DRAFT COVID-19 Vaccination Plan

WEST VIRGINIA

Preliminary draft submitted to CDC for comment and review. Subject to change based upon final guidance to be released by CDC and ACIP.

WEST VIRGINIA
Department of
Health **&**
Human
Resources
STATE OF WEST VIRGINIA

WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES, DIVISION OF IMMUNIZATION SERVICES
10/16/2020

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Record of Changes

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

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Executive Summary

SARS-CoV-2 is the strain of coronavirus that has spread throughout the United States, significantly impacting every American in all walks of life. This disease has changed many of our "normal practices" and initially resulted in severe restrictions to our way of life. The West Virginia Department of Health and Human Resources (WVDHHR) has developed the West Virginia COVID-19 Vaccination Program plan with guidance from the Centers for Disease Control and Prevention (CDC). The primary purpose of this plan is to provide clear instruction from the State of West Virginia on the implementation of the COVID-19 Vaccination Program. Proper execution of this plan will allow West Virginia to see a drastic decline in the prevalence of COVID-19, its impacts on society, and ultimately assist in the return to a "normal" way of life.

This plan provides an overview of the planning process and the three phases of program implementation. The first phase is characterized by limited availability of a COVID-19 vaccine. While supply is constrained, vaccine will only be made available to specific population groups. In Phase 2, we anticipate a significant increase in supply that will allow for widespread access to West Virginians through a broader network of vaccination providers. The final phase, Phase 3, will be when vaccine supply outpaces demand and the program will shift to more routine vaccination strategies. The result will be a dramatic decrease in all citizens' susceptibility to the COVID-19 virus and statewide COVID-19 mortality rates. WVDHHR continues to work with a diverse group of stakeholders and partners to accomplish this task. This document clarifies vaccine planning organization structure, the phased approach to COVID-19 vaccination, defines critical populations, provider enrollment, vaccine administration capacity, vaccine allocation, ordering, and distribution, and vaccine storage. It also provides guidance on vaccine documentation, second dose reminders, requirements for reporting systems, program communication and regulatory considerations.

The goal of the WV COVID-19 Vaccination Plan is to see a unified effort across state, federal, and local agencies to decrease COVID-19 infection rates and mortality rates. A successful vaccination campaign in West Virginia will reduce the ability of COVID-19 to spread and impact our most vulnerable populations. The West Virginia COVID-19 Vaccination Plan provides the blueprint to vaccinate West Virginians and allow us to return to our Mountain State way of life.

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Section 1: COVID-19 Vaccination Preparedness Planning

Pandemic vaccination response planning requires collaboration among a wide range of public- and private-sector partners, including immunization and public health emergency preparedness programs, emergency management agencies, healthcare organizations, policymakers, etc. to create a whole of government planning approach to this endeavor. More information about the specific internal and external agencies involved in the planning and implementation of the COVID-19 Vaccination Program can be found in Section 2: COVID-19 Organization Structure and Partner Involvement. Many of these partners are engaged regularly in seasonal influenza and other outbreak vaccination campaigns, and some may have served as vaccination providers during the 2009 H1N1 pandemic. However, significant planning is needed to operationalize a comprehensive vaccination response to COVID-19, which is much larger in scope and complexity than seasonal influenza or other previous outbreak-related vaccination responses. WVDHHR recognizes the importance of leveraging and strengthening existing partnerships, while also identifying new, potentially less traditional partners who are positioned to support the planning and/or implementation of a COVID-19 Vaccination Program.

Planning Workshops

Once the West Virginia COVID-19 Vaccination Plan is complete, WVDHHR will facilitate planning workshops with each of the eight preparedness regions throughout the state. This will give local jurisdictions the opportunity to discuss different planning scenarios, engage in cross jurisdictional coordination, proactively identify potential gaps in preparedness, and leverage regional resources. Local Health Departments from each county in the region will be the primary stakeholders, but all partners who have expressed interest in supporting the COVID-19 Vaccination Program will be invited to participate including pharmacies, Federally Qualified Health Centers, long-term care facilities, Emergency Medical Services (EMS) agencies, and more. WVDHHR representatives will attend these workshops to assist with identifying and addressing shortfalls. These planning workshops will allow WVDHHR to identify potential deficiencies early on and ensure that necessary resources are put in place ahead of program implementation.

Section 2: COVID-19 Organizational Structure and Partner Involvement

Organizational Structure

In accordance with the WV Public Health All Hazards Threat Response Plan, an incident command system, known as WVDHHR Health Command, has been established for mobilization of the WVDHHR's COVID-19 response. The COVID-19 vaccination program planning and implementation has been incorporated within the Operations Section of the response structure. The lead planners for this initiative include members of Health Command and the Division of Immunization Services (DIS). Leads have also been identified to oversee key components of the vaccination program including provider outreach and enrollment, data systems, vaccine management, and vaccine communications. DIS is currently recruiting and onboarding both permanent and temporary staff to serve as back-ups and support each of the leads and managers. This structure is scalable and can be built out even further as the planning process continues and eventually shifts from planning to implementation. A general illustration of the current structure is below:
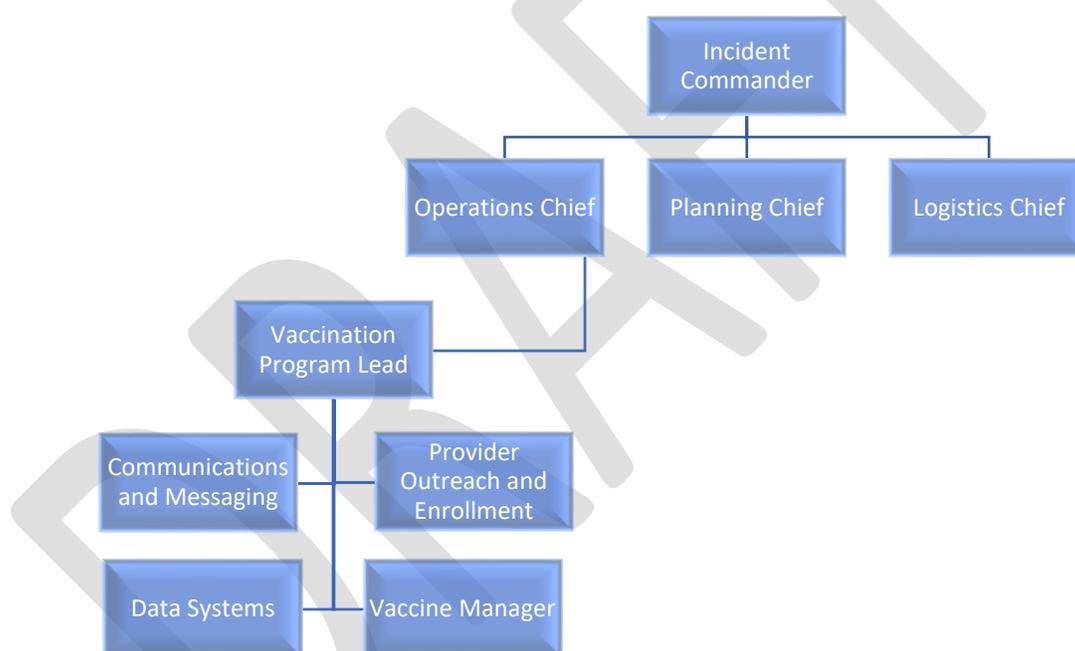
Vaccination Program Planning and Implementation Working Groups

Several working groups have been established to support the planning of robust COVID-19 Vaccination Program. These groups include a diverse group of internal and external partners to ensure the different facets of a vaccination program are addressed early in the planning process. An overview of the different working groups is below.

COVID-19 Vaccination Planning and Implementation Workgroup

A core planning and implementation group was established in mid-August and has been meeting weekly since then. It includes a broad coalition of internal and external stakeholders whose buy-in and support

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will be critical to the success of a vaccination program. This group continues to expand to include additional partners to ensure a variety of perspectives and expertise are incorporated into the planning process and that all key impacted groups enjoy some form of representation. Agencies represented in this working group include:

- Herbert Henderson Office of Minority Affairs
- Local Health Officer Representative
- West Virginia Association of Local Health Departments
- West Virginia Board of Pharmacy
- West Virginia Division of Emergency Management
- West Virginia Health Care Association
- West Virginia Hospital Association
- West Virginia National Guard
- West Virginia Primary Care Association
- West Virginia State Medical Association
- West Virginia University

DIS will continue to engage additional partners throughout the program, specifically those which can assist with reaching critical populations including but not limited to the West Virginia Division of Corrections and Rehabilitation (WVDOCR), the WVDHHR's Bureau for Behavioral Health (BBH), the West Virginia Department of Education (WVDE), and the West Virginia Higher Education Policy Commission (WVHEPC), etc.

COVID-19 Vaccine Communications and Messaging Workgroup

Clear and consistent messaging about the COVID-19 Vaccine will be imperative to ensure vaccine confidence among key target groups and the general population. To help achieve this goal, a sub-workgroup was established to focus solely on communications and messaging. The core members of this group include representatives from DIS, WVDHHR Office of Communications, WV National Guard Public Affairs, and the Center for Rural Health Development. Over time, this workgroup will engage other key partner agencies and local leaders to help disseminate messaging strategically through a variety of channels. These additional partners will include but are not limited to:

- Advisory Task Force on African American Disparities
- Faith-Based Community Leaders
- West Virginia Association of Local Health Departments
- West Virginia Chamber of Commerce
- West Virginia Chapter of the American Academy of Family Physicians
- West Virginia Department of Education
- West Virginia Health Care Association
- West Virginia Primary Care Association
- West Virginia State Medical Association

More information about West Virginia messaging and communications strategies can be found in Section 12: COVID-19 Vaccination Program Communication.

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COVID-19 Vaccine Medical Advisory Group

A Medical Advisory Group has also been established and meets monthly. Meetings may be more frequent if deemed necessary. This group includes 20-25 pharmacists and physicians from across the state with specialties in public health, pediatrics, infectious diseases, and medical ethics. The intent of this workgroup is to review the state's distribution plan, specifically the prioritized population groups, to ensure our plan is medically equitable and ethical. This group will also review studies on vaccine efficacy and monitor adverse events throughout the program to determine if changes to the WV COVID-19 Vaccine strategy are warranted.

State and Local Coordination

Alignment of state and local efforts has been critically important throughout the COVID-19 response. This is also true for the vaccination program planning and will be for the COVID-19 Vaccine Plan implementation. Several LHD representatives are members of the core planning group as well as involved in different sub-workgroups to ensure local input and insight are incorporated throughout the planning process. WVDHHR holds several weekly COVID-19 response calls with all Local Health Departments (LHDs) to disseminate information and identify support needs. These calls have been used as a forum to provide updates on the state's vaccine planning efforts and the recommended actions that should be taken locally. Prior to implementation, weekly calls will be established that focus on detailed aspects of the vaccination program planning and implementation by LHDs. These calls will continue throughout the vaccination program at whatever frequency is deemed appropriate and necessary. Additionally, planning workshops for each of the seven preparedness regions will be scheduled to provide an opportunity for LHDs to engage in cross-jurisdictional coordination and leverage regional resources (See Section 1: COVID Vaccination Preparedness Planning). If additional support is needed beyond the weekly information calls and regional meetings, the planning group is prepared to stand up a technical assistance center that would allow LHDs and potential other local partners to call in and work one-on-one with DIS staff members.

Section 3: Phased Approach to COVID-19 Vaccination

The WV COVID-19 Vaccination Program will be implemented in three phases based on the anticipated levels of supply and demand. Each phase targets different priority groups, engages different key partners, and employs different vaccination strategies. The phased approach is a flexible framework that can be adjusted to different supply level scenarios. The three phases are generally defined as follows:

- Phase 1: Limited Doses Available
- Phase 2: Large Number of Doses Available, Supply Likely to Meet Demand
- Phase 3: Likely Sufficient Supply, Slowing Demand

The image below illustrates the three phases of the COVID-19 Vaccination Program:
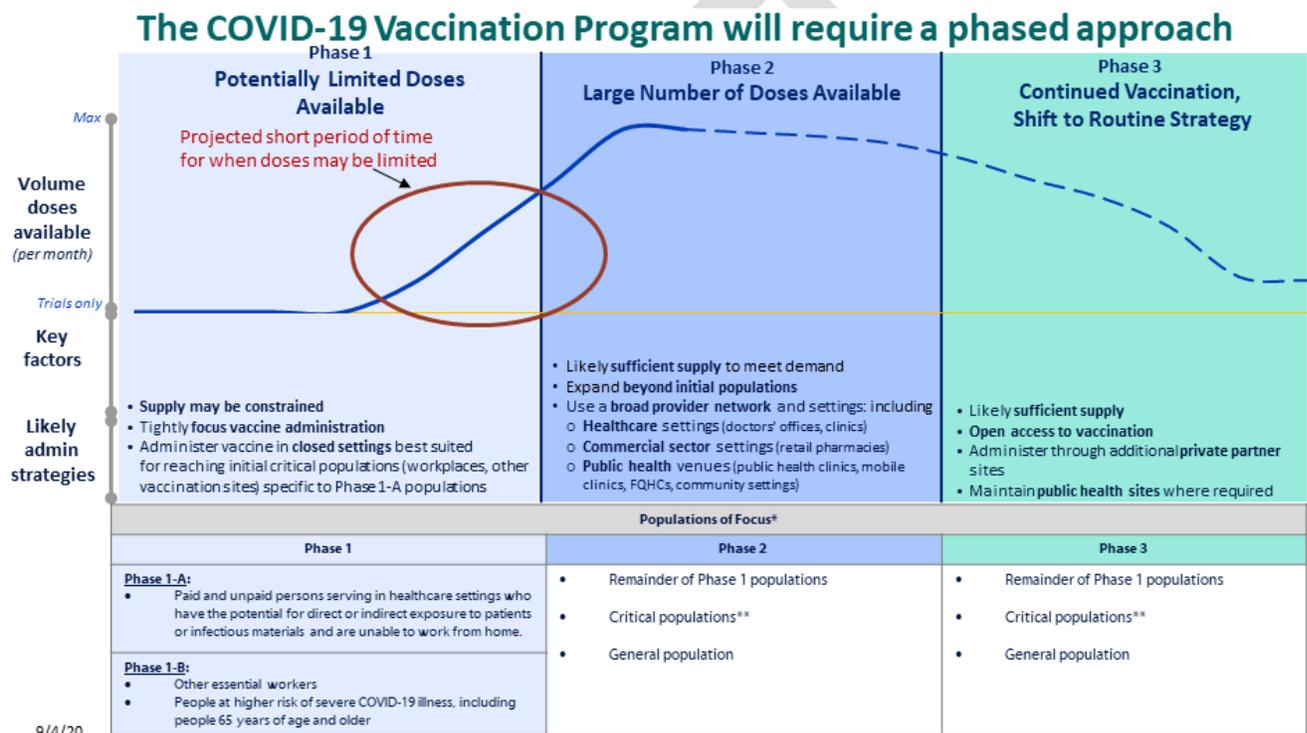
Phase 1

Phase 1 is the period of time when vaccine first becomes available and supply is extremely limited. Vaccine administration will be highly concentrated on identified Phase 1 groups to ensure sufficient access and coverage among these populations. Inventory and distribution will be most closely monitored during this phase to achieve maximum efficiency and minimize waste. It is anticipated that West Virginia's initial allocation(s) will be insufficient to meet complete demand for the first several months of the vaccination program. For this reason, prioritization of population groups is required. Changes to the prioritization framework outlined below will be necessary based on proven efficacy of vaccine candidates, disease epidemiology, further prioritization guidance from CDC and the Advisory Committee on Immunization Practices (ACIP) and vaccine acceptance among target populations.

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Phase 1 Prioritization

The first group to receive the COVID-19 Vaccine, referred to as Phase 1-A, will be healthcare personnel. This is a broad category that is defined as "any paid or unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or other infectious materials and are unable to work from home." It is possible that West Virginia's initial vaccine allocation will be insufficient to vaccinate 100% of workers who qualify as Phase 1-A, therefore more granular prioritization of healthcare personnel may be required (See Section 4, Critical Populations).

Once the COVID-19 Vaccine has been made available to all healthcare workers, vaccination will shift to targeting the non-healthcare critical workforce, or Phase 1-B. This includes any workers that are deemed necessary to maintaining the essential functions of society (See Section 4: Critical Populations). Other individuals at increased risk for severe illness from COVID-19 will be assessed and vaccinated by local health departments or sites designated by the LHD within their jurisdiction. Local jurisdictions will remain the final authority for vaccine administration based upon WVDHHR guidance but using their knowledge of local community demographics.

Administration Strategies

COVID-19 vaccination providers selected in Phase 1 will be those that demonstrate the ability to efficiently reach target populations with as much throughput as possible. This will be assessed by reviewing the method with which providers plan vaccinate (drive thru/curbside vaccination clinic, off-site clinic, mobile clinic, walk-in only, etc.) To increase efficiency, large healthcare facilities with a substantial number of employees will be given the option to manage vaccination of their own workforce. Healthcare workers not vaccinated by their employers will receive vaccine at off-site clinic locations or other closed point-of-dispensing (POD) settings. Whenever possible, vaccine will be made available at the individual's place of employment through off site clinics. Vaccinating providers who can accomplish this include pharmacies, local health departments, rural health clinics, etc. These decisions will be made in coordination with local health departments and communicated to the state.

Phase 2

In Phase 2, vaccine supply will increase dramatically, and should be sufficient to meet demand. Vaccination will remain closely monitored by WVDHHR throughout this phase. Additional availability of vaccine will allow for additional enrolled COVID-19 vaccination providers to receive vaccine. Vaccine demand should be closely monitored by local jurisdictions and strategies should be adjusted accordingly to minimize wastage.

Phase 2 Prioritization

Phase 2 will focus on ensuring access to vaccine for members of Phase 1 who were unable to be vaccinated during Phase 1 either due to lack of supply or other reasons. Vaccine will also be made available to the public during Phase 2; however, vaccination sites and strategies will be carefully selected to promote high vaccine uptake among additional critical populations. More information about additional critical populations can be found in Section 4: Critical Populations.

Administration Strategies

Phase 2 strategies will largely be the same as Phase 1, however the COVID-19 vaccination provider network will be expanded to efficiently manage the increased vaccine supply. COVID-19 vaccination

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providers selected will still be those that are best positioned to reach critical populations. Mass vaccination strategies, such as the existing drive thru model used for community testing events, will be used throughout Phase 2. Vaccination venues will be placed strategically to promote access for target populations. For example, setting up a drive thru site on a college campus to vaccinate the student population. Determining vaccination sites and strategies will be the responsibility of local health departments based on overall amounts of COVID-19 Vaccine allocated to the jurisdiction.

Phase 3

Ultimately, COVID-19 vaccine will be integrated into routine vaccination programs, run by both public and private partners. In Phase 3, WVDHHR will focus efforts on ensuring vaccine is widely available through a variety of different venues. COVID-19 Vaccine supply will be sufficient to fulfill the requests of all enrolled COVID-19 vaccination providers. WVDHHR and local jurisdictions will work to ensure that COVID-19 Vaccine is accessible to all who want it. Vaccine uptake among critical populations will continue to be monitored and assessed by WVDHHR. Strategies will be adjusted to target jurisdictions and critical populations with lower rates of uptake.

Section 4: Critical Populations

Critical Populations to Receive Initial Doses

As outlined above in Section 3, Phase 1-A and 1-B vaccination will be limited to the healthcare and non-healthcare critical workforce, respectively. These broad occupational groups are defined as follows:

- Healthcare Personnel: Paid and unpaid people serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials and are unable to work from home.
- Critical Workforce: People who play a key role in keeping essential functions of society running and cannot socially distance in the workplace.

It is unlikely that West Virginia's initial allotment will cover 100% of the entire critical workforce. Therefore, Phase 1-A and 1-B will be broken down further into smaller, more specific subgroupings. Phase 1 population subgroupings are detailed in the table below:

Phase	Subgroup	Occupation Setting/Group
Phase 1-A: Healthcare Personnel	A.1	Long term care facility staff
	A.2	Emergency Medical Services (EMS) personnel
	A.3	Hospital-based staff
	A.4	State and Local Health Department staff
	A.5	Clinic/outpatient facility staff
	A.6	Home Health/ Hospice care providers
	A.7	Pharmacy staff
	A.8	Dental office staff
	A.9	Other healthcare workers not listed above
Phase 1-B: Critical Workforce	B.1	Firefighters
	B.2	Law Enforcement
	B.3	Other First Responders
	B.4	National Guard deployed for COVID-19 response
	B.5	Childcare providers
	B.6	Congregate care facility staff
	B.7	Teachers and staff in school settings
	B.8	State and County Officials
	B.9	National Guard held in reserve
	B.10	Correctional Staff
	B.11	Postal Service Workers
	B.12	Food production, processing, and delivery
	B.13	Transportation and Material Moving

Note: Population groups outlined above are subject to change. Local jurisdictions will remain the final authority for vaccine administration based upon WVDHHR guidance but using their knowledge of community demographics.

Critical Workforce Subgroup Worksheets will be completed by each local health department to prepare for scenarios where supply is extremely limited, and subgroupings are necessary. A sample of the Critical Workforce Subgroup Worksheet is included in Appendix A.

Additional Critical Populations

In addition to the population groups which will receive the initial limited doses, other identified key population groups must be enumerated and located to ensure vaccine is accessible to all critical groups. Additional critical population groups include but are not limited to:

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

Estimating Critical Populations

Population estimates for all groups should be as accurate as possible. For some groups and subgroups, accurate estimates can be obtained from a governing body, membership organization, trade organization, etc. For example, the West Virginia Health Care Association (WVHCA) will provide the number of staff and residents in all long-term care facilities within West Virginia. Similarly, the West Virginia Division of Corrections and Rehabilitation (WVDOCR) will provide the number of staff and inmates in all prisons and jails.

Other data sources will be accessed to enumerate other population groups including the U.S. Census Bureau, CMS Quality Insights, and WVDHHR's Bureau for Medical Services, etc. When a more accurate estimate cannot be easily obtained, population data provided by CDC will be used for planning purposes.

Critical Population Mapping

WVDHHR intends to partner with the West University-affiliated group, Data Driven WV, on a data visualization project. The scope of this work is still being determined, but the primary output will be an interactive map of critical populations across the state. Data will be as granular as the county and/or zip code level. Locations of provider sites will be overlaid on this map once provider enrollment begins. This tool will be used in both the planning phase and throughout the vaccination program to assist in identifying potentially underserved areas. A basic product will be available for use by December 2020, with functionality expanding over the following 1-2 months. WVDHHR plans to make this visualization tool available to key external partners. A public-facing component is still being considered at this time.

Section 5: COVID-19 Provider Recruitment and Enrollment

Provider Outreach and Recruitment

Current recruitment efforts are focused on engaging vaccination providers that will be administering the COVID-19 Vaccine during Phase 1. These are the agencies that are best positioned to vaccinate the healthcare and critical workforce rapidly and efficiently and will include:

- Health systems/Hospitals
- Local Health Departments
- Long-term care facilities
- Free clinics
- Federally Qualified Health Centers
- Pharmacies

If a specific need or location is identified to support the direct immunization of a specific critical population additional sites may be recruited from the list below. As vaccine supply increases, WVDHHR will also continue to recruit additional vaccination providers to expand equitable access to the COVID-19 Vaccine throughout WV. These will include a variety of provider types and vaccination settings, including:

- Pharmacies
- Outpatient facilities
- Occupational Health Clinics
- Long-term care facilities
- School based health clinics
- Private provider offices
- Congregate settings
- Colleges and Universities

Local Health Departments will support the recruitment process by leveraging existing relationships with jurisdictional partners to identify vaccination providers and administration sites.

Recruitment information will be pushed to individual facilities through membership organizations engaged in the planning process including; the West Virginia Hospital Association (WVHA), West Virginia Primary Care Association (WVPCA), West Virginia Health Care Association (WVHCA), West Virginia Board of Pharmacy (WVBOP), and West Virginia State Medical Association (WVSMA). Information for COVID-19 vaccination providers will be made available on the coronavirus.wv.gov website. The Provider Enrollment Coordinator will serve as the sole point of contact to address provider inquiries and provide technical assistance throughout the enrollment process.

A map of COVID-19 vaccination provider locations will be updated and maintained throughout the COVID-19 Vaccination Program and available on the WVDHHR website. This map will be routinely monitored and distributed to DIS staff, WVDHHR and stakeholders. Review will be done to ensure statewide coverage and help identify potentially underserved areas. Targeted outreach to specific

pharmacies, clinics, and providers in underserved areas may occur to ensure the COVID-19 vaccine is accessible to all West Virginians, especially those residing in rural areas.

Provider Enrollment

All providers who wish to enroll as a COVID-19 vaccination provider must complete and submit all documentation required by CDC and WVDHHR. Information will be submitted by providers to WVDHHR using web-based forms. Provider enrollment data will be shared with CDC twice weekly. A description of the enrollment forms are as follows:

- CDC COVID-19 Vaccination Program Provider Agreement
- CDC COVID-19 Vaccination Provider Profile
- WVSIIS Provider Agreement (if not already enrolled in WVSIIS)
- WVSIIS Enrollment Form (if not already enrolled in WVSIIS)
- Vaccine Storage Agreement

Additional information will also be provided at the time of enrollment, including:

- CDC COVID-19 Vaccine Redistribution Agreement
- Instructions for documenting doses administered data via direct data entry in WVSIIS
- Instructions for ordering COVID-19 vaccine using WVSIIS
- WSIIS HIPAA Information Sheet
- WVSIIS Information Access and Confidentiality Standards
- Vaccine Adverse Event Reporting System (VAERS) information
- Emergency Use Authorization (EUA) fact sheets

Enrollment forms will be retained by WVDHHR for a minimum of 3 years and will be made available to CDC upon request.

Provider Enrollment Coordinator

A Provider Enrollment Coordinator will be identified to manage all enrollment activities. Their roles and responsibilities will include:

- Reviewing enrollment forms upon receipt to verify information is complete and accurate
- Verifying providers are licensed in the jurisdiction where vaccination will be administered using information obtained from the West Virginia Board of Medicine
- Ensuring providers are successfully onboarded into WVSIIS
- Ensuring provider information is updated in all necessary data systems (WVSIIS, VTrckS)
- Maintaining an email distribution of list of all Vaccine Coordinators and Backup Vaccine Coordinators for each site location
- Tracking the number and types of enrolled providers
- Responding to inquiries and providing technical assistance to providers, as needed
- Reporting provider enrollment data electronically to CDC twice weekly using the CDC-provided Comma Separated Values (CSV) template
- Disseminating guidance, training materials, and other information to COVID-19 vaccination providers throughout the program

- COVID-19 Vaccination Provider Training

COVID-19 Vaccination Provider Training

Training of COVID-19 vaccination providers is vital to ensure the success of the COVID-19 Vaccination Program. Pre-recorded webinars and other training materials will be made available to all enrolled provider. Training topics include but are not limited to:

- ACIP COVID-19 vaccine recommendations, when available
- How to order and receive COVID-19 vaccine
- COVID-19 vaccine storage and handling (including transport requirements)
- How to administer vaccine, including reconstitution, use of adjuvants, appropriate needle size, anatomic sites for vaccine administration, avoiding shoulder injury with vaccine administration, etc.
- How to document and report vaccine administration via WVSIIS and/or CDC's Vaccine Administration Management System (VAMS)
- How to manage vaccine inventory, including accessing and managing product expiration dates
- How to report vaccine inventory
- How to manage temperature excursions
- How to document and report vaccine wastage/spoilage
- Procedures for reporting moderate and severe adverse events as well as vaccine administration errors to VAERS
- Providing EUA fact sheets or VISs to vaccine recipients
- How to submit facility information for COVID-19 vaccination clinics to CDC's VaccineFinder (particularly for pharmacies or other high-volume vaccination providers/settings)

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Section 6: COVID-19 Vaccine Administration Capacity

"Vaccine administration capacity" is defined as the maximum achievable vaccination throughput regardless of public demand for vaccination. Statewide vaccine administration capacity must rapidly increase to efficiently vaccinate remaining critical populations and the public in Phases 2 and 3 when vaccine supply increases substantially. The number and types of provider sites will vary throughout the program depending on vaccine availability and target populations.

Local Capacity

Local Health Departments (LHDs) will establish and maintain an understanding of sustainable total capacity of COVID-19 vaccination by providers operating within their jurisdiction. LHDs will accomplish this through their historic partnerships and relationships with providers in their jurisdictions. The relationships extend from the providers to the populations the LHDs serve in the community. LHDs are tied to their communities and have worked to solve problems in the past ranging from flooding to other disease control and eradication. Local jurisdictions are encouraged to utilize CDC's PanVax Tool for Pandemic Vaccination Planning, located on the CDC website (https://www.cdc.gov/flu/pandemic-resources/tools/panvax-tool.htm). The following factors must be considered when assessing a site's vaccine administration capacity:

- Whether the site is closed (vaccinating only a certain population such as the facility's workforce or patient population) or open to all members of the community
- Method for administering vaccine (walk-ins, drive thru lanes, appointment-based, etc.)
- Vaccine storage capacity for both refrigerated, frozen, and ULC temperatures
- Population group served by the administration site
- Number of personnel available to support COVID-19 vaccination

Statewide Capacity

WVDHHR will estimate total vaccination capacity by aggregating information obtained and reported by local health departments for their respective jurisdictions.

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

Allocation

The COVID-19 Vaccine will be allocated to local jurisdictions based on the reported size of target populations within that jurisdiction. Initial Phase 1 planning allocations will be estimated for the personnel in Phase 1 priority groupings based on statewide estimates, historic reporting, and potential vaccine supply. Phase 1 estimates will be updated and refined as more information becomes available about viable vaccine products and county estimates are confirmed by LHDs.

Throughout the vaccination program, and especially when supply is limited, the COVID-19 Vaccine will be allocated to administering locations which are best positioned to efficiently vaccinate multiple target groups. See Section 3, Phased Approach to COVID-19 Vaccination.

Throughout Phase 1, all vaccination providers are expected to have administered 100% of first doses within 14 days of receipt. To minimize the need for redistribution and potential for waste, facilities should not request more COVID-19 Vaccine than they can reasonably expect to administer in a two-week timeframe.

Information about facilities' cold chain capability will be collected at the time of provider enrollment. This information will be maintained at the LHD as well as a master database with WVDHHR throughout the vaccination program and adjusted as facilities increase or reduce capacity. Specifically, this information will be collected in a master list of enrolled providers documented in VTrckS which enables WVDHHR to designate providers as being "frozen vaccine eligible." This information will be referenced at the time the COVID-19 Vaccine is allocated to different sites. If there is a point in time when two or more COVID-19 Vaccines are available for use with one vaccine having more stringent temperature requirements (ULC), sites will be selected for allocation based on capability to maintain temperatures necessary for specific vaccines.

Ordering

Notification of availability of the COVID-19 Vaccine for West Virginia to allocate across local jurisdictions will come to the WVDHHR Division of Immunization Services (DIS). Enrolled vaccination providers will request vaccine through the West Virginia Statewide Immunization Information System (WVSIIS) Vaccine Order Management System (VOMS). The Immunization Program Vaccine Manager and their designees will approve, deny, or modify requests based on current availability of the COVID-19 Vaccine and in accordance with the approved Phased Approach to COVID-19 Vaccination allocation plan. Approved vaccine requests and allocations will be transmitted to the CDC through the CDC Vaccine Tracking System (VTrckS).

Order Details

The current CDC minimum order size and increment for vaccines distributed to vaccination sites will be 100 doses per order. One Phase III trial of COVID-19 Vaccine requires ultra-cold storage temperatures between -60°C to -80°C and will likely be shipped directly from the manufacturer to administration site with a minimum order size of 975 doses. CDC will share more information on these shipments as it becomes available.

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All vaccination sites must take care to ensure accurate and complete shipping information (e.g., shipment address, provider contact information, shipping hours, phone number) are made available in their enrollment information. The Immunization Program Vaccine Manager will ensure that this information is accurate in VTrckS.

Ancillary supplies will be packaged in kits and will be automatically ordered in amounts to match vaccine orders in VTrckS. Each kit will contain supplies to administer the COVID-19 Vaccine, including:

- Needles (various sizes for the population served by the ordering vaccination provider)
- Syringes
- Alcohol prep pads
- Surgical masks and face shields for vaccinators
- COVID-19 vaccination record cards for vaccine recipients

For COVID-19 vaccines that require reconstitution with diluent or mixing with adjuvant at the point of administration, mixing kits with syringes, needles, and other needed supplies will also be included. Ancillary supply kits <u>will not include sharps containers, gloves, and bandages</u>. Additional personal protective equipment (PPE) may be needed depending on vaccination provider site requirements but will not be provided by the CDC. The State of West Virginia currently has a six-month reserve supply of PPE which it will be prepared to distribute if needed. WVDHHR is prepared to provide some of the ancillary supplies if available through an ETEAMs request which can be made at any time by a provider or site with a final determination of need made by WVDHHR.

Certain federal facilities will order and receive the COVID-19 vaccine directly from CDC and will not impact the allocation number for vaccine distribution to the State of West Virginia. These sites include but are not limited to federal prisons and federal pharmacy partners with the CDC responsible for approval of those orders. These orders are not expected to be tracked and reported by WVDHHR.

Distribution

Upon approval by WVDHHR, most vaccine requests and allocations of vaccines and ancillary supplies will be distributed by the CDC's distribution center directly to the provider site in West Virginia. If the ultra-cold COVID-19 Vaccine is approved, it will be shipped directly from the manufacturer to the vaccination provider site. The COVID-19 Vaccine (and diluent or adjuvant, if required) will be shipped to vaccination provider sites within 48 hours of order approval. Because of cold chain requirements, ancillary supply kits (and diluent, if applicable) will ship separately from the vaccine but should arrive before or on the same day as the vaccine.

The CDC Vaccine Distribution Centers use validated shipping procedures to maintain the COVID-19 Vaccine cold chain and minimize the likelihood of vaccine loss or damage during shipment. Once a vaccine product has been shipped to a COVID-19 vaccination provider site, it is the responsibility of the WVDHHR and/or the vaccination provider site to store and handle the vaccine appropriately to ensure its viability.

Redistribution

Whenever possible, the COVID-19 Vaccine will be shipped to the location where it will be administered to minimize potential breaks in the cold chain. However, there may be circumstances where the 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 such as large multi-county health systems whose vaccine is shipped from a central depot and requires redistribution to additional clinic locations).

The WVDHHR Immunization Program will be judicious in allowing redistribution and may limit any redistribution to refrigerated vaccines only. Vaccine redistribution will only be approved if there is reason or circumstances to conclude that redistribution will result in more people being vaccinated that otherwise would not. Redistribution will not be considered merely for the convenience of the administering provider. If redistribution is approved, validated cold-chain procedures must be adhered to in accordance with the manufacturer's instructions and CDC's guidance on the COVID-19 Vaccine storage and handling. These entities must sign and agree to conditions in the *CDC COVID-19 Vaccine Redistribution Agreement* for the sending facility/organization and have a fully completed and signed *CDC COVID-19 Vaccination Provider Profile* form for each receiving location. Redistribution requests will be sent to the Local Health Departments via email ensuring to provide location requesting to redistribute from, reason for the request, and the proposed timeline to complete the request. This email will be forwarded to both WVDHHR DIS AND WVDHHR Incident Command for complete situational awareness and final approval or denial will be granted as soon as possible (anticipated to be within 24 hours) by DIS.

Inventory Management

COVID-19 vaccination providers will be required to report inventory of their COVID-19 Vaccine stockpile to allow for oversight of vaccine distribution. Further, COVID-19 vaccination providers will be required to update their current inventory with each request for vaccine via the HL7 and/or direct data entry reporting systems. During the initial phase of the vaccine program CDC's VAMS system may also be used to ensure all data-based needs are met.

COVID-19 Vaccine Recovery

Details of any COVID-19 Vaccine recovery are still being finalized and will be communicated when available. Recovery of the COVID-19 Vaccine will depend on on-hand supplies, public demand, and current phase of distribution.

Section 8: COVID-19 Vaccine Storage and Handling

COVID-19 vaccine products are temperature-sensitive and must be stored and handled correctly to ensure efficacy and maximize shelf life. Proper storage and handling practices are critical to minimize vaccine loss and limit risk of administering COVID-19 vaccine with reduced effectiveness.

It is expected that cold chain storage and handling requirements for the various COVID-19 vaccines will vary in temperature from refrigerated (2°C to 8°C) to frozen (-15 to -25°C) to ultra-cold (-60°C to -80°C). Updated information about cold chain storage requirements as the vaccine candidates move through the FDA process will be communicated to providers as it becomes available.

All COVID-19 vaccination provider sites will be required to complete a Vaccine Storage Agreement as part of the COVID-19 Vaccination Provider enrollment process. The submission of this form certifies that the facility has the appropriate storage units to store potential COVID-19 Vaccines according to the temperature requirements for current refrigerated and frozen vaccines candidates. Ultra-cold storage capacity will not be a requirement for COVID-19 vaccination sites. If providers do receive the ultra-cold COVID-19 Vaccine candidate, it will be shipped in a container equipped with dry ice that can safely house the vaccine until administration.

Provider Storage and Handling Requirements

- Staff training on vaccine storage and handling
- Standalone Refrigerator and Freezer units that can maintain 2°C to 8°C and -15 to -25°C
- A continuous temperature monitoring device that records refrigerator and/or freezer temperatures periodically and stores the data on a retrievable USB port
- A reliable vaccine inventory management system, preferably an "HL7" medical records management system to interoperate with WVDHHR's WVSIIS Vaccine Order Management System (VOMS)

Satellite, Temporary, and Off-Site Clinic Storage and Handling Considerations

Satellite, temporary, or off-site clinics will be approved by the Immunization Program only after careful consideration of the circumstances necessitating them. If approved, these situations will require additional oversight and enhanced storage and handling practices.

Section 9: COVID-19 Vaccine Administration Documentation and Reporting

Provider Reporting

All vaccinating providers will use CDC's VAMS program to submit "doses administered" data, during Phase 1. An evaluation of VAMS will discern when and if West Virginia will start using the WV Immunization Information System (IIS). If possible, WV providers will transition electronic reporting to "HL7," however, facilities that do not have an HL7 capable EMR will submit information via direct data entry (DDE) into the IIS.

All providers will be required to enroll their facility and their individual users in the system before any vaccine orders will be filled. Training materials will be provided by the CDC for the use of VAMS at the time of enrollment if the provider is using VAMS and materials will be supplied by WVDHHR DIS is providers are using HL7 within IIS. The expectation to enter doses administered data at the time of vaccination will be communicated in the enrollment process. Division of Immunization Services (DIS) staff will develop a checklist for each site before their go-live with COVID-19 Vaccine administration, to ensure that each site is ready and able to submit data to the IIS.

IIS staff will be available through IIS Helpdesk to provide technical assistance to COVID-19 vaccination providers throughout the program. In the event of a network outage or other unforeseen technology issue that prevents a facility from reporting, providers must immediately notify IIS staff. A form will be provided for analog recording of the patient/vaccine information.

Reporting to CDC

During Phase 1, while using VAMS, West Virginia will be receiving data through HL7 from CDC using the connect/Share component of the Immunization (IZ) Gateway. If/when WV switch to using the IIS full time to collect data, then the data from the IIS will be pushed to CDC to flow into the data lake. This data is gathered to ensure that all doses are accounted for and accountability is maintained.

Monitoring

COVID-19 vaccine orders will be tracked using VAMS in Phase 1 and efforts will be made to use the WV IIS (Immunization Information System) in Phase 2. The vaccine ordering module and the CDC application, VACMAN will be used to place orders for vaccine after an approved pandemic. IIS staff will routinely monitor facility level data for all provider sites to ensure timely and accurate reporting. All COVID-19 reporting should happen within 24 hours of vaccine administration. If a facility fails to meet reporting requirements, IIS staff will contact the facility to identify and resolve the issue. If the problem persists, no subsequent vaccine orders for that provider site will be filled.

Vaccination Coverage Reports

During Phase 1, VAMS reports will be used for coverage and when using the IIS, the built-in data coverage reports will be used to review vaccinations given. The data will then be used to produce GIS maps for graphical representation of statewide coverage. COVID-19 vaccination data will be added to West Virginia's existing influenza dashboard. This will allow coverage to be assessed at both the state and county level and compared to identified pockets of need.

Preliminary draft submitted to CDC for comment and review. Subject to change based upon final guidance to be released by CDC and ACIP.

Section 10: COVID-19 Vaccination Second-Dose Reminders

For most COVID-19 vaccine candidates, two doses of vaccine, separated by 21 or 28 days, will be needed. Because different COVID-19 vaccines will not be interchangeable, a vaccine recipient's second dose must be from the same manufacturer as their first dose. Second-dose reminders for vaccine recipients will be critical to ensure compliance with vaccine dosing intervals and achieve optimal vaccine effectiveness. Ensuring patients receive the full series is the responsibility of COVID-19 vaccination providers.

COVID-19 vaccination record cards will be provided as part of vaccine ancillary kits. Vaccination providers will be highly encouraged to complete these cards with accurate vaccine information (i.e., vaccine manufacturer, lot number, date of first dose administration, and second dose due date), and give them to each patient who receives vaccine to ensure a basic vaccination record is provided. Providers should make every attempt to schedule a patient's second-dose appointment when they get their first dose.

Additionally, VAMS has built in functionality for second dose reminders. This includes text messages to patients that reminds them to schedule another appointment after they receive their first dose. VAMS also sends appointment reminders 24 hours before a scheduled appointment. More information about the full scope of the system's capabilities is forthcoming.

DIS will routinely analyze doses administered data captured in WVSIIS to determine the percentage of patients who successfully complete the series. If a specific provider site is identified as having consistently high numbers of patients with incomplete series, the facility will be notified and provided with additional guidance and technical assistance to help improve second-dose compliance.

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

During Phase 1, West Virginia will be using the VAMS application to track all healthcare workers under Phase 1A and critical workforce under Phase 1B. During Phase 2, WV DIS will attempt to transition to IIS and associated systems to allow providers streamlined service in connection with their normal vaccination procedures.

Immunization Information System (IIS) Enrollment

Providers will enroll their facility and users in the IIS at the time they enroll as COVID-19 vaccination providers. The ability to provide the COVID-19 vaccine will occur separately and any facilities that are already enrolled in the WVSIIS will not need to enroll again for the IIS. However, all providers should verify that their facility information is correct and that the appropriate users are enrolled. Enrollment information will be collected using the standard IIS enrollment forms and entered into WVSIIS by program staff. Enrollees will be notified of their status within two weeks and enrolled in the COVID-19 vaccine ordering group.

Documentation in high-volume vaccination settings

WVSIIS contains a mass immunization module that allows for setup of vaccine lots and then quick entry of demographic information and association of the lot to the demographic info via a click/select. There is a paper form that can be used as a contingency in the event of network outages that is filled out and entered in the IIS within 12 hours, this form will be included in the pandemic enrollment packet.

Data Variables

CDC requires the following elements be captured and reported for each person who receives COVID-19 vaccine:

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

In addition to the data elements listed above, West Virginia will collect the following for maximum target population vaccination and total inoculation measurements:

- Recipient race
- Recipient ethnicity
- Serology results (presence of positive results)
- Occupation/membership in critical group

Immunization Information System (IIS) Capacity

West Virginia Statewide Immunization Information System (WVSIIS) can accept data via direct data entry, a flat file, and HL7. Providers who are not currently sending HL7 files they will need to go through a testing phase to ensure that all data elements are being sent completely and captured in the IIS. WVSIIS will work with vendor (STC) to prioritize testing and implement fixes for defects and enhancements that impact the IIS's ability to support COVID-19 response efforts. We will also check new software releases/ fixes on our platform before we move to production.

Data storage is auto expanded when necessary, per yearly agreement. The IIS will be updated in late October to have the ability to collect the professions of immunized persons and record serological evidence of immunity to the COVID-19 virus.

Immunization (IZ) Gateway

West Virginia plans to onboard to the IZ Gateway "Connect" and "Share" components to enable data sharing with CDC and other jurisdictions. The data use agreement provided is under legal review at this time.

Data Quality

Immunization Staff will monitor vaccines ordered vs. wasted/given, as well as patient record fields to ensure that we are collecting required information and all COVID-19 Vaccine doses are accounted for. For vaccine accountability, WVSIIS tracks inventory via lot numbers and will monitor receiving, use and expirations. Vaccine waste is reported in the IIS and monitored by DIS.

Section 12: COVID-19 Vaccination Program Communication

Starting before the COVID-19 Vaccine is available, clear and effective communication will be essential to implementing a successful COVID-19 Vaccination Program. Building vaccine confidence broadly and among groups anticipated to receive early vaccination, as well as dispelling vaccine misinformation, are critical to ensure vaccine acceptance and uptake.

Objectives of COVID-19 Vaccination Program Communications

- Communicate to all West Virginians that:
    - COVID-19 remains a risk to individuals and their communities and that every individual plays an important part in keeping their community safe.
    - West Virginians can protect themselves and each other if they are vaccinated.
    - West Virginians can continue to protect themselves and each other by washing their hands, wearing masks, socially distancing, and staying home when sick.
    - Vaccination will play a significant role in bringing an end to the COVID-19 pandemic and an eventual return to "normalcy".
- Provide timely information to the public about COVID-19 vaccine(s) development, recommendations, and public health's efforts.
- Inform the public about the State of West Virginia's Vaccine Distribution Plan and COVID-19 vaccination provider locations.
- Work with partners and stakeholders to utilize key influencers and a targeted messaging campaign to inform the public about the COVID-19 vaccine and its benefits.
- Track and monitor public receptiveness to COVID-19 vaccination messaging.
- Use the Crisis and emergency risk communication (CERC) principles include:
    - Be First
    - Be Right
    - Be Credible
    - Express Empathy
    - Show Respect

Communications Campaign

COVID-19 vaccine communication strategies will be employed by the Governor's Office, the West Virginia Department of Health and Human Resources (DHHR), and the National Guard. The West Virginia Immunization Network (WIN), a program of the Center for Rural Health Development, will also conduct a statewide communication campaign to increase knowledge and acceptance of COVID-19 vaccine(s) in West Virginia. To do so, WIN will collaborate with a university research team (WVU Reed College of Media Public Interest Communication Research Lab) to develop and conduct preliminary and ongoing vaccine communication research, including both qualitative and quantitative methods, to understand vaccine-relevant perceptions, behaviors, and message reception among residents of West Virginia. The findings will be used to inform the development and implementation of a communication campaign to increase awareness among residents of West Virginia, including high-risk, minority and rural populations, about the availability, safety, and efficacy of COVID-19 vaccines. The COVID-19 vaccine communications messaging will align with the allocation and distribution of vaccine through phases as identified in this plan; incorporate additional vaccines that come on the market after others; and adjust for potentially varying indications and/or ACIP recommendations for each vaccine.

The COVID-19 Vaccine Communications and Messaging Workgroup, as detailed in Section 2, will be also be engaged in the development and dissemination of messages to ensure support from their organizations as well as broad distribution of messages.

Messaging

Key messaging will convey the following:
- Safety and efficacy of the vaccine but also in the people, institutions, and policies behind the vaccine.
- Transparency and community engagement to boost public confidence in allocation decision-making.
- Amplification of vaccine-affirming, personally relevant messages to help neutralize misinformation about COVID-19 vaccines and vaccination operations.
- Address likely delays during vaccine testing, licensure, distribution, and administration, and convey to the public how this could affect vaccine availability. Frank acknowledgment of positive and negative vaccine outcomes – for example, ranging from no available vaccine, to limiting vaccination to high-risk groups, to having a licensed product in ample supply – could help further calibrate public expectations around vaccine availability.

Messaging Considerations

- Key messaging must align with the CDC, as well as the U.S. Department of Health and Human Services, but also needs to be tailored to a West Virginia-specific audience to address challenges and opportunities in the Mountain State. Traditional messaging promoting vaccinations utilizing authoritative and fact-filled data has been shown to not work outside of the operational medical community. Effective strategic and specific messaging must instead target emotional response and speak directly to the fears, concerns, and both short- and long-term advantages of receiving the COVID-19 vaccine (e.g. personal and family safety, ability to return to "normal" lifestyles). Information must be presented in culturally and linguistically responsive language. Shifts in messaging will occur to reflect the current stage of vaccine distribution (before vaccine is available, limited availability, and widespread availability).
- Messaging must use plain language that is easily understood.
- Messaging must be developed with consideration for health equity

Messaging Research

The Center for Rural Health Development has contracted with the West Virginia University (WVU) Public Interest Communication Research Lab to monitor vaccine-relevant perceptions, behaviors, and message reception among residents of West Virginia to inform the creation of effective messaging with critical and diverse communities in the state.

Communication Channels

Free

- Posts on social media
  - These can include messages from state officials and/or messages from community members to humanize the message.
- Editorials from state/local health officials and other earned media, such as press releases and interviews
- Social media graphics/messaging

- Internal e-blast to encourage employees to share messaging from new campaign; possibly include links to download any materials that can be displayed in county offices
- Engage stakeholders at the local level, such as local health departments and healthcare providers, as well as community partners to disseminate information to the public
- Governor, WVDHHR, national guard, other applicable state agencies (ex. OEMS) and community partners share accurate and consistent messages created by partners, such as the West Virginia Immunization Network through the Center for Rural Health Development and CDC

Paid

- Public Service Announcements (30 second videos) through the WV Broadcaster's Association to air statewide
- Radio Spots
- Postcards to hand out at high density testing events OR posters to hang in high visibility areas in these testing locations (cost due to printing)
- Digital advertising and/or social media advertising to boost posts (cost due to placement)
    - Geofencing
    - OTT (Over-the-Top) video on streaming services to reach "cord-cutters'
    - Display with keyword targeting impressions
- Billboard purchases
- Place messages on public transportation, intersections, and other high traveled areas
- Texting

Target Audiences

This campaign aims to reach all West Virginians. Key audiences include minority and vulnerable populations such as the elderly, individuals with underlying health conditions, and residents of congregate care facilities. Additional audiences include health care workers, first responders, and essential workers.

Spokespersons and Influencers

Key influencers and social media champions will be engaged to promote and amplify messaging and disseminate pertinent information related to COVID-19 vaccine and distribution. Examples of key influencers/populations:

- Governor Jim Justice
- MG James Hoyer, WVNG Adjutant General
- Cabinet Secretary Bill Crouch, WVDHHR
- Dr. Ayne Amjad, State Health Officer and Commissioner of the Bureau for Public Health
- Dr. Clay Marsh, Coronavirus Czar, WVU Medicine Vice President and WVU Health Sciences Executive Dean
- Public Health experts – Health or Medical Directors of Local Health Depts.
- Health professionals – physicians, nurses, pharmacists
- Minority populations
- Disabled populations
- Sports – WVU, Marshall
- Politics – Legislature, County Commissions, Mayors, etc.
- Media
- Celebrity
- Artists
- Academics

- Faith-based leaders
- West Virginia Immunization Network, Center for Rural Health Development

Section 13: Regulatory Considerations for COVID-19 Vaccination

It is anticipated the COVID-19 Vaccine will initially be authorized under an Emergency Use Authorization (EUA). It will be important for vaccinating providers to maintain current knowledge of the EUA to ensure it is being administered in accordance with all stated requirements. Product-specific EUA fact sheets for COVID-19 vaccination providers will be made available by the Food and Drug Administration (FDA) and 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. Once available, WVDHHR will disseminate EUA information to all providers enrolled in the COVID-19 Vaccination Program via email. There will also be links to EUA information posted on the https://www.coronavirus.wv.gov website so they are easily accessible to both providers and the public. Vaccinating providers will be required to provide the recipient fact sheet to each patient prior to administering vaccine.

Vaccines *authorized* under an EUA will contain slight variations from *approved* Food and Drug Administration (FDA) products, including:

- Expiration Date**:** The vaccine vials and cartons will not contain a printed expiration date. Expiration dates may be updated based on vaccine stability studies occurring simultaneously with COVID-19 vaccine distribution and administration. Current expiration dates by vaccine lots for *all authorized* COVID-19 vaccines will be posted on a US Department of Health and Human Services (HHS) website (weblink pending) and will be accessible to all COVID-19 vaccination providers. To ensure that information systems continue to work as expected, CDC has worked with FDA and the manufacturers to include a two-dimensional (2D) barcode on the vaccine vial (if possible) and carton (required) labels that includes a National Drug Code (NDC), lot number, and a placeholder expiration date of 12/31/9999 to be read by a scanner. The placeholder 12/31/9999 expiration date is not visible on the vaccine packaging nor found anywhere else; it is only to facilitate information system compatibility. CDC is developing "beyond use date" (BUD) tracker labels to assist clinicians with tracking expiration dates at the point of vaccine administration. The label templates will be available on the CDC website.
- Manufactured Date**:** A ***manufactured*** date will be on the packaging and ***should not be used as or confused with an expiration date*** when documenting vaccine administration. This date is provided to help with managing stock rotations; however, expiration dates should also be considered (see above) as using manufactured date alone could have some limitations.
- 2D Barcode**:** The 2D barcode available on the vaccine carton (also on the vials for some vaccines) will include NDC, lot number, and a placeholder expiration date of 12/31/9999.
- QR Code**:** Each vaccine manufacturer will include a Quick Response (QR) code on the vaccine carton for accessing FDA-authorized, vaccine product-specific EUA fact sheets for COVID-19 vaccination providers and COVID-19 vaccine recipients.

Section 14: COVID-19 Vaccine Safety Monitoring

Per the *CDC COVID-19 Vaccination Program Provider Agreement*, COVID-19 vaccination providers are required to report adverse events following COVID-19 vaccination and should report clinically important adverse events even if they are not sure if the vaccination caused the event. Guidance on adverse events following immunization and instructions for reporting electronically will be provided at the time of provider enrollment.

Reporting of COVID-19 Vaccine Adverse Events

Healthcare providers are required to report clinically important adverse events following COVID-19 vaccination to VAERS. VAERS is a national early warning system to detect possible safety problems with vaccines. Anyone—a doctor, nurse, pharmacist, or any member of the public—can submit a report to VAERS. VAERS is not designed to detect whether a vaccine caused an adverse event, but it can identify "signals" that might indicate possible safety problems requiring additional investigation. The main goals of VAERS are to:

- Detect new, unusual, or rare adverse events that happen after vaccination
- Monitor for increases in known side effects
- Identify potential patient risk factors for particular types of health problems related to vaccines
- Assess the safety of new vaccines such as COVID-19 vaccines
- Detect unexpected or unusual patterns in adverse event reports

WVDHHR will ensure that all COVID-19 vaccination providers understand the procedures for reporting adverse events to VAERS as part of the COVID-19 vaccine program enrollment process.

Additional COVID-19 Vaccine Safety Monitoring System

The Vaccine Safety Datalink (VSD) is a collaboration between CDC's Immunization Safety Office and nine healthcare organizations. This active, real-time surveillance system monitors electronic health data on vaccination and medical illnesses diagnosed in various healthcare settings and conducts vaccine safety studies based on questions or concerns raised from medical literature and VAERS reports. This national level system looks for macro-level trends that may signal to the CDC or FDA further study is required to ensure the safety of a vaccine.

The Clinical Immunization Safety Assessment (CISA) Project is a partnership between CDC and several medical research centers that provides expert consultation and conducts clinical research on vaccine-associated health risks.

Post-Licensure Monitoring

Phase 4 safety monitoring and research begins after a vaccine is licensed and recommended for public use. The ACIP continues to monitor vaccine safety and effectiveness data even after the vaccine's routine use and may change or update recommendations based on that data. Additionally, the FDA requires all manufacturers to submit samples from each vaccine lot prior to its release. Manufacturers must provide the FDA with their test results for vaccine safety, potency, and purity. Each lot must be tested because vaccines are sensitive to environmental factors like temperature or contamination.

Collection of VAERS Reports by WVDHHR

A designated VAERS Coordinator will be identified to serve as the sole point of contact for adverse events occurring in and reported by facilities administering COVID-19 vaccine. The VAERS Coordinator will ensure timeliness of reporting and will work with vaccination providers to report all adverse events. The VAERS Coordinator will be responsible for:

- Receive reports and organize them in a system that makes reports retrievable by patient name, jurisdiction, and after characterization by the FDA, serious and non-serious
- Summarize reports for the WVDHHR Secretary, State Health Officer and other officials within the WVDHHR command structure
- Submit reporting information to CDC and the FDA as required
- Prepare essential communications for COVID-19 vaccine providers and WVDHHR officials
- Answer questions from COVID-19 vaccine providers concerning the submission of VAERS reports

Section 15: COVID-19 Vaccination Program Monitoring

The DIS will oversee continuous monitoring throughout the COVID-19 Vaccination Program to ensure the program is achieving desired outcomes. Data for key indicators will be routinely collected and analyzed to assess progress and identify areas for improvement. Monitoring activities will include programmatic and budgetary oversight and accountability, providing assistance for partners and stakeholders, and utilizing data from both the Weekly Flu Vaccination Dashboard and COVID-19 Vaccination Response Dashboard to identify trends and emerging issues to improve the outcome of the program.

A COVID-19 Vaccination Response Dashboard will be utilized from SAMs and the CDC public facing website for data, specifically for planning estimates of critical population categories, number and attributes of healthcare providers, and facilities and other priority areas. Implementation data will be accessed for the number of enrolled COVID-19 vaccination providers, COVID-19 vaccine supply and distribution, COVID-19 vaccine administration locations along with COVID-19 vaccine administration data. Providers will be able to review the CDC website for COVID-19 Vaccination Response data.

Resource Monitoring

The DIS will regularly monitor resources to avoid unexpected obstacles to the progress of the COVID-19 Vaccination Program.

Staffing

The WVDHHR DIS understands a key to a successful COVID-19 Vaccination Program is to employ enough staff to adequately handle any adverse situations that may arise during the execution of the plan and ensure situational awareness throughout. Specialized expertise is required at all levels for this effort to be a success.

We are currently working to add five employees as soon as possible that will be contracted to build DIS workforce capacity during the planning and implementation of the COVID-19 Vaccination Program. These additional personnel will be hired to conduct activities such as COVID-19 vaccination provider outreach and developing and disseminating training for enrolled providers. Employees will be introduced to providers as they are onboarded in an effort to allow a smooth transition for this additional workforce.

We will have backups for each specialty area to guard against any interruption of the execution of the COVID-19 Vaccination Plan because of illness or other limiting personal situations. DIS managers and supervisors will regularly check in with and support assigned staff's wellness and overall resilience to perform the assigned tasks which will ensure longevity of the program.

Supplies

Certain supplies required for vaccination will be stockpiled to prepare for potential supply chain disruptions that may impact the availability of supplies. WVDHHR Health Command will be responsible for monitoring inventory levels and tracking all distribution of stockpiled materials. When quantities and specific items are physically acquired by West Virginia, they will be published for situational awareness on ETeams.

WVDHHR will have limited visibility into supply levels at individual provider sites. It is important that inventory is routinely monitored at the facility level, so any resource needs are quickly identified and reported immediately to DIS and WVDHHR Health Command.

Communications Monitoring

DIS will continuously monitor CDC's messaging throughout the COVID-19 vaccination response through all-jurisdiction calls, regular email communication, and website updates. WVDHHR Communications will routinely monitor both CDC and local-level messaging to avoid variations in messaging that could create confusion and hamper the effective implementation of the vaccination program. Messaging will be created with the goal to be clear, current, and appropriate for the intended audience. The WVDHHR Office of Communications will monitor social media to assess message delivery, reception and dispelling inaccurate information. More information about communications and messaging can be found in Section 12, COVID-19 Vaccination Program Communication.

Local Jurisdictions Monitoring

Throughout the COVID-19 Vaccination Program, the DIS will monitor and maintain awareness of local-level strategies and activities, providing technical assistance as needed. The DIS will track common issues and areas of concern to make recommendations and provide guidance from CDC and state and local authorities.

Public-facing Metrics

The COVID-19 Vaccination Program will be of significant interest to stakeholders, the media, and the public. Key programmatic metrics will be added to the existing West Virginia COVID-19 Dashboard, housed on the https://www.coronavirus.wv.gov website. Metrics will include the number of doses distributed, number of doses administered, number of provider sites that have received COVID-19 vaccine, and number of provider sites actively administering COVID-19 vaccines. Data will be updated daily to promote program transparency.

Appendix A – Critical Workforce Subgroup Worksheet

Subgroup	Agency/ Organization	POC Name	POC Number	POC email	Estimated #
Long-term care					
Hospitals/ Health Systems					
Public Health					
EMS					
FQHCs/RHCs					
Pharmacies					
Home Health Agencies					
Dental Offices					
Other					