOH plans on utilizing these mobile units to administer influenza vaccine in conjunction with the COVID-19 vaccination plan, including the registration software, PrepMod.

Section 2: COVID-19 Organizational Structure and Partner Involvement

Instructions:

A. *Describe your organizational structure.*

Pennsylvania has 12.8 million residents in 67 counties, with the four most populated cities accounting for over 16% of the total population. The logistical and operational requirements for the administration of COVID-19 vaccine will vary greatly from the urban to the rural settings of Pennsylvania. Six counties have their own county health department and four cities have their



own municipal health department. DOH is the health department in the 61 counties without a county health department. The Pennsylvania Emergency Management Agency (PEMA) coordinates state level responses to emergencies by bringing together representatives from state agencies, volunteer organizations, and private partners organized under emergency support functions (ESF) related to their capabilities. The Wolf Administration is operating under an Incident Command Structure, which means we are operating in a coordinated fashion in close partnership with the Pa. Emergency Management Agency, the Pa. Department of Human Services, the Governor's Office, the Office of Administration Informational Technology HHS Delivery Center and various other state agencies.

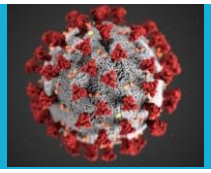
B. *Describe how your jurisdiction will plan for, develop, and assemble an internal COVID-19 Vaccination Program planning and coordination team that includes persons with a wide array of expertise as well as backup representatives to ensure coverage.*

A COVID-19 Vaccine Crisis Committee (VCC) has been developed as an advisory group to the Secretary of Health. Utilizing the public and private partnerships established in the commonwealth will greatly increase the effectiveness of vaccine distribution. The VCC includes specialists from a variety of Pennsylvania hospitals, including vaccinologists, gerontologists and ethicists, the Veterans Administration, Federally Qualified Health Centers, pharmacist association, educators, business and the Departments of Aging, Health and Human Services.

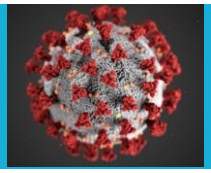
C. *Describe how your jurisdiction will plan for, develop, and assemble a broader committee of key internal leaders and external partners to assist with implementing the program, reaching critical populations, and developing crisis and risk communication messaging.*

On April 23, 2020, DOH convened a COVID-19 Vaccine Planning Workgroup with diverse representation from other state agencies, county and municipal health departments and the University of Pittsburgh's School of Pharmacy. On October 1, 2020, DOH activated a COVID-19 Vaccine Task Force (VTF) to operationalize our COVID-19 vaccine plans. The VTF is an extension of DOH's Department's Operation Center. The Vaccine Planning Workgroup and the VTF meet weekly to discuss and make recommendations on the planning and operational efforts of distributing COVID-19 vaccine and vaccinating individuals. See Appendix 3 for VTF Organizational Chart.

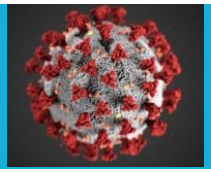
D. *Identify and list members and relevant expertise of the internal team and the internal/external committee.*



COVID-19 Vaccine Planning Workgroup	
Organization	**Title**
Allegheny County Health Department	Emergency Preparedness and Response Coordinator
DOH/Bureau of Communicable Diseases	Bureau Director
DOH/Bureau of Community Health Systems	Assistant Bureau Director Bureau Director Community Health Nurse Supervisor District Nurse Supervisor
DOH/Bureau of Emergency Preparedness and Response	Bureau Director Director/ Division of Planning and Operations Public Health Program Administrator/Distance Learning Coordinator Public Health Preparedness Coordinator Public Health Administrator Public Health Program Assistant Administrator Public Health Program Manager
DOH/Bureau of Emergency Medical Services	Emergency Medical Services Program Specialist EMS Program Manager – Preparedness EMS Program Manager for System Operations Public Health Program Manager Radio Telecommunications Specialist
DOH/Bureau of Epidemiology	COVID Medical Epidemiologist
DOH/Bureau of Facility Licensure and Certification	DOH/Bureau of Facility Licensure and Certification

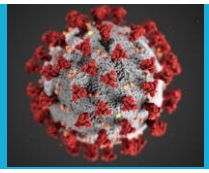


COVID-19 Vaccine Planning Workgroup	
Organization	**Title**
DOH/Bureau of Health Statistics and Registries	Bureau Director Director/Division of Statistical Registries PA SIIS Registry Manager
DOH/Office of Communications	Public Information Officer
DOH/Health Promotion and Disease Prevention	Deputy Secretary Executive Advisor
DOH/Health Policy Office	Deputy Director
DOH/Division of Immunizations	CDC Senior Public Health Advisor Community Health Nurse Supervisor Director
DOH Office of the Secretary	Assistant Counsel Chief Counsel Deputy Chief Counsel Special Advisor to the Secretary
PA Department of Community and Economic Development	Economic Development Consultant
PA Emergency Management Agency	Emergency Management Supervisor Emergency Management Specialist, Bureau of Technical Hazards
PA Department of Community and Economic Development	Director/Office of Corporate Relations
PA National Guard	
Philadelphia Department of Public Health/Immunization Division	Director, Nursing Care Facilities
Public Health Management Corporation	Director Healthcare Emergency Management



COVID-19 Vaccine Planning Workgroup	
Organization	**Title**
University of Pittsburgh School of Pharmacy	

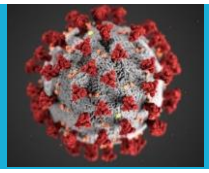
COVID-19 Vaccine Task Force	
Organization	**Title**
DHS/Office of Medical Assistance Programs	Office of Child Development and Early Learning
DHS/Medical Director	Medical Director
DHS/Chief Medical Officer	Chief Medical Officer
DOH/Bureau of Communicable Diseases	Bureau Director
Bureau of Community Health Systems	Assistant Bureau Director Community Health Nurse Supervisor District Nurse Supervisor
DOH/Bureau of Emergency Medical Services	Emergency Medical Services Program Specialist EMS Program Manager for System Operations Program Manager/Community Preparedness, Planning and Response Radio Communications Specialist
DOH/Bureau of Emergency Preparedness and Response	Director/ Division of Planning and Operations Public Health Program Administrator/Distance Learning Coordinator Public Health Program Administrator Public Health Program Assistant Administrator Public Health Program Manager
DOH/Bureau of Epidemiology	COVID Medical Epidemiologist
DOH/Bureau of Health Statistics and Registries	Director/Division of Statistical Registries



COVID-19 Vaccine Task Force	
Organization	**Title**
	PA SIIS Registry Manager
DOH/Health Policy Office	Deputy Director
DOH/Health Promotion and Disease Prevention	Deputy Secretary Executive Advisor
DOH/Division of Immunizations	CDC Senior Public Health Advisor Community Health Nurse Supervisor Director
DOH/Office of Communications	Public Information Officer
DOH/Office of the Secretary	Assistant Counsel Special Advisor to Secretary of Health
PA Emergency Management Agency	Emergency Management Supervisor

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

In jurisdictions without local public health departments, DOH is responsible for coordinating COVID-19 vaccine administration. County and Municipal Health Departments (CMHDs) are developing COVID-19 vaccine plans for their jurisdictions. DOH is collaborating with the CMHDs preparedness and immunizations staff to ensure there is support for their operations. Weekly calls are scheduled to provide the most current COVID vaccine information, and answer questions. The DOH provides an updated list of statewide pharmacies that have signed the DOH Pharmacy Memorandum of Agreement (MOA) to the CMHDs so they are aware of and can include in their plans those pharmacies within their jurisdiction. The DOH is also procuring a registration and scheduling product for MVCs and will make it available to the CMHDs free of charge. The Philadelphia Department of Public Health (PDPH) receives independent federal funding and is establishing its own COVID-19 vaccination administration plan. In addition to being a member of the Vaccine Planning Workgroup, PDPH immunizations coordinator has weekly calls with DOH Immunizations director to share planning information. The DOH COVID-19 Vaccination Plan will be provided to the CMHDs and PDPH when it is submitted to CDC.



F. *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:*

The organizational structure of the VTF includes a closed mass vaccination unit that includes long term care facilities, prisons, schools and universities, military and federal government, critical workforce, private businesses, hospitals, primary care providers, community and federally qualified health centers and state government. The lead for this unit may work directly with representatives or through the commonwealth response and the emergency coordination center emergency support function agency representatives to engage them in COVID-19 response activities.

The VTF organizational structure also includes representation through the Office of Health Equity unit such as, religious groups, limited English, disabilities, intellectual and developmental disabilities, homeless, children from vulnerable communities, immigrant/refugee, LGBTQ and racial and ethnic minorities whom they can contact and work directly with community leaders.

The DOH has 210 existing memoranda of agreement (MOAs) with pharmacies that cover 1,098 locations statewide. During Phase 1, pharmacies may be engaged to vaccinate staff and residents at long term care facilities and first responders. During Phases 2 and 3, it is estimated that many residents will be in a reasonable proximity to pharmacies providing COVID-19 vaccinations. The DOH is working with the seven Pennsylvania schools of pharmacy to recruit and enroll pharmacy students in the State Emergency Registry of Volunteers (SERVPA) as vaccinators at MVCs. The DOH will continue to explore all options to leverage Pennsylvania's resources and partnerships to safely get vaccines administered.

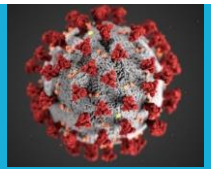
PA Voluntary Organizations Active in Disaster (PA VOAD) member organizations have direct connections with community-based organizations and aid the citizens of the Commonwealth when a disaster strikes. PEMA may coordinate with volunteer organizations to support state and county response efforts to implement the COVID-19 Vaccination Program.

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:*

Due to changing vaccine supply levels at various points during the COVID-19 Vaccination Program, planning needs to be flexible but as specific as possible to accommodate a variety of scenarios. A key point to consider is that vaccine supply will be limited at the beginning of the



program, so the allocation of doses must focus on vaccination providers and settings for vaccination of limited critical populations, ability to handle vaccine storage requirements, as well as outreach to these populations. The vaccine supply is projected to increase quickly over the proceeding months, allowing vaccination efforts to be expanded to additional critical populations and the general public. It is important to note that recommendations on the various population groups to receive initial doses of vaccine could change after vaccine is available, depending on each vaccine's characteristics, vaccine supply, disease epidemiology, and local community factors. This plan will follow the vaccine recommendations made by the Advisory Committee on Immunization Practices (ACIP). In particular, individuals listed in the phases below should only be vaccinated if they are clinically eligible under a potential Emergency Use Authorization.

Final decisions are being made about use of initially available supplies of COVID-19 vaccines based on the DOH COVID-19 Vaccine Planning Grid (Appendix 4). DOH will follow the U.S. Centers for Disease Prevention and Control (CDC) ACIP recommendations in identifying populations of focus. These decisions will be partially informed by the proven efficacy of the vaccines coming out of Phase 3 trials, but populations of focus for initial COVID-19 vaccination may include: (see *Section 4: Critical Populations*)

Phase 1: Potentially Limited Doses Available

Phase 1 vaccine administration applies when initial doses of vaccine first become available and are expected to be in limited supply (potentially very limited supply initially) compared to demand. Focus should be on the target populations advised by CDC to include:

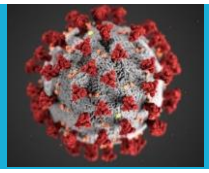
- Those most essential in sustaining the ongoing COVID-19 response;
- Those at greatest risk of severe illness and death, and their caregivers;
- Those most essential to maintaining core societal functions;
- Healthcare personnel likely to be exposed to or treat people with COVID-19; and
- Other essential workers.

Populations considered for Phase 1 include select populations from the following categories:

- Healthcare Personnel
- First Responders
- Critical Workers
- People with high-risk conditions (defined on page 16)

Phase 1A: As instructed by CDC, Pennsylvania is planning for very small initial allocations of vaccine when product first becomes available. ACIP has recommended 1) health care personnel and 2) residents of long-term care facilities (LTCFs) be offered vaccination in Phase 1A of the COVID-19 vaccination program. Pennsylvania is adopting these recommendations.

The DOH recognizes the sub-prioritization approach recommended by ACIP, because initial vaccine allocation is expected to be scarce compared to the number of healthcare personnel in the state who would require vaccination, and there is expected to be a constrained supply



environment for some months. In addition to the sub-prioritization endorsed by ACIP, DOH is including additional sub-prioritization categories to better inform providers to ensure ethical allocation of scarce vaccine.

Initial allocation of vaccine in Phase 1A will be distributed to hospitals, which will be responsible for vaccinating healthcare personnel, and the Pharmacy Partnership for Long-Term Care Program, which will be responsible for vaccinating residents and healthcare personnel who work in long-term care facilities. Hospitals should use the appendix 8 tool.

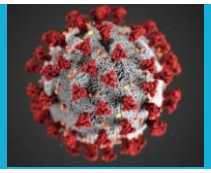
Healthcare Personnel: Phase 1A:

"Health care personnel" are defined by ACIP as paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials. These health care personnel may include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, students and trainees, direct support professionals, clinical personnel in school-settings or correctional facilities, contractual staff not employed by the health care facility, and persons (e.g., clerical, dietary, environmental services, laundry, security, maintenance, engineering and facilities management, administrative, billing, and volunteer personnel) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted among from healthcare personnel and patients. "Healthcare settings" refers to the CDC definition of the places where healthcare is delivered and includes, but is not limited to, acute care facilities, long term care facilities, inpatient rehabilitation facilities, nursing home and assisted living facilities, home healthcare, vehicles where healthcare is delivered (e.g., mobile clinics), and outpatient facilities, such as dialysis centers, physician offices, adult day facilities and others.

Sub-prioritization of Healthcare Personnel: Phase 1A:

ACIP recommends that healthcare personnel be prioritized in the earliest phases of COVID-19 vaccination. However, if there is initially insufficient supply to cover all healthcare personnel, ACIP recommends further sub-prioritization. As such, "COVID-19 facing healthcare personnel," should be prioritized. The Department is defining "COVID-19 facing healthcare personnel" as healthcare personnel who:

1. Have direct patient contact (within 6 feet) and are unable to telework. This includes individuals who provide services to patients or patients' family members, or who handle infectious materials; AND
2. Are personnel without a known infection in the prior 90 days (but serologic testing is not recommended); AND
3. Are personnel who work the majority of the time in a "COVID-19 facing unit." A COVID-19 facing unit is an area of a health care facility that is expected to care for individuals with COVID-19. This includes emergency departments, intensive care units, inpatient medical or



surgical floors in acute care facilities, emergency medical services units, outpatient respiratory care clinics, and urgent care centers.

Long-term care facilities (LTCFs): Phase 1A:

"Long-term care facilities" are defined by ACIP as facilities that provide a spectrum of medical and non-medical services to frail or older adults unable to reside independently in the community. In Pennsylvania facilities that may serve frail or older adults in a residential setting include Skilled Nursing Facilities, Personal Care Homes, Assisted Living Facilities, Private Intermediate Care Facilities for Individuals with Developmental Disabilities, Community Group Homes, Residential Treatment Facilities for Adults, Long-term Structured Residences, State Veterans Homes, State Centers, private psychiatric hospitals, and State Hospitals.

Sub-prioritization of LTCFs: Phase 1A

ACIP recommends that LTCF residents be prioritized in the earliest phases of COVID-19 vaccination. LTCF staff are considered healthcare personnel. However, in settings where initial vaccine is insufficient to vaccinate residents of all LTCFs, ACIP recommends further sub-prioritization.

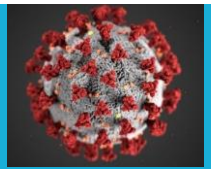
1. Skilled Nursing Facilities should be prioritized among LTCFs as they provide care to the most medically vulnerable residents.
2. After skilled nursing facilities have been vaccinated, the remaining LTCFs should be prioritized by licensure type based on factors related to COVID-19 infection risk.

Phase 1B: As instructed by CDC, Pennsylvania is planning for limited but expanding supply of vaccine where people at higher risk and critical workers may receive initial doses. Critical workers will be identified through ACIP recommendations and the advisement of the Vaccine Crisis Committee.

"Critical workers" and "essential workers" refers to the ACIP's definition that can be found here and is based off of the Cybersecurity & Infrastructure Security Agency's guidance. This includes workers who are essential to continue critical infrastructure and maintain the services and functions Americans depend on daily and workers who cannot perform their duties remotely and must work in close proximity to others.

First Responders: Phase 1B: On scene, cannot work remotely or maintain social distancing

- Law enforcement
    - Personnel with direct public contact and possible COVID exposure



- Fire/rescue personnel
  - Personnel with direct public contact and possible COVID exposure

- PA National Guard responders not included otherwise in Phase 1a
  - Personnel with direct public contact and possible COVID exposure

- Older Adult Protective Services, Adult Protective Services, Child Protective Services
  - Personnel with direct public contact and possible COVID exposure

Critical Workers: Phase 1B: Essential business personnel who cannot work remotely or maintain social distancing.

- Critical Manufacturing Sector
  - People who manufacture medical supplies, PPE, pharmaceuticals, vaccines
  - People who manufacture other essential products

- Emergency Services Sector
  - Field workers with direct public exposure
  - Volunteer response organization field personnel
  - Supportive housing field personnel

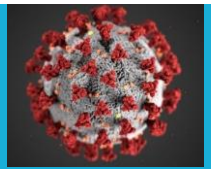
- Energy Sector
  - People who conduct home/business visits for electrical assessments and repairs, gas supply assessments and repairs
  - Oil refinery workers, others in petrochemical processing and distribution

- Food and Agriculture Sector
  - Meat processing and other food processing facility workers

- Workers serving people in congregate settings not otherwise included in Phase 1A
  - Correctional facilities/juvenile justice facilities
  - Homeless shelters
  - Domestic violence/rape crisis shelters
  - Office of Children, Youth, and Families Child Residential Facilities

- Nuclear Reactors, Materials, and Waste Sector
  - Onsite technical personnel, emergency responders

- Transportation Systems Sector
  - Drivers of high occupancy vehicles (more than 6) or drivers participating in medically necessary services
  - TSA workers
  - Airport/train security



- Medical Assistance Transportation Program Drivers

- Water and Wastewater Systems Sector
  - Field workers making assessments and repairs in the community
  - Wastewater treatment facilities technicians
  - Emergency responders

- Education
  - Teachers, school staff working directly with students

- Employees caring for Children or Adults in Early Childhood and Adult Day Programs
  - Child Care
  - Part Day School Age Programs
  - Home Visiting Programs
  - Early Intervention staff not otherwise included in 1A
  - Early Childhood programs including Head Start, Pre-K, and Family Center
  - Adult Day Programs

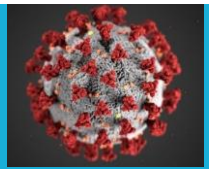
- Other high-risk services/activities
  - Environmental cleaning of patient care areas
  - Laboratory processing of COVID-19 specimens
  - Mortuary care for deceased COVID persons

High Risk Conditions: Phase 1B: People with high risk conditions leading to more severe disease and poor outcomes if infected with COVID-19

- Underlying Medical Conditions
  - Cancer
  - Chronic kidney disease
  - COPD (chronic obstructive pulmonary disease)
  - Immunocompromised state (weakened immune system) from solid organ transplant
  - Obesity (body mass index [BMI] of 30 kg/m²or higher but less than 40)
    - Severe obesity (BMI of 40 kg/m² or higher)
  - Serious heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies
  - Sickle cell disease
  - Type 2 diabetes mellitus
  - Smoking
  - Pregnancy

- Age associated high risk
  - People age 65 years and older

- Residents of congregate settings and individuals receiving home and community-based services not otherwise specified as a LTCF



- Behavioral Health/Rehabilitation Facilities
- Community Residential Rehabilitation Services
- Correctional Facilities/Juvenile Justice Facilities
- Domestic Violence Shelters
- Homeless
- Intensive or Partial Treatment Programs
- Office of Developmental Programs Home and Community-Based Services
- Office of Long-Term Living Home and Community-Based Services
- Office of Children, Youth and Families Child Residential Facilities

Phase 2: Large Number of Doses Available, Supply Likely to Meet Demand: Focus on ensuring access to vaccine for members of Phase 1 critical populations who were not yet vaccinated as well as for the general population; expand provider network.

- Those involved in broader health provision
- Those who face greater barriers to access care if they become seriously ill
- Those contributing to maintenance of core societal functions
- Those whose living or working conditions give them elevated risk of infection, even if they have lesser or unknown risk of severe illness and death

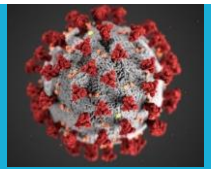
Populations considered for Phase 2 include select people from the following categories:

- Critical Workers
- People with high-risk conditions
- People with vaccine access challenges

Critical Workers: Phase 2: Essential business personnel who cannot work remotely or maintain social distancing not considered in Phase 1. Also, people who interact directly with the public. "Critical workers" and "essential workers" refers to the ACIP's definition that can be found here and is based off of the Cybersecurity & Infrastructure Security Agency's guidance. This includes workers who are essential to continue critical infrastructure and maintain the services and functions Americans depend on daily and workers who cannot perform their duties remotely and must work in close proximity to others

High Risk Conditions: Phase 2: Expanded health conditions as per CDC guidance and additional age category and additional residents of congregate settings not as

- Underlying health conditions who might be at high risk
  - Asthma (moderate-to-severe)
  - Cerebrovascular disease (affects blood vessels and blood supply to the brain)
  - Cystic fibrosis
  - Hypertension or high blood pressure
  - Immunocompromised state (weakened immune system) from blood or bone marrow transplant, immune deficiencies, HIV, use of corticosteroids, or use of other immune weakening medicines
  - Neurologic conditions, such as dementia
  - Liver disease



- Pulmonary fibrosis (having damaged or scarred lung tissues)
- Overweight (BMI of 25 kg/m² and higher, but less than 30 kg/m²)
- Intellectual or neurological disabilities
- Thalassemia
- Type 1 diabetes mellitus age-associated higher risk
- People age 40 - 64 years
- Residents of a congregate setting
- College dormitories
- Military barracks
- Boarding schools
- Summer camps

Phase 3: Likely Sufficient Supply, Slowing Demand

Focus on remainder of all Phase 1 and Phase 2 populations, expand to general population, complete vaccine series

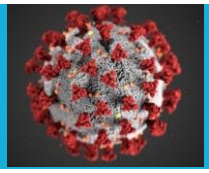
General Population: Phase 3:

- All persons of any age not previously vaccinated

Vaccine Access Challenges: Phase 3:

The DOH will partner with professional member organizations for hospitals, including Public Health Management Corporation (PHMC), Hospital and Health system Association of Pennsylvania (HAP), and Pennsylvania Association of Community Health Centers (PA ACHC) and CMHDs. A letter will be drafted to notify the organizations and their members to inform them of the upcoming COVID-19 vaccination efforts in accordance to CDC guidelines through group prioritizations. Shortly thereafter of this notification, guidance in completing the provider agreement will be distributed to all eligible hospitals, Federally Qualified Health Centers (FQHCs) and CMHDs. In addition, the DOH will engage the pharmacies as needed to assist with LTCF vaccinations. The DOH has identified a potential workflow with needed resources for onboarding potential COVID-19 providers for Phase 1 of the COVID-19 vaccination campaign.

- Reach out to HAP and PA ACHC to inform them of upcoming correspondence as related to provider agreements and enrollment
- Draft high-level correspondence to HAP and PA ACHC
- Determine how DOH will receive and process the completed provider agreements
  - Create an email resource account to receive the completed provider user agreements
  - The short-term solution for processing provider agreements in Phase 1 will be entering into a form developed in Microsoft Access which is a virtual spreadsheet.
  - DOH will develop a long-term solution that will improve the efficiency of processing provider agreements.
- Establish a toll free line to support providers in addressing any questions they encounter



- The DOH is obtaining a current listing of all hospitals, FQHCs and CMHDs (excluding Philadelphia) to compare to those currently enrolled and actively reporting to the Pennsylvania Statewide Immunization Information System (PA-SIIS) in order to identify those facilities that have not adopted the PA-SIIS. The focus will then lie on the training of those facilities that have not adopted the PA-SIIS.

Section 4: Critical Populations

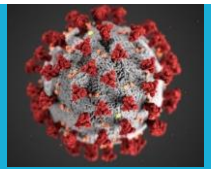
Instructions:

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:*
   - *Healthcare personnel;*
   - *Other essential workers;*
   - *Long-term care 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; and/or*
   - *People who are under- or uninsured.*

Critical populations in Pennsylvania are derived from many sources. Estimates for the above listed populations are derived from the 2019 U.S. Census, the Behavioral Risk Factor Surveillance System (BRFSS), and health systems patient databases (Medicaid, IBX, others), and Tiberius. DOH will review several preparedness reports to obtain detailed estimates of vulnerable populations that have been geocoded and presented by census tract. Such reports have been prepared by Drexel University's Center for Public Health Readiness & Communication Drexel University School of Public Health and include:

- Public Health Risk Assessment Report for the Philadelphia Metropolitan Statistical Area (2012)
- Public Health Risk Assessment Report for the Commonwealth of Pennsylvania (2016)

DOH will coordinate with its CMHDs to share additional lists and locations of populations for specific vaccine targeting. As part of routine public health preparedness work, all CMHDs identify and



estimate counts of people in their jurisdictions that live in poverty, speak languages other than English as a primary spoken language in the household, have a physical or intellectual disability, have a serious mental illness or emotional disturbance, and who have chronic health conditions warranting use of medical devices. These data will be used to better estimate prioritized populations, but to also ensure access to vaccine.

The planning team looked at reported cases of COVID-19 in the state's disease surveillance database (PA-NEDSS). Demographic information, geography, occupation, residence in a congregate living facility, etc. are all available for many of the state's more than 165,000 cases. These data, in addition to national data sources, has helped to identify those who are more likely to contract the disease and to suffer more severe outcomes.

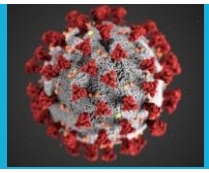
Phase 1A populations to receive vaccine are focused on those at greatest risk for illness and death. Healthcare personnel evaluating and treating patients with COVID-19 are at greatest risk of exposure, especially those involved in life saving activities that increase respiratory aerosols (cardio-pulmonary resuscitation, intubation, suctioning, etc.). To date in Pennsylvania, healthcare workers accounted for 6.7% of reported COVID-19 cases though this is considered an underestimate as investigation data is needed to determine this association.

In Pennsylvania, residents and staff of long-term care (LTC) and personal care (PC) facilities accounted for 68.6% of the state's reported COVID-19 deaths. Among deaths with known comorbidity data, 33.8% had existing dementia. Given asymptomatic and pre-symptomatic transmission of SARS-CoV-2, healthcare workers including those who work in long-term care settings are at great risk to transmit virus to these most vulnerable patients and residents.

Table: COVID-19 Case and Death Information in Pennsylvania as of December 8, 2020

Variable	Count	Percent
Total reported cases	436,614	100%
Cases among healthcare workers (underestimate; depends on investigation data)	15,766	3.6%
Cases among residents of LTCF, PCH	40,541	9.2%
Cases among employees of LTCF, PCH	7,447	1.7%
Total deaths	11,542 (EDRS)	4.8%
Deaths among LTCF/PCH facilities	7,005 (NEDSS)	60.6%

The DOH will utilize several existing data sources to get population estimates for several healthcare associated priority groups. These include Hospital Reports and Nursing Home reports which is data collected through Department of Health, Division of Health Informatics from 2018 that include counts of licensed health professionals by specialty, number of licensed beds, numbers of staff (available at:



https://www.health.pa.gov/topics/HealthStatistics/HealthFacilities/HospitalReports/Pages/hospital-reports.aspx).

The DOH, the PA Department of Human Services, the PA Department of Drug and Alcohol Programs, and/or the PA Department of Aging provide oversite of all LTC, personal care, inpatient behavioral healthcare, and home health care agencies in Pennsylvania. Spreadsheets are broken down by county and by facility and estimate the number of residents, or patients currently enrolled. For all of these estimates, Philadelphia county facilities were deleted, and those data shared with immunizations and preparedness colleagues in that county.

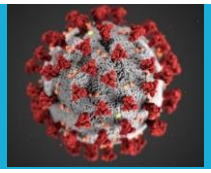
Health statistics for several conditions listed by the CDC that are or might be at high risk for complications from COVID-19 were derived from multiple sources including the Data & Dashboards Team in the Vaccine Planning Unit at CDC. These data were not exclusive and so were of limited value when determining separate counts of people in multiple categories and not duplicating people to receive vaccine. DOH planners have had to adjust these estimates to avoid overcounting individuals.

The DOH, in conjunction with PEMA, will utilize Geographic Information Systems (GIS) to identify critical populations in conjunction with available COVID-19 Mass Vaccine Clinics, pharmacies and other vaccine provider locations.

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

The DOH will utilize data from the PA Vital Statistics Report, PA Center for Workforce Information and Analysis, United States Census Bureau, and Bureau of Labor Statistics to identified population estimates for persons working in the critical infrastructure workforce. Critical infrastructure has been identified using the Cybersecurity & Infrastructure Security Agency (CISA) Critical Infrastructure Sectors list. The DOH planners have identified all the sectors relevant to Pennsylvania and have made decisions to assign personnel from each sector into a vaccine administration phase (see section 3). Sectors that are included for vaccine allocation are:

- Chemical Sector;
- Commercial Facilities Sector;
- Communications Sector;
- Critical Manufacturing Sector;
- Dams Sector;
- Emergency Services Sector;
- Energy Sector;
- Financial Services Sector;
- Food and Agriculture Sector;



- Government Facilities Sector;
- Healthcare and Public Health Sector;
- Information Technology Sector;
- Nuclear Reactors, Materials, and Waste Sector;
- Transportation Systems Sector; and
- Water and Wastewater Systems Sector.

Partner agencies and organizations will be used, whenever possible, to get the most up-to-date estimates.

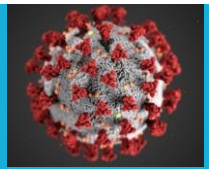
C. *Describe how your jurisdiction will determine additional subset groups of critical populations if there is insufficient vaccine supply.*

The DOH will utilize the healthcare coalitions, partner agencies and organizations, and surveys to determine additional subset groups of critical populations. When vaccine is in limited supply (Phase 1), DOH planners will assess occupational risk and will prioritize populations that have closer or more frequent contact with COVID patients, vulnerable populations (seniors, people with underlying medical conditions), and large numbers of the public (service industries, retail if operational, etc.).

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*

DOH will utilize established relationships through the Bureau of Emergency Preparedness and Response's PHPCs. The DOH's PHPCs will communicate with the counties in their respective regions to organize efforts within the critical population groups. DOH will also utilize Regional PEMA offices, Health Care Coalitions, and CMHDs. DOH will utilize a variety of communications platforms to ensure the exchange of information. DOH conducts weekly conference calls with its 10 CMHDs related to the COVID-19 response. In addition to surveillance and case management, vaccine planning and distribution is reviewed in detail on these calls. There are other standing calls with vaccine partners, and email list servs to communicate information. The state uses its Health Alert Network as its primary way to disseminate critical response information to the clinical community statewide. Information on vaccine eligibility, prioritization and administration will be issued through this network as needed.

The DOH will make use of all available verified resources at its disposal in order to accumulate the relevant data sets and demographic information to make important vaccine allocation decisions. It is anticipated the Department will rely heavily on the CDC's Tiberius software to accumulate key population data sets.



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*

COVID-19 provider recruitment during phase one is currently under way. Facility types targeted by Phase 1 recruitment efforts consist of hospitals, Federally Qualified Health Centers (FQHCs), CMHDs, State Health Centers, and pharmacies allowing the DOH the ability to ensure COVID-19 vaccine will be available for critical population groups identified by the CDC and the DOH.

It is estimated Pennsylvania will recruit 200 FQHCs, nine CMHDs, 60 State Health Centers, 200 hospitals and 900 LTCFs in phase one using the following recruitment strategies.

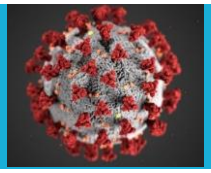
- Collaborative messaging – DOH has held meetings with the Pennsylvania Association for Community Health Centers and the Public Health Management Corporation allowing consistent messaging for all phase one hospitals and FQHC facilities. DOH will also coordinate closely with other state agencies to ensure coordinated messaging to stakeholders and the public.
- Electronic messaging – Facilities and oversight agencies have received information regarding PA's COVID-19 plan, priority facilities and populations, the COVID-19 Provider Enrollment Agreement and requirements of COVID-19 administration sites.

Phase 2 and 3 recruitment efforts will be expanded to Vaccine for Children (VFC) and non-VFC providers and pharmacies throughout Pennsylvania. During phases 2 and 3, the DOH estimates an additional 1,500 VFC and non-VFC facilities and 2,000 pharmacies will be enrolled in the COVID-19 Vaccination Program.

The Division of Immunizations (DOI) will verify COVID-19 vaccination providers (prescribers only, e.g., MD, DO, RPh, NP, PA) have active, valid licensure/credentials to possess and administer vaccine through the Pennsylvania Department of State during the COVID-19 Vaccination Provider onboarding and approval process.

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.*

The DOH has decided to include hospitals, FQHCs, CMHDs and State Health Centers to maximize the number of individuals who can be vaccinated according to the identified priority groups with the first available COVID-19 vaccine. The size and setup of their facilities will allow for social distancing



and other necessary infection control procedures while the geographic distribution of sites will provide adequate points of service for the identified populations.

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.*

The DOH will implement a stopgap COVID-19 provider enrollment process allowing Phase 1 providers the opportunity to enroll while the long-term enrollment process is under development. Phase 1 providers will complete the fillable CDC COVID-19 Provider Enrollment Agreement that is posted on the DOI website with links located in relevant areas throughout DOH's website. Once the fillable form has been submitted by the enrolling provider, DOH staff will enter the data into Excel which will be exported into a CSV file to provide CDC with biweekly provider enrollment updates. Sites interested in becoming a COVID-19 vaccination site will complete the web based COVID-19 provider enrollment agreement. Data from the completed web form will be exported to an Access database twice daily. The access database will then be used to generate a CSV file to provide CDC biweekly COVID-19 provider enrollment updates.

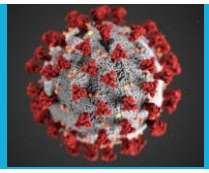
D. *Describe the process your jurisdiction will use to verify that providers are credentialed with active, valid licenses to possess and administer vaccine.*

DOI will ensure the provider agreement, profile form, and redistribution agreement (if necessary) are thoroughly and accurately completed by each enrolled provider. DOI will verify COVID-19 vaccination providers (prescribers only, e.g., MD, DO, RPh, NP, PA) have active, valid licensure/credentials to possess and administer vaccine through the Pennsylvania Department of State. Any volunteers working in the vaccine administration process will undergo a training and robust onboarding process.

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

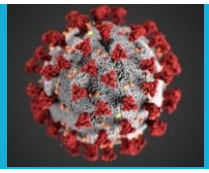
The DOH will utilize DOI and Bureau of Health Statistics and Resources (BHSR) staff to provide both in person and web based COVID-19 training for enrolled providers and distribute educational resources provided by CDC to ensure success of the COVID-19 Vaccination Program. Provider COVID-19 training and education will focus on the following topics:

- ACIP COVID-19 vaccine recommendations – In person and/or virtual training will be provided by DOI field staff. Training resources and materials will also be available on the DOH website.



- COVID-19 vaccine ordering and accountability - In person and/or virtual training will be provided by PA-SIIS staff. Training resources and materials will also be available on the DOH website.
- COVID-19 vaccine storage and handling (including transport requirements) - In person and/or virtual training will be provided by DOI field staff. Training resources and materials will also be available on the DOH website.
- COVID-19 vaccine administration - In person and/or virtual training will be provided by DOI field staff. Training resources and materials will also be available on the DOH website.
- COVID-19 vaccine documentation via PA-SIIS and/or other external system - In person and/or virtual training will be provided by PA-SIIS staff. Training resources and materials will also be available on the DOH website.
- COVID-19 vaccine inventory management - In person and/or virtual training will be provided by PA-SIIS staff. Training resources and materials will also be available on the DOH website.
- Reporting vaccine inventory - In person and/or virtual training will be provided by PA-SIIS staff. Training resources and materials will also be available on the DOH website.
- Temperature excursion management - In person and/or virtual training will be provided by DOI field staff. Training resources and materials will also be available on the DOH website.
- Documentation and reporting of vaccine wastage/spoilage - In person and/or virtual training will be provided by DOI field staff. Training resources and materials will also be available on the DOH website.
- Reporting of moderate and severe adverse events and vaccine administration errors to VAERS - In person and/or virtual training will be provided by DOI field staff. Training resources and materials will also be available on the DOH website.
- Providing Emergency Use Authorization (EUA) fact sheets or VISs to vaccine recipients - In person and/or virtual training will be provided by DOI field staff. Training resources and materials will also be available on the DOH website.
- Submitting facility information for COVID-19 vaccination clinics to CDC's VaccineFinder. - In person and/or virtual training will be provided by DOI field staff. Training resources and materials will also be available on the DOH website.

Provider education and technical assistance provided through in person meetings, phone and webinars will be documented in an excel tracking form. Prerecorded training will be available through the PA TRAIN system and can be tracked using the system training certifications that are provided upon successful completion of each training module.



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).*

The DOH will require all vaccine redistribution to be pre-approved through the COVID-19 vaccine management team. To be considered for approval, the provider must complete and submit the CDC Supplemental COVID-19 Vaccine Redistribution Agreement (Appendix 8) and provide documentation regarding the number of doses to be transferred, the site name and location that will be receiving the vaccine, cold chain history to ensure the efficacy of the vaccine has not been compromised and agree to proper packing and temp monitoring during the transport process. Once the request has been approved and the site has accepted the transfer, the transferring and receiving sites will be required to adjust their vaccine inventory to reflect the vaccine transfer.

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

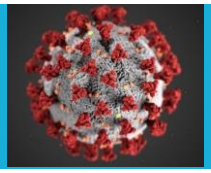
The DOH has developed GIS mapping tools to identify both geographic and access barriers to COVID-19 immunization services. All enrolled COVID-19 vaccine providers will be included in the ongoing GIS analysis to continually improve and ensure equitable access to COVID-19 vaccine. DOH is estimating roughly 200 FQHCs, 60 State Health Centers, nine CMHDs and 200 hospitals will be providing COVID-19 immunization services during Phase 1. Participation will then be expanded in phases 2 and 3 to include an additional 1,500 VFC and non-VFC facilities, 2,000 pharmacies and LTCFs. In addition, we will work with the Office of Health Equity in identifying populations and barriers to obtaining vaccine. The DOH will also continue to reference the CDC's Coronavirus Health Equity Considerations and Racial and Ethnic Minority Groups.

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.*

The DOH has 210 existing MOAs with pharmacies that cover 1,098 locations statewide. Recruitment began in 2016 during meetings with pharmacies and public health partners to roll out the PA Pharmacy Pandemic Influenza MOA. In 2018 a webpage on the DOH website was designed for continued recruitment of pharmacies. During Phase 1, pharmacies may be engaged to vaccinate staff and residents at LTCFs and first responders. During phases 2 and 3, it is estimated that many residents will be in reasonable proximity to pharmacies providing COVID-19 vaccinations. The DOH is working with the seven Pennsylvania schools of pharmacy to recruit and enroll pharmacy students in the SERVPA as vaccinators at MVCs.

Section 6: COVID-19 Vaccine Administration Capacity

Instructions:

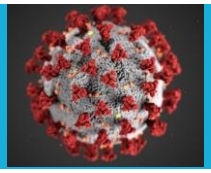


A. *Describe how your jurisdiction has or will estimate vaccine administration capacity based on hypothetical planning scenarios provided previously.*

- Health and Medical Infrastructure

  Vaccine administration capacity in Pennsylvania is robust as the state has 242 hospital and inpatient medical facilities (all specialties), 65 rehabilitation and transitional care facilities, 1,098 pharmacies, 693 SNFs, 7 VA hospitals, 2,974 home and personal care service providers where patients, residents and employees may be able to receive COVID-19 vaccine. All of the above-mentioned facilities will likely be utilized during Phase 1 of vaccine administration when healthcare staff, EMS providers, workers and residents of long-term care facilities become eligible to receive vaccine. All of the populations listed in Phase 1 typically receive medications, immunizations (e.g., seasonal influenza vaccination) and other health services through these existing mechanisms, therefore we assume that much of the work in receiving and administering COVID-19 vaccine to these populations can be integrated into an expanded health promotion program. As more vaccine becomes available, acute care facilities will be expected to expand vaccine to additional healthcare workers and patients in phases 1 and 2. Pennsylvania has 210 existing memoranda of agreement (MOAs) with pharmacies to administer emergency medical countermeasures that cover 1,098 individual locations statewide. During Phase 1, pharmacies may be engaged to vaccinate staff and residents at long term care facilities and first responders. During phases 2 and 3, it is estimated that many residents will be in reasonable proximity to pharmacies providing COVID-19 vaccinations.

  Outpatient clinics are extensive including an expanded array of FQHCs and FQHC look-alike clinics that provide health services to Pennsylvania residents with no or limited health insurance. Pennsylvania (excluding Philadelphia) has approximately 267 providers that are able to provide adult immunizations which consist of FQHCs, rural health centers, and state health centers. There are 82 behavioral health facilities in Pennsylvania where vaccine may be administered to people with high risk health conditions and other healthcare personnel working in these settings. The state has many colleges and universities with robust student health services able to administer vaccine. Existing relationships with preparedness and infectious disease control personnel at DOH with college/university student health services to control other outbreaks (mumps) will be leveraged to onboard these entities. Health services in the state's correctional facilities (prisons, jails) will be utilized to deliver vaccine directly to inmates and employees in these settings when indicated (Phases 1B, 2, 3).



- Occupational Health Clinics and Closed Points of Dispensing (PODs)

  Many of the prioritized groups in the vaccination scheme are related to occupation (healthcare worker, first responder, food processing, education, etc.). Jobs that put the individual at high risk for contracting COVID-19 like health care workers are expected to receive vaccine through their existing occupational health programs at their place of employment. These employers will become vaccine providers, and in doing so, they will estimate the number of patients they see in their practices in total, number of patient visits they conduct per week, and the number of influenza vaccines they administer per week during the height of influenza season in accordance with each provider profile. These data will give providers and DOH vaccine staff an assessment of capacity and will identify which providers might require additional resources to vaccinate eligible populations in a timely manner.

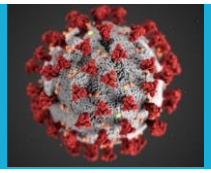
  The DOH has a robust mass vaccination response plan as part of emergency preparedness routine activities. Closed Points of Dispensing (PODs) are locations where agencies have agreed to administer an emergency medical countermeasure to their own internal populations (e.g., employees, students, contractors, family members, etc.) and not to the general public. Types of agencies among established Closed PODs in Pennsylvania include universities and colleges, state, local and federal government agencies, local utility companies, prisons and jails, behavioral health facilities, businesses, in addition to acute healthcare facilities. Agreements have been established with some of the identified Closed PODs, and various levels of training and planning have occurred.

Table: Total number of Closed PODs Previously Identified in Pennsylvania less Philadelphia

Region	# Closed PODs
Northeast	49
North Central	25
Northwest	20
Southeast (less Philadelphia)	119
South Central	52
Southwest	115
Total	**380**

- Expanded Outreach to Ensure Vaccine Access

  PODs that serve the public are a fast and effective way to administer a medical countermeasure and will be a component of the Pennsylvania COVID-19 mass vaccination response. The grid in Appendix 4 also identifies populations at high risk who are members of the general public (high risk conditions, advanced age) where additional measures will need to be taken to ensure access to vaccine in disparate and rural communities. County-based public PODs, FQHCs, and rural and state health centers will



all play a critical role in providing vaccine to these populations. In addition, DOH is expanding its mobile vaccination capabilities by procuring two mobile vans that can drive to specific neighborhoods and other locations where access to vaccine is severely limited.

There are 10 CMHDs in Pennsylvania that serve a significant proportion of the state's urban and suburban populations and are an essential partner in this effort. All of them have mass vaccination response plans that include identification of hundreds of venues and partners, staffing and transportation resources, training and inventory management capabilities.

- Staffing

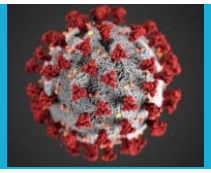
  Staffing a mass vaccination response will require recruitment and activation of many people. Utilizing existing health infrastructure and Closed POD partners is a great way to leverage skilled resources. Command and coordination, Public PODs, mobile outreach and staff to supplement response will all be needed from government, the community and additional surge resources. DOH and other state agencies have an extensive group of qualified professionals to serve in an administrative capacity working through the DOC and overall ICS organizational framework.

  Pennsylvania has an active volunteer corps with several locally administered programs in many of its most densely populated areas managed by CMHDs or local emergency management agencies. There are currently 29,000 volunteers registered in SERVPA. Among this total, 55.2% are a health professional. To boost existing staff resources for this response, the DOH is working with the seven Pennsylvania schools of pharmacy to recruit and enroll pharmacy students in SERVPA as vaccinators to be used at several vaccination clinics.

B. *Describe how your jurisdiction will use this information to inform provider recruitment plans.*

The COVID-19 Vaccine Distribution and Administration Site Planning Grid by Phase (Appendix 4), organizes all the identified target populations by prioritization phase. It also estimates the total number of people in each target group (data continues to be collected and cleaned). Thought has been given to assigning probable and likely vaccine administration sites/locations that will target individual populations. This information comes from previous vaccine expansion projects (H1N1 influenza), existing routine vaccine administration efforts and knowledge of expandable capacity for COVID-19 vaccine response.

DOH will use the information on prioritized populations to determine which Closed PODs would be best for activation. Not all Closed PODs identified through previous planning efforts are suitable for administration of COVID-19 vaccine. Managing cold chain (and ultra-cold chain), staffing, strict infection control, reporting doses, public messaging and other requirements may



not be practical for all of the previously identified organizations. DOH will select Closed PODs that can reach target populations described in the phased prioritization and invite them to become a COVID-19 vaccine provider. Assessments will occur to ensure suitability of alternative provider sites (Closed PODs) during the application process. Outreach to additional partners known to serve high risk and target populations with some understanding of appropriate capacity will occur as well. It is expected that additional organizations will wish to become Closed PODs and so DOH will recruit new Closed PODs that serve target populations and can fulfill all provider requirements.

DOH in partnership with its CMHDs (less Philadelphia) will determine and activate a public POD framework that will provide at least one venue in each county and will ensure access to densely populated as well as remote areas of the state. CMHDs will likely become COVID-19 vaccine providers to administer vaccine in their established public POD and health clinic systems. In doing so they will assume responsibility for inventory management, staffing, training, infection control, local public messaging, and reporting, all of which will be advised and coordinated with DOH.

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

Instructions:

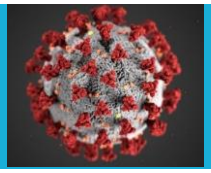
A. *Describe your jurisdiction's plans for allocating/assigning allotments of vaccine throughout the jurisdiction using information from Sections 4, 5, and 6. Include allocation methods for populations of focus in early and limited supply scenarios as well as the variables used to determine allocation.*

The CDC will allocate COVID-19 vaccine 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).

The DOH has implemented a COVID-19 Vaccine Taskforce that will assess Pennsylvania's populations through GIS mapping, census data, the annual healthcare worker survey and data provided by partner organizations to identify pockets of high-risk populations and areas affected by outbreaks among Phase 1 eligible populations during early and limited phases of vaccine supply. Upon receiving this direction, the vaccine management team will begin approving vaccine orders for enrolled providers serving the identified populations of each phase as outlined in section 4.

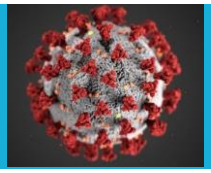
The DOH will allocate COVID-19 vaccine for critical populations based on population assessment results, enrolled COVID-19 providers and available vaccine. Upon provider enrollment DOH will determine COVID-19 vaccine order allowances for each facility based on the populations served. Allotments of COVID-19 vaccine doses will be based on:

- ACIP recommendations;
- Estimated number of doses allocated to the jurisdiction and timing of availability;
- Populations served by vaccination providers and geographic location to ensure distribution throughout the jurisdiction;
- Vaccination provider site vaccine storage and handling capacity;
- Minimizing the potential for wastage of vaccine, constituent products, and ancillary supplies; and
- Other local factors.

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.*

The DOH has collected ultra-cold storage capabilities of hospitals in Pennsylvania using a storage and handling survey completed by the Bureau of Emergency Preparedness and Response. In addition to the hospital storage and handling survey, the DOI will collect storage and handling capabilities for each facility completing the COVID-19 provider agreement. Site storage and handling capabilities will be documented in an Access database that will be used in the vaccine allocation and distribution process to ensure vaccine shipments, i.e. vaccine brand cold chain requirements, comply with the facility's storage and handling capabilities.

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., SIIS) used for provider ordering. Describe how you will incorporate the allocation process described in step A in provider order approval.*



The DOI COVID-19 vaccine distribution staff will cross reference PA-SIIS vaccine orders with approved COVID-19 vaccine providers using an Access database to ensure order quantity does not exceed vaccine allocation levels and storage and handling capacity for each COVID-19 provider site. COVID-19 vaccine orders will follow the workflow below.

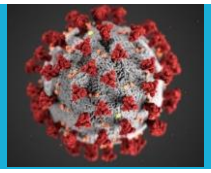
- Each jurisdiction, federal agency and commercial partner will receive allocations (order caps) weekly in VTRKS.
- Providers will place COVID-19 vaccine orders using PA-SIIS.
- The DOI staff will review PA-SIIS vaccine orders and crosswalk the vaccine order, provider storage and handling capabilities and allocation to ensure vaccine is distributed to approved sites.
- Once approved, vaccine orders are transferred to VTRKS. These orders will be processed against the allocation (order cap).
    - Federal and commercial partners may pull order files from the Vaccine Provider Ordering Portal (VPoP) to upload into VTrckS.
- If necessary, updated provider and facility information will be uploaded into VTRKS. Daily shipments from VTRKS will be downloaded and processed within PA-SIIS creating facility shipments and notifications of inventory for COVID-19 vaccine providers.
- Upon receiving the COVID-19 vaccine, providers are required to adjudicate and accept the electronic shipment within the PA-SIIS.
- Orders will be scheduled for delivery Monday through Friday.

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

Redistribution will not be considered in Phase 1 as providers identified for this phase will have adequate storage capacity and accommodate a large number of doses. For subsequent phases, the DOH will require all vaccine redistribution to be pre-approved through the COVID-19 vaccine management team. To be considered for approval, the provider must complete and submit the CDC Supplemental COVID-19 Vaccine Redistribution Agreement and provide documentation regarding the number of doses to be transferred, the site name and location that will be receiving the vaccine, cold chain history to ensure the efficacy of the vaccine has not been compromised and agree to proper packing and temperature monitoring during the transport process. Once the request has been approved and the site has accepted the transfer, the transferring and receiving sites are required to adjust their vaccine inventory to reflect the vaccine transfer.

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

All COVID-19 vaccine shipments and doses administered are required to be documented in PA-SIIS. This documentation provides a complete inventory allowing the DOH to monitor vaccine inventory, wastage and expiration.



The following process will be in place to monitor wastage and expiration of COVID-19 vaccine.

Expired Vaccine PA-SIIS HL7 Users - The Bureau of Health Statistics and Registries is developing a report to monitor expired vaccine as vaccine inventory does not decrement upon expiration. The report will be run monthly and will provide the following information:

- Site Name;
- Address;
- Contact Name;
- Contact Phone Number;
- Vaccine Brand Names; and
- Number of Doses Expired.

The DOH staff will contact sites with expired vaccine and begin the vaccine return process with the site to ensure expired vaccine is not administered.

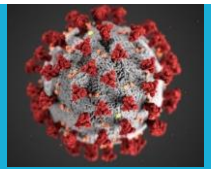
Inventory PA-SIIS HL7 Users – PA-SIIS does not decrement inventory based on doses administered for HL7 users. To monitor inventory in HL7 users, DOI will require COVID-19 sites to reconcile inventory in PA-SIIS prior to fulfilling COVID-19 vaccine orders to prevent unnecessary overstocking and expiration of vaccine.

Expired Vaccine PA-SIIS Web App Users – PA-SIIS web app users are required to document each dose of COVID-19 vaccine administered in PA-SIIS. Doses administered will decrement from the site inventory providing a point in time inventory. PA-SIIS staff will run the COVID-19 expired vaccine report to identify each site's expired vaccines, the report will contain the following fields:

- Site Name;
- Address;
- Contact Name;
- Contact Phone Number;
- Vaccine Brand Names; and
- Number of Doses Expired.

The DOH staff will contact sites with expired vaccine and begin the vaccine return process with the site to ensure expired vaccine is not administered.

Inventory PA-SIIS Web App Users - PA-SIIS web app users are required to document each dose of COVID-19 vaccine administered in PA-SIIS. Doses administered will decrement from the site inventory providing a point in time inventory. To monitor inventory in web app users, DOI will



require COVID-19 sites to document each dose in PA-SIIS and reconcile inventory in prior to fulfilling COVID-19 vaccine orders to prevent unnecessary overstocking and expiration of vaccine.

Section 8: COVID-19 Vaccine Storage and Handling

Instructions:

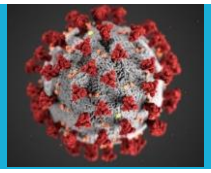
A. *Describe how your jurisdiction plans to ensure adherence to COVID-19 vaccine storage and handling requirements, including cold and ultracold chain requirements, at all levels:*
   - *Individual provider locations*
   - *Satellite, temporary, or off-site settings*
   - *Planned redistribution from depots to individual locations and from larger to smaller locations*
   - *Unplanned repositioning among provider locations*

The DOH has implemented a phased recruitment approach to ensure Pennsylvanians have access to the COVID-19 vaccine as it becomes available. The phased approach includes the following assessment criteria to ensure access for both the high-risk and general populations of PA.

- GIS evaluation to identify prepositioning sites. The GIS evaluation has been supplemented by the following data:
  - Ultra-cold storage capabilities; and
  - Number of healthcare workers at the facility and in the geographic area.
- Safety-net providers
  - FQHCs
  - Long-term care facilities
  - Sliding fee scale facilities
- Population based care

The DOH is requiring all sites to document their storage and handling capabilities in the COVID-19 Provider Agreement and provide copies of their digital data logger calibration certificates and the emergency back-up plan during provider enrollment. All primary and back-up facility contacts will be required to complete CDC's You Call the Shots Storage and Handling training https://www.cdc.gov/vaccines/ed/youcalltheshots.html.
Ultra-Cold - Sites with ultra-cold storage capabilities are included in Phase 1 of COVID-19 vaccine distribution. These sites will be required to meet the following storage and handling requirements.

- Have a back-up emergency plan in the event of a power outage or equipment failure.
- Have an assigned staff member responsible for documenting the minimum, maximum and current temperature twice daily and receiving COVID-19 vaccine shipments.



- Have an assigned back-up staff member to document the minimum, maximum and current temperature twice daily and receiving COVID-19 vaccine shipments if necessary.

Frozen Vaccine - Sites that receive frozen vaccine will be required to meet the following storage and handling requirements.

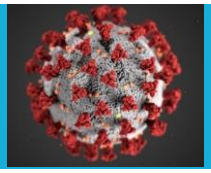
- Have a back-up emergency plan in the event of a power outage or equipment failure.
- Vaccine must be stored in a single use freezer.
  - Monitored by a continuously recording certified and calibrated digital data logger.
- Have an assigned staff member responsible for documenting the minimum, maximum and current temperature twice daily and receiving COVID-19 vaccine shipments.
- Have an assigned back-up staff member to document the minimum, maximum and current temperature twice daily and receiving COVID-19 vaccine shipments if necessary.

DOI is requiring all sites to provide temperature logs for the previous four weeks to ensure proper storage and handling with each COVID-19 vaccine order prior to vaccine shipment to a stable environment.

The DOH may utilize satellite, temporary, or off-site clinics in collaboration with community or mobile vaccinators to assist in providing equitable access for COVID-19 vaccination. To ensure storage and handling requirements are met in these situations the following actions will be taken.

- Satellite, temporary, and/or off-site COVID-19 vaccination clinics will be based on the anticipated number of COVID-19 vaccine recipients and the ability of the provider to store, handle, and transport the vaccine appropriately.
- COVID-19 vaccines may be transported—not shipped—to a satellite, temporary, or off-site COVID-19 vaccination clinic setting using vaccine transportation procedures outlined in the COVID-19 addendum to CDC's *Vaccine Storage and Handling Toolkit*.
- Upon arrival at the COVID-19 vaccination clinic site, vaccines must be stored correctly to maintain appropriate temperature throughout the clinic day.
- Temperature data must be reviewed and documented according to guidance in the COVID-19 addendum to CDC's *Vaccine Storage and Handling Toolkit*. At the end of the clinic day, temperature data must be assessed prior to returning vaccine to fixed storage units to prevent administration of vaccines that may have been compromised. As with all vaccines, if COVID-19 vaccines are exposed to temperature excursions at any time, the temperature excursion must be documented and reported according to DOI's temperature excursion policy. Vaccines that were exposed to out-of-range temperatures must be labeled "do not use" and stored at the required temperature until further information on usability can be gathered or further instruction on disposition or recovery is received.

CDC will provide additional product-specific materials, including storage, handling and administration job aids. The CDC Vaccine Storage and Handling Toolkit can be found at:



https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html. Appendices 5 through 8 details more information on vaccines A and B.

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

Redistribution will not be considered in Phase 1 as providers identified for this phase will have adequate storage capacity and accommodate a large number of doses. For subsequent phases, the DOH will require all vaccine redistribution to be pre-approved through the COVID-19 vaccine management team. To be considered for approval, the provider must complete and submit the CDC Supplemental COVID-19 Vaccine Redistribution Agreement and provide documentation regarding the number of doses to be transferred, the site name and location that will be receiving the vaccine, cold chain history to ensure the efficacy of the vaccine has not been compromised, five days of temperature logs from the receiving site to ensure proper storage and handling and agree to proper packing and temperature monitoring during the transport process. Once the request has been approved and the site has accepted the transfer, the transferring and receiving sites are required to adjust their vaccine inventory to reflect the vaccine transfer within 24 hours.

Section 9: COVID-19 Vaccine Administration Documentation and Reporting

Instructions:

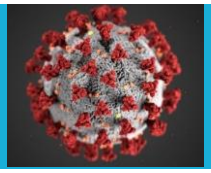
A. *Describe the system your jurisdiction will use to collect COVID-19 vaccine doses administered data from providers.*

The core system for data collection will be the PA-SIIS and will support the connect with the IZ Gateway. Users of PA-SIIS can submit either via HL7 or through the Web Application.

In instances where sites are experiencing network outages, registration workers will collect vaccine administration information on paper forms and enter the information into PA-SIIS once connectivity resumes.

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

After recent testing on October 2nd, of the CDC Web Service Definition Language (WSDL) with the American Immunization Registry Association (AIRA), we were told that the WSDL would be validated at the basic level and after correcting the XML failure, we will be validated at the complete level. The XML failure is being resolved by our vendor and is expected to be returned for testing by October 9th. The DUA is awaiting approval by APHL and will then be routed for



signatures by general counsel, attorney general and bureau director. We are hopeful that DUA signatures will be completed by mid-November 2020. The MOA is being reviewed by PA-SIIS and will be forwarded on for legal review and signature the week of October 12th.

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.*

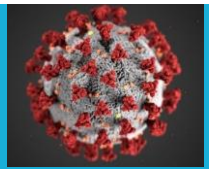
Upon distribution of provider agreements, facilities will be notified of COVID vaccine reporting requirements, including internet access. If not actively participating in PA-SIIS, facilities will need to be enrolled and have staff trained to navigate various functions through the PA-SIIS and will be required to report vaccines administered within 24 hours. Training for newly enrolled providers will be done by PA-SIIS field staff and include needed functionality such as searching for patients, charting vaccination events, receiving shipments, reconciling inventory etc. There is a dependency on the reporting system to capture and report to the PA-SIIS.

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.*
The DOH plans to assign dedicated staff to work alongside clinicians to search/enter patient information, verify demographics and enter vaccine information in real time as the vaccine is being administered. PA-SIIS will work with the Bureau of Emergency Preparedness and Response (BEPR) to capture COVID-19 data in real time for mass vaccination sites. If there is an internet interruption at a location, staff will revert to paper collection of vaccine administration and data entry will resume when internet resumes, or at a location that has internet access. Contingency planning to have staff available to assist with data entry is being developed.

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.*

PA-SIIS will monitor facilities that receive COVID-19 vaccine inventory against data being reported to the PA-SIIS within 24 hours to identify those facilities that have no activities with reporting COVID-19 vaccine administration. PA-SIIS field staff will send notification to those facilities to identify the root cause of inactivity and both DOH and facility leadership will be notified. Leadership notification will include facility name, current inventory, last transmission, doses administered and contact information.

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



Daily and weekly dashboards will be generated to assess coverage among race, ethnicity, gender, age, facility type and residence for monitoring disease outbreak or disease spread. A decision has not yet been made on how the dashboards will be published.

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.*

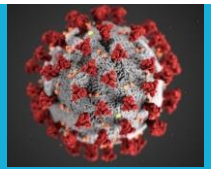
The short-term goal is for PA-SIIS to develop SAS code to generate reminder recall files that will be used for mass mailings of postcards, text messaging and phone call reminders if possible. PA-SIIS is also investigating if the pharmacy community and the medical community through adopted technology are planning to perform reminder recalls as well. In addition to the above, the DOH intends to operationalize PrepMod for registration purposes that offers functionality to support reminder recall. The reminder recall that will be reported through SAS code will contain information that will help assure that the second dose is of the same product as the first dose and assure that proper spacing intervals are maintained between the two-dose series. The long-term goal is to enhance CDSI to support COVID-19 reminder recalls. A Quick Reference Sheet (QRS) will be created to walk facility staff through generating reminder recall through CDSi. In addition, every COVID-19 vaccine recipient will receive documentation at the time of vaccination that will include a date for the second dose if appropriate.

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.*

The PA-SIIS will be the primary system for collecting COVID-19 vaccination events. PrepMod is being explored as an alternative to support system redundancy. In the event of a network outage or other access issues, the vaccination event would be documented on paper and entered into the PA-SIIS as soon the issue has been resolved. PA-SIIS will explore creating an Access database to collect the paper vaccination records that will be loaded into PA-SIIS when the outage is resolved.



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.*

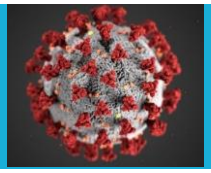
Required Data Elements

Data Element	PA Analysis
Administered at location: facility name/ID	Available
Administered at location: type	Available
Administration address (including county)	Available
Administration date	Available
CVX (Product)	Available
Dose number	Available
IIS Recipient ID*	Available
IIS vaccination event ID	Not Available
Lot Number: Unit of Use and/or Unit of Sale	Available
MVX (Manufacturer)	Available
Recipient address	Available
Recipient date of birth	Available
Recipient name	Available
Recipient sex	Available
Sending organization	Available
Vaccine administering provider suffix	Available
Vaccine administering site (on the body)	Available
Vaccine expiration date	Available
Vaccine route of administration	Available
Vaccination series complete	Available

Optional Data Element

Data Element	PA Analysis
Comorbidity status (Y/N)	Not Available
Recipient ethnicity	Available
Recipient race	Available
Recipient missed vaccination appointment (Y/N)	Not Available
Serology results (Presence of Positive Result, Y/N)	Available
Vaccination Refusal (Y/N)	Available

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.*



PA-SIIS currently supports HL7 2.5.1 IG for immunization reporting. There are currently over 9,600 facilities reporting to PA-SIIS via HL7. System capacity and performance is continuously monitored by PA-SIIS and the Bureau of Informatics and Information Technology (BIIT) and additional resources are quickly increased as identified through daily monitoring tools. PA-SIIS plans for promotion to production the .net release the end of October that will include enhancements to CDSI tools and CDC WSDL.

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

The DOH has identified the targeted facilities that will support Phase 1a. Those facilities are hospitals, FQHCs, and CMHDs. PA-SIIS will receive a listing of all the facilities within the selected groups and link them to the PA-SIIS to identify facilities already participating in the PA-SIIS. Those that are not participating will be onboarded quickly to the PA-SIIS and end users trained using different training methods such as online training course, quick reference sheets, and real time video training.

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

PA-SIIS plans to promote to production an update to IIS that includes the CDC WSDL enabling PA to connect to the IZ Gateway by the end of October.

F. *Describe the status of establishing:*

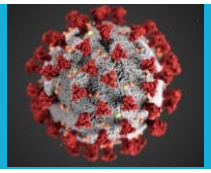
1. *Data use agreement with the Association of Public Health Laboratories to participate in the IZ Gateway*

   The DUA is awaiting approval by APHL and will then be routed for signatures by general counsel, attorney general and bureau director. We are hopeful that DUA signatures will be completed by October 16th.

2. *Data use agreement with CDC for national coverage analyses*

   This data use agreement has been signed and sent back to the CDC.

3. *Memorandum of Understanding to share data with other jurisdictions via the IZ Gateway Share component*



The Memorandum of Understanding is being reviewed by PA-SIIS and was approved by the Office of Legal Counsel and has been returned the CDC.

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

In the event of a network outage or other access issues, the vaccination event would be documented on paper and entered into the PA-SIIS as soon the issue has been resolved.

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.*

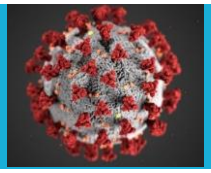
PA-SIIS will monitor facilities that receive COVID-19 vaccine inventory against data being reported to the PA-SIIS within 24 hours to identify those facilities that have no activities with reporting COVID-19 vaccine administration and or data quality issues. Notification will go out to those facilities to identify the root cause of inactivity and or data quality issues and both DOH and facility leadership will be notified. PA-SIIS will perform periodic checks to ensure facilities are reporting all required fields. Notification will go out to those facilities not reporting all required fields and both DOH and facility leadership will be notified.

Section 12: COVID-19 Vaccination Program Communication

The public information and communication messages, methods, and materials for use in mass COVID-19 vaccination administration efforts will be led by the Office of Communications. Specifically, the Public Information Officer (PIO) will be the point of contact within the Office of Communications on the messaging for the COVID-19 vaccine.

Objectives

A. Educate the public about the development, authorization, distribution, and execution of COVID-19 vaccines and that situations are continually evolving.
B. Ensure public confidence in the approval or authorization process, safety, and efficacy of COVID-19 vaccines.
C. Help the public to understand key differences in FDA emergency use authorization and FDA approval (i.e., licensure).
D. Engage in dialogue with internal and external partners to understand their key considerations and needs related to COVID-19 vaccine program implementation.
E. Ensure active, timely, accessible, and effective public health and safety messaging along with outreach to key state/local partners and the public about COVID-19 vaccines.
F. Provide guidance to local health departments, clinicians, and other hosts of COVID-19 vaccination provider locations.
G. Track and monitor public receptiveness to COVID-19 vaccination messaging.

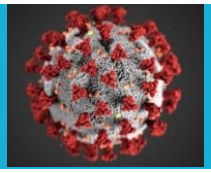


Messaging

A. The ability to quickly collect, analyze and disseminate information at a fifth-sixth grade reading level in an incident is crucial. Today's web-based technology, complemented by more traditional tools, provides many ways to accomplish these tasks. The paid media campaign on COVID-19 allows DOH to spread messages through traditional and web-based outlets. DOH ensures the chosen form(s) of technology is tested and that those responsible for using it have been trained prior to the administration of the COVID-19 vaccine.

B. Web-based communication

- Increasingly, the public is turning to the Internet for breaking news and information. (See Bureau of Emergency Preparedness and Response Emergency Operations Plan Appendix B, *"Website.")*
- The DOH website can easily be linked to the incident website where information can be made available to external audiences.
  - Press briefings are streamed live on our social media pages, by local media online and on TV, broadcast in Spanish on Facebook, and available to be streamed on radio as well.
  - Use Email as a notification tool and to direct audiences to the COVID-19 section of the DOH website for more comprehensive information.
  - Use social media (such as Facebook and Twitter) in order to communicate with the public, stakeholders, media and other state agencies. Be sure to share relevant information from other partners as well. It is important to remember that social media can be seen by anyone, so any information shared socially needs to be approved just like any information released in a press release or fact sheet.
    - As part of general policy, the DOH maintains an active status on both Facebook and Twitter. This will allow for recognition and credibility during an incident.
    - The Digital Director for the Office of Communications evaluates social media participation, including looking at interaction, metrics and the types of users interacting with the DOH.
    - The PIO, along with the Digital Director will work on developing a time frame for creating and adding new posts as relevant information becomes available, and also on making sure that scheduled posts not relevant to the COVID-19 vaccine are cleared.
      - For Twitter, information should be shared as soon as it is available and verified.
  - Posts to social media should provide links with more information as often as possible to help give viewers as much information as possible. Even if that means pointing back to the DOH website.
  - Once vaccines are given, monitor Internet information and social media to discern message effectiveness and accuracy. Also, a useful tool in rumor control. (See Bureau of



Emergency Preparedness and Response Emergency Operations Plan Appendix D, *"Rumor Control and Message Dissemination.")*

C. Traditional communications mediums

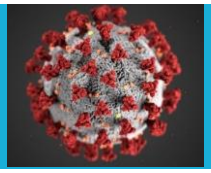
- Press briefings
  - COVID-19 vaccines will be extensively covered in press briefings. Full press briefings are available as both audio and videos to media to use afterwards. This ensures that messages reach traditional media including TV, radio, and newspapers.
- Written communication (press releases)
- Partnerships with key stakeholders, including local officials, associations and CMHDs.

D. Key Audiences

- Tailor messages for each of the following audiences to ensure communication is effective:
  - Healthcare personnel (i.e., organizations and clinicians who will receive information about receiving and administering vaccine)
  - Health insurance issuers and plans (coverage for vaccine, in-network providers)
  - Employers
  - Government and community partners and stakeholders
  - Public/consumers
    - Essential workers
    - Those in groups at risk for severe outcomes from COVID-19 infection
    - Those in groups at increased risk of acquiring or transmitting COVID-19
    - Those with limited access to vaccination services
- DOH's Office of Intergovernmental Affairs will lead on communications with local government stakeholders.
- The Pennsylvania Department of Human Services Office of Intergovernmental Affairs will lead on communications with long-term care facility stakeholders.
- DOH's Bureau of Epidemiology will lead on communications with healthcare personnel through their Health Alert Notices (HANs).
- The Commonwealth of Pennsylvania Quality Assurance Deputate will lead on communications with healthcare facilities including nursing homes and ambulatory surgical facilities.

E. Message Dissemination

- To prepare the public before the vaccine is available and during Phase 1-3 of the COVID-19 Vaccination Program
  - Translation Services
    - DOH will translate COVID-19 vaccine information into Spanish, German, and Chinese using a company within the commonwealth network: http://www.emarketplace.state.pa.us/BidContracts.aspx?SID=4400017786&From=Parent. DOH also makes available the option to view its website in other languages.
- Messaging on the Mass Vaccination Clinics (MVCs)
  - This includes FAQ about MVCs, when and where people should go to be vaccinated in accordance with the three phases and what information they need to bring with them.

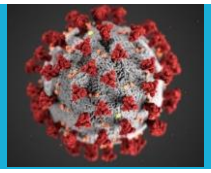


- Messaging on "Getting the COVID-19 Vaccination During a Pandemic in Pennsylvania"
  - This includes FAQ about the COVID-19 vaccine and virus, when it would be used, and other MVC info.
- Messaging on Registration
- To inform the public during an event
- Messaging that includes numerous materials on the social distancing, mask-wearing, side-effects, and MVCs.

- To inform the public about MVCs
  - Messaging with talking points on MVCs
    - This includes information about COVID-19 and the vaccine that will be administered and what to do.
  - To provide information to people after they leave the MVCs
  - Messaging with talking points on MVCs
    - This includes information about how health officials will keep the public informed as well as medication compliance recommendations and patient information sheets that are specific to the COVID-19 vaccine.

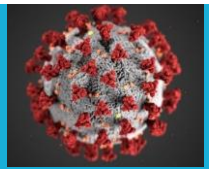
Methods

A. Utilization of public information and communication mechanisms
- Press release
  - The releases will be issued to media through Cision, a public relation and earned media software, from the Governor's Communications Office, the DOH Office of Communications or the Joint Information Center (JIC).
- Press briefings
  - Timely, regular briefings will be conducted with the Governor, Secretary of Health, Deputy Secretaries, or another appropriate spokesperson.
- Social Media
  - Consistent messaging and updates on vaccine information and procedures throughout the COVID-19 Vaccination Program via the Pennsylvania Department of Health Facebook page and @PAHealthDept Twitter account.
- Briefing of MVC Managers
  - To avoid miscommunication with the public, it is essential that MVC managers communicate what DOH is saying about the crisis to field staff.
  - MVC Managers will receive regular updates from the Department Operations Center or Joint Information Center (JIC), communicate new developments to MVC staff, and assist in rumor control.
  - MVC Managers will be directed to refer all press inquiries to the DOH Office of Communications or the Joint Information Center.
- Toll-free telephone information line
  - 877-PA-HEALTH (877-724-3258)
- Pre-scripted Public Service Announcements (PSAs)
  - The DOH would request that pre-scripted PSAs be broadcast on local television and radio news networks.
- State and local websites



- Websites can relay detailed information to people and are likely places that people will turn to for information about COVID-19 and its vaccine. DOH will continue to post COVID-19 information on its website – www.health.pa.gov. The Governor's office will also include information and a link to the DOH website on the main Pennsylvania website, www.pa.gov, as well as the Governor's website, www.governor.pa.gov. Other commonwealth agencies will also include a prominent link to DOH on their websites.

- Information sheets
  - Fact sheets allow people to read important information in their own time and in any environment. They have been revised to a plain language format. They are useful for many different populations as information sheets can be translated into many different languages. Fact sheets will be disseminated via the DOH website and will also be sent to county/municipal health departments and other partners before and during an emergency.
  - Communications staff and subject matter experts will help distribute information to get people to and through MVCs via the news media and all other available outlets.
  - Numerous communication mechanisms should be used to relay instructions and ensure that messages are distributed to everyone that is affected. Consistent messages need to be transmitted repeatedly to make sure they are received and understood. Methods that DOH will use to disseminate messages during the COVID-19 vaccine distributions include but are not limited to: news releases, social media channels, press briefings, use of the toll-free 1-877-PA-HEALTH help line, special hotlines, DOH website, and email distribution listings.
  - All information posted will also be available in non-English languages so that the information is accessible to non-English speaking populations.
- Identifying local media outlets
  - Development of pre-event media relationships
    - The DOH Office of Communications has established long-standing relationships with statewide media outlets.
    - The office responds to media inquiries on a daily basis, produces and distributes press releases, and facilitates interviews with spokespersons/subject matter experts.
      - DOH Office of Communications develops a daily media tracker to maintain contact information for media inquiries regarding COVID-19 vaccines.
      - DOH Office of Communications also has a number of former media members among its staff who have existing relationships and is apt at pitching to media and receiving coverage.
    - The DOH Press Secretary is on-call and can be reached via cell 24/7.
- To mass produce printed materials
  - The DOH will produce graphics, fact sheets, and other public information materials and house them on our website. From there, MVC staff can print materials on their own for the patients being vaccinated at the respective MVCs.



- In addition to posting the information on the DOH website, the DOH will also work with the Pennsylvania Department of General Services if necessary, to print the public information materials required for the emergency.
- The DOH will also work with local quick-copy services to print materials.

Additional communication plans during an incident can be found in Annex H, the Incident Risk Communications Plan. Reference the PIO checklist for medical countermeasures in Attachment D *"Mass Distribution of Medical Countermeasures (Strategic National Stockpile Activation)"* of the Bureau of Emergency Preparedness and Response Emergency Operations Plan Annex H, Incident Risk Communications Plan.

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.*
All applicable information will be put on our DOH website.

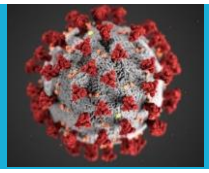
B. *Describe how your jurisdiction will instruct enrolled COVID-19 vaccination providers to provide Emergency Use Authorization (EUA) fact sheets or vaccine information statements (VISs), as applicable, to each vaccine recipient prior to vaccine administration.*

Initially available COVID-19 vaccines may be authorized for use under an EUA issued by FDA or approved as licensed vaccines.

The DOH is currently building a listserv for the COVID-19 vaccine providers. This listserv will be utilized to communicate information such as COVID-19 EUAs and VISs to our providers. The DOH will also communicate COVID-19 vaccine information on the DOH public-facing website.

Emergency Use Authorization Fact Sheets

The EUA authority allows FDA to authorize either (a) the use of an unapproved medical product (e.g., drug, vaccine, or diagnostic device) or (b) the unapproved use of an approved medical product during an emergency based on certain criteria. The EUA will outline how the COVID-19 vaccine should be used and any conditions that must be met to use the vaccine. FDA will coordinate with CDC to confirm these "conditions of authorization." Vaccine conditions of authorization are expected to include distribution requirements, reporting requirements, and safety and monitoring requirements. The EUA will be authorized for a specific time period to meet response needs (i.e., for the duration of the COVID-19 pandemic). Additional information on EUAs, including guidance and frequently asked questions, is located on the FDA website.



Product-specific EUA fact sheet for COVID-19 vaccination providers will be made available that will include information on the specific vaccine product and instructions for its use. An **EUA fact sheet for vaccine recipients** will also be developed, and both will likely be made available on the FDA website and through the CDC website. Jurisdictions should ensure providers know where to find both the provider and recipient fact sheets, have read and understand them, and are clear on the requirement to provide the recipient fact sheet to each client/patient prior to administering vaccine.

Vaccine Information Statements (VIS)

VISs are required only if a vaccine is added to the Vaccine Injury Table. Optional VISs may be produced, but only after a vaccine has been licensed (e.g., such as with zoster vaccines). Plans for developing a VIS for COVID-19 vaccine are not known at this time but will be communicated as additional information becomes available.
Additional information on VISs is located at https://www.cdc.gov/vaccines/hcp/vis/current-vis.html.

Registered and approved organizations that meet the criteria for COVID-19 vaccination administration receives email updates about the vaccination program, including the following:

1. A vaccine provider agreement
2. A vaccine information statement
3. Consent form
4. Ordering instructions

Section 14: COVID-19 Vaccine Safety Monitoring

Instructions:

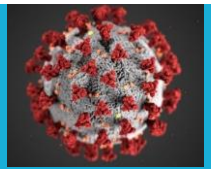
A. *Describe how your jurisdiction will ensure enrolled COVID-19 vaccination providers understand the requirement and process for reporting adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS).*

The following outlines the DOH's Adverse Events Standard Operating Guidelines.

Adverse Events Standard Operating Guidelines

I. Purpose

The purpose of this policy is to provide guidelines that define adverse drug reactions (ADRs), identify procedures for reporting ADRs to the Food and Drug Administration (FDA) and the CDC.



II. Policy Statement

It shall be the policy of the *Pennsylvania Department of Health,* to identify adverse reactions to vaccines, used during COVID-19 vaccine administration in *the Commonwealth of Pennsylvania*, as reported by consumers, physicians, and/or medication incident reports. Furthermore, for the purpose of assisting vaccine safety evaluation, ADRs will be reported using MedWatch (or other FDA required mechanisms) and vaccine reactions will be reported using the VAERS (or other FDA/CDC required system).

III. Definitions

ADR: "An appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product." 1 ADRs are unintended and occur in consumers at recommended on-label dosage.

A. ADRs include:

1. Any reaction that is clinically significant;
2. New, rare, or previously poorly documented reactions;
3. ADRs associated with newly marketed medications;
4. Serious, life-threatening, or fatal reactions. According to the FDA, a serious adverse event is one in which the patient outcome is death, life-threatening, disability, hospitalization (initial or prolonged), a congenital anomaly, or necessitates medical or surgical intervention to prevent permanent impairment or damage;
5. Unusual increases in numbers or severity of reactions;
6. Allergic reactions and idiosyncratic reactions are also considered ADRs, if they are deemed to be serious, life threatening, or fatal, as described above; and
7. Reportable reactions listed in the VAERS system.

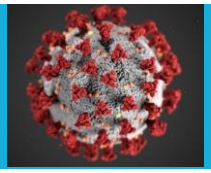
B. The definition of ADR shall not include:

Side effects of the drug which are expected, well-known reactions which do not result in changing the care of the patient. These adverse effects are those effects occurring predictably and effects whose intensity and occurrence are related to the size of the dose.

IV. Procedure Actions

A. Mechanisms to ***monitor adverse events***.

1. At the time of pharmaceutical administration, consumers will receive information sheets with instructions about reporting ADRs. Consumers will be requested to call their health care provider or LHD if they suspect an ADR. Information handed out at the vaccination site must include instructions including a call-back number for MedWatch or the LHD/HSR to report adverse event emergencies.
2. The consumer's health care provider shall be responsible for confirming or ruling out any suspected adverse reaction.
3. The consumer may complete the form without involvement of the health care provider through the MedWatch website.
4. The location receiving the adverse event calls, must document pertinent information including name of person calling, the adverse event, recommended



actions, etc. and report to MedWatch.

B. For **vaccines**, the entity receiving the report shall submit the report to the CDC via the VAERS on-line at https://secure.vaers.org/scripts/VaersDataEntry.cfm, or other required database, and shall encourage the consumer to contact his/her healthcare Provider. VAERS education will be provided by DOI field staff at time of vaccine distribution and via mail merge at two months and six months post vaccine distribution.

C. The reporting entity will follow up with each consumer reporting a severe ADR to determine the outcome.

D. The state health department will coordinate with the MedWatch coordinator to stay informed of reports and will share this information as appropriate with LHDs and Regional distribution centers.

E. If it is found that a systemic problem exists with the vaccine provided due to a bad lot, or other issue calling into question the effectiveness of the provided vaccine, then a recall of the vaccine may be directed.
1. The HSR, in coordination with appropriate LHDs and regional distribution centers, will inspect shipment records for identified lot numbers / vaccines and issue appropriate instructions to segregate and stop all dispensing of the vaccine lot in question.
2. Vaccination locations will be asked to identify, through analysis of client history records, those individuals who may be affected by the ineffective vaccine, and to contact them for vaccine replacement, if possible.

F. Local emergency management and public health officials will be advised of the adverse event information and steps being taken to resolve the adverse event.

G. A media release will be prepared and issued through the processes identified in the Crisis and Emergency Risk Communication Plan.

H. If dictated by the situation, replacement vaccines will be provided to vaccination locations, as appropriate.

I. Reports of adverse events will be summarized and maintained on an adverse event log sheet (see attached) by each entity receiving reports. This log will be made available to appropriate public health and emergency management officials as required.

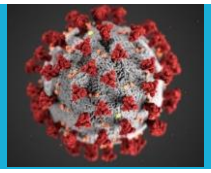
V. References

A. FDA Medical Products Reporting Program: http://www.fda.gov/medwatch/
B. FDA/CDC VAERS Program: http://vaers.hhs.gov/
C. FDA IND website:
http://www.fda.gov/oc/ohrt/irbs/drugsbiologics.html#emergency

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:*



CDC Dashboards

To provide situational awareness for jurisdictions and the general public throughout the COVID-19 vaccination response, CDC will have two dashboards available.

The **Weekly Flu Vaccination Dashboard** will include weekly estimates of influenza vaccination for adults, children, and pregnant women (when approved for these groups) using existing (National Immunization Survey [NIS]-Flu) and new (IQVIA) data sources. Data and estimates from additional sources will be added, as available.

The **COVID-19 Vaccination Response Dashboard** will include:

- Data for planning (e.g., estimates of critical population categories, number and attributes of healthcare providers and facilities);
- Implementation data (e.g., number of enrolled COVID-19 vaccination providers, COVID-19v vaccine supply and distribution, COVID-19 vaccine administration locations); and
- COVID-19 vaccine administration data.
- The COVID-19 Vaccination Response Dashboard will be implemented in stages based on data availability and shareability. Both dashboards will include a view tailored for jurisdictions, available through SAMS, and a view for the general public on CDC's website.

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

- *Budget*
- *Staffing*
- *Supplies*

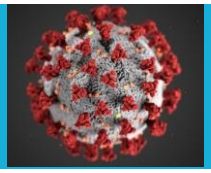
The DOH Department Operations Center Finance and Administration section and the Logistics section will monitor and track all resources utilized for COVID-19 vaccine response.

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

- *Message delivery*
- *Reception of communication messages and materials among target audiences throughout jurisdiction*

CDC will provide timely messaging throughout the COVID-19 vaccination response via all-jurisdiction calls, regular e-mail communication, and website updates. Jurisdictions organizations should routinely monitor both CDC and local-level messaging to inform their communications efforts. Variations in messaging can create confusion and hamper the effective implementation of the vaccination program. Messaging must be clear, current, and received as intended by the audience. Monitoring social media can be helpful in assessing message delivery and reception and dispelling inaccurate information.

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



Constant communication and coordination with CMHDs is instrumental during all phases of the COVID-19 Vaccination Program in both centralized and decentralized operational structures. Long before the vaccination program begins, roles and responsibilities should be established and well understood at all levels. This will help avoid misperceptions as well as gaps in planning and implementation. Throughout the COVID-19 Vaccination Program, jurisdictions should monitor and maintain awareness of local-level strategies and activities, providing technical assistance as needed. This visibility can help ensure local jurisdictions and providers adhere to recommendations and guidance from CDC and state and local authorities.

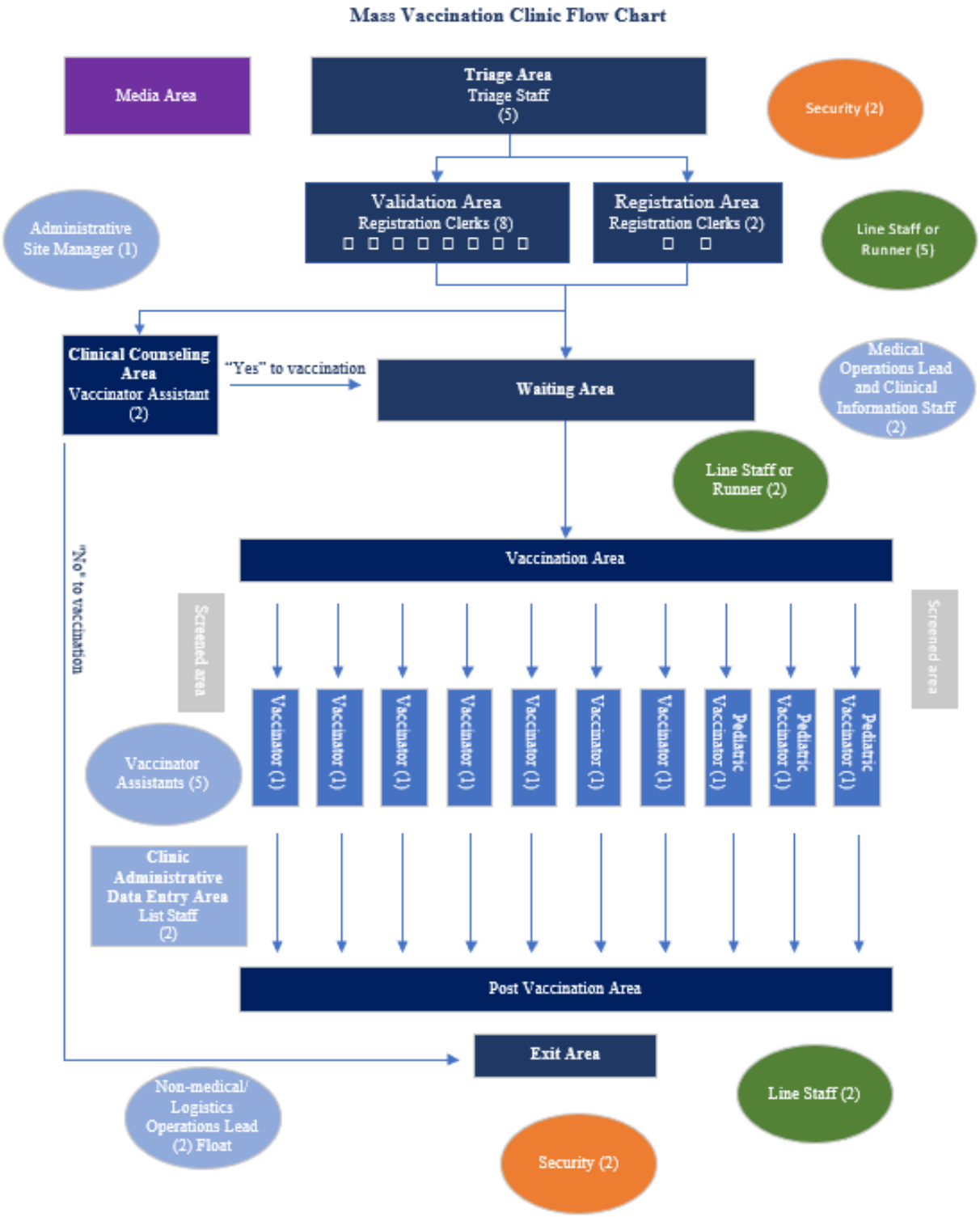
E. *Describe the COVID-19 Vaccination Program metrics (e.g., vaccination provider enrollment, doses distributed, doses administered, vaccination coverage), if any, that will be posted on your jurisdiction's public-facing website, including the exact web location of placement.*

All metrics will be shared via our existing COVID-19 Data Dashboard on the DOH's public website at www.health.pa.gov/topics/disease/coronavirus/Pages/Cases.aspx. These metrics will be published as updates are made to the dashboard and could include but are not limited to location of providers enrolled in the COVID-19 Vaccination Program, doses distributed to enrolled providers, doses administered by enrolled providers, and vaccination coverage. The Program also plans to utilize Tiberius for our planning purposes and will release metrics to our dashboard from Tiberius as applicable.

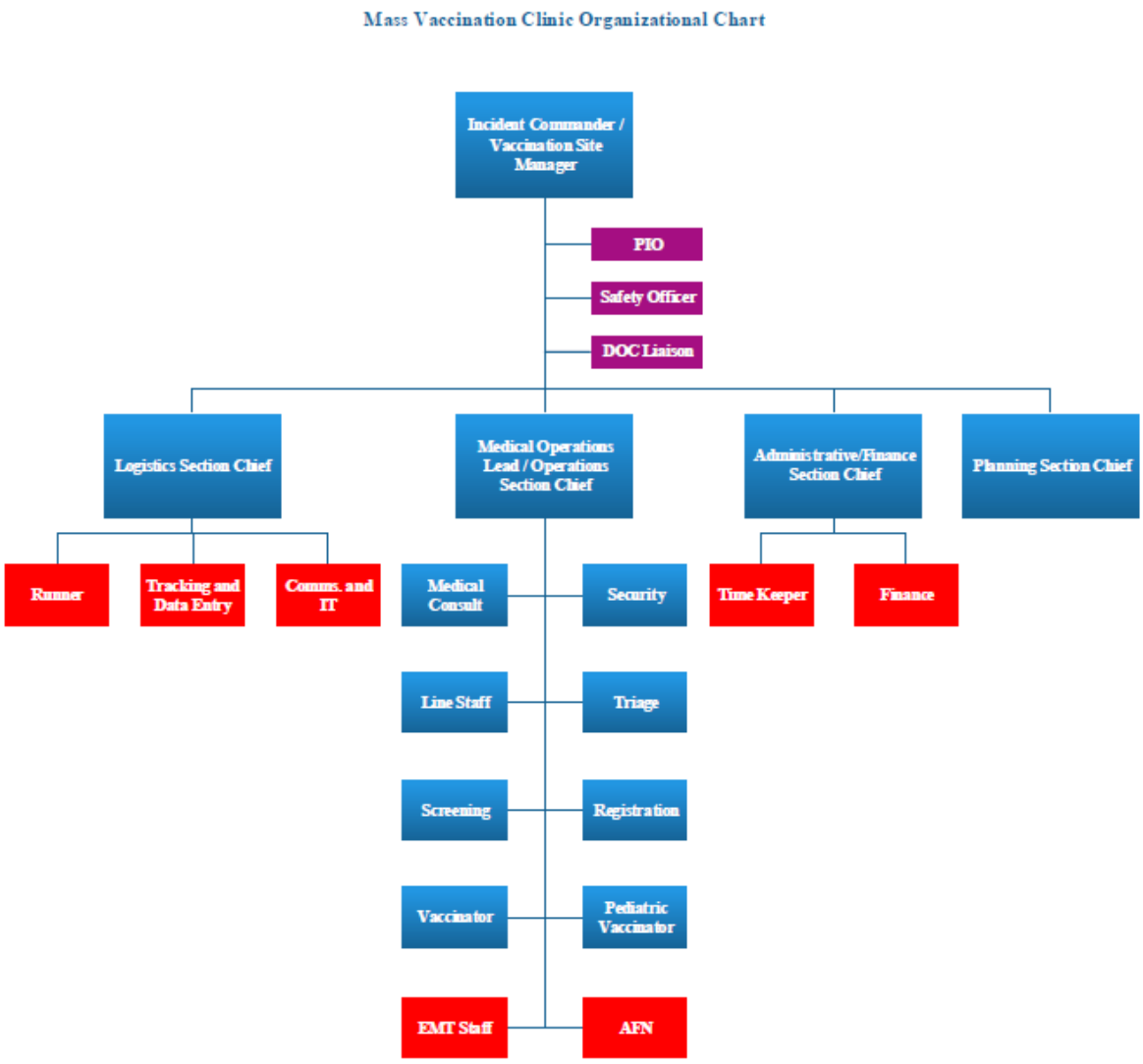
Appendices

Instructions: *Jurisdictions may choose to include additional information as appendices to their COVID-19 Vaccination Plan.*

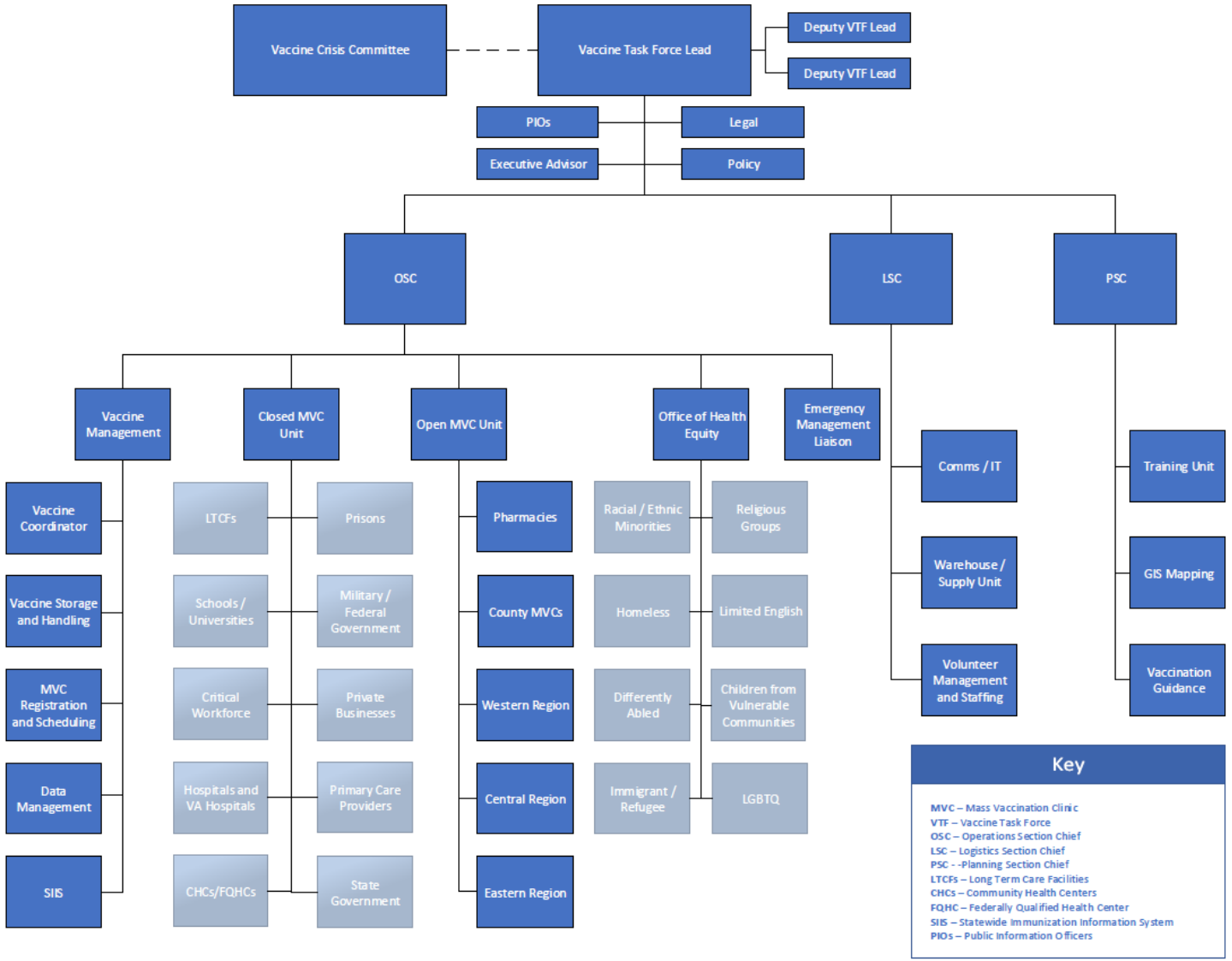
Appendix 1 – Mass Vaccination Clinic Flow Chart



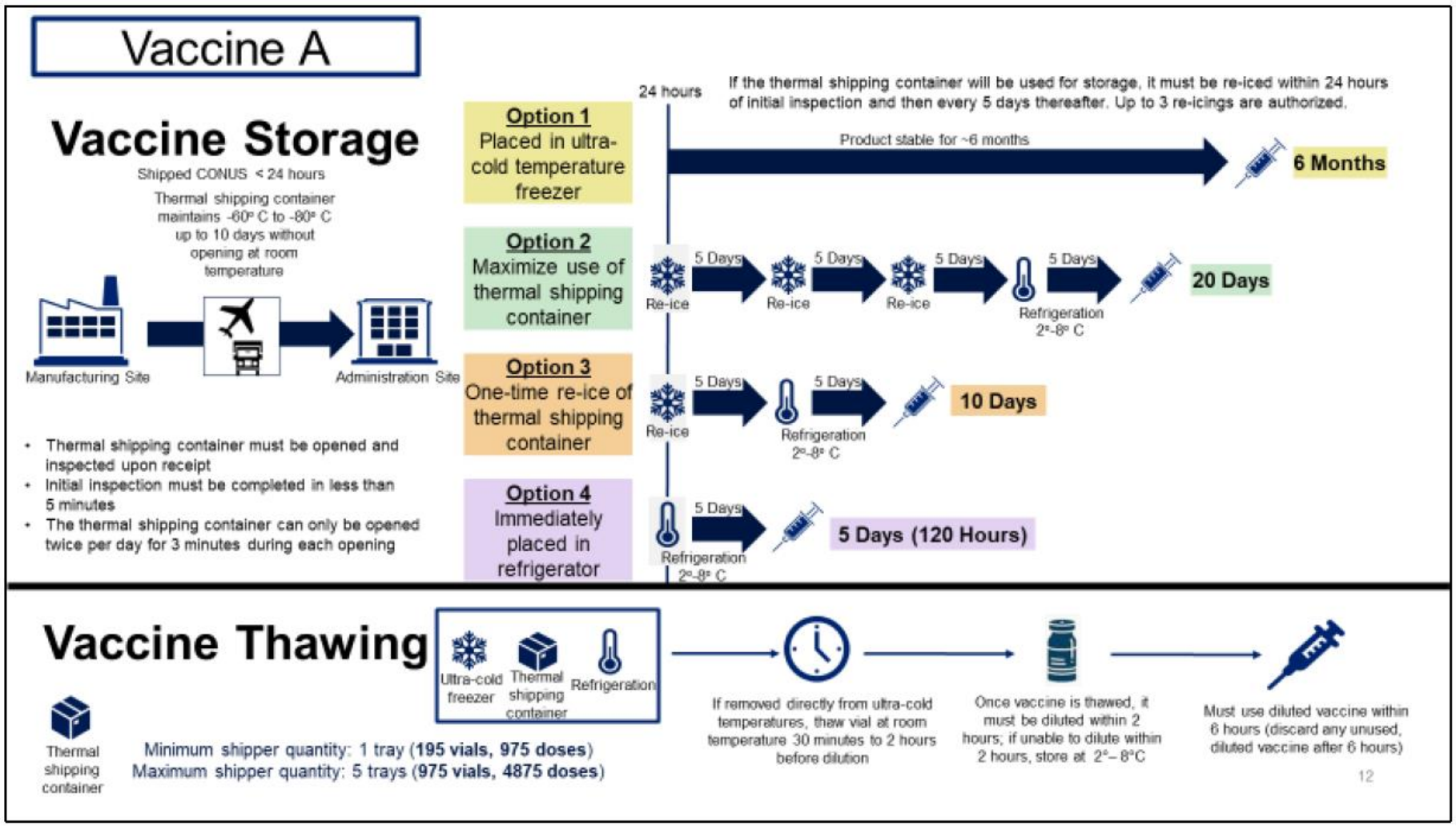
Appendix 2 – Mass Vaccination Clinic Staffing



Appendix 3 – Vaccine Task Force Organizational Chart



Appendix 4 – Vaccine A Storage and Handling Guide



Appendix 5 – Vaccine A Vaccination Provider Site Archetypes for Shipment Timing and Site Planning

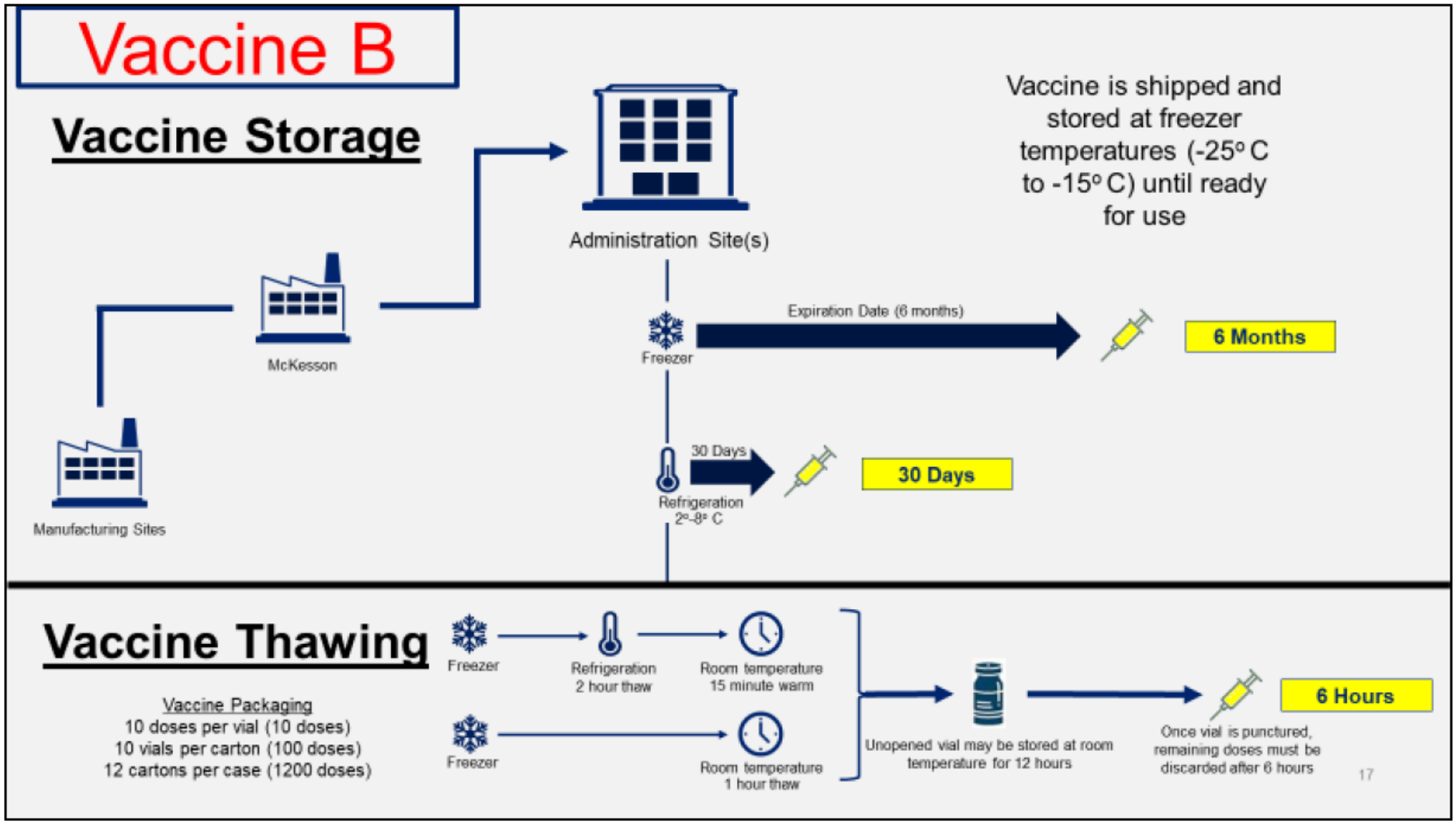
Site Types for Vaccine A Product

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

Site Types for Vaccine A Product

Vaccination provider site	Order size	Storage conditions	Patient flow	Number of immunizers	Patients per HCP	Hours per day	Vaccines per day	Shipment model
 **F – large indoor spaces** not used during pandemic (convention hall)	5 trays (4,875 doses)	Thermal box with dry ice, 2-8C fridge, for product estimated at site (5 days)	Variable	10 immunizers	6 patients/hour (~10 min/Vx)	8 hours	480 vaccinations	2-3 trays; every week
 **G – Drive-through vaccination clinic**	3 trays (2,925 doses)	Thermal box with dry ice, 2-8C fridge, for product estimated at site (5 days)	Variable	10 immunizers	6 patients/hour (~10 min/Vx)	8 hours	480 vaccinations (by 7 days)	2-3 trays; very week

Appendix 6 – Vaccine B Storage and Handling Guide



Appendix 7 – CDC Supplemental COVID-19 Vaccine Redistribution Agreement

CDC Supplemental COVID-19 Vaccine Redistribution Agreement

The Centers for Disease Control and Prevention (CDC) plans to ship a minimum order size of COVID-19 vaccine, constituent products, and ancillary supplies at no cost directly to enrolled COVID-19 vaccination providers throughout the United States. The federally contracted vaccine distributor uses validated shipping procedures to maintain vaccine cold chain and minimize the likelihood of vaccine loss or damage during shipment. There may be circumstances where COVID-19 vaccine needs to be redistributed beyond the identified primary CDC ship-to sites (i.e., for orders smaller than the minimum order size or for large organizations whose vaccine is shipped to a central depot and requires redistribution to additional clinic locations). In these instances, vaccination provider organizations/facilities, third-party vendors, and other vaccination providers may be allowed to redistribute vaccine, if approved by the jurisdiction's immunization program and if validated cold-chain procedures are in place in accordance with the manufacturer's instructions and CDC's guidance on COVID-19 vaccine storage and handling. There must be a signed *CDC COVID-19 Vaccine Redistribution Agreement* for the facility/organization conducting redistribution and a fully completed *CDC COVID-19 Vaccination Provider Profile Information* form (Section B of the CDC COVID-19 Vaccination Program Provider Agreement) for each receiving vaccination location.

The parties to this agreement are CDC and healthcare organizations, third-party vendors, and vaccination providers that redistribute COVID-19 vaccine. CDC cannot reimburse costs of redistribution beyond the initial designated primary CDC ship-to site(s), nor for purchase of any vaccine-specific refrigerators or qualified containers. Therefore, organizations planning for redistribution of COVID-19 vaccine must carefully assess the associated risks and costs (e.g., vaccine loss due to temperature excursions, purchase of vaccine-specific portable refrigerators and/or containers) before planning this activity.

ORGANIZATION INFORMATION			
Organization/facility name:	*For official use only:* *VTrckS ID:* _____ *Unique COVID-19 Organization ID (from Section A):* _____		
PRIMARY ADDRESS and CONTACT INFORMATION OF COVID-19 VACCINATION ORGANIZATION			
Street:			
City:	County:	State:	ZIP:
Telephone:		Fax:	
RESPONSIBLE OFFICERS			
Medical Director (or Equivalent) Information			
Last name	First name	Middle initial	
Title	Licensure (state and number)		
Telephone number:	Email:		
Address:			
Chief Executive Officer (or Chief Fiduciary) Information			
Last name	First name	Middle initial	
Telephone number:	Email:		
Address:			

CDC COVID-19 Vaccine Provider Agreement Form

PRIMARY POINT OF CONTACT RESPONSIBLE FOR RECEIPT OF COVID-19 VACCINE (if different than medical director listed above)	
Last name, first name, middle initial:	
Telephone number:	Email:
SECONDARY POINT OF CONTACT FOR RECEIPT OF COVID-19 VACCINE	
Last name, first name, middle initial:	
Telephone number:	Email:

COVID-19 VACCINATION ORGANIZATION REDISTRIBUTION AGREEMENT REQUIREMENTS	
To redistribute COVID-19 vaccine, constituent products, and ancillary supplies to secondary sites, this organization agrees to:	
1.	Sign and comply with all conditions as outlined in the CDC COVID-19 *Vaccination Program Provider Agreement.*
2.	Ensure secondary locations receiving redistributed COVID-19 vaccine, constituent products, or ancillary supplies also sign and comply with all conditions in the *CDC COVID-19 Vaccination Program Provider Agreement.*
3.	Comply with vaccine manufacturer instructions on cold chain management and CDC guidance in CDC's Vaccine Storage and Handling Toolkit[1], which will be updated to include specific COVID-19 conditions for any redistribution of COVID-19 vaccine to secondary locations.
4.	Document and make available any redistribution records of COVID-19 vaccine to secondary sites to jurisdiction's immunization program as requested, including dates and times of redistribution, sending and receiving locations, lot numbers, expiration dates, and numbers of doses. *Neither CDC nor state, local, or territorial health departments are responsible for any costs of redistribution or equipment to support redistribution efforts.*

By signing this form, I understand this is an agreement between my Organization and CDC, implemented and maintained by my jurisdiction's immunization program. I also certify on behalf of myself, my medical practice or other legal entity with staff authorized to administer vaccines, and all the practitioners, nurses, and others associated with this Organization that I have read and agree to the COVID-19 vaccine redistribution agreement requirements listed above and understand my Organization and I are accountable for compliance with these requirements. Non-compliance with the terms of this Redistribution Agreement may result in suspension or termination from the CDC COVID-19 Vaccination Program and criminal and civil penalties under federal law, including but not limited to the False Claims Act, 31 U.S.C. § 3729 et seq., and other related federal laws, 18 U.S.C. §§ 1001, 1035, 1347, 1349.

Organization Medical Director (or Equivalent)		
Last name	First name	Middle initial
Signature:		Date:
Chief Executive Officer (Chief Fiduciary Role)		
Last name	First name	Middle initial
Signature:		Date:

[1] Requirements incorporated by reference; refer to https://www.cdc.gov/vaccines/hcp/admin/storage-handling.html

Appendix 8: COVID-19 Vaccine Hospital Decision Tool for Phase 1A

Background

The goal of this Appendix is to provide guidance on how to justly allocate vaccine in a time of scarcity. These recommendations are based on recent guidelines from the Advisory Committee on Immunization Practices (ACIP), local epidemiological data on hospitalizations and deaths in Pennsylvania in the current wave of illness, and knowledge of health systems' capacity. ACIP identifies 4 ethical principles that guide development of their recommendations for targeted vaccine prioritization:[i]

1. Maximize benefits and minimize harms
2. Promote justice
3. Mitigate health inequities
4. Promote transparency

The ethical principles that ACIP outlines for vaccine allocation are consistent with the ethical goals outlined previously by the Commonwealth in the Interim Pennsylvania Crisis Standards of Care for Pandemic Guidelines[ii] and the Ethical Allocation Framework for Emerging Treatments of COVID-19.[iii]

As before, the Commonwealth is affirming that no one is excluded from access based on age, disability, religion, race, ethnicity, national origin, immigration status, gender, sexual orientation, or gender identity and to ensure that no one is denied access based on stereotypes, perceived quality of life, or even implicit perceptions about a person's worth.

On December 1st, 2020, ACIP voted to approve the following interim recommendation:

"When a COVID-19 vaccine is authorized by FDA and recommended by ACIP, health care personnel and residents of long-term care facilities should be offered vaccination in the initial phase of the COVID-19 vaccination program (Phase 1A)."

With this recommendation and the corresponding ethical principles in mind, PA DOH planners and medical and ethical experts have developed the following approach to guide providers in Pennsylvania through Phase 1A of vaccine administration.

Pennsylvania's Approach for Phase 1A:

The Pennsylvania Department of Health is adopting the ACIP recommendation that healthcare personnel and long-term care facility residents should be offered vaccination in the initial phase. Because the long-term care facility (LTCF) staff and residents will be vaccinated as part of the Pharmacy Partnership for Long-Term Care Program, health systems in Pennsylvania will focus on the remaining health care personnel in Phase 1A.

"Health care personnel" are defined by ACIP as paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious

materials. These health care personnel may include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, students and trainees, direct support professionals, clinical personnel in school-settings or correctional facilities, contractual staff not employed by the health care facility, and persons (e.g., clerical, dietary, environmental services, laundry, security, maintenance, engineering and facilities management, administrative, billing, and volunteer personnel) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted among from healthcare personnel and patients.

"Healthcare settings" refers to the CDC definition of the places where healthcare is delivered and includes, but is not limited to, acute care facilities, long term care facilities, inpatient rehabilitation facilities, nursing home and assisted living facilities, home healthcare, vehicles where healthcare is delivered (e.g., mobile clinics), and outpatient facilities, such as dialysis centers, physician offices, adult day facilities and others.

Pennsylvania Department of Health endorses the sub-prioritization approach recommended by ACIP, because initial vaccine allocation is expected to be scarce compared to the number of healthcare personnel in the state who would require vaccination, and there is expected to be a constrained supply environment for some months.[iv] In addition to the sub-prioritization endorsed by ACIP, DOH is including additional sub-prioritization categories to better inform providers to ensure ethical allocation of scarce vaccine.

Healthcare personnel should be prioritized who are "COVID-19 facing healthcare personnel," which the Department is defining as healthcare personnel who:

1. Have direct patient contact (within 6 feet) and are unable to telework. This includes individuals who provide services to patients or patients' family members, or who handle infectious materials; AND
2. Are personnel without a known infection in the prior 90 days (but serologic testing is not recommended); AND
3. Are personnel who work the majority of the time in a "COVID-19 facing unit." A COVID-19 facing unit is an area of a health care facility that is expected to care for individuals with COVID-19. This includes emergency departments, intensive care units, inpatient medical or surgical floors in acute care facilities, emergency medical services units, outpatient respiratory care clinics, and urgent care centers.

If there is insufficient supply to cover all COVID-19 facing healthcare personnel, "high-risk COVID-19 facing healthcare personnel" should be prioritized, defined as those COVID-19 facing healthcare personnel who:

1. Are age 65 or older; OR
2. Have underlying medical conditions putting them at increased risk for severe COVID-19. These conditions are listed by the CDC, available here.[v] Each of these

conditions are to be treated equally, meaning if a person has any of these conditions, they are treated the same with respect to COVID risk and vaccine prioritization.

How this Allocation Framework aligns with the ACIP ethical principles:

There are several ethical justifications for this approach. Firstly, vaccination of healthcare personnel preserves health care services essential to the COVID-19 response and the overall healthcare system, maximizing benefit. Healthcare personnel who work in a COVID-19 facing unit are more likely to be exposed to the virus, potentially requiring them to remain home during a time when their services are critical to our Commonwealth's COVID-19 response. Healthcare personnel who are older or with certain health conditions are most likely to require hospitalization or die in the event of infection, potentially removing them from the workforce for a much longer period of time. This is referred to as a multiplier effect: by vaccinating healthcare personnel, we not only protect the healthcare personnel but also protect the patients that they are caring for.

Second, the Commonwealth has designed this prioritization for Phase 1A in a way that promotes justice. By adopting the ACIP definition of healthcare personnel, which is broad, it promotes justice by giving every at-risk individual a fair chance of receiving vaccine and also addressing the elevated occupational risk for exposure for those who are unable to work from home.

Third, this approach will help redress some of the socioeconomic and racial inequities brought about the pandemic which has disproportionately affected the Latinx and Black or African American community. While racial and ethnic minorities tend to be underrepresented as clinicians, they are overrepresented as other low wage healthcare personnel.[vi] So, by including a broad definition of healthcare personnel, it incorporates those racial and ethnic minorities in forward-facing roles who would otherwise not be prioritized if there was solely a focus on clinicians. Additionally, because individuals who have certain preexisting health care conditions are being prioritized within Phase 1A, and racial and ethnic minorities tend to have a higher prevalence of many of these conditions,[vii] this approach further mitigates inequities.

Lastly, the Commonwealth is being as transparent as possible by issuing this document and communicating it to the public, rounding out the 4 ethical principles identified by the ACIP. The Commonwealth is committed to a transparent decision-making process in addition to soliciting public comment.

Institutional Instructions

1. Each week identify health care settings in your community that have not received a vaccine allocation. Your hospital will also be responsible for administration of vaccine to healthcare personnel in those settings.

2. Proactively reach out to these health care settings through the local healthcare coalition to inform them of the responsibility of your hospital/ health system to provide vaccine to the healthcare personnel who work there.

3. Identify COVID-facing units (see definition in "Pennsylvania's approach") in your hospital/ health care system and assigned facilities.

4. Count or estimate the number of healthcare workers who work the majority of the time in these COVID-facing units, who also have direct contact (within 6 feet) of patients to receive the initial vaccination, and who have not been infected with COVID-19 in the past 90 days. These are the COVID-19 facing healthcare personnel.

5. Determine the subset of COVID facing healthcare personnel who are 65 years of age or older or have underlying medical conditions causing increased risk for severe COVID-19. These are the high-risk COVID-19 facing healthcare workers. There are a variety of strategies to accomplish this. For example, a health system could ask each individual in the COVID-facing units if they are 65 years of age or older or have one of the certain underlying medical conditions causing increased risk for severe COVID-19. To safeguard privacy, the health system could ask these questions in a binary yes/no fashion.

6. At the time of vaccine distribution, if there is enough vaccine for all health care personnel, then aim to vaccinate every healthcare personnel without further sub-prioritization. If there is not enough vaccine for all healthcare personnel, COVID-19 facing health care personnel should receive priority for the vaccine. If there is not enough vaccine for all COVID-19 facing health care personnel, then prioritize high-risk COVID-19 facing health care personnel.

7. If there is not enough vaccine to vaccinate all high-risk COVID-19 facing healthcare personnel, consider a birth-month lottery, further sub-categorization, or other approach to establish a fair allocation methodology given the scarcity (see Appendix B for examples).

8. After vaccinating high risk COVID-facing healthcare personnel, vaccinate the rest of the COVID-facing healthcare personnel, followed by all healthcare personnel.

9. Prioritization can occur by designating the initial vaccination days and times for high-risk COVID-19 facing healthcare personnel, while designated subsequent vaccination days and times for all COVID-19 facing healthcare personnel, followed by designated the remaining days and times for all healthcare personnel. Use estimates of how many healthcare personnel are in each category to make determinations of how long to designate for each category of healthcare personnel. Make sure to communicate to all

assigned facilities what categories of healthcare personnel are eligible to receive the vaccine on each vaccination day.

10. Providers should keep diligent records of who has been vaccinated, and how many doses of the vaccine have been administered to that person. This is important because individuals who have received one dose of the vaccine will need to have a second dose of the vaccine as it becomes available. Communicate with PA DOH Immunizations Program which individuals in which COVID-facing units have received the vaccine. This is done by reporting through the Pennsylvania Statewide Immunization Information System (PA-SIIS), a requirement of becoming a COVID-19 vaccine provider.

11. Everyday assess the inventory of vaccines still available and determine the number of healthcare workers who still need to receive the vaccine. Continue to vaccinate until every healthcare personnel has been vaccinated and await further instructions from Pennsylvania Department of Health for Phase 1B.

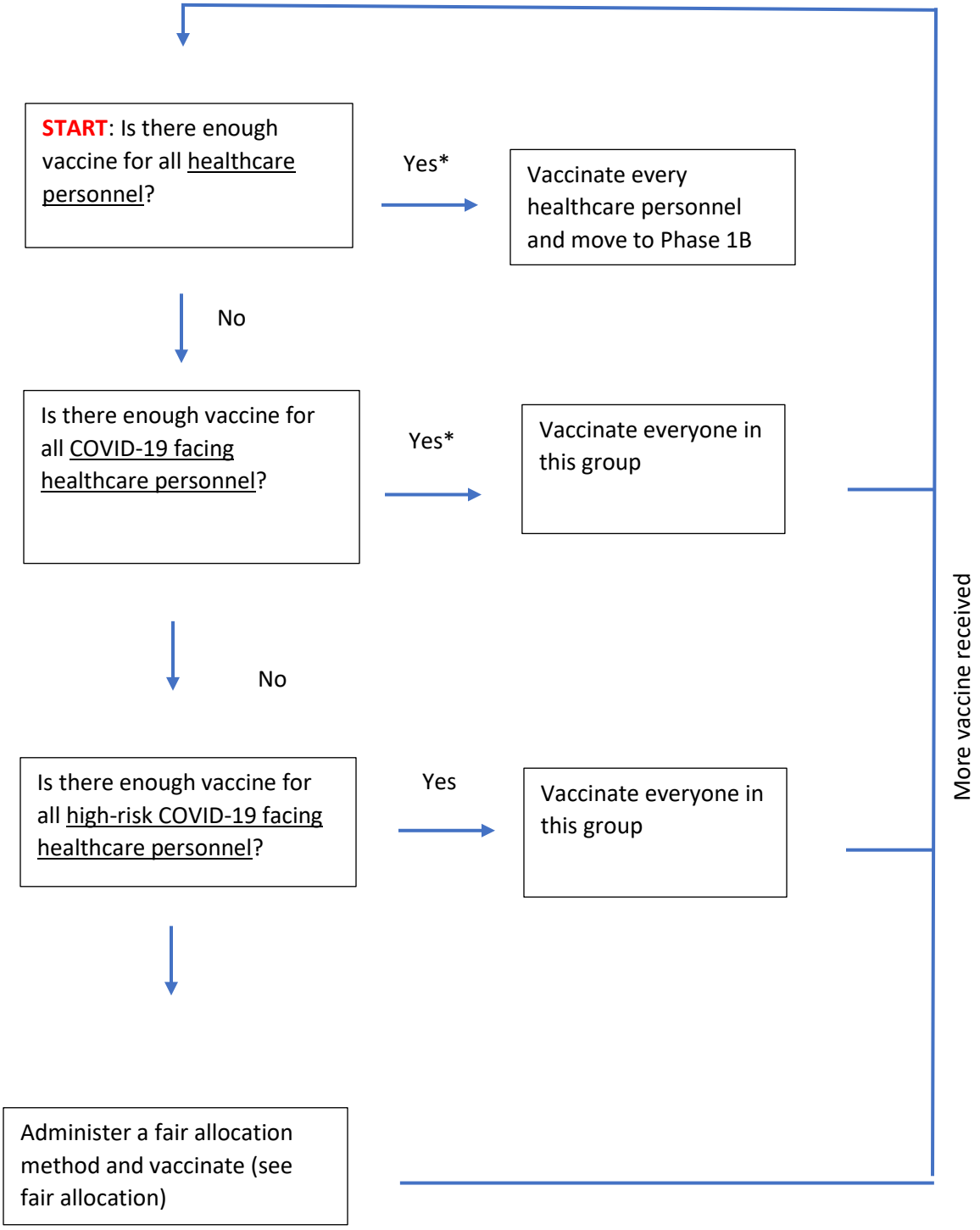
Vaccination of pregnant and breastfeeding HCP:

Evidence suggests that pregnant people are potentially at increased risk for severe COVID-19-associated illness and death compared to non-pregnant people, underscoring the importance of disease prevention in this population. Given the predominance of women of child-bearing potential among the healthcare workforce, a substantial number of HCP are estimated to be pregnant or breastfeeding at any given time. Currently, there are no data on the safety and efficacy of COVID-19 vaccines in these populations to inform vaccine recommendations. Further considerations around use of COVID-19 vaccines in pregnant or breastfeeding HCP will be provided once data from phase III clinical trials and conditions of FDA Emergency Use Authorization are reviewed.

Post-vaccination symptoms in HCP

Based on available data, COVID-19 vaccination is expected to elicit systemic post-vaccination symptoms, such as fever, headache, and myalgias. While the incidence and timing of post-vaccination symptoms will be further informed by phase III clinical trial data, strategies are needed to mitigate possible HCP absenteeism and resulting personnel shortages due to the occurrence of these symptoms. ACIP recommends staggering delivery of vaccine to HCP in facilities so personnel from a single department or unit are not all vaccinated at the same time. Based on greater reactogenicity observed following the second vaccine dose in phase I/II clinical trials, staggering considerations may be more important following the second dose.[viii] Because Pennsylvania's approach prioritizes those who are high-risk COVID-19 healthcare personnel, this is expected to stagger initial vaccination somewhat across COVID-19 facing units.

Summary Diagram for Phase 1A Distribution



*If there is not enough vaccine to be administered in this category, but the downstream categories have already been vaccinated, please consider using one of the fair allocation methodologies presented in the "Fair allocation" section below.

Fair allocation methods when there is not enough vaccine to administer to everyone within a group.

These examples are ways to distribute to vaccines within a group. For example, if there are not enough vaccines to administer to every high-risk COVID-19 healthcare personnel.

Example 1: Birth Month Lottery

1. Use an online program to create a randomly-ordered string of numbers from 1 to 12, using each number only once. An online program to do so is accessible here: https://www.random.org/sequences/. Alternatively, this can be done by writing the numbers 1-12 on individual pieces of paper and drawing from a hat.
2. The sequence of numbers will describe the order of priority in terms of months. For example, if the numbers are randomly drawn in this order: 10,5,4,7,11,9,3,2,6,1,8,12, then the prioritization order would be everyone born in October (month 10) is vaccinated first, May (month 5) is vaccinated second, April (month 4) is vaccinated third, and so on.
3. Certain time periods for vaccination could be reserved for individuals with the requisite birth months. If individuals miss their scheduled time, they could arrive later and be prioritized.

Example 2: Additional sub-category prioritization

1. Create subcategories of individuals to receive the vaccine within the larger categories of Phase 1A. Note that it is important to maintain the same underlying ethical goals in mind when creating new subcategories.
2. Examples of potential subcategories (where a "risk factor" includes being 65 or older, or any one of the underlying conditions putting someone at higher risk for severe COVID-19) is as follows:
    a. Further subcategorization of high-risk COVID-19 facing healthcare personnel:
        i. In a COVID-19 facing unit with 3 or more risk factors
        ii. In a COVID-19 facing unit with 2 or more risk factors
        iii. In a COVID-19 facing unit with 1 or more risk factors
    b. Further subcategorization of COVID-19 facing healthcare personnel:
        i. In a COVID-19 facing unit and performing aerosol generating procedures
        ii. In a COVID-19 facing unit with work duties in patient rooms that have COVID-19
        iii. In a COVID-19 facing unit with any other work duties in the unit.

3. Arrange the vaccination schedule such that the first block of time is reserved for individuals in 2(a)(i), the second block of time is reserved for individuals in 2(a)(i) or 2(a)(ii), the third block of time is reserved for individuals in 2(a)(i), 2(a)(ii), and 2(a)(iii), and so on.

4. After each block of vaccination, review how many vaccines are left, and keep on vaccinating additional subcategories until vaccine runs out.

[i] https://www.cdc.gov/mmwr/volumes/69/wr/mm6947e3.htm?s_cid=mm6947e3_e&ACSTrackingID=USCDC_921-DM43026&ACSTrackingLabel=MMWR%20Early%20Release%20-%20Vol.%2069%2C%20November%2023%2C%202020&deliveryName=USCDC_921-DM43026#T2_down

[ii] https://www.health.pa.gov/topics/Documents/Diseases%20and%20Conditions/COVID-19%20Interim%20Crisis%20Standards%20of%20Care.pdf

[iii] https://www.health.pa.gov/topics/disease/coronavirus/Pages/Guidance/Ethical-Allocation-Framework.aspx

[iv] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/COVID-03-Oliver.pdf

[v] https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html#:~:text=Adults%20of%20any%20age%20with%20the%20following%20conditions,immune%20system%29%20from%20solid%20organ%20transplant%20%20

[vi] https://bhw.hrsa.gov/sites/default/files/bhw/nchwa/diversityushealthoccupationstechnical.pdf

[vii] https://www.cdc.gov/nchs/nhis/ADULTS/www/index.htm

[viii] https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19/clinical-considerations.html