

COVID-19 Vaccination Plan

OHIO

Ohio Department of Health
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Instructions for Jurisdictions

The COVID-19 Vaccination Plan template is to assist with development of a jurisdiction's COVID-19 vaccination plan. Jurisdictions should use this template when submitting their COVID-19 vaccination plans to CDC.

The template is divided into 15 main planning sections, with brief instructions to assist with content development. While these instructions may help guide plan development, they are not comprehensive, and jurisdictions are reminded to carefully review the *CDC COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations* as well as other CDC guidance and resources when developing their plans. Jurisdictions are encouraged to routinely monitor local and federal COVID-19 vaccination updates for any changes in guidance, including any updates to the *CDC COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations*.

INTERIM DRAFT

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.*

Since the beginning of the COVID-19 pandemic, the State of Ohio has led a robust response to the virus focusing on education, prevention, testing, tracing and treatment, setting an example for the rest of the country. Ohio responded quickly to COVID-19 by organizing a multi-agency and collaborative unified response team comprising of individuals from the Governor's Office, Emergency Management Agency, the Ohio Department of Health, and others to ensure the identification of priorities, and rapid problem-solving. Our first priorities included creating a comprehensive hospital and health care response plan, addressing the unique needs of congregate settings, establishing a comprehensive PPE procurement plan, and creating a data infrastructure to help inform decisions and ensure public transparency.

The state acted quickly and decisively to control the spread of the virus and responsibly reopen, through the early implementation of stay at home orders and business restrictions. Ohio's economy is showing signs of recovery, adding 45,500 jobs in August. When the national 'surge' in new cases began in July, Ohio had already begun ramping up testing capacity. In September, Ohio achieved a 7-day average of 31.5 thousand COVID-19 tests administered per day, with a positivity rate below 3%.¹ The creation of a statewide distribution infrastructure, limiting virus spread, successful phased-in reopening, deployment of PPE and supplies, establishment of a public engagement strategy and public trust together set the stage for Ohio to launch a comprehensive COVID-19 vaccination program, bringing an end to the COVID-19 pandemic in the state.

As the state prepares for the approval and delivery of a vaccine, the state's key priorities remain to flatten the epidemiologic curve, limiting the spread of COVID-19 and saving lives. Through the rigorous and proactive implementation of a comprehensive vaccine delivery program, Ohio will once again lead the nation with its public health response.

The Ohio Department of Health Immunization Program and Bureau of Health Preparedness have been collaborating on pandemic plans along with local health departments and other partners since the 2009 H1N1 vaccination campaign, including most recently a response to a surge in Hepatitis A cases beginning in April 2018.

In early March, the State of Ohio created a standalone, dedicated entity to coordinate and lead the end-to-end pandemic response and report directly to the Office of Governor Mike DeWine. This structure, the Governor's Pandemic Response and Recovery Leadership Team, is led by Adjutant General of Ohio John C. Harris and includes senior leaders from numerous

¹ Methodology limitation to note: positivity rate is connected to number of tests administered

organizations, including but not limited to: Ohio Governor's Office, Ohio Department of Health, Ohio Emergency Management Agency, Ohio National Guard, and Ohio Bureau of Workers' Compensation. In March, members of the Ohio Department of Health began reviewing lessons learned from H1N1 and flu vaccination campaigns and started preparing for a COVID-19 vaccination campaign.

Beginning in mid-August, the Ohio Department of Health began a weekly strategy meeting with broad representation from various programs and sections in the department about COVID-19 vaccination. Beginning in early September, the Governor's Pandemic Response and Recovery Leadership Team stood up a Vaccine Preparedness Office, which is a subcommittee of senior leaders, project managers, and subject matter experts dedicated to vaccination program planning. This team includes Ohio Department of Health Interim Director Lance Himes, senior Department of Health Immunization Program Chiefs, public sector operations experts from the Ohio Emergency Management Agency, and others. The team is charged with vaccination program planning and readiness across each step in the vaccine lifecycle (from site enrollment and registration to tracking and funding). In referencing the 2009 H1N1 vaccination campaign, seasonal influenza campaign knowledge, Hepatitis A campaign learnings, federal guidance, and expert knowledge (e.g., university centers), the team identified unique issues that will define the scope and complexity of this vaccination effort in order to proactively address them. These include:

- Pace of vaccine development multiple times faster than any previous effort.
- Scale of vaccine administration multiple times larger given aspirations for broad vaccine adoption and necessity to track adult vaccinations.
- Complexity of vaccines exceeds any other set of vaccines as multiple products may come to market together with differences in administration (e.g., second-dose), transport requirements, and storage protocols (e.g., freezer, ultra-cold).
- Increasing vaccine hesitancy (e.g., 50% of Americans report they are unsure or would refuse being vaccinated²).
- Impact the vaccination has on lives and livelihoods as broad vaccination will play a role in both limiting the virus's spread as well as enabling continued economic reopening.
- Urgency for accelerated flu vaccination to prevent concurrent peaks in administration and mitigate potential risk of simultaneous flu and COVID-infected patients; and resulting impacts on healthcare capacity.
- Anticipating public perception about a new vaccine and initiation of the necessary efforts to ensure maximum participation and health equity in the campaign.

Finally, previous vaccination campaigns have strengthened relationships between the Ohio Department of Health, local health departments, and some new partners, such as correctional facilities and behavioral health centers. These relationships will benefit the state during the COVID-19 vaccination response.

As far as H1N1 lessons learned, the Association of Ohio Health Commissioners (AOHC), in collaboration with researchers from The Ohio State University's (OSU) College of Public Health's

²The AP-NORC Center for Public Affairs Research; National Governor's Association

Center for Public Health Practice and The University of Cincinnati's College of Medicine, developed and implemented a comprehensive H1N1 response evaluation project. This dynamic evaluation system addresses a broad array of public health emergency response operational issues, best practices, and challenges faced in providing essential public health services to Ohioans during a pandemic. Six capabilities are addressed including: 1) Mass Vaccination, 2) Volunteer Management, 3) Community Mitigation, 4) Interoperable Communications, 5) Risk Communications, and 6) Epidemiologic Surveillance and Investigation. Sixty-one local public health departments in the State of Ohio voluntarily participated in the evaluation, providing data for phase one (August – December 2009) and phase two (January – March 2010). Findings provided in this report include qualitative data analysis which is intended to give an in-depth understanding of how things developed and were managed over the 2009-2010 H1N1 mass vaccination response.

Several overarching themes did emerge from the analysis of the evaluation data collected for this project. These themes can serve as touchstones for future policy adaptations that will allow for even greater effectiveness in mounting the public health response for future emergencies, such as COVID-19. These themes are described below.

Communication:

Consistency of information was a significant issue throughout the six month data evaluation period. Of critical importance was that public health emergencies are fluid, constantly changing with the passage of time. As new information and best practices regarding response emerge, local public health officials are charged with implementing real-time responses to maximize public health protections. Communications are central to effective response plans. These communications are multi-directional including within the workforce (up and down the chain of command), across affiliated organizational partners, between media, and to the general public. Of particular importance is that local area leadership be afforded the flexibility in establishing and implementing methods that best serve the populations they serve. Local area leadership will be given the flexibility to tailor messages to their particular audiences. Therefore, Ohio is emphasizing the importance of communications and stakeholder engagement throughout the COVID-19 vaccination deployment efforts.

Training and Education:

Advanced preparation as well as just-in-time training are essential for future public health emergency response operations. Maintaining core clinical skillsets within the public health workforce as well as available volunteers are equally essential. Local leadership must continue to be vigilant about maintaining fundamental, basic clinical skill sets and assure the workforce is appropriately trained. Given the immediacy and complexity of the H1N1 immunization response, the ability to reach out to volunteer workers within the community was instrumental. The clear and consistent message received in their public health practice response was that the volunteer base was less than sufficient to meet community-level needs during a large scale response. Databases and systems to coordinate voluntary workers need to be improved in an intentional and on-going systematic manner. Education differs from training. Training can be understood as hands-on, skill-set oriented, and/or process outcomes-oriented. Education is more overarching, encompassing understanding and awareness among individuals. As

demonstrated in this evaluation, there are different levels of educational needs and educational resources. Messages are dynamic; changing with time. Although both training and education are active, it is important to recognize that training is skills-based and should be assured in a systematic on-going manner. Education is multi-directional and needs to be implemented in effective and responsive ways. From these lessons learned, Ohio is planning robust trainings, especially for local partners and providers, to ensure adequate preparation.

Coordination:

Finally, coordination of activities in a changing, complex, and dynamic environment is critical. Articulation and awareness of the Incident Command System (ICS) protocols are necessary but not sufficient, full and effective communications are required throughout the multiple-evolved communities and are necessary to inform, engage, and evolve the community-wide system stakeholders. A consistent theme over the course of the evaluation period was fear and concern over conflicting and/or changing information being directed at the public by public health information officers, the media, schools, and a host of other sources. An effective communication plan requires transparency, full participation, centralization, and coordination. Above all, the effective coordination of public health emergency response takes advanced planning and effective coordination requires significant time and diligence. Ohio has applied this lesson learned by launching communications and coordination early with various stakeholders including local health departments. Specifically, the state is enrolling new COVID-19 vaccine providers rather than locals have the responsibility to do so with the goal of increasing coordination.

- 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.*

Prior to vaccine availability, vaccine preparedness leaders plan to hold a series of COVID-19 vaccine tabletop exercises to ensure that the team is prepared for a range of scenarios. Participants in this exercise will include all relevant stakeholders in the State's Vaccine Preparedness Office (Coordinators, Subject Matter Experts, Workstream Leads) and members of the Governor's Office, Ohio Department of Health, and the Pandemic Response and Recovery Leadership Team. The Vaccine Preparedness Coordinators will develop a set of scenarios that will include various factors (e.g. number of doses, cold chain requirements) for the group, which will be split into teams, to practice deploying the planned responses to scenarios. This exercise will include state-wide partners (e.g., members of external stakeholder committee, other agency partners, healthcare providers, local leaders) to ensure coordination and preparedness and to get their input in the planning process.

Based on responses from all teams, the group will review the results, consider the potential implications, and discuss insights. The intended output of these exercises is to learn what adjustments need to be made and what gaps exist.

The planned vaccine distribution phases will give Ohio's public health officials opportunities to learn and improve processes as the response expands to new providers and new patient populations. Ohio will explicitly monitor lessons learned and reform the response as needed based on early wave lessons learned. Vaccination activities around influenza vaccination will also provide instructive insights.

This will be an ongoing process where feedback will be asked from partners, stakeholders, and collaborators to continually improve Ohio's preparedness and vaccine deployment.

Section 2: COVID-19 Organizational Structure and Partner Involvement

Instructions:

A. Describe your organizational structure.

Governor DeWine assembled a Pandemic Response and Recovery Leadership Team led by Adjutant General John C. Harris and Interim Director of the Department of Health, Lance Himes who, in turn, report to the Governor's Office. Within this Pandemic Response Leadership Team, there is a dedicated organizational structure for vaccine readiness activities:

1. **Vaccine Preparedness Office (i.e., Planning and Coordination Team):** Led by Adjutant General John C. Harris and Interim Director of the Ohio Department of Health Lance Himes, the state Vaccine Preparedness Office acts as an integrated entity coordinating with the Governor's office, the Governor's Pandemic Response and Recovery Leadership Team, and the Ohio Department of Health, and is dedicated to vaccination readiness efforts. The office leverages consistent processes, meeting cadences, governance channels, and decision-making criteria. In turn, the office achieves coordination across various departments and agencies including: the Governor's office, Ohio Department of Health, Ohio National Guard, Ohio Bureau of Workers' Compensation, and Opportunities of Ohioans with Disabilities. The team has been assembled with input from the Governor's office and cabinet, Adjutant General, and the Director of Ohio Department of Health.
2. **Local Coordination Committee:** Ohio is a home-rule state and local coordination is critical. Given the complexity involved, Ohio is planning to make central recommendations, following federal guidelines, on paths forward and ask for local input. A Local Coordination Committee consisting of representatives from all local departments of health will set clear responsibilities for local personnel and engage the group for input on various topics (e.g., communications, population identification, site identification) given their understanding of the unique opportunities and challenges in their jurisdictions. Currently, the Ohio Department of Health Immunization Program and Bureau of Health Preparedness staff have begun meeting weekly with local health department colleagues for information-sharing and input to assist with their planning. Vaccine Preparedness leaders have also launched regular meetings with health systems,

the Ohio Hospital Association, Ohio State Medical Association, pharmacy partners, and other physician groups.

3. **External Stakeholder Engagement and Outreach:** The State of Ohio recognizes the breadth of stakeholders and external collaboration necessary to plan and achieve a successful vaccine deployment effort. In that regard, Ohio is planning to engage external and community partners to support our various teams. Coordinated by leadership and a team of stakeholder engagement advisors, representative of the spectrum of parties needed to deploy vaccines will be engaged. The stakeholder outreach will include representatives from the following:

- **Emergency Management Agencies:** Ohio Emergency Management Agency, select county-level emergency management agencies (e.g., Hamilton, Cuyahoga, Franklin);
- **Healthcare Coalitions:** Ohio Hospital Association, Ohio Children's Hospital Association, Ohio Medical Association, Ohio Osteopathic Association, Ohio Association of Community Health Centers, county boards of Mental and Behavioral Health, County Boards of Developmental Disabilities, Area Agencies on Aging
- **Immunization Coalitions:** Adult Immunization Coalition of Central Ohio, Fairfield Immunization Coalition, Greater Cincinnati Immunization Coalition, ImmunizeOhio.org (i.e., Consortium for Health & Immunized Communities)
- **Local Health Departments:** Representatives from each of Ohio's 113 local health departments representing general health districts (county-level), city health districts, and combined health districts (county and city-level)
- **Rural Health Clinics:** State Office of Rural Health (SORH)
- **Pharmacies:** Ohio Pharmacists Association, Board of Pharmacy
- **Long-Term Care Facilities:** Ohio Health Care Association (represents more than 1,000 assisted living communities, home care, and hospice service providers); Leading Age Ohio; Ohio Assisted Living Association
- **Aging Network:** Ohio Department of Aging; Ohio Association of Area Agencies on Aging; AARP Ohio
- **Business and Occupational Health Organizations:** Ohio Business Roundtable, Ohio Chamber of Commerce, NFIB, Ohio Association of Occupational Health Nurses, Society for Ohio Occupational Health Professionals
- **Health Insurance Issuers and Plans:** Ohio Association of Health Plans
- **Education Agencies and Providers:** Ohio Department of Education, Ohio Department of Higher Education, select local school districts (t colleges and universities. (
- **Correctional Facilities:** Ohio Department of Rehabilitation and Correction
- **Churches, Religious Leaders and Institutions:** To be identified in local jurisdictions as needed (e.g., mobile clinic, communications); Office of Faith Based and Community Initiatives

- **Organizations Serving Racial and Ethnic Minority Groups:** Ohio Commission on Minority Health, Ohio Latino Affairs Commission
- **Organizations Serving People with Disabilities:** Department of Developmental Disabilities, Opportunities for Ohioans with Disabilities
- **Organizations Serving People with Limited English Proficiency:** Lau Resource Center for English Leaders (part of Ohio Department of Education), Office of Opportunities for New Americans
- **Community Representatives:** To be identified in local jurisdictions as needed (e.g., influencers, local politicians)
- **Local Government entities:** County Commissioners, Mayors
- **Entities Involved in COVID-19 Testing Center Organization:** The Governor's Pandemic Response and Recovery Leadership Team, who is coordinating the vaccine deployment campaign, has and also continues to lead statewide testing organization

This list is an example of the entities the state of Ohio will engage and is not reflective of all of the stakeholders that will have the opportunity to collaborate on vaccination distribution efforts.

Note: The State of Ohio does not currently plan to stand up a Tribal Communities Committee separate of the tribal leaders representation in the proposed external committee (above) given the low prevalence of tribal communities in the state.

- 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.*

The Vaccine Preparedness Office (VPO) consists of ten distinct workstreams to plan and validate vaccine readiness across the entire lifecycle of a vaccine (from ordering, to distribution, administration, funding, and tracking). The ten workstreams include:

- **Project Management:** Manage team structure, processes and workplan;
- **Public Policy and Regulatory:** Provide regulatory and legal input on all work;
- **IT Infrastructure and Interoperability:** Provide IT support to all workstreams;
- **Flu Vaccine Delivery:** Monitor opportunities and risks within influenza campaign;
- **Ordering and Logistics:** Coordinate all ordering, allocations and government interaction;
- **Site Identification and Onboarding:** Lead end-to-end provider strategy and readiness;
- **Population Segmentation:** Lead population identification per federal guidance;
- **Public Communications:** Address public concerns and questions regarding vaccination;
- **Funding and Reimbursement:** Address cost barriers to vaccination; and
- **Tracking and Reporting:** Ready all administrators and systems for CDC reporting needs.

Each workstream consists of a workstream project manager, a backup leader, and a team of experts, analysts, and advisors from different agencies and departments who together

collaborate to complete necessary preparations. The Ohio Department of Health Immunization Program is central to many of the workstreams and team structure.

- 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.*

We will be engaging external partners in two ways – close stakeholder interactions workstream by workstream and broad engagement via the stakeholder engagement and outreach team referenced above.

- **Workstream by Workstream:** Each workstream project manager and team will be required to identify relevant stakeholders to achieve workstream priorities (e.g., public communications workstream would need to connect with local influencers, media channels) and develop working cadences to receive input on work.
- **External Stakeholder Outreach:** The team will periodically send communications and/or hold touchpoints with the broader stakeholder committee (or subsets thereof) to receive input. The Governor’s Office also regularly updates a wide array of key stakeholders on progress and priorities.

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

Internal team consists of three primary groups:

Executive Sponsors. Primary leadership, overseeing all vaccine readiness work and reporting directly to the Office of Governor Mike DeWine.

- **Adjutant General John C. Harris**, Ohio National Guard, Leader of the Governor’s Pandemic Response and Recovery Leadership Team
- **Interim Director Lance Himes**, Ohio Department of Health
- **Workstream Project Managers.** Primary, day-to-day, leads for each workstream driving on work and leveraging subject matter experts and external stakeholders, as needed.

Workstream	Project Manager (i.e., Lead)
Project Management	John Joseph Immunization Program Chief Ohio Department of Health Simona Vaclavikova State Partnership Program Advisor

	Ohio Adjutant General's Office
Public Policy and Regulatory	Matt Lampke Chief Legal Counsel Opportunities for Ohioans with Disabilities Back-up: Bridget Harrison Assistant Policy Director, Health and Human Services Office of Governor Mike DeWine
Flu Vaccine Delivery	Theresa Bonn Health Services Policy Analyst Ohio Department of Health Back-up: John Joseph Immunization Program Chief Ohio Department of Health
Ordering and Logistics	Ryan Morrison Medical Countermeasure Coordinator Ohio Department of Health Back-up: Stephanie Poling Office of Health Preparedness Ohio Department of Health
Site Identification and Onboarding	Kristen Dickerson Statewide Manager of Health and Wellness Ohio Bureau of Workers' Compensation Back-up: Sarah Duade Health Services Policy Analyst Immunization Program Ohio Department of Health
Population Segmentation	Tiffany Huber Program Administrator and Health Equity Specialist Ohio Department of Health Back-up: Brian Napier Immunization Registry Manager Ohio Department of Health
Public Communications, Messaging, Education and Stakeholder Engagement	Fern Miele Director of External Affairs Special Olympics Back-up and supervisor: Breann Almos Communications Advisor Office of the Governor

Funding and Reimbursement	<p>John Palermini Senior Financial Manager Ohio Office of Budget and Management</p> <p>Back-up: Bridget Harrison Assistant Policy Director, Health and Human Services Office of Governor Mike DeWine</p>
IT Infrastructure, Tracking and Reporting	<p>Cynthia Lee Opportunities for Ohioans with Disabilities</p> <p>Back-up and co-lead: Nate Huskey Chief Information Officer Ohio Department of Health</p> <p>Laura Pientopol Deputy Director DAS InnovateOhio Platform</p>

Subject Matter Experts. Key thought leaders with expertise in specific aspects of the workstream, provide initial review and input as work is planned and started.

Workstream	Subject Matter Experts and Contributors
Public Policy and Regulatory	<p>Bridget Harrison Assistant Policy Director, Health and Human Services Office of Governor Mike DeWine</p>
Flu Vaccine Delivery	<p>John Joseph Immunization Program Chief Ohio Department of Health</p>
Ordering and Logistics	<p>Tamara McBride Chief of Health Preparedness Ohio Department of Health</p> <p>Holly Welch Administrative Officer, Preparedness Ohio Emergency Management Agency</p> <p>Andrew Elder Administrative Officer, Operations Ohio Emergency Management Agency</p>
Site Identification and Onboarding	<p>Tamara McBride Chief of Health Preparedness Ohio Department of Health</p> <p>Dr. Mary Kate Francis Interim Medical Director Ohio Department of Health</p>

	<p>Sarah Duade Health Services Policy Analyst Immunization Program Ohio Department of Health</p> <p>Stephanie Polling Office of Health Preparedness Ohio Department of Health</p> <p>Wally Burden Deputy Director, Health Policy and Planning Ohio Department of Health</p> <p>Russ Kennedy Deputy Director, External Affairs Ohio Department of Health</p>
Population Segmentation	<p>Gene Phillips Chief Bureau of Environmental Health & Radiation Protection Ohio Department of Health</p> <p>Sietske de Fijter Chief, Bureau of Infection Diseases and State Epidemiologist Ohio Department of Health</p> <p>Brian Napier Immunization Registry Manager Ohio Department of Health</p>
Public Communications, Messaging, Education & Stakeholder Engagement	<p>Breann Almos Communications Advisor Office of Governor Mike DeWine</p> <p>Arundi Venkayya Chief Communications Officer Ohio Department of Health</p> <p>Haylee Dunahay Director of Coalitions Office of the Governor</p> <p>Russ Kennedy Deputy Director, Director of External Affairs Ohio Department of Health</p>
Funding and Reimbursement	<p>Bridget Harrison Assistant Policy Director, Health and Human Services Office of Governor Mike DeWine</p> <p>Anthony Perry Chief Financial Officer</p>

	Ohio Department of Health
Tracking and Reporting	<p>Brian Fowler Chief, Bureau of Informatics and Data Management Ohio Department of Health</p> <p>Nate Huskey Chief Information Officer Ohio Department of Health</p> <p>Laura Pientopol Deputy Director DAS InnovateOhio Platform</p>

External Stakeholder Engagement

Ohio will incorporate a team of stakeholder engagement advisors into the Public Communications, Messaging and Education workstream. The team will focus on consistent, timely outreach to organizations mentioned in 2a. They will also provide support to Ohio officials in general and in specific workstreams, as necessary. Stakeholder outreach will be done in close coordination with the communications team from the Office of the Governor.

Additionally, Ohio is consulting with leading scientists, doctors, and health experts who provide support in advising on vaccine safety, efficacy, and other relevant topics.

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

From the beginning of this pandemic, the Governor's Office, the Ohio Department of Health, the Emergency Management Agency, and our partner departments have been working collaboratively, in partnership with Ohio's 113 local health departments and local government officials, to prepare and protect Ohioans. Meetings between officials with these organizations occur regularly to align efforts, identify gaps and provide resources.

As Ohio prepares for COVID-19 vaccine distribution, this collaboration will continue and expand. For example, staff from the Ohio Department of Health's Immunization Program and Bureau of Health Preparedness have begun weekly meetings to specifically coordinate with local health department colleagues to share information and assist with planning. The local health departments have registered with the Ohio Department of Health as COVID-19 vaccination providers. Their experience in the registration process will help streamline and refine the experience as the registry expands.

A coordination committee, comprised of local points of contact for all health districts, will be created to streamline communication and logistical coordination between each district and the

state. At a leadership level, the Vaccine Preparedness Office and officials with the Ohio Department of Health have met twice with the Ohio Hospital Association and leads from the state's three hospital zones to leverage their expertise and experience in the planning process. Periodic meetings of these groups will continue.

The Governor's Office will continue to lead the effort to coordinate and communicate with local government leaders in parallel with the Ohio Department of Health working with local health departments to continue a unified effort to fight COVID-19.

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

Ohio has no recognized tribes with whom to engage and does not plan to stand up a tribal committee. That being said, through our external stakeholder committee, we will ensure that any tribal citizens who live in Ohio, as well as tribal community organizers will be included as required. We will also charge our local coordination committee members to raise any tribal considerations or contacts as we begin to progress on deployment readiness.

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

Per the National Academies of Sciences, Engineering and Medicine's Committee on Equitable Allocation of Vaccine – Ohio is preparing to deploy the COVID-19 vaccine to the following groups as critical populations, organized in the Phase groupings provided:

Phase	Group
Phase 1A	<ul style="list-style-type: none"> • High-risk healthcare workers • First responders
Phase 1B	<ul style="list-style-type: none"> • Older adults living in congregate or overcrowded settings • People at significantly higher risk due to comorbid or underlying conditions
Phase 2	<ul style="list-style-type: none"> • Critical risk workers essential to society (e.g., healthcare and public health operations and human services operations) and at high risk of exposure • Teachers and school staff • People of all ages with comorbid and underlying conditions³ • All older adults not included in Phase 1 • People in homeless shelters

³ As minority populations have higher prevalence of comorbidities, minority populations and health equity will be integrated into planning for this phase

	<ul style="list-style-type: none"> • People in group homes for individuals with physical or mental disabilities or in recovery • People and staff in prisons, jails, detention centers
Phase 3	<ul style="list-style-type: none"> • Young adults • Children • Workers in industries and occupations important to the functioning of society and at increased risk of exposure and not included in phases 1 and 2
Phase 4	<ul style="list-style-type: none"> • Everyone else residing in Ohio who did not have access to the vaccine in previous phases.

With this in mind, we plan to engage the following critical population groups in order to 1) ensure current location identification methods accurately 2) determine proper administration channels 3) collaborate on potential concerns or questions to address and 4) review any additional barriers that specific groups may face in receiving the vaccinations.

The State of Ohio will assess the application of this framework to the needs of Ohioans and supplement with additional considerations, e.g., the disproportionate impact of COVID-19 on minority communities, with the advisement of the Governor's Minority Health Strike Force.

Table. Partners for each critical population group on the items above:

Critical group	Key partners to engage
Healthcare facility workers	<ul style="list-style-type: none"> • Ohio Hospital Association • Ohio Children's Hospital Association • Ohio Association of Ambulatory Surgery Centers • Ohio Association of Occupational Health Nurses • Society for Ohio Occupational Health Professionals • Governor DeWine's Minority Health Strike Force
First responders	<ul style="list-style-type: none"> • Ohio Association of Emergency Medical Services • Ohio Department of Public Safety • Ohio Association of Chiefs of Police • Ohio Small Police Department Association • Ohio State Highway Patrol • Ohio Fire Chiefs Association • County and City Police Departments • County and City Fire Departments • Governor DeWine's Minority Health Strike Force

Individuals with comorbid or underlying conditions	<ul style="list-style-type: none"> • MyCare Ohio (State Medicaid and Medicare Services) • Ohio Department of Aging • Ohio Council for Home Care and Hospice • Governor DeWine's Minority Health Strike Force
Individuals living in congregate or overcrowded settings	<ul style="list-style-type: none"> • Ohio Health Care Association • LeadingAge Ohio • Ohio Assisted Living Association • Nursing Home and Long-Term Care Facilities • Ohio Department of Health Nursing Home Regulatory Program • Ohio Department of Medicaid • Ohio Department of Aging
Critical risk workers (i.e., essential to society, high exposure risk)	<p>Plan to identify employers and organizing bodies of the following list of critical industries, per CISA Critical Infrastructure Workers guidance:</p> <ul style="list-style-type: none"> • Communications • Chemicals • Critical Manufacturing • Commercial Facilities / critical trades • Dams • Defense Industrial Base • Energy • Financial • Food & Agriculture (including grocery stores) and food production • Government Facilities/utilities • Nuclear Reactors, Materials and Waste • Utilities (e.g., water, sewer, gas, electric) • Information Technology • Transportation Systems
Teachers and school staff	<ul style="list-style-type: none"> • Ohio Department of Education • Ohio Department of Higher Education • Ohio Education Association • Local School Districts (e.g., Columbus City, Cleveland Municipal, Cincinnati City, Akron City, Toledo City, South-Western City, Olentangy Local, Lakota Local, Hilliard City, Dublin City, Westerville City, Dayton City, others) • Colleges and Universities (e.g., The Ohio State University, University of Cincinnati, Ohio University, Kent State University, Columbus State Community College, Cuyahoga Community College, University of Toledo, Miami University, University of Akron, Sinclair Community College, Bowling Green State University, others) • Governor DeWine's Minority Health Strike Force
Individuals in homeless shelters	<ul style="list-style-type: none"> • Ohio Development Services Agency (Homeless and Supportive Housing Programs Division) • Coalition on Homelessness and Housing in Ohio • Governor DeWine's Minority Health Strike Force

Individuals in prisons, jails or detention centers	<ul style="list-style-type: none"> • Ohio Department of Rehabilitation and Correction • Ohio Department of Youth Services • Governor DeWine's Minority Health Strike Force
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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:*

As Centers for Disease Control and Prevention (CDC) guidance outlines, COVID-19 vaccination will occur in three main phases defined by supply availability and targeted populations. The CDC has advised that the approach to COVID-19 vaccine deployment will occur in phases where the first phase will have very limited doses available that scale quickly. The second phase will include mass vaccination reaching a peak of vaccination numbers. The third phase will stabilize to a long-term steady state vaccination campaign such that people will get boosters or the initial vaccine as needed. The State of Ohio has structured the work in these three phases by maintaining team structure, responsibilities, roles, and actions while expanding the scope of infrastructure readiness required in each phase. In particular, Ohio is focused on swift administration during the first phase to identified high-risk populations. However, the state is focused on securing the infrastructure to smooth the transition to a higher volume of vaccine administration required in phase 2. Below are some illustrative details:

- The **Population Segmentation Workstream** will employ the same tools and processes by which to identify target populations location and density and simply change the target populations being addressed phase by phase (e.g., high-risk healthcare workers in Phase 1A, older adults in congregate settings in Phase 1B per NESM);
- The **Site Identification and Onboarding Workstream** will maintain the same process of identifying, onboarding, and validating administration sites from phase to phase but will expand the number of providers over phases as new critical population groups are added and the program scales to reach all Ohioans(i.e., all residing in the US);
- The **Ordering and Logistics Workstream** will ensure that the same storage, handling, and distribution tactics being undertaken in Phase 1A channels (e.g., central depot) are being employed and carried over in any new distribution pathways (e.g., health systems). Ordering may become democratized and provider-led in the future;

- The **Public Communications, Messaging, Education and Stakeholder Engagement Workstream** will maintain the same core messages prepared in early phases but expand and change communications channels, and external partners to reach target populations; outreach to external partners will be broad and proactive as well as more targeted in order to address operational needs of each workstream.

In addition, the State of Ohio will create clear markers by which to determine when planning is beginning to approach subsequent phases to ensure visibility and forward-planning into the body of work. Markers the State of Ohio will track will be based on:

- The supply of vaccine nationally and supply allocated to the State of Ohio.
- The percentage and locations of target populations vaccinated, organized by Phase.

Finally, as the State of Ohio begins to reach the latter stages of Phase 3, the team will plan to begin shifting focus to transitioning COVID-19 vaccines to a steady state, annual model. The State of Ohio will model the structure off of annual influenza campaigns and address any unique differences COVID-19 vaccines may offer (e.g., second-dose need).

As for specific actions and approach within each phase, please refer below for current proposed actions in phase 1 and 2 of the vaccination campaign. Please also reference Table 1 which can serve as an example of how Ohio could frame approach during phase 1.

Phase 1:

According to CDC guidance, the vaccine may be available in limited quantities initially.

Ohio plans to begin with the vaccination of high-risk health care workers and first responders during this phase⁴.

The state is currently reviewing three potential administration and distribution strategies for phase 1A vaccination. These are all outlined below in Table 1: Phase 1A Deployment Options.

Ohio expects that as the above actions are occurring, the vaccine will be shipped by the federal government directly to pharmacy chains who will then vaccinate patients and perhaps staff in long-term care facilities. However, recent guidance from the CDC indicates that the timing of this may be in question⁵. If pharmacies are not included as administration sites for CDC direct shipments, Ohio will determine the best way to reach Ohioans who may not easily be able to access regional/hub--based administration sites through redistribution efforts based on Ohio capabilities and needs.

Table. Phase 1A Deployment Options

⁴ Per NASEM and CDC guidance

⁵ Per CDC weekly jurisdiction call on 9/30/2020

Option	Administration	Distribution
One	Health System/Hospital Regional Open PODs	Direct shipment to providers
Two	<p>Broad collection of open points of dispensing (POD) provider sites (prioritized by capabilities, critical populations reached and willingness to administer) could include:</p> <ul style="list-style-type: none"> • Health systems and hospitals • Commercial and independent pharmacies • Local departments of health 	Direct ship to state Receipt, Store, Ship (RSS) warehouse (i.e., central depot), subsequent redistribution among providers
Three	<p>Hybrid approach:</p> <ul style="list-style-type: none"> • Health System/Hospital Regional Open PODs (prioritized) • Additional providers (e.g., local departments of health, pharmacies) as needed to fill reach gaps 	<p>Direct ship to health systems/hospitals</p> <p>RSS redistribution model for additional providers</p>

For phase 1B, the plan is to retain one of the operating models of phase 1A with a transition increasingly towards direct shipment to providers as more doses and vaccine products are available and the ability to direct ship smaller dose sizes increase (e.g., minimum shipments of 100 doses).

Overall, Ohio's preferred approach that is actively being pursued is option 3, which is a hybrid of direct-ship and RSS redistribution to enable broader reach to more Ohioans. In this option, Ohio would redistribute some vaccine through the RSS to local partners (e.g., local departments of health or pharmacies) as need to reach high-risk populations (e.g., LTCF staff).

Phase 2:

As vaccine supply increases, Ohio will support the prioritization of COVID-19 vaccine distribution to more populations. Ohio will expand providers as necessary to ensure effective and equitable access to vaccines. Reliance on RSS redistribution, if any, will be lowered as we expect minimum orders to decrease with greater vaccine availability and approvals of non-ultra-cold vaccines.

Phase 3:

As Phase 3 approaches, Ohio will continue expanding to all providers who are interested and capable to administer. All shipments are expected to be direct to the providers and redistribution will be providers' responsibility (after state has validated capabilities and provided approvals).

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:*

As outlined in the question above, Ohio dividing critical populations planning in three steps, including:

- **Identify:** Determine specific populations CDC has suggested for phases 1A/1B and where they are in Ohio and how to reach them.
- **Estimate:** Determine how to estimate number and density of critical populations.
- **Locate:** Map number and density of critical populations on a county-level.

On the “identify” component, Ohio will reference on recommendations from the CDC and National Academies of Sciences, Engineering and Medicine’s Committee on Equitable Allocation of Vaccine on population criticality and prioritization. Our current planning approach for Phase 1A, Phase 1B, and Phase 2 can be found in the answer of Question 2G above. Ohio may augment these recommendations to meet the specific needs of Ohioans.

Regarding components of “estimate” and “locate”, Ohio, with support from third-parties, has prepared a robust vaccine deployment analytical tool. One of the tool’s capabilities is the ability to select specific critical population groups and size and locate them based on publicly available census, medical claims, labor, and school district and university enrollment data.

The tool can currently filter on the following populations (per phase 1A, 1B and 2 population groups the Committee on Equitable Allocation of Vaccine have developed). The population was segmented on a county-by-county level using data from medical claims, Bureau of Labor Statistics, U.S. Census, and CMS COVID-19 nursing home data. To avoid double-counting when multiple segments are selected, logic was applied to sub-segment populations and conservative estimates taken. For example, using Agency for Health Research and Quality estimates of the percentage of the population at each age group with multiple chronic conditions, and census data on the age distributions of each occupation, we estimated the number of people in each occupation with multiple chronic medical conditions and subtracted that number from the “moderately high risk” population on a county-by-county level; using medical claims data and census data on age distributions of each occupation, we subtracted high-risk populations from

those in the 55-65 and 65+ and so on. Below is the full list of populations segmented with sub-segments noted where relevant:

- Healthcare High Risk Workers – Clinical Elective
- Healthcare High Risk Workers – Clinical Non-Elective
- Healthcare High-Risk Workers – Nurses
- Healthcare High-Risk Workers – Nursing Support Staff
- Healthcare High-Risk Workers – Technicians
- Healthcare High-Risk Workers – Therapists
- First Responders
- Nursing Home Residents
- Significant High-Risk Population (defined as people of all ages with cancer, liver disease, COPD, kidney disease or heart failure, minus nursing home residents)
- Critical Workers at High-Risk (defined as workers who are both in industries essential to the functioning of the society and at substantially high risk of exposure to COVID-19)
- Teachers and School Staff
- Moderately High-Risk Population (defined as people of all age with asthma, diabetes, hypertension, or Ischemic heart disease who did not have any conditions that would put them at significantly high risk, and were not in any high-risk occupation)
- Other Institutionalized Population (defined as all congregate settings other than nursing homes, e.g. prisons, homeless shelters, psychiatric hospitals etc.)
- Incarcerated Population (65+ Age)
- 55-65 Age (Non-High-Risk i.e. population aged 55-65 minus those with high risk medical conditions or in high risk occupations)
- 65+ Age (Non-High-Risk i.e. population aged 65+ minus those with high risk medical conditions or in high risk occupations)
- College Enrollments

In addition, vaccine administration will be assessed using the CDC's Social Vulnerability Index both a priori when deciding geographic distribution of vaccines and post-hoc to ensure that state's goals to protect the most-at-risk and vulnerable Ohioans are upheld. The Ohio Department of Health Equity Specialists will collaborate with the Governor's Minority Health Strike Force to ensure that there is equitable access to vaccines, especially for racial and ethnic minorities.

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

The definition of critical workforce categories has been identified and previously established according to Cybersecurity and Infrastructure Security Agency (CISA) and CDC. The team has begun estimating the number of and locations of critical infrastructure workers in Ohio, specifically in the population group "Critical Workers at High-Risk" which contains the following:

All occupations involved in food services, funerals and morticians, rehabilitation and substance use, child, family, mental health, school and community social workers, utilities (e.g., water, sewer, power), janitors and cleaners (excluding maids and housekeepers), courts and municipal clerks, postal services, couriers and messengers, aircraft and automotive services, bus drivers and transit, including flight attendants. To estimate the number of critical workforce by jurisdiction, the team will:

- Utilize an ODH Bureau of Health Preparedness survey to local health department grant recipients requiring identification of all critical workforce. The survey responses will cover all 113 jurisdictions. Results will be available by October 21st.
- Use identified SME's to report number of critical workforce by jurisdiction for phases that follow.
- Conduct additional research as necessary in collaboration with community partners to identify the number of workers who meet criteria established for Phase 1A and Phase 1B.

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

In preparation for an event in which the State of Ohio's allocation is insufficient, the team is beginning to break priority populations into further sub-groups when possible (e.g., high-risk healthcare workers split by role above) and is planning to continue to break groups down to their most granular level of separation.

To aid more granular population segmentation under conditions of resource constraints, additional characteristics of counties were examined:

- CDC's Social Vulnerability Index: to assist in identifying geographies / populations with vulnerabilities or structural disadvantages (e.g., low access to healthcare, or populations disproportionately affected by COVID-19 such as minorities)
- Current COVID-19 spread rates: to identify which geographies are at highest risk of continued growth in spread (tracked by state and available on coronavirus.ohio.gov)
- Population density: to identify locations where social distancing may be most challenging for individuals
- Historical flu vaccination rates: to potentially identify areas where vaccination rates may be higher or there might be other structural challenges

Ohio will consider these factors in addition to the population segmentation guidance provided by NSEM, CDC, and ASIP. In the case that insufficient vaccine supply exists, Ohio will reference the most current CDC and Committee on Equitable Allocation of Vaccines guidance, and engage senior members of the Department of Health and statewide experts to prioritize within subgroups. These leaders include, but are not limited to: Lance Himes (Interim Director) Mary Kate Francis, M.D. (Interim Medical Director), Sietske de Fijter (Chief, Bureau of Infectious Diseases and State Epidemiologist) and members of our health equity team.

- 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.*

As outlined in the answers for Question 2A and 2G, Ohio is planning to engage external stakeholders through two avenues: workstream-by-workstream connections and representation on the external stakeholders committee.

To establish the primary points of contact at each of these organizations, employers, and community groups, the team plans to prepare an outline of the type of roles and responsibilities a point of contact will have in support of both workstreams and by joining the external stakeholders committee. The team will then send requests for support to all organizations, employers, and groups asking for one point of contact to serve as a representative on the external stakeholders committee. This representative can serve as the initial point of contact in case any workstream requires input from an external body. In the case that the point of contact cannot provide the input requested, s/he can identify additional individuals to support the specific workstream at hand (i.e., in turn, developing the workstream-by-workstream connections outlined above).

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.*

The State of Ohio recognizes that vaccination provider recruitment and enrollment is one of the most critical activities to facilitate a successful vaccination campaign. Ohio plans to:

- 1. Define Criteria:** Determine the requirements and capabilities that a potential COVID-19 vaccine provider requires, including but not limited to: location, populations reached, throughput, storage, licenses and credentials.
- 2. Provider Listing and Outreach:** Having created a comprehensive criteria list for a potential candidate, the team will create and manage a reference list of all potential providers in the state. These providers could include, but are not limited to: local departments of health, healthcare systems, pharmacies (independent, large chains, grocery stores), long-term care facilities, community health centers (Federally Qualified Health Centers and Regional Health Centers), emergency medical services (EMS), correctional facilities, behavioral health and rehabilitation centers and Ohio Department of Health Internal Constituents (e.g., VFC Program, Perinatal Hepatitis B Program). The state will proactively reach out to these groups through a communication campaign to facilitate registration.

3. **Candidate Registration:** The Ohio Department of Health Immunization Program has developed a registration website ([accessible here⁶](https://www.ohiopublichealthreporting.info/Enrollment/)) to gather provider information and facilitate COVID-19 vaccine provider enrollment. The provider will be prompted to register online and answer questions referencing necessary capabilities, guidelines, and enrollment forms the CDC has provided.
4. **Candidate Approval and Onboarding:** Having received registration responses, the VPO will review all submitted information and signed agreements, confirming or creating a provider profile in ImpactSIIS, Ohio's Immunization Information System, and will allow the site to place vaccine orders and report administered doses.
5. **Candidate Training and Validation:** The Ohio Department of Health Immunization Program will create process, administration, and IT (e.g., ImpactSIIS user) training for all providers to ensure readiness and understanding of their role as a vaccine provider – working primarily with the provider's primary and back-up "Vaccine Coordinators" as primary points of contact. Project staff will assist in this training. Additionally, at times, it will be required that staff visit and validate provider capabilities and identify gaps (e.g., storage issues) that will need to be addressed before final confirmation.

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.*

Provider types are predetermined per federal guidance. Providers and settings will be determined and enrolled based on their eligibility and ability to safely and effectively administer the COVID-19 vaccine. As follows, the Ohio Department of Health will be deploying a standard and transparent approach that will determine the number of vaccines each provider will receive in any given shipment cycle (in particular, during early, limited-dose phases). This approach will take provider characteristics into account as they relate to location, throughput, storage and handling capabilities, and access to vulnerable populations. More detail on this algorithm is located in the answer to question 7A.

For example, Ohio will employ a capabilities and catchment areas analysis to determine which provider types will administer the first available vaccines. The process is as follows:

- At the start of each order approval and shipment cycle, Ohio will measure the priority populations locations by county – taking into account any existing vaccine uptake from previous cycles.
- Leverage an additional capability of the aforementioned vaccine deployment analytics tool, Ohio will then overlay priority populations by approved providers. Estimating a one-hour drive catchment area, provider throughput and county need, Ohio will determine the set of providers that will receive vaccines in the coming shipment cycle

⁶ <https://www.ohiopublichealthreporting.info/Enrollment/>

and amount of orders (i.e., vaccines) to approve for each. Potential participation as an open administration point of distribution will be discussed with providers in advance and it is the expectation that not all providers will participate.

After eligibility has been determined and providers have completed their enrollment as a registered, and CDC approved, COVID-19 administration site, Ohio will determine based on geography, patients and communities served, and ability to reach Ohioans within critical segments of the population most at risk, an appropriate selection of providers to administer the vaccine in early phases of deployment. As the vaccine becomes more available and deployment reaches more Ohioans, it is expected that all registered and licensed providers who would like to administer the vaccine will be able to.

- 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.*

Ohio is currently pursuing the implementation of a web-based tool to efficiently collect provider enrollment information for the 2,000-5,000 providers who will be enrolling as pandemic vaccine providers. Providers will be able to submit both the required data fields and signed provider agreements. Ohio will export the CDC-required data from that system.

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

During the registration process, medical license and distribution information will be gathered from each provider that is registered into the pandemic vaccine program. During review, the Ohio Department of Health staff will verify the license against the Board of Pharmacy and Medical Board databases to assure it is valid and current.

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

Ohio will be providing educational presentations for providers to review. Providers will be attesting to the fact that they reviewed and are familiar with this information as part of the registration process. Educational material, or links to the material, will be provided on Ohio Department of Health website.

Each provider will be required to review general, administration, and IT educational materials before receiving final confirmation and inclusion in the COVID-19 Vaccination Program. The Ohio Department of Health will track completed training via a master provider reference list.

Training will be grouped into three components:

- **General:** Training on all general and operational components of the COVID-19 Vaccination Program. This includes, but is not limited to: role and responsibility mapping with state and local COVID-19 Vaccination Program leads, ACIP vaccine recommendations (when available), vaccine storage, handling and transport requirements, management of vaccine inventory (including assessing and managing product expiration dates), temperature excursion management, vaccine wastage/spoilage documentation and reporting, safety monitoring and adverse events reporting, provision of Emergency Use Authorization information sheets and Vaccine Information statement information sheets to vaccine recipients, submitting information to CDC's VaccineFinder (particularly for pharmacies), communications protocols, allocation and ordering, and other operations topics;
- **Administration:** Healthcare workforce education on the vaccine including, but not limited to: reconstitution, use of appropriate needle size, anatomic sites for vaccine administration, avoiding shoulder injury with vaccine administration, and expected common patient questions and answers.
- **IT:** Training on how to document and report vaccine administration. Training will aim to familiarize providers with entering provider and vaccine administration data into ImpactSIIS, Ohio's Immunization Information System. Education and guidance documents will be provided during the enrollment process and updated as COVID-19 vaccine information is added to the system. Ohio will also offer educational webinars for providers and post webinar recordings.

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).*

Currently, the only planned redistribution of vaccine is from the state Receipt, Store, and Stage (RSS) Warehouse. Warehouse staff, experienced in vaccine storage and handling, will take large orders and repackage them in smaller amounts more appropriate to areas with less population to ensure more equitable access to the vaccine.

Local health departments wanting to redistribute vaccine will work with state staff to ensure their procedures meet CDC guidelines, and Ohio will encourage direct shipments to approved providers as the preferred method. Any provider that redistributes COVID-19 vaccine will be required to sign the CDC Supplemental COVID-19 Vaccine Redistribution Agreement. Ohio will only provide this form to organizations that are approved to redistribute COVID-19 vaccine. Each location receiving redistributed COVID-19 vaccine, constituent products, and ancillary supplies, will have fully completed the provider enrollment and have signed agreements on file. Ohio Department of Health will maintain records of COVID-19 vaccine and constituent products redistributed, and report this information to CDC, as requested.

At this time, Ohio does not plan to approve redistribution requests (at least in early phases). However, if a provider wants to redistribute their allocation, they will need to submit a written request explaining their case and capabilities to do so to the Ohio Department of Health Immunization Program. The Ohio Department of Health Immunization Program will consider case by case.

Further information on the guidelines and requirements around redistribution can be found in question 8A.

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

Ohio will operate with equity and transparency to ensure equitable allocation of vaccines for the residents of Ohio to reduce COVID-19 infection and mortality among at-risk and vulnerable populations, including but not limited to racial and ethnic disparities, health access disparities, disparities related to age, geography (e.g., rural/urban) and living situation. This includes but is not limited to:

- Using federal guidance to determine populations of focus for COVID-19 vaccination and ensure equity in distribution across Ohio.
- Engaging subject matter experts, stakeholders, and community focus groups throughout planning to foster a collective responsibility and impact for public health.
- Establishing accountability mechanisms that include stakeholder involvement, metrics for evaluating effectiveness and equity, and reporting on allocation strategies and their implementation.
- Utilizing social vulnerability and opportunity indices to identify geographic disparities to protect those who need it most including hard to reach groups working in occupations that include a disproportionate percentage of disadvantaged groups. Monitoring vaccine uptake across all vulnerable and underserved populations, locating groups and locations where additional action is required.
- Developing a comprehensive and culturally-appropriate communications plan to ensure vulnerable and underserved populations also have equitable access to information that promotes legitimacy and builds trust in the vaccine and distribution process.
- Disseminate culturally-appropriate messaging for different populations in different languages, as needed, that also addresses health literacy and access and functional needs and utilizes various mediums and trusted community messengers to disseminate resources and information.
- Determining funding and reimbursement avenues for those who are under- or uninsured.
- Partnering with healthcare providers and Federally Qualified Health Centers in geographically disadvantaged areas to distribute the vaccine. Developing a plan that adapts to changing conditions and evolving evidence and provides room to adjust with lessons learned as we gain knowledge throughout the response.

These efforts will be lead in coordination between the Ohio Department of Health, the Pandemic Response and Recovery Leadership Team, and the Governor's Minority Health Strike Force.

- 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.*

We plan to use the same five-step process outlined for providers above to engage and enroll independent, large-chain, and grocery store pharmacies. For large-chains, grocery store, and charitable pharmacies, we are also planning to engage senior overarching leadership groups in order to streamline onboarding and enrollment when possible.

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.*

The Ohio Department of Health's Bureau of Health Preparedness has been working with local departments of health to help determine provider capacity and critical workforce population. This year, the Ohio Department of Health developed a critical infrastructure personnel (CIP) tool for local jurisdictions to plan for critical workforce vaccination. Priority groups identified from PPE distribution and relevant occupations with direct care to patients were also identified. This tool used Bureau of Labor statistics and provides local health departments with occupational estimates to base their planning.

Local departments of health, Licensing boards, and other community partners, may also provide estimates of population numbers of each tier. During the registration process, we will ask providers to share information on the types of patients they generally serve. Providers will also describe what types of clinics they currently offer, their cold storage capacity for the vaccine, and their staffing policies. These data will help identify the capacity of each provider and help inform our understanding of regional capacity.

Variable factors that impact planning include, but are not limited to inclement weather, holidays, staffing limited by illness, reporting requirements, and the additional time to implement infection control measures.

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

Provider recruitment efforts will be directly related to the estimated need and in turn, throughput, required during each phase of the COVID-19 Vaccination Program. Ohio will work with local departments of health to monitor provider capacity in a given geographic area in comparison to the population. In the event a gap is identified, Ohio will support local departments of health in identifying potential partners and encouraging their participation.

Guidelines will be shared and education regarding each of the directions will be communicated. The providers will have an understanding of all supplies and staff required to host vaccination clinics while maintaining infection control standards.

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.*

Ohio will be communicating to local departments of health and provider partners on all allocation decisions and in turn, ordering will be done centrally and supported by a transparent process.

The Ohio Department of Health will be developing an allocation approach that will appropriately allocate the total incoming shipment of a vaccine among counties and providers at each shipment cycle. This algorithm will take numerous data points into account, these include but are not limited:

- Estimated number of target population group in county
- Social vulnerability and health equity
- Current county epidemiological landscape (i.e., what is current case count)
- Estimated county seroprevalence (i.e., what level of natural immunity may exist)
- Provider vaccine administration capacity and capabilities (e.g., storage, type)

Once the algorithm has run for each shipment cycle, Ohio will order for all providers in the state based on the result and communicate the expected number of incoming vaccines to providers. The algorithm will be refined over time as any additional critical factors are identified.

- 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.*

Because the COVID-19 vaccine is a valuable federal asset, it will be essential to minimize vaccine loss and account for every dose received and used, whether administered, wasted, compromised, expired, or transferred.

Prior to enrollment, the Ohio Department of Health will require each potential vaccine provider to document and validate cold-chain capabilities including providing evidence (both digitally, and at times, in person) of storage capabilities, temperature monitoring equipment, and proof of concept in inventory management and documentation processes. The Ohio Department of Health will not approve a vaccine provider until all requirements met.

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

As described above in Question 7A, allocation will be determined through a central VPO allocation algorithm. In turn, Ohio will conduct all ordering on behalf of enrolled providers who will receive part of the State's allocation – inputting pre-collected provider information into VTrckS and notifying providers of allocations approved for any given shipment cycle. This process will evolve as supply expands.

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

Unplanned repositioning will be strictly prohibited with the exception of certain emergencies that require unforeseen transport (i.e., fire at a facility). In that case, providers will be asked to mark all unplanned repositioned vaccines as suspected non-viable and follow standard Ohio Department of Health actions to confirm or deny viability.

The Ohio Department of Health will retroactively open an inquiry into the unplanned repositioning to determine if the repositioning could have been foreseen and addressed. Likewise, in the case that a trend of truly unforeseen repositioning events emerges, the Ohio Department of Health will begin to reassess methods to mitigate this event (e.g., repeated power outages).

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

Ohio will require that all vaccine inventory be monitored and reported on a tight and consistent schedule to flag potentially non-viable vaccines, manage vaccine wastage, and have visibility into inventory levels across all providers at any given time.

All reporting will be done through ImpactSIIS and providers will need to validate working processes and IT connectivity prior to finalizing enrollment. Inventory metrics that will be tracked will include, but are not limited to:

- Identifying characteristics for each individual vaccine (tracked by unique 2D barcode or QR code) including manufacturer, type, manufactured date, expiration date.
- Temperature monitoring of vaccine inventory at lowest possible granularity (i.e., temperature of freezer bin rather than entire bay, when possible).

Providers will be required to update and report on inventory at a regular cadence. Temperature monitoring cadence will be determined as manufacturers announce further information on vaccine viability at varying temperature excursion levels.

Section 8: COVID-19 Vaccine Storage and Handling

Instructions:

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

- *Individual provider locations*
- *Satellite, temporary, or off-site settings*
- *Planned redistribution from depots to individual locations and from larger to smaller locations*
- *Unplanned repositioning among provider locations*

Introduction

The following serves as Ohio's preliminary strategies for vaccine storage, handling, and distribution according to the provided CDC vaccine planning assumptions. This strategy has been informed by current CDC guidance which advises cold chain storage and handling requirements for each COVID-19 vaccine product will vary from refrigerated (2°C) to frozen (-20°C) to ultra-cold (-60°C to -80°C) temperatures. Ultra-cold vaccine may be shipped from the manufacturer in coolers that are packed with dry ice, can store the vaccine for an extended period of time, and be repacked for longer use.

Due to the sensitivities surrounding appropriate storage and handling for COVID-19 vaccine in a limited resource environment, there may be a multitude of strategies for receiving and distributing vaccine. The Ohio Receipt, Stage, Store warehouse is an option to augment direct shipment by serving as a "depot" for repackaging and reallocation to identified facilities. The storage and distribution methodology will evolve through different phases of COVID-19 vaccination efforts.

The State of Ohio plans to address the four scenarios listed above in the following manners:

Individual Provider Locations

All vaccine providers that will receive direct shipment of the vaccine will be registered and verified within the pandemic registration system. This process allows for appropriate verification of all required cold-chain equipment and capabilities.

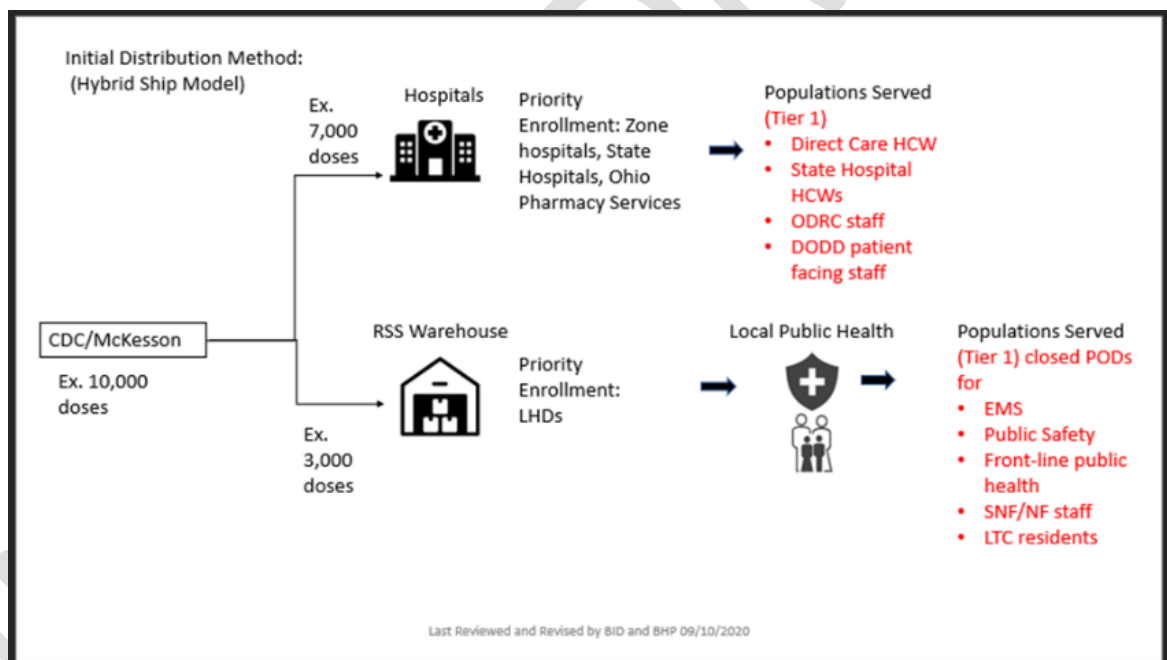
Satellite, Temporary, or Off-Site Settings

All satellite, temporary, or off-site settings that will receive direct shipment of the vaccine will be registered and verified within the pandemic registration system. This process allows for appropriate verification of all required cold-chain equipment and capabilities.

Planned Redistribution from Depots to Individual Locations and From Larger to Smaller Locations

Based upon the minimum and maximum quantities of vaccine products shipped in each federal allotment, in some cases (particularly in early phases) it may be advantageous for Ohio to receive the allotment at the RSS warehouse for repackaging, further breakdown of the product, and distribution to ensure vaccine access for priority counties and facilities. As such, much of the early focus has been devoted to this channel.

This strategy may support direct shipment as a hybrid model. Under this hybrid model repackaging and further breakdown of large orders to identified counties in allocated quantities would address low vaccine uptake, targeted priority groups, and avoid product waste. Ohio will provide the RSS the allocation for each receiving provider.



It is critical that the RSS receive facilitation information from all identified providers intended to receive vaccine shipment for entry into IMATS at minimum three days in advance or in a format where information can be imported in the IMATS system.

Once cold chain shipments arrive, if shipped in a refrigerated vehicle, RSS staff will verify that the delivery vehicle stayed within the appropriate temperature range. If shipped in containers such as EnduroTherms, RSS staff will also verify that the shipping containers have also stayed within viable temperature levels. This ensures supplies have maintained the correct

temperature range during transport to the state and that RSS storage equipment is at the correct range to receive supplies.

Once temperature ranges have been verified, RSS staff will unload all cold chain materials, check for tampering or damage, and ensure all supplies have been received. In the event of tampering and/or damage to products, RSS staff will notify the shipper and CDC.

This process must be done quickly as to limit the amount of time that cold chain medical countermeasures (mitigation processes to ensure that vaccines are preserved) are out of cold storage. All other normal receipt and reporting processes remain the same (i.e. saving shipping manifests, reporting deliveries, etc.).

Once verified, RSS staff will quickly move supplies to the cooling unit. This must be done rapidly to minimize exposure to temperatures outside of the recommended range and the amount of time the doors remain open, which will likely result in temperature fluctuation in the unit.

The RSS will sustain logs and use temperature monitoring devices to monitor all vaccine containers. Any deviations will be reported to the Ohio Department of Health Immunization Program and follow procedures as outlined in the Ohio Cold-Chain Standard Operating Procedures (SOP).

Storage at the RSS

- The RSS is currently establishing contracts for additional cold storage to accommodate the arrival of vaccine
- The RSS possess back-up power to support electrical equipment during power failures
- The RSS currently maintains inventory of appropriate containers for vaccine and will be purchasing additional containers in preparation for vaccine arrival

While CDC does not recommend jurisdictions or providers purchase ultra-cold storage, it is recommended that the Ohio Department of Health identify and confirm the location of sub-80°C freezers across the state. The existing infrastructure will most likely reside in large hospitals, scientific research facilities, and some large pharmacies. Security upgrades may be necessary at these locations because of the scarcity of the vaccine.

RSS Product Tracking

The inventory management function of the RSS Warehouse ensures that all vaccine, supplies, and equipment are tracked, distributed, and managed appropriately. The Ohio Department of Health currently utilizes CDC-designed IMATS (IT system) to receive, track, and report all inventory levels. The RSS will confirm the amount of vaccine received and will reconcile with federal shippers.

Storing Vaccine at the RSS Warehouse

To facilitate effective distribution and best inventory management procedures, cold chain supplies will be arranged/organized inside storage areas by:

- Temperature range
- Item type (vaccine, laboratory, etc.)
- Item name/NDC (National Drug Code)
- Lot number.

Once supplies have been placed into storage, RSS staff will close and lock the unit. Each time vaccines are received and placed into RSS cold storage, the following information will be documented on the Ohio Department of Health Cold Chain Temperature Log:

- Date
- Time
- Temperature
- Reason for opening storage (in this case receipt of “XXX” supplies)
- Notes (any other information as needed)

Distributing

To repack for distribution, RSS staff will first check and document the temperature of each storage unit to be opened on the Ohio Department of Health Cold Chain Temperature Log. This will be done immediately before they open the unit to begin picking. Staff will then enter the walk-in freezer and collect the needed supplies for each shipment. This should be done as close as possible to the time the order will be picked up (taking into account time needed to inspect, pack, and wrap each order). RSS staff move one order at a time to the quality assurance area, then immediately notify appropriate staff that the order needs to be verified, wrapped, and staged. Care should be taken to ensure that the cold storage area is NOT left open for extended periods during this process. After each order is filled (or if a group of orders is filled together) the RSS staff will make certain to reclose the storage area.

Shipping/Distribution

Transport and Short-Term Storage Guidelines for Refrigerated Medical Counter Measures (MCMs).

Use the following procedures for packing refrigerated MCMs during transport. These procedures are intended to keep MCMs within recommended temperatures for 12 hours during transport and/or temporary storage.

The vaccine will be shipped to identified and registered vaccination providers through a contracted transportation vendor or state transportation partner. During transport, the following guidelines must be followed:

- An Ohio Department of Health -supplied temperature monitoring device (TMD) must be placed in the transport containers with the MCMs.
- MCMs should not be left unattended. MCMs shall be monitored at all times during transport and promptly placed into appropriate storage units upon arrival.

- When transporting MCMs in passenger vehicles, the passenger compartment should be utilized, not the trunk.
- Check TMD after each transport to verify temperatures were in range.
- For additional guidelines, see <http://www.immunize.org/catg.d/p3049.pdf>.

Unplanned Repositioning Among Provider Locations

The State of Ohio will employ standard verification techniques to ensure cold-chain continuity in any instances where unplanned repositioning among provider locations occurs.

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

Any provider/redistribution depot will need to meet the capabilities listed above within section “Planned Redistribution from Depots to Individual Locations and From Larger to Smaller Locations” and in reference to the State of Ohio RSS. All provider/redistribution storage and temperature monitoring capabilities will be verified prior to allowing for redistribution.

The State of Ohio does not expect redistribution to occur among providers in early phases of vaccine distribution – any required redistribution in these early phases would be routed through the RSS using the processes listed above. Subsequent phases, with increased supply of vaccines and expanded population groups, may allow for greater redistribution among providers (and not routed back via the RSS).

Section 9: COVID-19 Vaccine Administration Documentation and Reporting

Instructions:

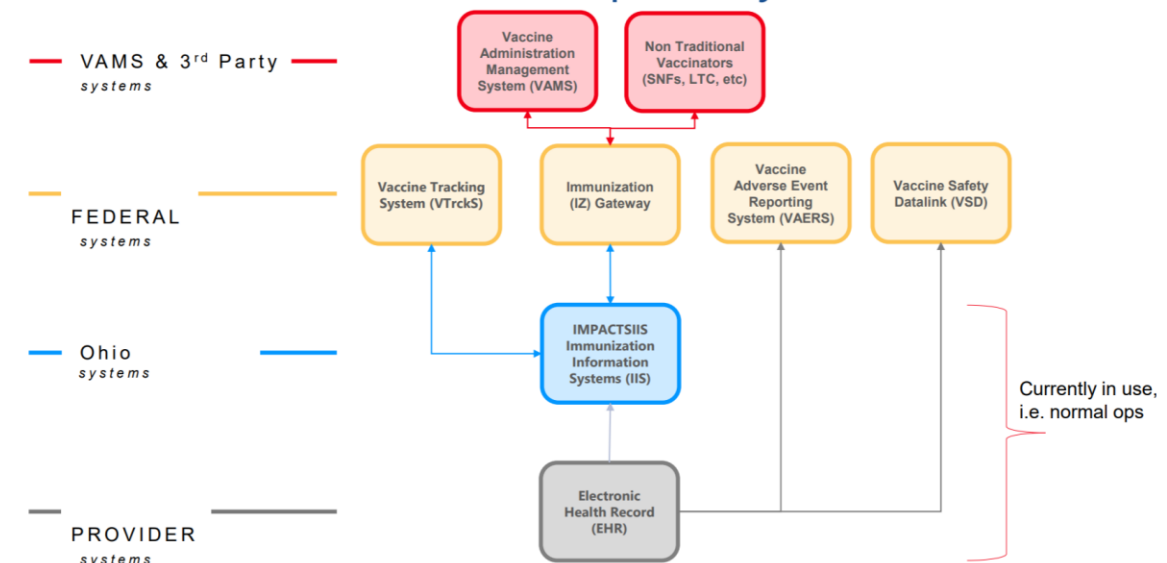
A. *Describe the system your jurisdiction will use to collect COVID-19 vaccine doses administered data from providers.*

Ohio will use the existing IIS system (ImpactSIIS) and connect to the IZ Gateway via Connect and Share. This will be beneficial, particularly in early phases of vaccination when limited doses are expected to be available, and vaccines will likely go to large healthcare providers, who already have access and are comfortable using the existing IIS infrastructure. Also, a lesson learned from previous vaccination campaigns is that using the same system decreased confusion and increased system fidelity. Though the State realizes there will be challenges that come with this approach, including less depth of data and less transparency of scheduling and distribution chain (vs. utilizing a different system), utilizing ImpactSIIS will provide a high likelihood of operational readiness while allowing anticipated providers the ability to use existing ordering, scheduling, and reporting modalities.

To exchange and query data with other jurisdictions, as well as to enable systems for satellite/temporary/off-site clinic settings to report, Ohio plans on utilizing the IZ Gateway Connect and Share components.

Exhibit. Intended plan for information flow of systems

The Current Landscape of Systems



In Phase II, when a larger number of doses are expected to be available, the State plans to keep using ImpactSIIS as the primary system. Ohio is considering the possibility of using VAMs or another commercial product. The key drivers in expanded capabilities and solutions in Phase II are added ease of patient registration and scheduling along with ease of expanded provider registration and use (as more providers will be administering the vaccine). Finally, in Phase III, when it is expected that there will be a steady supply of the vaccine and a shift to a more routine vaccination strategy (i.e. availability to all population segments), the State will reassess operations to determine a new normal state. This will allow Ohio to plan for the future of the immunization registry based on real-world needs and healthcare provider feedback.

The State will ensure that the system can handle increased capacity for COVID-19 vaccine administration. We are planning to collect all required data according to Appendix D of the CDC's Vaccination Playbook (CDC IIS Data Requirements for COVID-19 Vaccine Monitoring). There are some gaps in the existing infrastructure which we are working to address.

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

At this time, based on the approach of using the current IIS infrastructure, ImpactSIIS, the State plans on connecting to the IZ Gateway to share data and information with the CDC and federal departments, as required. The State will connect to the IZ Gateway, and also utilize Connect and Share functions of the Gateway to exchange information.

Currently, Ohio does not have a Data Use Agreement in place with the Association of Public Health Laboratories (APHL), the organization that hosts the Immunization Gateway. While Ohio is currently evaluating the APHL draft of the agreement August 7, 2020 and the Data Use Agreement, it is expected to be finalized in the Ohio Department of Health legal team and leadership for a review and decision about whether Ohio would participate. Ohio has signed an memorandum of understanding (MOU) with other jurisdictions including: Arkansas, Colorado, Delaware, Idaho, Indiana, Iowa, Kansas, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Jersey, New York, North Dakota, Oklahoma, Philadelphia, San Diego, South Dakota, Vermont, Virginia, West Virginia, Wisconsin.

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

First, to ensure ease of registration for providers, the Department of Health is working with the InnovateOhio Platform team to digitize all provider registration forms and agreements. These will be accessed behind authentication with accounting details to support ownership and attestation. Additionally, electronic signature capabilities will be implemented to ease this process for providers.

Based on the current understanding of the CDC's phased approach to vaccination, Ohio will first ensure that large healthcare systems and hospitals are ready and able to provide the vaccine, and subsequently smaller providers and providers in more rural areas. In order to ensure that providers are ready to vaccinate, Ohio plans on taking the following steps:

- Develop list of prioritized provider sites (i.e. Phase 1 expected providers, expanded Phase 2, etc).
- Conduct outreach to all identified potential sites to assess capabilities required to set up and run administration sites and required tracking/reporting actions (e.g., ability to track administration, multi-dose dispensing and monitoring).
- Provider Enrollment Site Visit Training will include online instruction but may require a site visit to validate that the location has the requisite vaccine storage and handling capacity. Trainers would receive enrollment site visit training and ImpactSIIS user training to assist providers.
- Provide administration and IT training to identified sites, facilitate CDC, VTrckS, and ImpactSIIS enrollment to avoid delays.
- Establish a regular data and information reporting cadence to ensure accurate capture and adherence to federal guidelines and additional state-led data/tracking requests.
- Ensure access to reporting and monitoring systems across all registered providers, local and state public health agencies, and federal public health agencies.
- Run trials of both existing and new infrastructure with all administration sites to ensure ImpactSIIS and state-prepared data integration and reporting flows work, and address any issues as needed.
- Provide IT training resources for use at identified sites (e.g., VTrckS, VAERS and ImpactSIIS).

- Gather and disseminate key training materials provided by other stakeholders (e.g., government, manufacturers) and fill any gaps by creating training materials for the administration of most likely vaccine candidates (e.g., use of adjuvant, reconstitution, ancillary supplies use)

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

Providers will be responsible for reporting to Ohio's ImpactSIIS. Providers will be required to send data each 24-hour period. Ohio's ImpactSIIS is web-based, so providers will be trained and required to upload data entries from vaccination efforts every 24 hours.

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

The Ohio Department of Health Immunization Program and ImpactSIIS team will check data daily as data are uploaded from providers. These data will then be linked with the InnovateOhio Platform to include in public-facing and internal operational dashboards. Data will be double-checked at this step. The State is still considering options for how or whether to continue working with providers who do not comply with documentation and reporting requirements.

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

In addition to providing the required data and reports to the CDC and federal government to track at a national level, Ohio will use collected data to generate reports at the State and county levels. Data can be tracked and used on an ongoing basis to:

- Track the number of patients vaccinated in the state and each county.
- Track the number of patients vaccinated at each provider site.
- Understand rates of both COVID-19 infections and vaccination rates in a particular county (i.e. is the county seeing a decline in overall cases).
- Make decisions around more targeted deployment of the vaccine, particularly once available in larger doses (e.g. to areas with higher risk populations, rural areas).
- Identify regions that may need additional communications or support to encourage uptake across the population.

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.*

We are investigating several potential interventions. We will refine and finalize based on additional research into effectiveness, feasibility, and the needs of Ohioans. Interventions may include the following:

Public communications: We will launch public communications at large emphasizing the importance of the second dose of the vaccine to provide immunity. This will be one of the key messages in the public communications planning and will be delivered through omnichannel messaging.

Direct contact from the state: Based on meta-analytic evidence⁷, we plan to utilize two methodologies to encourage a second dose: postcards and text messages. As part of the provider data reporting, Ohio will collect the contact information of vaccine recipients and deliver postcard reminders and text messages (~2.5 weeks later) encouraging them to get the second dose.

Provider calls to schedule a second dose: Before receiving the first dose of the vaccine, providers will be trained to emphasize the importance of the second dose vaccine. They will also be encouraged to schedule the second visit at the time of the first visit (or before the first visit). Providers will be responsible for calling/texting vaccine recipients ahead of the visit to remind them to attend.

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.*

For Phase I, the State believes that the current IIS (IMPACTSIIS) will be adequate in documenting required administration data. Given current assumptions, a portion of the data will be submitted through existing Electronic Health Record (EHR) connections and the remaining portion will be manually entered asynchronously (not at point of service) into ImpactSIIS.

- 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.*

The IIS is able to collect a patient's date of birth, from which current age and age at administration of vaccination can be calculated. ImpactSIIS is able to collect race and ethnicity, but we do not require this information. Other optional fields include address, telephone number, guardian name and phone number, and email address. Ohio is considering various options for collecting information about chronic medical conditions, occupation, membership in

⁷ Cochrane Review of vaccine dose reminder techniques <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6491344/>

other critical population groups, including enhancements to ImpactSIIS, but it should be noted that most vaccine providers would either not routinely collect this information or not routinely send it in immunization messages.

Below please find the elements from Tables 1 and 2 from the CDC's Operations Playbook and the ImpactSIIS status for each. Chronic medical conditions, occupation, and membership in other critical population groups are not captured in the ImpactSIIS today, and they cannot be transmitted in Health Level 7⁸ (HL7) messages, the most commonly used format for transmitting immunization information electronically. However, the ImpactSIIS vendor is working to make these fields possible to capture in a direct entry module for ImpactSIIS.

Table 1. Required Data Elements
Data elements required for IIS to report

Required Data Element	ImpactSIIS
Administered at location: facility name/ID	Yes
Administered at location: type	Yes
Administration address (including county)	Yes
Administration date	Yes
CVX (Product)	Yes
Dose number	Yes
IIS Recipient ID	Yes
IIS vaccination event ID	Yes
Lot Number: Unit of Use and/or Unit of Sale	Yes
MVX (Manufacturer)	Yes
Recipient address	Yes
Recipient date of birth	Yes
Recipient name	Yes
Recipient sex	Yes
Sending organization	Yes
Vaccine administering provider suffix	Yes; rarely recorded
Vaccine administering site (on the body)	Yes

⁸ Framework for exchange and retrieval of electronic health information

Vaccine expiration date	Yes
Vaccine route of administration	Yes
Vaccination series complete	Yes
Recipient ethnicity	Yes
Recipient race	Yes

Table 2. Optional Data Elements
Data elements optional for IIS to report (e.g., state mass vaccination tool collects this information)

Optional Data Element	ImpactSIIS
Comorbidity status (Y/N)	Mass Vaccination Module only – requires direct entry
Recipient missed vaccination appointment (Y/N)	No
Serology results (Presence of Positive Result, Y/N)	Available; not currently used
Vaccination Refusal (Y/N)	Yes; rarely recorded

- 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.*

The state's IIS, ImpactSIIS, is currently connected unidirectionally to thousands of Ohio's medical providers, including many pharmacy chains. On a typical weekday, ImpactSIIS processes about 75,000 incoming electronic immunization update messages from about 2,800 administering locations around the state and also receives and responds to approximately 125,000 electronic queries. ImpactSIIS staff members are working to connect to employee health records from health care systems and university student health centers, two of the groups to which the ImpactSIIS has not historically been connected.

Storage is hosted by the ImpactSIIS vendor, Scientific Technology Corporation (STC), and has not been an issue nor do we anticipate an issue with storage. The vendor has made a commitment to regularly monitor storage capacity and scale up as required. However, the load on the vaccine management system is going to be unprecedented.

All data and information from all vaccination systems is planned to be sourced to the InnovateOhio Platform where it can be aggregated and visualized as the sole source of accurate information.

- 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.*

Immunization Program staff will assist in facilitating registration and ImpactSIIS enrollment. Additional temporary support outside programmatic staff will be required to assist with registration reviews and approvals. The process will include reviewing all submitted information for errors (duplication, incomplete or missing data, duplicate registrations, address changes) and signed, completed, and returned participation agreements.

Upon the completion of the online registration and submission of signed agreements, a profile for the site will be created in ImpactSIIS, which would allow the site to place vaccine orders and report administered doses.

ImpactSIIS has onboarded most large healthcare systems in the state and all local health departments.

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

The State plans on onboarding to both the IZ Gateway Connect and Share, given the execution of the APHL MOU to onboard and begin exchanging information.

F. *Describe the status of establishing:*

1. *Data use agreement with the Association of Public Health Laboratories to participate in the IZ Gateway.*
2. *Data use agreement with CDC for national coverage analyses*
3. *Memorandum of Understanding to share data with other jurisdictions via the IZ Gateway Share component.*

Ohio will submit a document with suggested revisions to the Association of Public Health Laboratories (APHL) in order to participate and connect to the IZ Gateway. The contract unit at the Ohio Department of Health has been reviewing the data use agreement with CDC for national coverage analyses and Ohio expects to reach a decision soon.

Ohio has signed the Memorandum of Understanding to share data with other jurisdictions.

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

Use of the ImpactSIIS is not currently supported if internet connectivity is lost or not possible. Providers would need to capture information in a different manner, saving locally, and later transfer the data to ImpactSIIS. All providers are required to sign ImpactSIIS security agreement and are required to be HIPPA compliant.

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.*

Ohio plans to monitor data quality through a process involving numerous areas at the Ohio Department of Health, which is already being done for COVID-19 tracking and reporting. All data will go through extensive quality assurance checks driven by both local health departments and the Bureau of Infectious Disease epidemiologists. ImpactSIIS can be configured to reject submitted data if records are incomplete or inconsistent. It also automates warnings at data consumption if the sender sends data with quality that is substandard or incomplete.

Section 12: COVID-19 Vaccination Program Communication

Instructions:

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

The State of Ohio vaccine preparedness communication plan includes five core groupings of initiatives (i.e. audience analysis, message development, message delivery, stakeholder outreach, and executive preparation) that will be refreshed during each of the three phases of the COVID-19 Vaccination Program. Within each of these groupings, the plan identifies a number of discrete initiatives that will be accomplished (e.g. sentiment analysis through polling and research). Each of these groupings and initiatives will be revisited during each new phase or as new messaging is required.

Key Components of Communications

Understand and identify target populations: During phase one, the communications team will first partner with the Vaccine Preparedness Office to determine which population segments are likeliest to receive treatment (e.g. Ohioans with comorbid conditions, Ohioans over 65, minority communities, or Ohioans in high-risk professions). Using data from surveys, polling, and other existing research, the communications team will move forward with message development following the Governor's decision.

Draft initial messaging: Once the team has a firm understanding of target populations and their sentiments, the communications team will draft initial messaging aligned with phase one goals, including messaging to the general public to clarify the three-phase vaccine delivery approach and share information about the vaccine itself, as well as messaging to specific groups identified that are likely to receive vaccines during phase one. When this messaging has been drafted, it will then be syndicated among stakeholders.

Syndicate initial messaging for stakeholder input: Stakeholder input will be key to both refining a message to VPO strategy and tailoring a message to both the general public and to specific populations. The communications plan allows for time to identify and expand the initial list of stakeholders. A preliminary list of stakeholders is included below:

Table. Preliminary list of Phase One Stakeholders & Partners

Audience	Potential partner/stakeholder
<i>General public</i>	
	The Governor's Office, Ohio Department of Health, Ohio Medical Association, Ohio Department of Medicaid, Ohio Hospital Association, municipal and local governments, Association of Ohio Health Commissioners, Ohio Public Health Association
<i>Possible target populations</i>	
65+ populations, long-term care facilities, nursing homes, senior centers	Ohio Department of Aging, Ohio Healthcare Association, Ohio Association of Senior Centers, Ohio Assisted Living Association, Ohio Association of Area Agencies on Aging (O4A), AARP Ohio
Minority communities	COVID-19 Minority Health Strike Force (established by Gov. DeWine in April to develop and deliver COVID-19 messaging to reach minority communities), Governor's Office of Faith-Based and Community Initiatives, Ohio Latino Commission, Ohio Commission on Minority Health, racial/ethnic minority chambers of commerce
High-risk employment populations	OH Chamber of Commerce, JobsOhio, Ohio Manufacturing Association, Ohio Farm Bureau, Ohio Grocers Association, Ohio Restaurant Association, local chambers of commerce, Ohio Small Business Association, Ohio Latino Commission, Office of Minority Health, the Governor's Office of Faith-Based and Community Initiatives, and the Office of New Americans

Populations with comorbid conditions	Ohio Medical Association, Ohio Hospital Association, Ohio Pharmacy Association, the Diabetes Association (Ohio chapter), American Cancer Society (Ohio chapter)
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Stakeholders will provide critical input into the messaging strategy, but will also serve as important partners in communicating phase one messaging to target populations.

Working in conjunction with the Governor's Office and the Ohio Department of Health, tailored messaging will be approved and prepared for delivery.

Message Delivery: In addition to identifying and building out communications capabilities, the communications team will ensure tracking mechanisms are in place to conduct regular audits on the efficacy of these channels, in order to make real-time improvements.

Once messaging has been solidified, a communications budget will be determined in partnership with the Funding & Reimbursement Workstream.

Align and launch messaging: Once budget has been allocated, communications approaches have each been identified and messaging has been confirmed, statewide messaging will be launched.

Phased Messaging

While the communications team will use the same methodology across the three phases, messaging and population targeting considerations will change. Below are listed several (non-exhaustive) considerations and implications for communications and messaging strategy for each of the three phases:

Table. Communications implications of vaccine delivery phases

Phase	Possible communications implications	Possible target populations
<i>Phase 1: Limited dosage available</i>	<p>Important to introduce and clarify three-phase federal strategy for vaccine delivery to general public</p> <p>Need to tailor messaging to specific populations likely to receive early vaccinations, in order to encourage vaccination and share</p>	<p>General Public</p> <p>Vulnerable populations likely to receive vaccination during Phase 1</p>

	<p>information about delivery, cost</p> <p>Begin information campaign around vaccine efficacy to the general public to prepare for broader vaccination</p>	
<i>Phase 2: Large number of doses available, supply likely to meet demand</i>	<p>Need for campaign to deliver information around vaccination likely to amplify drivers of vaccination</p> <p>Continue campaign around vaccine efficacy information</p>	<p>General Public</p> <p>Vulnerable populations</p>
<i>Phase 3: Likely sufficient supply, slowing demand</i>	<p>Continue broad-based information campaigns to encourage vaccination for those who want it, emphasizing vaccine efficacy and vaccination process</p>	<p>General Public</p>

Ad hoc communications

Over the course of the COVID-19 Vaccination Program, the CDC is expected to issue new directives which need to be quickly disseminated to the public. To achieve that goal, the communications plan also includes ad hoc communications, which formalizes the procedure for the communications team to receive CDC guidance, circulate with key stakeholders, develop communications assets, and deliver these messages to the public using pre-identified communications channels.

As CDC issues new guidance, the communications team will work to translate this guidance into communications to key in-state audiences, using a similar methodology as the earlier phase-related work. First, the communications team will syndicate this guidance with key partners relevant to the guidance (e.g. the ordering and logistics team for new guidance regarding delivery dates). Second, the communications team will map new messaging to appropriate communications channels being used to advance phased messaging. Third, the communications team will prepare a 'communications packet,' combining messages, draft assets (incl. press release, messaging points, or media assets needed), as well as identifying channels and responsibilities for approval by the Governor's Office. Given the weekly cadence described above, this process could be completed rapidly, over the course of several days or less.

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

Close coordination with the Governor's Office and Vaccine Preparedness Office, supported by a simplified escalation/reporting structure will empower the vaccine preparedness communications team to quickly develop, syndicate, and establish tailored messaging, as well as launch messages across communications channels. Ohio Department of Health and the Pandemic Response and Recovery Leadership Team, working hand-in-hand with Governor DeWine's communications team will ensure close coordination and agility on key topics. The expedited procedure for risk/crisis/emergency communication involves the daily opportunity to flag emergency communications to the Governor's Office. In addition, weekly meetings stakeholders and regular reporting creates multiple opportunities throughout the week to identify lower-priority risks or decisions that need to be made. By identifying communications levers early in the process, the vaccine preparedness communications team is able to act quickly on short-term communications needs.

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.*

The Vaccine Preparedness Office has established a Site Identification & Onboarding workstream, which will focus primarily on identifying and enrolling vaccine administration sites throughout the state of Ohio. During onboarding and enrollment, all providers will be required to acknowledge receipt of Emergency Use Authorization (EUA) fact sheets, as well as vaccine information statements (VISs) and will be given guidance by the state during this enrollment process around where to locate fact sheets online and how to interpret information included.

- 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.*

During enrollment and onboarding of vaccination providers, led by the SIO workstream, all enrolled providers will be instructed to provide EUA fact sheets or VISs as needed to each vaccine recipient prior to vaccine administration. Once recipient-targeted fact sheets have been developed by the CDC, this information (where to locate, how to use), will be communicated to providers, in partnership with the communications workstream. It will be included as part of the

regulations that providers must give every patient the option to receive information about EUA fact sheets and vaccine information statements prior to receiving the vaccine.

INTERIM DRAFT

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).*

As part of the enrollment process to become a pandemic vaccine provider, each provider acknowledges and verifies willingness to comply with reporting clinically important adverse events following vaccination, even if they are not sure if the vaccination caused the event, to the Vaccine Adverse Event Reporting System (VAERS). More information on submitting a VAERS report electronically can be found at <https://vaers.hhs.gov/reportevent.html>.

The signed contract of each provider demonstrates their acceptance of responsibilities in reporting any adverse events with regards to the pandemic vaccination. Most providers are familiar with the online process of event reporting; however, providers will receive education regarding the website and instructions on pertinent information needed to complete the report.

The VAERS link is also available to providers through the Ohio Department of Health's Pandemic Vaccine Provider website (<https://odh.ohio.gov/wps/portal/gov/odh/know-our-programs/immunization/pandemic-vaccine-provider/>) and the state immunization registry home page (<https://ohioimpactsiis.org/siisprod/main.jsp>).

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:
- Provider enrollment
 - Access to COVID-19 vaccination services by population in all phases of implementation
 - IIS or other designated system performance
 - Data reporting to CDC
 - Provider-level data reporting
 - Vaccine ordering and distribution
 - 1- and 2-dose COVID-19 vaccination coverage

Find below tracking and monitoring procedures and methods used in Ohio's COVID-19 Vaccination Program implementation:

Provider enrollment: Facilities registering as pandemic vaccine providers will be tracked by VPO staff by provider type and county. Provider enrollment has been projected by the Ohio Department of Health (using ImpactSIIS reports and identifying long-term care facilities) and will be monitored by the Ohio Department of Health central dashboard.

Vaccination access: Ohio, with support from third parties, will use a robust vaccine deployment analytical tool that can be used to size and locate critical population groups using publicly available information. This baseline information can be used in concert with vaccination tracking to ensure groups are able to access vaccination services across each of the three phases of vaccine delivery.

IIS system performance: Ohio Department of Health periodically performs both security and performance (load) testing against applications within the portfolio when there are significant upgrades or code changes. The last dates for ImpactSIIS were in March of 2018. They will be repeated in anticipation of this plan.

CDC reporting: By connecting to the IZ Gateway, as well as the Connect and Share functionalities, the CDC should get all data and metrics required. ImpactSIIS capabilities will align with CDC/federal requirements, and be exchanged via the IZ Gateway.

Provider reporting: Provider-level reporting capabilities will be added to ImpactSIIS reports already in use by the Ohio Department of Health.

Vaccine ordering and distribution: Vaccine ordering and distribution will be done centrally and allocated to locations. Ohio Department of Health Immunization Program will engage in VTrckS directly.

Vaccination coverage by dosage: 1-and-2-dose vaccination coverage will be monitored via vaccine administration records in ImpactSIIS and through the collection and aggregation of CDC-

provided vaccination report cards. The team will reference CDC guidance on 1-and-2-dose reminders to encourage providers and partners to use appropriate and effective second-dose reminders.

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

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

Through the efforts of two workstreams (Funding & Reimbursement and Ordering & Logistics) Ohio plans to create, track, and monitor workstream budgets and reimbursements, as well as support providers in inventory management and procurement of administration kits and ancillary supplies.

Through efforts of two workstreams, Ohio's Department of Health's Immunization Program and the Bureau of Health Preparedness have assigned staff to the COVID-19 vaccine deployment preparedness efforts. In addition, staff from other agencies have been re-assigned to the Vaccine Preparedness Office – a collaboration between Ohio Department of Health and the Governor's Pandemic Response and Recovery Leadership Team to support ongoing efforts lead by the Ohio Department of Health's Immunization Program. And, temporary staff have been hired to onboard new providers as registered COVID-19 vaccine administrators. The Ohio Department of Health has mobilized these additional resources to ensure successful implementation.

Workstream budgets: Ohio has established a workstream dedicated to funding and reimbursement, which will liaise with each workstream to develop and monitor workstream budgets. In addition, workstreams have been empowered to flag resource constraints (staffing, inventory, etc.) to VPCs each week.

Inventory: With regard to specific equipment (i.e. PPE), the Ordering and Logistics workstream has been tasked with projecting demand for ancillary supplies not included in the administration kits, including sharps containers, bandages, as well as PPE. Once a projection has been made, the O&L workstream will develop a plan to support Providers in procuring additional resources as needed.

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*

Communications will be monitored by the communications workstream, which, as a component of its communication plan, will establish mechanisms for tracking messaging both delivery and efficacy among target populations.

In addition, the communications workstream will monitor communications on social media and traditional channels for misinformation regarding the vaccination program and statewide response, in order to prepare a rapid-response. Further, the communications workstream will monitor communications from internal government agencies and partner-stakeholders, to ensure that simple, clear, accurate messaging is disseminated.

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

Ohio has established two channels for monitoring local-level activities, progress, and situations: through regular liaisons and communications with local government officials, and by tracking key metrics at the local level in a centralized office within the Ohio Department of Health.

Regular local-level touchpoints: Monitoring local-level activities and progress will be conducted through regular liaisons with local and municipal-level leadership throughout the vaccine delivery program. As part of the communications workstream, the WPM will conduct regular stakeholder engagement with population-specific groups and associations, as well as local and city leadership and municipal associations (i.e. the Municipal Alliance, and others). During these regular meetings, the communications team will be able to check-in on local situations and escalate challenges quickly up to the VPCs, Executive Sponsors, and Governor's Office as needed.

Local-level vaccination status dashboard: In parallel, the Office of the Chief Information Officer of Ohio Department of Health has developed a multi-dimensional dashboard of local-level data, which captures key vaccination metrics, and will be used to identify and flag local-level situations as they arise.

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.

Ohio is still determining what metrics are most appropriate to be posted on a public-facing website (coronavirus.ohio.gov). The goal of the public-facing website could be to provide the public with a transparent, accurate information in order to answer high-level questions about vaccine administration and uptake across the state. Exact metrics and dashboard layout are under consideration. These might include, but are not limited to:

- Percentage and number of Ohioans vaccinated:
 - By county
 - By priority group (e.g. healthcare workers, congregate care facilities)
- Vaccine dose information:
 - Number of dual-doses administered state-wide (indicator of vaccination reach)
 - Updates on dose shipments expected
- Provider information:
 - Number of providers currently administering vaccinations
 - Once into phase 2, list of vaccination locations