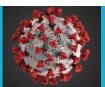


# COVID-19 Interim Vaccination Plan V.5

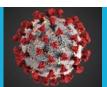
Pennsylvania

PA COVID-19 Vaccine Task Force/PA Department of Health JANUARY 19, 2021 | VERSION 5.0



# **Table of Contents**

Introduction	2
Section 1: COVID-19 Vaccination Preparedness Planning	3
Section 2: COVID-19 Organizational Structure and Partner Involvement	4
Section 3: Phased Approach to COVID-19 Vaccination	1
Section 4: Critical Populations	1
Section 5: COVID-19 Provider Recruitment and Enrollment	2:
Section 6: COVID-19 Vaccine Administration Capacity	2!
Health and Medical Infrastructure	
2. Occupational Health Clinics and Closed Points of Dispensing (PODs)	26
3. Expanded Outreach to Ensure Vaccine Access	2 <sup>.</sup>
4. Staffing	2 <sup>-</sup>
Section 7: COVID-19 Vaccine Allocation, Ordering, Distribution, and Inventory Management	28
Section 8: COVID-19 Vaccine Storage and Handling	32
Section 9: COVID-19 Vaccine Administration Documentation and Reporting	
Section 10: COVID-19 Vaccination Second-Dose Reminders	36
Section 11: COVID-19 Requirements for IISs or Other External Systems	36
Section 12: COVID-19 Vaccination Program Communication	39
Section 13: Regulatory Considerations for COVID-19 Vaccination	44
Section 14: COVID-19 Vaccine Safety Monitoring	4!
Section 15: COVID-19 Vaccination Program Monitoring	48
Appendices50	
Appendix 1 – Mass Vaccination Clinic Flow Chart	5
Appendix 2 – Mass Vaccination Clinic Staffing	52
Appendix 3 — Vaccine Task Force Organizational Chart	53
Appendix 4 – Vaccine A Storage and Handling Guide	54
Appendix 5 – Vaccine A Vaccination Provider Site Archetypes for Shipment Timing and Site Planr	ning 5!
Appendix 6 – Vaccine B Storage and Handling Guide	5
Appendix 7 – CDC Supplemental COVID-19 Vaccine Redistribution Agreement	58
Appendix 8 - COVID-19 Vaccine Hospital Decision Tool for Phase 1A	60



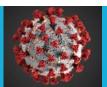
## Introduction

The Pennsylvania Department of Health has developed the COVID-19 Interim Vaccination Plan to inform Pennsylvanians about the plan for vaccination in Pennsylvania. This plan follows the blueprint set forth by the Centers for Disease Control and Prevention (CDC) regarding a COVID-19 Vaccination Plan. This is an interim plan which is being continuously updated to reflect the latest recommendations from the US Department of Health and Human Services (HHS), CDC's Advisory Committee on Immunization Practices (ACIP), Operation Warp Speed (OWS), and other guidance available and feedback received.

Getting Pennsylvanians immunized with a safe and effective COVID-19 vaccine is an essential step in reducing the number of COVID-19 cases, hospitalizations and deaths. The Pennsylvania Department of Health (Department or DOH) guides the distribution and administration of the COVID-19 vaccine throughout 66 of the 67 counties in the Commonwealth of Pennsylvania. Philadelphia County receives independent federal funding, its own vaccine allotment, and has established its own COVID-19 vaccination administration plan.

The Department's goals are to prioritize persons, while the vaccine supply remains limited, who receive the vaccine to maximize benefits and minimize harms caused by the virus, promote justice, mitigate health inequities, and promote transparency.

For the most up-to-date information regarding the COVID-19 vaccine, visit the <u>vaccine section of the website</u>.



## Section 1: COVID-19 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.

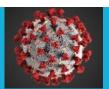
This Interim plan is provided as guidance for distribution and administration of COVID-19 vaccine throughout 66 of the 67 counties in the Commonwealth of Pennsylvania by the Pennsylvania Department of Health (DOH) and its public and private partners. Philadelphia County receives independent federal funding, its own vaccine allotment, and has established 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 based upon the 2009 H1N1 plan. Based on the playbook and the draft plan, planning gaps were 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 Mass Vaccination Clinics (MVCs). MVCs will account for physical 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 MVCs 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 arranged for one MVC in each county. Locations will be identified in collaboration with the Department's District Health Offices, PHPCs, County EMAs, and other stakeholders.

In preparation for receipt of COVID-19 Vaccine, DOH utilized influenza MVCs to test its COVID-19 Plans, including its MVC registration and scheduling software (PrepMod). Understanding the importance of testing counties of varied sizes, the Department conducted four influenza MVCs in the following counties on the following dates:

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

Once the MVCs were completed, DOH conducted evaluations and prepared an After-Action Report within 14 days of MVC completion. The After-Action Report addressed 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 are encouraged to provide feedback during the After-Action Report process. DOH issues After-Action Reports to identify gaps and deficiencies in its plans.

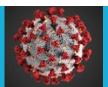
To further DOH's outreach, the Department is planning on using mobile vaccination units in underserved communities to provide direct access to vaccines among populations that may otherwise be excluded. DOH plans on utilizing these mobile units to administer influenza vaccine in conjunction with the COVID-19 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 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 remaining 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 DOH is operating in a coordinated fashion in close partnership with PEMA, the 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.

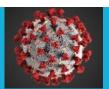
Pennsylvania has a Division of Immunizations that is in place to facilitate and encourage the immunization of Pennsylvanians from a number of life-threatening diseases such as polio, tetanus, and whooping cough that affect infants, children, adolescents and adults. This team is well-trained in the importance of immunizations, vaccine transport, cold chain requirements, ordering, and the logistics related to specific immunizations requirements.

The Department's Bureau of Emergency Preparedness and Response works to respond to public health emergencies and protect public health through readiness and resilience. Staff are involved in planning and coordination, using their logistics expertise in a number of areas, to assist in the planning efforts of local, state and federal entities, as well as private organizations, such as hospitals and other healthcare entities.

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 Operations Center. The VTF meets weekly to discuss and make recommendations on the planning and operational efforts related to distributing and administering COVID-19 vaccine. See Appendix 3 for the VTF Organizational Chart.

The Department has designated a Vaccine Information Officer to assist in the messaging regarding the COVID-19 vaccine in Pennsylvania. The Vaccine Information Officer is assisting in developing plans and information to share with all Department stakeholders, which then can be shared broadly with stakeholders, including the general public, legislators, media, industry.

**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.



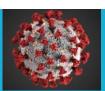
A COVID-19 Vaccine Crisis Committee (VCC) has been developed as an advisory group to the Secretary of Health. The VCC includes specialists from a variety of Pennsylvania hospitals, including vaccinologists, gerontologists and ethicists, the Veterans Administration, Federally Qualified Health Centers (FQHCs), the Pennsylvania Pharmacists Association, educators, business and the state Departments of Aging, Health, and Human Services. The diverse perspectives represented by this group will improve the effectiveness and ethical allocation of vaccine distribution.

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. The Vaccine Planning Workgroup meets weekly to discuss and make recommendations on the planning and operational efforts related to distributing and administering COVID-19 vaccine.

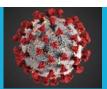
**D.** Identify and list members and relevant expertise of the internal team and the internal/external committee.

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





COVID-19 Vaccine Planning Workgroup	
Organization	Title
	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
DOH/Bureau of Health Statistics and Registries	Bureau Director  Director/Division of Statistical Registries  PA SIIS Registry Manager
DOH/Office of Communications	Vaccine Information Officer  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



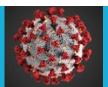
COVID-19 Vaccine Planning Workgroup	
Organization	Title
	Chief Counsel
	Deputy Chief Counsel
	Special Advisor to the Secretary
	COVID-19 Response Director
PA Department of Community and Economic Development	Economic Development Consultant
PA Emergency Management Agency	Emergency Management Supervisor
	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
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
DOH/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





COVID-19 Vaccine Task Force	
Organization	Title
	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
	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	Vaccine Information Officer
	Public Information Officer
DOH/Office of the Secretary	Assistant Counsel



COVID-19 Vaccine Task Force	
Organization Title	
	Special Advisor to Secretary of Health
PA Emergency Management Agency	Emergency Management Supervisor

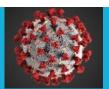
**E.** Describe how your jurisdiction will coordinate efforts between state, local, and territorial authorities.

In jurisdictions without local public health departments, DOH is responsible for coordinating COVID-19 vaccine administration. County and municipal health departments (CMHDs) have developed 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 conducted 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) or are part of the HHS Retail Pharmacy Partnership to the CMHDs so they are aware of and can include in their plans the enrolled pharmacies within their jurisdiction. The DOH procured a registration and scheduling product for MVCs and had made it available to the CMHDs free of charge. The Philadelphia Department of Public Health (PDPH) receives independent federal funding, its own vaccine allotment, and is establishing its own COVID-19 vaccine administration plan. In addition to serving on the Vaccine Planning Workgroup, the PDPH Immunizations Coordinator has weekly calls with the DOH Immunizations Director to share planning information. The DOH COVID-19 Interim Vaccination Plan was provided to the CMHDs and PDPH when it was submitted to the 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 FQHCs, 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 of diverse populations identified through the Office of Health Equity such as religious groups, individuals with limited English proficiency, individuals with disabilities, individuals with intellectual and developmental disabilities, individuals experiencing homelessness, children from vulnerable communities,



immigrants and refugees, LGBTQ individuals, and racial and ethnic minorities whom they contact and work directly with as community leaders.

The DOH has 210 existing memoranda of agreement (MOAs) with pharmacies that cover 1,098 locations statewide. DOH has also entered into the Retail Pharmacy Partnership with Rite Aid and Topco. The partnership has the potential to expand vaccine availability throughout the retail stores, potentially close to 800 Rite-Aid and TopCo store locations statewide. Topco is a member-owned cooperative in many grocery stores throughout Pennsylvania. 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.

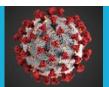
PA Voluntary Organizations Active in Disaster (PA VOAD) member organizations have direct connections with community-based organizations and aid residents of the Commonwealth when disaster strikes. PEMA may coordinate with volunteer organizations to support state and county response efforts to implement 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. Because the vaccine supply has been limited since the beginning of the program, the allocation of doses focused on vaccination of providers and settings for vaccination of limited critical populations, the ability to handle vaccine storage requirements, and 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 receiving 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 CDC's ACIP. This latest update, in version 5.0, adds individuals ages 65 and older and those ages 16-64 with certain underlying medical conditions in Phase 1A as recommended on January 12, 2021 by U.S. Health and Human Services Operation Warp Speed. In addition, this version includes further alignment with the CDC's Interim List of Essential Workers Mapped to Standardized Industry Codes and



<u>Titles</u>. Industries that are not delineated in Pennsylvania's plan will follow the <u>CDC's assigned vaccination phase</u>. 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 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*). The DOH's goals while the vaccine supply remains limited are to maximize benefits and minimize harms caused by the virus, promote justice, mitigate health inequities, and promote transparency and prioritize populations accordingly.

DOH is continuing to receive feedback and comments from the public regarding prioritization. Stakeholders are invited to provide feedback on the Pennsylvania COVID-19 Interim Vaccination Plan by submitting written feedback through the <a href="Pennsylvania Vaccination">Pennsylvania Vaccination</a> Feedback Form.

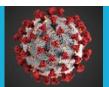
Nothing in these prioritization phases should be construed as prohibiting the distribution of vaccine to subsequent phases if vaccine needs to be administered within a certain timeframe in order to avoid wastage and there are no individuals in the current vaccinating phase available, or if a provider has on hand more vaccine than is necessary to vaccinate all individuals in the current phase of vaccine administration.

#### **Phase 1: Limited Doses Available**

<u>Phase 1:</u> Vaccine administration applies when initial doses of vaccine first become available and are in limited supply compared to demand. With this occurring, DOH, following CDC and ACIP recommendations, has divided Phase 1 into Phase 1A, 1B and 1C. The focus is on the target populations advised by the 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;
- Health care personnel likely to be exposed to or treat people with COVID-19; and
- Other essential workers.

<u>Phase 1A</u>: Pennsylvania is receiving limited allocations of vaccine as product has become available. On December 11, 2020, the <u>CDC adopted the</u> recommendations of the federal advisory panel, ACIP, that 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 has also adopted these recommendations. This latest update adds individuals ages 65 and older and those ages 16-64 with certain underlying medical conditions in Phase 1A as recommended by Operation Warp Speed on January 12, 2021. In addition, Version 5.0 of the Pennsylvania Interim Vaccination Plan includes further alignment with the CDC's Interim List



of Essential Workers Mapped to Standardized Industry Codes and Titles. Industries that are not delineated in Pennsylvania's plan are to follow the CDC's assigned vaccination phase.

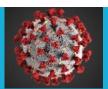
Vaccine is also being distributed to pharmacies as part of the HHS Retail Pharmacy Partnership program with Rite-Aid and TopCo, and planning for mass vaccination clinics (MVCs) is also underway. Both of these programs aim to help administer the vaccine to those who fall under Phase 1A, particularly as this phase is expanded with the addition of individuals age 65 and older and ages 16-64 with certain underlying medical conditions, followed by subsequent phases as needed to ensure efficient distribution of vaccine. There is also a new partnership between DHS and Rite Aid through the Retail Pharmacy Partnership to vaccinate residents and staff in non-FPP eligible DHS-licensed facilities that fall under Phase 1A.

#### Phase 1A: Health Care Personnel:

"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 (HCP) may include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, dentists, dental hygienists, , chiropractors, therapists, phlebotomists, pharmacists, technicians, pharmacy technicians, health professions students and trainees, direct support professionals, clinical personnel in school settings or correctional facilities, contractual HCP not directly employed by the health care facility, and persons (e.g., clerical, laboratory, dietary, environmental services, laundry, security, maintenance, engineering and facilities management, mortuary, administrative, billing, clergy when working in health care settings, regulatory staff who perform on-site assessments in hospitals and facilities that meet the definition of Phase 1A long-term care facilities, long-term care ombudsmen, individuals providing services for the elderly and persons with disabilities including unpaid caregivers, Older Adult Protective Services, Adult Protective Services, and Child Protective Services staff, and volunteer personnel) not directly involved in patient care but potentially exposed to infectious material that can transmit disease among or from health care personnel and patients. "Health care settings" refers to the CDC definition of the places where health care 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 health care is delivered (e.g., mobile clinics), and outpatient facilities, such as dialysis centers, physician offices, adult day facilities and other sites.

## Phase 1A: Sub-prioritization of Health Care Personnel:

ACIP <u>recommends</u> that health care personnel be prioritized in the earliest phases of COVID-19 vaccination. While there is initially insufficient supply to cover all health care personnel, ACIP recommended further sub-prioritization. As such, "<u>COVID-19 facing health care personnel</u>" were prioritized. The Department defines "COVID-19 facing health care personnel" as health care personnel who:



- 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 engaged in the care of 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.

As larger quantities of vaccine become available, the Department is encouraging vaccination of all HCP, per the broadly inclusive ACIP definition.

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

"Long-term care facilities" are <u>defined</u> 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.

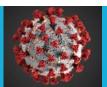
#### Phase 1A: Sub-prioritization of LTCFs:

ACIP <u>recommends</u> that LTCF residents be prioritized in the early phase of COVID-19 vaccination. LTCF staff are considered health care personnel. However, in settings where initial vaccine is insufficient to vaccinate residents of all LTCFs, ACIP recommends further subprioritization.

- 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 1A: Older adults and those with underlying medical conditions

This category includes individuals ages 65 or older and those ages 16-64 who have certain underlying conditions that put them at increased risk for severe illness from SARS-CoV-2, the virus that causes COVID-19. These conditions are outlined by the CDC <a href="https://example.com/here">here</a>, and also include an immunocompromised state (weakened immune system) from blood or bone marrow transplant, immune deficiencies, HIV, use of corticosteroids, or use of other immune weakening medicines. Otherwise these underlying conditions do not include the conditions



that "might" cause someone to be at increased risk. Note that at this time, only the Pfizer-BioNTech product is approved for those age 16 and 17.

<u>Phase 1B:</u> Pennsylvania is planning for limited but expanding supply of vaccine where people at higher risk and critical workers may receive initial doses. On December 22, 2020, ACIP recommended to vaccinate in Phase 1B non–health care frontline essential workers, persons in congregate settings not otherwise specified as a LTCF, as well as persons receiving home and community-based services. Frontline essential workers refers to the ACIP's definition that can be found <a href="here">here</a>. Version 5.0 of the Pennsylvania Interim Vaccination Plan includes further alignment with the CDC's Interim List of Essential Workers Mapped to Standardized Industry Codes and Titles. Industries that are not delineated in Pennsylvania's plan will follow the CDC's assigned vaccination phase. The populations identified in this section will be eligible for vaccination in Phase 1B unless already eligible and vaccinated under another category in Phase 1A.

<u>Phase 1B</u>: Non-Health Care frontline essential workers: <u>Defined by ACIP</u> as frontline essential workers are a subset of essential workers who perform duties across critical infrastructure sectors and maintain the services and functions that U.S. residents depend on daily and are likely at highest risk for work-related exposure to SARS-CoV-2, the virus that causes COVID-19, because their work-related duties must be performed on-site and involve being in close proximity (<6 feet) to the public or to coworkers.

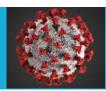
Pennsylvania has adopted the CDC's vaccination phase assignment of standardized industry codes and titles. Industries that are not delineated in Pennsylvania's plan will follow the CDC's assigned vaccination phase. Sectors recommended by ACIP for vaccination in Phase 1B include, but are not limited to:

<u>First Responders:</u> Refers to only those first responders who are on scene, cannot work remotely or maintain physical distancing and need to work closely to the public.

- Law enforcement
- Fire/rescue personnel
- PA National Guard
- Emergency and other relief services sector
- Regulatory staff that are required to do on-site assessments of the 1B congregate care settings

<u>Frontline Essential Workers:</u> Maintain services and functions Pennsylvanians depend on daily. Within each sector, refers to only essential workers who cannot work remotely or maintain physical distancing and need to work in close proximity to the public.

- Correctional officers and other workers serving people in congregate care settings including:
  - Domestic violence/rape crisis shelters



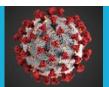
- Office of Children, Youth, and Families Child Residential Facilities
- Homeless Shelters
- Food and agricultural workers
- Veterinarians
- U.S. Postal Service workers
- Manufacturing workers
- Grocery store workers
- Education workers
- Clergy and other essential support for houses of worship
- Public transit workers
- Early Childhood Program workers
  - o Child Care
  - o Part Day School Age Programs
  - Home Visiting Programs
  - Early Intervention staff
  - o Early Childhood programs including Head Start, Pre-K, and Family Center

## Phase 1B: Highest risk for severe disease:

- Persons in Congregate Settings not Otherwise Specified as a LTCF and Persons
   Receiving Home and Community-Based Services.
  - Behavioral Health/Rehabilitation Facilities
  - Community Residential Rehabilitation Services
  - Correctional Facilities
  - Juvenile Justice Facilities
  - o Domestic Violence Shelters
  - Homeless Shelters or Individuals Experiencing Homelessness
  - o Intensive or Partial Treatment Programs
  - o 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

<u>Phase 1C:</u> Pennsylvania anticipates further increases in vaccine availability. The populations identified in this section will be eligible for vaccination in Phase 1C unless already eligible and vaccinated under another category in Phase 1A or Phase 1B.

Phase 1C: Essential workers: Essential workers who do not meet criteria to make them eligible in Phase 1A or 1B will be vaccinated in this phase. "Essential workers" refers to the ACIP's definition that can be found <a href="here">here</a> and is based on the U.S. Cybersecurity & Infrastructure Security Agency's <a href="guidance">guidance</a>. This only 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 the public. Version 5.0 of the Pennsylvania Interim Vaccination Plan includes further alignment with the CDC's Interim List of Essential Workers Mapped to Standardized Industry



Codes and Titles. Industries that are not delineated in Pennsylvania's plan will follow the CDC's assigned vaccination phase.

Pennsylvania has adopted the CDC's vaccination phase assignment of standardized industry codes and titles. Industries that are not delineated in Pennsylvania's plan will follow the CDC's assigned vaccination phase. Sectors recommended by ACIP for vaccination in Phase 1C include, but are not limited to:

- Transportation and Logistics
- Water and Wastewater
- Food Service
- Shelter and Housing
- Finance, including bank tellers and insurance carriers
- Information Technology and Communication
- Energy, including Nuclear Reactors
- Legal
- Federal, state, county and local government workers, including county election workers, elected officials and members of the judiciary and their staff
- News Media
- Public Safety
- Public Health Workers

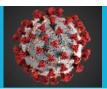
#### Phase 2: Expanded supply of vaccine available

Pennsylvania is planning for expanding supply of vaccine for individuals who are not already eligible and vaccinated within Phase 1 to receive initial doses. On December 22, 2020, ACIP recommended to vaccinate any individual over the age of 16 who agrees and does not have a contraindication for vaccine. Note that at this time, only the Pfizer-BioNTech product is approved for those age 16 and 17.

## 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 <u>underlying medical conditions</u> 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.

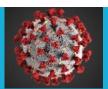
Critical populations in Pennsylvania are defined from many sources. Estimates for the above listed populations are derived from the 2019 U.S. Census, the Behavioral Risk Factor Surveillance System (BRFSS), and health systems patient databases (Medicaid, IBX, others), and Tiberius. DOH reviewed several preparedness reports to obtain detailed estimates of vulnerable populations that were geocoded and presented by census tract. Example 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 coordinates with its CMHDs to share additional lists and locations of populations for specific vaccine targeting. As part of routine public health preparedness work, the 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 have chronic health conditions warranting use of medical devices. These data will be used to better estimate prioritized populations and 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, such as geography, , and residence in a congregate living facility, are all available for many of the state's more than 165,000 cases. These data, in addition to national data sources, have helped to identify those who are more likely to contract the disease and suffer more severe outcomes.

Phase 1A populations to receive vaccine are focused on those at greatest risk for illness and death. Health care 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, health care workers accounted for 2.9% 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 January 19, 2021

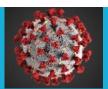
Variable	Count	Percent
Total reported cases	777,186	100%
Cases among healthcare workers (underestimate; depends on investigation data)	21,569	2.8%
Cases among residents of LTCF, PCH	59,995	7.7%
Cases among employees of LTCF, PCH	11,204	1.4%
Total deaths	19,467	2.5%
	(EDRS)	
Deaths among LTCF/PCH facilities	10,041	51.6%
	(NEDSS)	

The DOH utilizes 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 the DOH 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, PA Department of Human Services, PA Department of Drug and Alcohol Programs, and/or 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 excluded and those data, shared with immunizations and preparedness colleagues in that jurisdiction.

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 therefore 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.

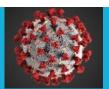
The DOH will utilize data from the PA Vital Statistics Report, PA Center for Workforce Information and Analysis, United States Census Bureau, and Bureau of Labor Statistics to identified population estimates for persons working in the critical infrastructure workforce. Critical infrastructure has been identified using the Cybersecurity & Infrastructure Security Agency (CISA) Critical Infrastructure Sectors list. 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 health care 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 public health preparedness consultants (PHPCs). The 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

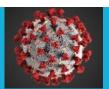
COVID-19 provider recruitment during Phase 1 is currently under way. Facility types targeted by Phase 1 recruitment efforts consist of hospitals, health systems, FQHCs, CMHDs, State Health Centers, and pharmacies allowing the DOH the ability to ensure COVID-19 vaccine will be available for critical population 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 more than 900 LTCFs in Phase 1 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 1 hospitals and FQHCs. 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.

The Division of Immunizations (DOI) verifies that 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, health systems, 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 physical 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 has implemented 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.

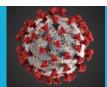
Sites interested in becoming a COVID-19 vaccination site will complete the web based COVID-19 provider enrollment agreement. Data from the completed web form will be exported to an Access database twice daily. The access database will then be used to generate a CSV file to provide CDC biweekly COVID-19 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.

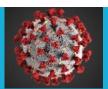
E. Describe how your jurisdiction will provide and track training for enrolled providers and list training topics.

The DOH utilizes 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).

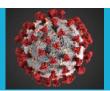
The DOH will require all vaccine redistribution to be pre-approved through the COVID-19 vaccine management team. To be considered for approval, the provider must complete and submit the CDC Supplemental COVID-19 Vaccine Redistribution Agreement (Appendix 8) and provide documentation regarding the number 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 1 and 2 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 statewid and recently added 800 Rite Aid and TopCo locations. 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. DOH has also entered into the Retail Pharmacy Partnership with Rite Aid and Topco. The partnership has the potential to expand vaccine availability throughout the retail stores, potentially close to 800 store locations statewide. During Phase 1A,



pharmacies have been engaged to vaccinate staff and residents at LTCFs and first responders. During phases 1B, 1C and 2, 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

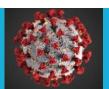
#### **Instructions:**

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, 692 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 health care workers and patients in Phase 1. 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 will be engaged to vaccinate staff and residents at long term care facilities and first responders as well as those 65 and older or 16 to 64 years of age with co-morbid conditions. During Phase 2, 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 lookalike 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, 1C, 2).

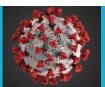
Occupational Health Clinics and Closed Points of Dispensing (PODs)

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 may receive vaccine through their existing occupational health programs at their place of employment. These employers will become or partner with vaccine providers, and in doing so, they will estimate the number of employees they see in their practices in total, number of employee 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. This data will give DOH vaccine staff an assessment of capacity and will identify which providers might require additional resources to vaccinate eligible populations in a timely manner. Employers will be responsible le for developing their own policies and partnerships to implement a job site closed POD.

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) 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. 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. Partnerships with occupational health will begin we allocation of vaccines are increased.

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 an effective 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 <u>SERVPA</u>. 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.

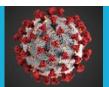
DOH will use the information on prioritized populations to determine which Closed PODs would be best for activation. Not all Closed PODs identified through previous planning efforts are suitable for administration of COVID-19 vaccine. Managing cold chain (and ultra-cold chain), staffing, strict infection 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 COVID-19 vaccine providers. 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 (excluding 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 allocates COVID-19 vaccine according to the following guidance:

- 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.

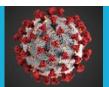
For both the Pfizer-BioNTech and Moderna vaccines, two doses are required, and the same product must be used for both doses. Two-dose vaccine allocations will be managed in the following way:

 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 and HHS/OWS 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
- 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.



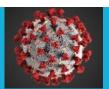
The DOH has collected ultra-cold storage capabilities of hospitals in Pennsylvania using a storage and handling survey completed by the Bureau of Emergency Preparedness and Response. In addition to the hospital storage and handling survey, the DOI will collect storage and handling capabilities for each 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 VTrckS.
- 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 VTrckS. 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 VTrckS. Daily shipments from VTrckS 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:

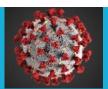
- o Site Name
- Address
- Contact Name
- Contact Phone Number
- Vaccine Brand Names
- Number of Doses Expired

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
- 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.

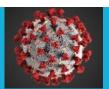
## Section 8: COVID-19 Vaccine Storage and Handling

#### 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 <a href="https://www.cdc.gov/vaccines/ed/youcalltheshots.html">https://www.cdc.gov/vaccines/ed/youcalltheshots.html</a>.

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.

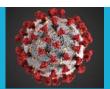
Frozen Vaccine - Sites that receive frozen vaccine will be required to meet the following storage and handling requirements.

- 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.
  - o 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: <a href="https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html">https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html</a>. 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.

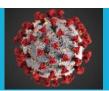
Redistribution will not be considered in Phase 1 as providers identified for this phase will have adequate storage capacity and accommodate a large number of doses. For subsequent phases, the DOH will require all vaccine redistribution to be pre-approved through the COVID-19 vaccine management team. 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:

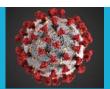
**A.** Describe the system your jurisdiction is using to collect COVID-19 vaccine doses administered data from providers.

The core system for data collection is the PA-SIIS which supports the connection 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 can collect vaccine administration information on paper forms and enter the information into PA-SIIS once connectivity resumes.

- **B.** Describe how your jurisdiction is submitting COVID-19 vaccine administration data via the Immunization (IZ) Gateway.
  - DOH is submitting a daily extract to CDC's COVID-19 IZ Data Clearinghouse based on the CDC's standards for the CRVS file extract. DOH is working towards implementing the WSDL tool based upon activation of this tool at the national level and after successful testing of the WSDL tool implemented in the PA-SIIS application.
- **C.** Describe how your jurisdiction has ensured 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 are notified of COVID vaccine reporting requirements, including internet access. If not actively participating in PA-SIIS, facilities are being enrolled and having staff trained to navigate various functions through the PA-SIIS and are required to report vaccines administered within 24 hours. Training for newly enrolled providers is 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 has taken to ensure real-time documentation and reporting of COVID-19 vaccine administration data from satellite, temporary, or off-site clinic settings.
  - The DOH has assigned 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 is working 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 is monitoring 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 is monitoring 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 is generating and using COVID-19 vaccination coverage reports.

Dashboards are being generated to assess coverage among race, ethnicity, gender, age, facility type and residence for monitoring disease outbreak or disease spread. The department will be working to publish these, so they are available publicly.

Section 10: COVID-19 Vaccination Second-Dose Reminders

#### Instructions:

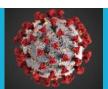
A. Describe all methods your jurisdiction will use to remind COVID-19 vaccine recipients of the need for a second dose, including planned redundancy of reminder methods.

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.



PA-SIIS will be the primary system for collecting COVID-19 vaccination events. PrepMod has been procured 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.

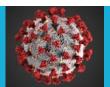
B. List the variables your jurisdiction's IIS or other system will be able to capture for persons who will receive COVID-19 vaccine, including but not limited to age, race/ethnicity, chronic medical conditions, occupation, membership in other critical population groups.

#### **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.

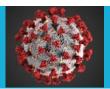
The DOH has identified the targeted facilities that will support Phase 1A. Those facilities are hospitals, health systems, FQHCs, CMHDs, and pharmacies. PA-SIIS will receive a listing of all the facilities within the selected groups and link them to the PA-SIIS to identify facilities already participating 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 16<sup>th</sup>.



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 Vaccine Information Officer (VIO) will be the point of contact within the Office of Communications on the messaging for the COVID-19 vaccine.

#### **Objectives**

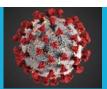
- A. Educate the public about the development, authorization, distribution, and execution of COVID-19 vaccines and that situations are continually evolving.
- **B.** Ensure public confidence in the approval or authorization process, safety, and efficacy of COVID-19 vaccines.
- C. Help the public to understand 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

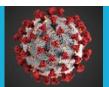
- Press briefings
  - COVID-19 vaccines will be extensively covered in press briefings. Full press briefings are
    available as both audio and videos to media to use afterwards. This ensures that
    messages reach traditional media including TV, radio, and newspapers.
- Written communication (press 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:
  - Health care 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)
  - o 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

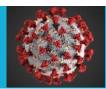
- To prepare the public before the vaccine is available and during Phases 1 and 2 of the COVID-19 Vaccination Program
  - Translation Services



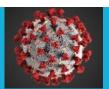
- DOH will translate COVID-19 vaccine information into Spanish, German, and Chinese using a company within the commonwealth network:
   <a href="http://www.emarketplace.state.pa.us/BidContracts.aspx?SID=4400017786&From=Parent">http://www.emarketplace.state.pa.us/BidContracts.aspx?SID=4400017786&From=Parent</a>. 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
  - o 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.
  - o 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
    - O 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
  - o 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 <a href="www.health.pa.gov">www.health.pa.gov</a>. The Governor's office will also include information and a link to the DOH website on the main Pennsylvania website, <a href="www.pa.gov">www.pa.gov</a>, as well as the Governor's website, <a href="www.governor.pa.gov">www.governor.pa.gov</a>. 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.

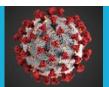
All applicable information will be put on our DOH website.

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.

Currently available COVID-19 vaccines are authorized for use under EUAs issued by the 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 the 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 outlines how the COVID-19 vaccine should be used and any conditions that must be met to use the vaccine. The FDA will coordinate with the 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 <a href="https://www.cdc.gov/vaccines/hcp/vis/current-vis.html">https://www.cdc.gov/vaccines/hcp/vis/current-vis.html</a>.

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 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).

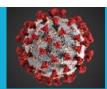
#### **III. Definitions**

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.

- ADRs include:
  - Any reaction that is clinically significant;
  - New, rare, or previously poorly documented reactions;
  - o ADRs associated with newly marketed medications;
  - 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;
  - Unusual increases in numbers or severity of reactions;
  - Allergic reactions and idiosyncratic reactions are also considered ADRs, if they are deemed to be serious, life threatening, or fatal, as described above; and
  - o Reportable reactions listed in the VAERS system.
- 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**

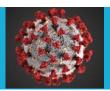
Mechanisms to monitor adverse events.



- 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.
  - The consumer's health care provider shall be responsible for confirming or ruling out any suspected adverse reaction.
  - The consumer may complete the form without involvement of the health care provider through the MedWatch website.
  - 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.
- 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.
- The reporting entity will follow up with each consumer reporting a severe ADR to determine the outcome.
- 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.
- 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.
  - 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.
  - 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.
- Local emergency management and public health officials will be advised of the adverse event information and steps being taken to resolve the adverse event.
- A media release will be prepared and issued through the processes identified in the Crisis and Emergency Risk Communication Plan.
- If dictated by the situation, replacement vaccines will be provided to vaccination locations, as appropriate.
- 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

FDA Medical Products Reporting Program: http://www.fda.gov/medwatch/



- FDA/CDC VAERS Program: http://vaers.hhs.gov/
- 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.

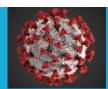
The Weekly Flu Vaccination Dashboard will include weekly estimates of influenza vaccination for adults, children, and pregnant women (when approved for these groups) using existing (National Immunization Survey [NIS]-Flu) and new (IQVIA) data sources. Data and estimates from additional sources will be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

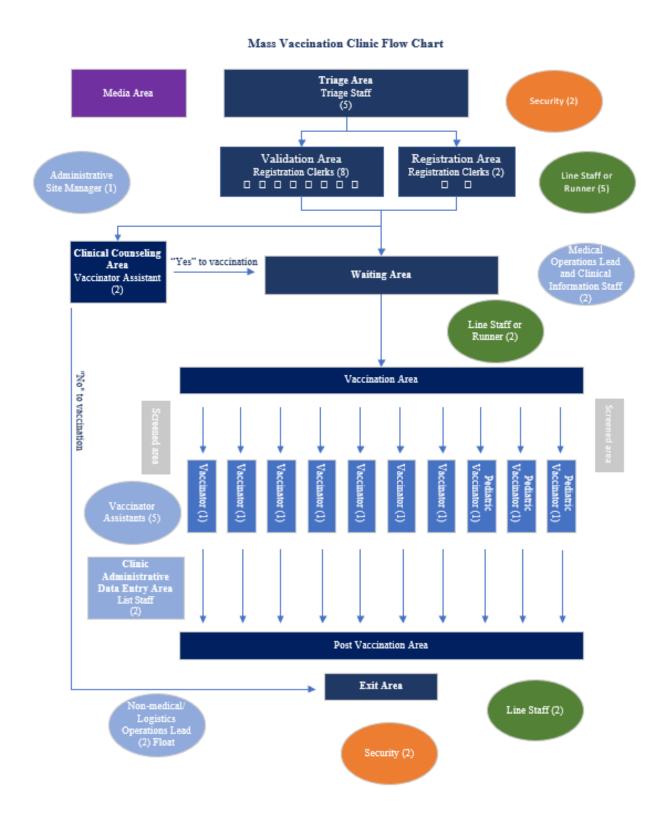


CDC will provide timely messaging throughout the COVID-19 vaccination response via all-jurisdiction calls, regular e-mail communication, and website updates. Jurisdictions organizations should routinely monitor both CDC and local-level messaging to inform their communications efforts. Variations in messaging 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.).
  - Regular communication and coordination with CMHDs are 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 <a href="www.health.pa.gov/topics/disease/coronavirus/Pages/Cases.aspx">www.health.pa.gov/topics/disease/coronavirus/Pages/Cases.aspx</a>. 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.

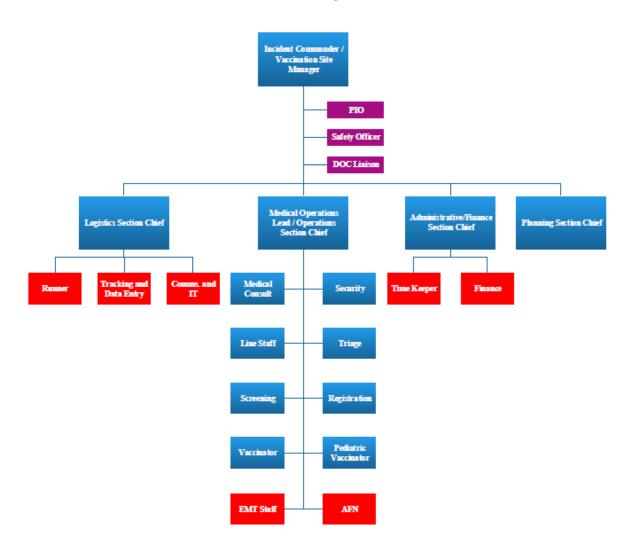
Append		
<b>Instructio</b> Vaccinati	<b>ons:</b> Jurisdictions may choose to include additional information as appendices to ion Plan.	their COVII)

## Appendix 1 – Mass Vaccination Clinic Flow Chart

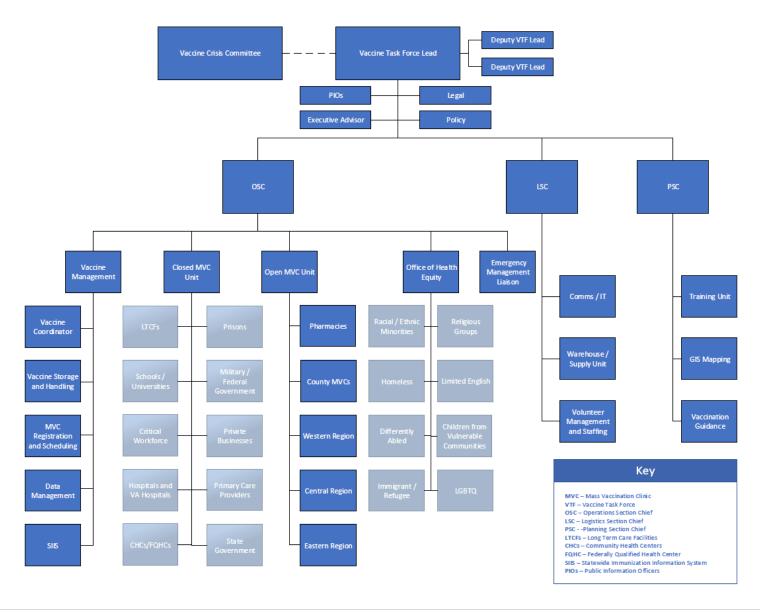


## Appendix 2 – Mass Vaccination Clinic Staffing

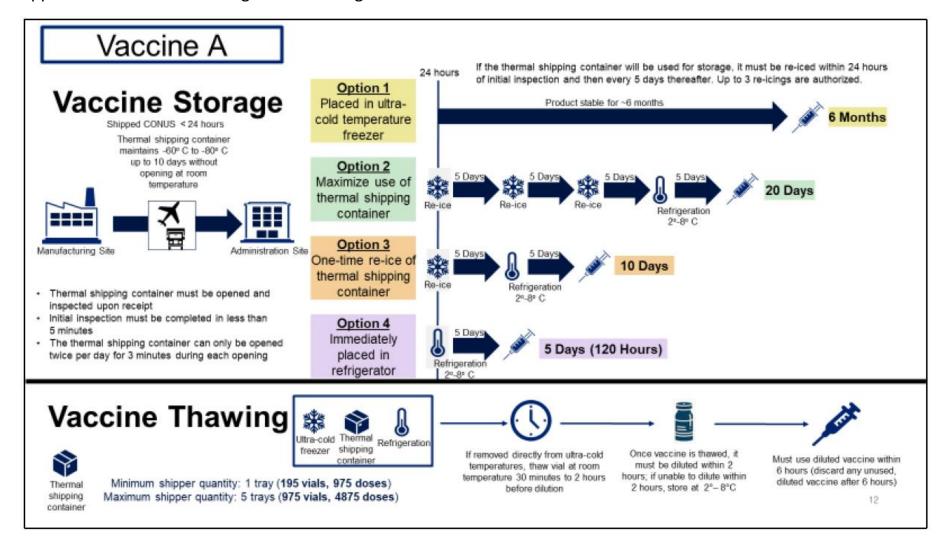
#### Mass Vaccination Clinic Organizational Chart



## 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

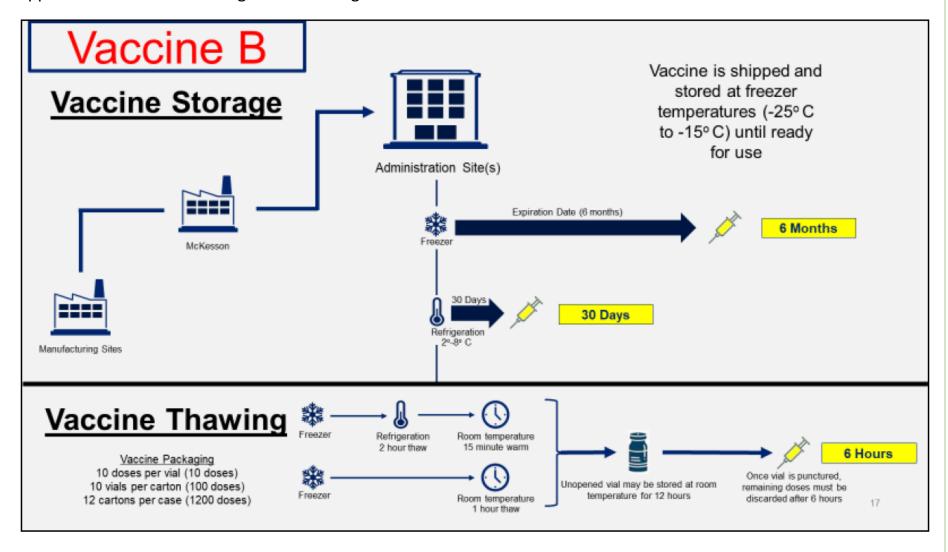
## **Site Types for Vaccine A Product**

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
P	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/facility name:		For official use only: VTrckS ID:Unique COVID-19 Organization ID (from Section A):				
and CONTACT INFORM	ATION OF COVID-19 VACC	INATION ORGANIZATION				
County:	State:	ZIP:				
	Fax:	Fax:				
RS						
valent) Information						
Last name Firs		Middle initial				
Lic	ensure (state and number)	sure (state and number)				
	Email:	Email:				
	1					
or Chief Fiduciary) Informat	tion					
Fire	st name	Middle initial				
Em	ail:					
	County:  County:  IRS  ivalent) Information  Firs  or Chief Fiduciary) Informat  Firs	County: State: Fax:  Fax:  Indicate Covid-19 Organia  County: State:  Fax:  Italian  First name  Licensure (state and number)				

## CDC COVID-19 Vaccine Provider Agreement Form

	IARY POINT OF CONTACT tor listed above)	RESPONSIBLE FOR	RECEIPT OF COVID-19 VACCINE (if different than medical				
	name, first name, middle	initial:					
Telep	ohone number:		Email:				
SECO	NDARY POINT OF CONTA	CT FOR RECEIPT OF	COVID-19 VACCINE				
Last	name, first name, middle i	initial:					
Telep	ohone number:		Email:				
covi	D-19 VACCINATION ORGA	ANIZATION REDIST	RIBUTION AGREEMENT REQUIREMENTS				
		ine, constituent pro	ducts, and ancillary supplies to secondary sites, this				
orga.	nization agrees to:  Sign and comply with a  Agreement.	ll conditions as outli	ned in the CDC COVID-19 Vaccination Program Provider				
2.	Ensure secondary locat		ributed COVID-19 vaccine, constituent products, or ancillary itions in the CDC COVID-19 Vaccination Program Provider				
3.	Comply with vaccine m	ndling Toolkit¹, whi	ions on cold chain management and CDC guidance in CDC's ch will be updated to include specific COVID-19 conditions 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.						
main other associ requi requi term inclu	tained by my jurisdiction's r legal entity with staff au ciated with this Organizati irements listed above and irements. Non-compliance ination from the CDC COVI	immunization prog thorized to administ on that I have read o understand my Orgo with the terms of th ID-19 Vaccination Pro False Claims Act, 31	ent between my Organization and CDC, implemented and ram. I also certify on behalf of myself, my medical practice or er vaccines, and all the practitioners, nurses, and others and agree to the COVID-19 vaccine redistribution agreement inization and I are accountable for compliance with these is Redistribution Agreement may result in suspension or orgam and criminal and civil penalties under federal law, U.S.C. § 3729 et seq., and other related federal laws, 18				
	nization Medical Director						
Last	name	First name	Middle initial				
Signa	ature:		Date:				
Chie	f Executive Officer (Chief	Fiduciary Role)	-				
Last	name	First name	Middle initial				
Signature:			Date:				

<sup>&</sup>lt;sup>1</sup> Requirements incorporated by reference; refer to https://www.cdc.gov/vaccines/hcp/admin/storage-handling.html

#### Appendix 8: COVID-19 Vaccine 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:

- 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<sup>ii</sup> and the Ethical Allocation Framework for Emerging Treatments of COVID-19.<sup>iii</sup>

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 1<sup>st</sup>, 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 <u>defined</u> 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. 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.

#### 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. 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, the social and ethnic minorities in the proposition of these conditions, the social and ethnic minorities tend to have a higher prevalence of many of these conditions, the social and ethnic minorities tend to have a higher prevalence of many of these conditions, the social and ethnic minorities tend to have a higher prevalence of many of these conditions, the social and ethnic minorities tend to have a higher prevalence of many of these conditions, the social and ethnic minorities tend to have a higher prevalence of many of these conditions.

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.

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.
- 4. 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 subprioritization. If there is not enough vaccine for all healthcare personnel, COVID-19 facing health care personnel should receive priority for the vaccine.
- 5. 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).
- 6. After vaccinating COVID-facing healthcare personnel, vaccinate the rest of the healthcare personnel.
- 7. 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.
- 8. 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.
- 9. 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 those 65 or older and with certain underlying medical conditions

Identify persons who visit primary care physicians within your hospital, health system, or FQHC (if applicable) or who regularly visit your pharmacy to receive medications, who are either 65 or older or have certain underlying conditions putting them at high risk for severe illness from the

virus that causes COVID-19. An effort should be made to identify those who have the highest number of such underlying conditions and scheduling them for vaccination first, but otherwise the effort should be focused on vaccinating as many people in this high-risk group as possible. Establish a scheduling methodology that also takes into consideration those without internet access, so they can also receive access to the vaccine.

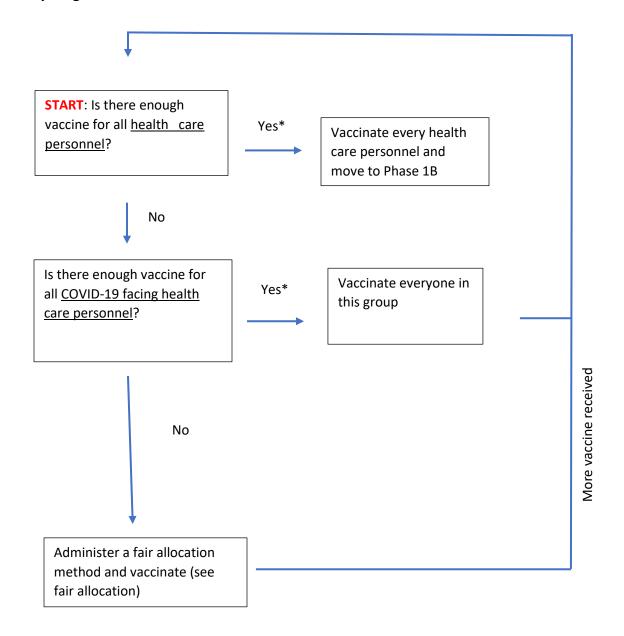
#### Vaccination of pregnant and breastfeeding HCP:

Observational data demonstrate that, while the chances for these severe health effects are low, pregnant people with COVID-19 have an increased risk of severe illness, including illness that results in ICU admission, mechanical ventilation, and death compared with non-pregnant women of reproductive age. Additionally, pregnant people with COVID-19 might be at increased risk of adverse pregnancy outcomes, such as preterm birth, compared with pregnant women without COVID-19. However, there is only limited data available on the safety of COVID-19 vaccines administered during pregnancy. People who are pregnant may choose to get vaccinated. If they have questions about getting vaccinated, a discussion with a healthcare provider might help them make an informed decision. .

#### 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. VII 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**



<sup>\*</sup>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: <a href="https://www.random.org/sequences/">https://www.random.org/sequences/</a>. 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 <u>underlying conditions</u> 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.

https://www.cdc.gov/mmwr/volumes/69/wr/mm6947e3.htm?s\_cid=mm6947e3\_e&ACSTrackingID=USCDC\_921-DM43026&ACSTrackingLabel=MMWR%20Early%20Release%20-

<sup>%20</sup>Vol.%2069%2C%20November%2023%2C%202020&deliveryName=USCDC\_921-DM43026#T2\_down

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

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

<sup>&</sup>lt;sup>iv</sup> https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/COVID-03-Oliver.pdf

<sup>&</sup>lt;sup>v</sup> https://bhw.hrsa.gov/sites/default/files/bhw/nchwa/diversityushealthoccupationstechnical.pdf

vi https://www.cdc.gov/nchs/nhis/ADULTS/www/index.htm

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