

COVID-19 Vaccination Playbook

STATE OF LOUISIANA

Louisiana Department of Health Office of Public Health OCTOBER 16, 2020 | VERSION 01



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Record of Changes

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Introduction

The State of Louisiana COVID-19 Vaccination Playbook provides a framework for the jurisdiction's COVID-19 vaccination response. This planning builds on a number of well-established emergency operation plans of the Governor's Office of Homeland Security and Emergency Preparedness, Parish Office of Homeland Security and Emergency Preparedness, the Louisiana Department of Health Office of Public Health. Past experiences involving the distribution and administration of vaccines, annual mass vaccination exercises of plans were used to influence this document. The security of systems, locations and transport has been assessed and will continue to develop to the current situation.

The State of Louisiana COVID-19 Vaccination Playbook follows the 15 main planning sections of the CDC COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations, September 16, 2020 Version 1.0. This Playbook is a living document that will evolve as knowledge about the COVID-19 pandemic and the COVID-19 vaccines develops. Louisiana will evaluate processes and procedures, sharing best practices and lessons learned throughout COVID-19 vaccination response.



Executive Summary

Louisiana has an established organizational structure and planning process to operationalize the COVID-19 vaccine response. Clear roles and responsibilities were established along with a commitment of collaboration by public and private sector partners. Existing infrastructure, processes and procedures will be used to monitor performance targets, resources, activities, procurement and expenses. Evaluation and improvement will be ongoing throughout the response to identify best practices and share lessons learned.

In February 2020, the Louisiana Department of Health (LDH) Office of Public Health (OPH) updated its Pandemic Influenza and Severe Viral Respiratory Pathogen Plan. A COVID-19 vaccine planning team with representatives from multiple state agencies formed in April 2020. The OPH established a formal Vaccine Action Collaborative (VAC) that includes a wide representation of professionals from both public and private sectors, to coordinate and update planning and response efforts for the allocation, distribution and dispensing of COVID-19 vaccines in July 2020. The VAC established work groups for the response effort: Prioritization and Allocation; Planning, Logistics and Operations; and Communications and Outreach. The collective work of the VAC and its work groups are represented in planning and allocation tools. This Playbook builds upon a number of existing plans related to public health emergencies. Past experiences involving the distribution and administration of vaccines were used to influence this planning document. The security of systems, locations and transport has been assessed and will continue to develop. Health equity is incorporated in every step of planning.

Pharmacy engagement and Closed Point of Dispensing (POD) planning will be the framework for the initial phase of the COVID-19 vaccine response. LDH OPH will follow the Advisory Committee on Immunization Practices (ACIP) and CDC recommendations for the use of a safe and effective COVID-19 vaccine and guidance for priority groups. The OPH and the VAC will communicate directly with facilities to ensure proper COVID-19 vaccine education, management, prioritization, documentation, and follow-up. As higher volumes of doses become available in Phase 2, administration of vaccine to priority groups will continue to occur through registered vaccine providers in the state immunization registry LINKS, such as hospitals, pharmacies and healthcare providers. Vaccine will be distributed to the public through multiple mechanisms, including a combination of public and private providers. In Phase 3, when a sufficient supply of vaccine is expected, we will expand distribution and vaccinators. Flexibility within this framework is necessary for an effective response which will depend on vaccine indications and priority groups at the time.

Prioritizing critical populations involves difficult ethical decisions. Guidelines involving critical populations evolve as information changes. Ethical principles used in the deliberation within the VAC include: Utilitarian Principle; Public Order Principle; Narrow Social Utility; Reciprocity; and Subsidiarity.

In Louisiana, most COVID-19 vaccine providers are already registered vaccine providers due to rulemaking in April 2020 that required all vaccinations be reported to LINKS. We will rely first on this base of providers to educate, register, and credential to be COVID-19 vaccinators. Potential new vaccine providers will be recruited to enroll through direct communications by OPH and disseminated through



established communication networks. Interested COVID-19 vaccination providers will be required to complete the CDC Provider Agreement along with the appropriate LINKS enrollment documents. Verification of providers for required credentials will occur through a review process conducted by OPH.

Louisiana conducts an annual series of influenza mass vaccination exercises, including drive-through vaccination. This year's exercise will be conducted following infection control, social distancing practices along with planning to ensure adherence to vaccine storage and handling requirements at every level. Louisiana participated in a CDC pilot project utilizing the Pandemic Flu Response Planning tool to estimate vaccine administration capacity. The *Modeling Pandemic Influenza Vaccination Capacity, Louisiana Report* was completed in March 2019 and shared with key partners.

Louisiana and vaccination providers are responsible for maintaining vaccine quality through the immediate receipt of shipments upon arrival at their respective sites. Each provider will have designated, trained staff to receive, inspect, transfer, and store COVID-19 vaccine. COVID-19 vaccines will be transported, not shipped, to a satellite, temporary, or off-site COVID-19 vaccination site. An evaluation process will be developed to ensure vaccine quality is maintained. Vaccine transportation procedures will be outlined in an upcoming addendum to the *COVID-19 Vaccine Storage and Handling Toolkit*.

The Louisiana COVID-19 Allocation Tool apportions vaccine by percentages based on the Advisory Committee on Immunization Practices (ACIP) guidance for priority groups. This tool includes planning by Phases. Louisiana has identified groups using the terminology of LDH Health Standards. COVID-19 vaccination providers will order COVID-19 vaccine through the LINKS integration with the CDC's Vaccine Tracking System (VTrckS) for provider direct order entry. Staff will manage COVID-19 vaccine, ancillary supplies, resource procurement and distribution. Plans ensure adherence to storage and handling requirements at every level. These plans will be further operationalized as more specific information becomes available. COVID-19 required vaccine administration information will be collected via LINKS and sent to the CDC.

LINKS is a robust, mature immunization information system that meets all requirements for the COVID-19 campaign. The LINKS team has successfully tested with the Immunization Gateway and updated the mass vaccination module. A privacy preserving linkage agreement is in final discussion. Detailed alternate planning is in place. There are several options for reminder recall with LINKS generating a reminder list/postcards/mailing labels/auto dialer files. Video trainings and reference guides are available. At the state level, vaccine recipients may also be reminded through the consumer access portal, MyIR Mobile.

The LDH Bureau of Media and Communications and GOHSEP have a well-established communication strategy to support the vaccination response. OPH has partnered with a private entity for a COVID-19 vaccination multi-media campaign. Direct communications with providers occur through the use of the OPH mass email and fax capability, and a Regional and State Health Alert Network (HAN). Communications with the general public are enhanced by the use of the "211" Statewide system and



will be used during the vaccination campaign. Higher-level communications will be achieved through trusted LDH OPH State and Regional designated spokespersons.

OPH staff will identify and develop training tools, including information on the Vaccine Adverse Event Reporting System, Emergency Use Authorization forms and Vaccine Information Statements. Staff will develop and implement a training plan. Regional staff will engage in a provider educational campaign. The LDH Immunization webpage includes information on how to report adverse events along with the importance of reporting for prompt investigation of signals. Trained staff effectively use state, CDC and national systems, tools and dashboards to monitor performance, inform decision-making and keep our citizens up-to-date. The Louisiana pandemic experience has been unique, complicated by hurricanes. Successful outcomes will require the engagement of all persons in Louisiana.



Section 1: COVID-19 Vaccination Preparedness Planning

The Louisiana Department of Health (LDH) developed a COVID-19 vaccine planning team in April 2020. Team members included representatives from the <u>Louisiana Department of Health</u>, the State Health Office of Emergency Preparedness, the Office of Public Health Immunization Program and an intelligence officer from the Governor's Office of Homeland Security and Emergency Planning (GOHSEP). This COVID-19 vaccination team met regularly with increasing frequency through August 2020. This Team drafted the *Louisiana COVID-19 Vaccination Plan* and an allocation tool for priority planning.

The LDH Office of Public Health (OPH) established a Vaccination Action Collaborative (VAC) to coordinate planning and response efforts for COVID-19 vaccine distribution and dispensing in July 2020. The VAC is a multi-disciplinary group inclusive of professional boards, representative organizations, academia, healthcare providers, first responders, emergency management and public health. Louisiana has a centralized public health system for 62 of the 64 parishes. The LDH OPH provides many public health services and has a strong collaborative relationship for preparedness and response with both Orleans and Placquemines parishes. Representatives have been included in the VAC.

The VAC met on August 19, 2020 and September 23, 2020 with monthly meetings scheduled through June 2021. All members volunteered or were assigned into VAC Work Groups to address specific areas. Those work groups include: Communications and Outreach Work Group; Planning Work Group; Prioritization-Allocation Work Group and the Logistics and Operations Work Group. Members with health equity expertise are in each Work Group to address health disparities in all areas. A charter was developed for each Work Group to guide their efforts over the past months. The preliminary planning and collective work of the VAC and its work groups are represented in this initial planning document.

Building Upon Existing Planning Efforts

Recent hurricanes and flooding have impacted the State. Regions not impacted by this year's storms have received and continue to house evacuees. Hurricane Laura caused significant damage in September 2020 in OPH Region 5 with rebuilding and repatriation efforts hindered by Hurricane Delta in October 2020. The OPH Strike Teams have provided tetanus and hepatitis A vaccination in Regions 2, 5 and 6. The Region 5 vaccination efforts continue at undamaged Parish Health Units and community outreach efforts. Similar planning is in development for flu vaccination campaigns. Maintenance of the cold-chain, inventory and vaccine management required to support the OPH Strike Teams has been successful with this recent experience and these efforts will be directly applicable to COVID-19 vaccination planning.

Southwest Louisiana suffered the greatest impact from two hurricanes six weeks apart. This area is home to a number of advanced manufacturing industries with operations ranging from traditional petrochemical companies for which Louisiana is well-known to chemical, metal and nuclear power plant components. An occupational health capacity assessment is currently underway, as the health system capabilities have been challenged by the 2020 hurricane season. The State is aware of the need for increased attention to the issues of this area for COVID-19 vaccine provider enrollment.



Louisiana COVID-19 vaccination strategy builds upon a number of existing plans related to public health emergencies. Those plans include:

- State of Louisiana Emergency Operations Plan
- State of Louisiana Unified Command Group Legislation
- State of Louisiana's Emergency Support Function 8 Emergency Management Plan
- Louisiana Department of Health's Emergency Operations Plan
- State of Louisiana's Strategic National Stockpile Plan
- State of Louisiana's Points of Dispensing Plan
- State of Louisiana's Regional Points of Dispensing Plans
- 64 Parish Points of Dispensing Plans
- Individual Points of Dispensing Plans for Closed or Open Locations
- State of Louisiana's Pandemic Influenza Plan
- Louisiana National Guard's Task Force: COVID-19

Exercise Experience

Past experiences involving the distribution and administration of vaccines were used to influence this initial planning document prepared for the State of Louisiana. The below examples are a small representation of the number of exercises state and regional public health staff participate in on a regular basis. Challenges related to natural disasters, nuclear emergencies, and terrorist acts require that the Office of Public Health prepare for and exercise their response plans for any of these emergencies. All exercises are multi-disciplinary and involve local and state public safety contacts. Examples of these experiences related specifically to mass vaccination campaigns include:

- 2009 H1N1 After Action Report from the Louisiana Department of Health
- 2015 Louisiana Office of Public Health Pandemic Flu Full Scale Exercise
- 2018 Louisiana Office of Public Health Mass Vaccination Campaign-After Action Report
- 2019 Louisiana Office of Public Health Mass Vaccination Campaign-After Action Report

Louisiana is a high-risk State for emergency events and disasters. Significant experience in coordination has benefited coronavirus pandemic response. Past experiences involving the distribution and administration of vaccines were used to influence this initial planning document prepared for the State of Louisiana. The following real-world events or exercises were used to support this planning process. Additional information regarding these exercises are included as an Appendix to this initial planning document.

2009 H1N1 After Action Report Louisiana Department of Health

The following strengths and weaknesses obtained from this experience were used to influence the current planning process.

Major Strengths

The major strengths identified during this response are as follows:



- Providing the citizens of Louisiana with timely and accurate information on the severity and scope of the disease, steps to protect themselves and their families, and Louisiana Department of Health Office of Public Health's (LDH-OPH) ongoing efforts responding to the event.
- The creation of a statewide system for the collection of clinical samples and their transport to the state public health lab for testing.
- Expanding state public health laboratory capacity to meet the demand for clinical laboratory testing.
- The distribution of antiviral medication and other medical supplies to all Tier 1 and 2 medical facilities in Louisiana within a 48-hour period.

Primary Areas for Improvement

Throughout the response, several opportunities for improvement in DHH-OPH's ability to respond to the incident were identified. The primary areas for improvement, including recommendations, are as follows:

- Enhance communication capabilities through update of Health Alert Network contact databases and improvement of communication methods.
- The State public health laboratory was overwhelmed by sample H1N1 submissions and the lag time between submission and results availability grew longer as the event progressed. This was partially mitigated by the acquisition of new equipment, but further expansion of lab testing capacity is needed.
- For future responses, specific trigger points must be incorporated into plans that dictate when specific actions within the plan are activated.

A top priority of the OPH will be to ensure and uphold Health Equity during COVID-19 vaccination program planning activities. Using the National Academies of Science, Engineering and Medicine *Framework for Equitable Allocation of COVID-19 Vaccine (2020)* (herein referred to as "The Framework"), these efforts will be strengthened by their comprehensive research and conclusions, including lessons learned from previous mass vaccination campaigns from the 2009 H1N1 influenza and the 2013-2016 vaccination efforts in the Ebola outbreak in West Africa.

According to The Framework, the goal for the equitable allocation of the COVID-19 vaccine is to reduce severe morbidity and mortality and negative societal impact due to the transmission of SARS-CoV-2. The Louisiana COVID-19 Vaccination Plan in addressing health equity shall align with this goal, while mitigating health inequities, showing equal concern for all, being fair and transparent, and building on the best available evidence. Ultimately, Louisiana's vaccination program aims to vaccinate all who choose to be vaccinated and are without medical contraindications to the vaccine.

The vaccination plan will be adaptive, capable of being changed as the understanding of the disease and its risk factors deepens, and as vaccines become available. If the criteria used to identify categories of individuals or groups for each phase change accordingly, those changes will be stated and applied clearly and in keeping with the framework's foundational principles.



COVID-19 Exercises

Mass Vaccination Exercises (Influenza)

A mass vaccination campaign is conducted every year by the Office of Public Health to provide influenza vaccination to citizens in all nine public health Regions and exercise planning. Each Region operates a centrally-located Point of Dispensing (POD) where people can walk in without an appointment and receive their influenza vaccine at no cost. Previous exercises have targeted hard to reach populations, critical infrastructure personnel, and use of the checklist to maintain vaccine at off-site clinics.

This year's mass vaccination exercises (MVE) are an opportunity to practice social distancing POD operations with key stakeholders in advance of real-world response for COVID-19 vaccination. Seventeen exercises are planned from mid-October through mid-November 2020. Many of the Regional MVEs will have a drive-through component.

Each Region plans, organizes and conducts their MVE according to guidance and toolkit provided by the Louisiana Strategic National Stockpile (SNS) Program. This provides for a consistent approach to mass dispensing operations in a way that addresses locally relevant needs within the population.

The mass vaccination exercises will include and test outreach activities and a media campaign coordinated by the Louisiana Department of Health Bureau of Media and Communications. This includes utilization of mass media, social media, and community events to promote the vaccination clinic.

Staffing for the points of dispensing are a combination of LDH OPH staff, and other state agency staff and local community partners in each Region. Assigned staff are routinely trained in POD operations along with other hazard-specific training as part of each Region's community preparedness efforts.

2020 Influenza MVE Toolkit Documents

- Flu Outreach Tracking Sheet
- 2020 MVE Exercise Schedule Regions 1-9
- Seasonal Flu Q&A 2020
- Flu Facts for Students Aug 2020
- Best Practices Off Site Vaccination Clinic Checklist
- CDC Vaccine Administration
- Flu Vaccine Toolkit Plan 2020 9-3-2020
- Immunization Policies and Procedures Manual August 2020
- Influenza Vaccination Pre-Vaccination Screening Tool IAC
- LDH Flu Talking Points 09 01 2020
- rr6908 Prevention and Control of Seasonal Influenza with Vaccines
- Safe Vaccine Administration during COVID-19
- Sample AAR Mass Vaccination Exercise 2020
- Sample Exercise Sign In Sheet
- Sample EXPLAN Flu Vaccine Exercise 2020
- Sample Mass Vaccination Exercise 2020 EEG



- Sample Participant Feedback Form
- Sample Planning Meeting Agenda
- Sample Safety Plan ICS 208
- You Call the Shots

Additional 2020-21 Influenza Activities

After the Louisiana COVID-19 Vaccination Playbook is finalized, additional training needs will be assessed and drills will be conducted to teach, refresh, and enhance the knowledge, skills, and abilities of the field members responsible for the safe and efficient execution of the operation.

Louisiana has requested and is set to receive no cost, late season flu vaccine from the CDC. This vaccine has been offered to the Federally Qualified Health Clinics (FQHC) and Rural Health Clinics (RHC) in Louisiana. This vaccine resource will provide an additional community outreach effort beyond the usual flu vaccination efforts at FQHCs and RHCs. Flu vaccination will decrease the rate and severity of influenza illness and test FQHC and RHCs COVID-19 vaccination capabilities. The Louisiana Primary Care Association has facilitated communication. Ongoing technological collaboration has resulted in all FQHC reporting vaccinations into LINKS. Work with the RHCs for LINKS interface continues.

Louisiana partners and stakeholders are striving to increase flu vaccination with a very aggressive flu campaign during the COVID-19 pandemic. Increased protection from influenza will benefit residents and decrease the burden to the healthcare ecosystem. Flu vaccination while following disease prevention and social distancing guidance will improve COVID-19 vaccination provider preparedness planning in this real-world response. Supplemental funding through CDC from Round 1 is being used for a multi-media campaign, Roll Up Your Sleeves, Louisiana. <u>Cumulative monthly influenza vaccination coverage</u> estimates for persons six months and older by state, National Immunization Survey-Flu (NIS-Flu) and Behavioral Risk Factor Surveillance System (BRFSS) for the past few flu seasons:

2016-2017	2017-2018	2018-2019	2019-2020
41.8% (44 th)	35.3 (50 th)	41.6 (47 th)	47.5 (41 st)

2020 COVID-19 Vaccination Exercise Schedule

The State of Louisiana will utilize FEMA's Homeland Security Exercise and Evaluation Process to provide a framework for a progressive exercise model which will consist of a series of three facilitated Table-Top exercises, each one building on the other, ultimately covering all the sections of the Louisiana Vaccination Plan. Additional tabletop exercises or workshops will be conducted on an as-needed basis to resolve or correct any items or issues identified as part of the planning or exercise process of the VAC.

The first exercise planned for late October 2020 will consist of two target audiences, functional and tactical levels to walk through Sections I-V, *Purpose, Situation & Assumptions, Concept of Operations, Activation & Implementation, and Assignment of Responsibilities*, of the LDH OPH COVID-19 Vaccination Plan, August 2020, which has been cross walked/correlated with the CDC Playbook. This exercise will



have two facilitated breakout sessions lasting four hours, spending approximately two hours to work through the previously identified planning assumptions and roles and responsibilities. The goal is to facilitate understanding and learning, as well as identify any additional concerns or gaps necessary to finalize the plan.

The second exercise will consist of two target audiences, functional and tactical levels to walk through Section VI, *Procedures*, of the LDH OPH COVID-19 Vaccination Plan, August 2020, which has been cross walked/correlated with the CDC Playbook that covers components such as Operations, Logistics, Security, and Public Information. This exercise will have two facilitated breakout sessions lasting 6-8 hours, spending approximately two hours per section as needed. The goal is to facilitate understanding and learning, as well as identify any additional concerns or gaps necessary to finalize the plan.

The third exercise will consist of three target audiences, strategic, functional, and tactical levels to conduct a walk through/discussion to leadership (strategic) before finalizing the completed draft plan. This will be a two-hour exercise followed by a workshop comprised of members from the functional and tactical levels to work through the finalization/publishing process of the plan.



Section 2: COVID-19 Organizational Structure and Partner Involvement

Organizational Structure

The Louisiana Department of Health (LDH) Office of Public Health (OPH) Pandemic Influenza and Severe Respiratory Pathogen Plan was finalized on March 1, 2020. Details of the organizational structure are in that overarching plan. LDH OPH is the lead agency for pandemic influenza and severe respiratory pathogen response within Louisiana.

The State Health Officer (SHO) holds the ultimate health authority in Louisiana to declare and cease a Public Health Emergency. The SHO will also control any subsequent actions, restrictions, re-openings, or guidance based on additional guidance from the CDC at the time of the event. The SHO is supported by the Assistant Secretary of the Louisiana Department of Health, in addition to the Office of Public Health Center Directors. These staff members would assume the temporary responsibilities of the SHO if he/she was unable to perform because of illness, etc. The LDH OPH Emergency Operations Plan, updated March 2017, describes the Assignment of Responsibilities along with Key Positions and three Alternates identified by position title.

The Louisiana Governor's Office of Homeland Security and Emergency Preparedness (GOHSEP) State of Louisiana Emergency Operations Plan adopts the National Incident Management System (NIMS) guidance and states that Louisiana will use the NIMS Incident Command System (ICS) to manage incidents or events. LDH OPH has also adopted NIMS and uses the Incident Command System (ICS) to manage incidents.

LDH staff are assigned emergency response roles and positions at the LDH EOC, Regional OPH EOCs, and local EOCs. NIMS and ICS training have been required for OPH staff since 2006.





The LDH EOC ICS is located in the Emergency Operations Plan (EOP), as Appendix D.

The State Health Officer or designee provides direction and authority for vaccination efforts. This includes activities to obtain and disseminate key medical-related information. Many of the other actions and requirements for vaccination are supported by other State and local agencies at various stages of the pandemic. Planning, emergency management, prevention, preparedness, response, recovery, and mitigation discussions are facilitated by LDH OPH and use subject matter experts for relevant contributions to Incident Command.

The VAC serves as the principal planning organization for the distribution and allocation of vaccine. The VAC is supported by the Office of Public Health's Center for Community Preparedness who manages the deployment and distribution of the Strategic National Stockpile. This initial plan builds upon Louisiana's prior experiences related to both vaccine distribution and the real-world deployment of the Strategic National Stockpile within Louisiana.



In order to address health equity in coordination efforts, OPH will utilize the *Framework for Equitable Allocation of COVID-19 Vaccine (2020)* (herein referred to as "The Framework"). According to The Framework, OPH may need to make adjustments to the recommended approach to accommodate the needs of their populations and resources available; however, continuing to be guided by the goal of reducing severe morbidity and mortality and negative societal impact due to the transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is essential. Implementing an effective and equitable COVID-19 vaccination program will require robust coordination across all agencies and partners.

COVID-19 Planning and Coordination

The LDH OPH is the lead agency for pandemic response within Louisiana. LDH works collaboratively with state, local, and private agencies to provide trainings and other educational opportunities to ensure preparedness in a pandemic situation.

Continuity of Operations Plans (COOP) plans allow OPH to maintain essential operations during public health emergencies. COOP planning was revised February and March 2020. Cross-training of staff has been completed to ensure capabilities during periods where absenteeism is increased. Additional positions, funded by supplemental funding as increased the depth of persons for core functions in the OPH Immunization Program.

The Office of Public Health will order, allocate, track, administer and provide guidance for decision makers and the public during COVID-19 vaccination response during the pandemic. OPH will coordinate communication with response partners through ESF 8. Plans and processes contained within this initial plan are based on existing state and local plans related to the distribution and administration of vaccine.

The LDH has established a VAC to coordinate planning and response efforts related to the distribution of COVID-19 vaccines. The VAC is a multi-disciplinary group inclusive of professional boards, representative organizations, academia, healthcare providers, first responders, emergency management and public health. The VAC met on August 19, 2020 and September 23, 2020. All members were assigned and engaged in VAC Work Groups to address specific areas. Those work groups include: Logistics and Operations Work Group; Planning Work Group; Communications and Outreach Work Group; and the Prioritization-Allocation Work Group. Health equity representatives are members of each Work Group in an effort to address health disparities in all areas. A charter was developed for each Work Group to guide their efforts over the past months. The collective work of the VAC includes the initial COVID-19 Vaccination Team and its work groups are represented in this initial planning document.

The Louisiana COVID-19 VAC Operations/Logistics Work Group has developed plans and processes that may now be used at the parish and community levels.

This core VAC Work Group is now expanding to include critical infrastructure for their expertise and experience.



To ensure equity, OPH will collaborate closely and foster community partnerships for continued development of the plan, recognizing that communities, especially those disproportionately impacted by COVID-19 or with limited access to care, must be effectively, authentically, and meaningfully engaged in local vaccination plans. To that end, strong partnerships need to be developed urgently with community-based organizations and other community partners in order to build effective vaccine delivery systems that are convenient for the people they are intended to reach.

Under the guidance of the CDC, OPH will plan for different components of the COVID-19 vaccination program, including (1) defining priority groups, (2) assisting with tracking vaccine supply and administration, (3) monitoring for adverse events following immunization (in collaboration with FDA), and (4) assessing vaccine coverage and effectiveness. In addition, OPH will use communication and educational materials developed by the CDC to address vaccine confidence concerns and increase vaccine demand, including strategies to reach underserved and hard-to-reach populations.

Vaccine Action Collaborative Work Groups

Organizations Represented on the Planning Work Group / Relevant Expertise

- Lead: Louisiana Office of Public Health / Immunization Program
- Governor's Office of Homeland Security and Emergency Preparedness
- Louisiana Board of Nursing
- Louisiana Board of Pharmacy
- Louisiana Department of Health / Health Equity
- Louisiana National Guard / Planning
- Louisiana Office of Public Health / Epidemiology
- LSU Health Sciences Center / Pediatric Infectious Diseases
- Xavier College of Pharmacy

Organizations Represented on the Communication & Outreach Work Group / Relevant Expertise

- Lead: Louisiana Office of Public Health / Immunization Program
- Governor's Office of Indian Affairs
- Louisiana Department of Health / Bureau of Media and Communications
- Louisiana Department of Health / Office of Community Partnerships and Health Equity
- Louisiana Department of Health / Epidemiology
- Louisiana National Guard / Planning
- Louisiana State Nurses Association
- Tulane University School of Medicine
- Tulane University School of Public Health and Tropical Medicine / Epidemiology and Health Economy
- Urban League of New Orleans



- Willis-Knighton Health System / EMS
- Xavier University / International Vaccine Access

Organizations Represented on the Prioritization & Allocation Work Group / Relevant Expertise

- Leads: Louisiana Office of Public Health / Immunization Program
- Lead: LSU Health Sciences Center / Medical Ethics
- Federally Qualified Health Clinics
- Governor's Office of Homeland Security and Emergency Preparedness / Fusion Center
- Louisiana Board of Pharmacy
- Louisiana Hospital Association / Clinical Affairs
- Louisiana National Guard / Planning
- Louisiana Nursing Home Association
- Louisiana Primary Care Association
- Louisiana Public Health Institute
- LSU Health Sciences Center / Epidemiology
- Ochsner Health System / Infectious Disease Control and Prevention
- Rural Health Clinics
- Tulane School of Public Health and Tropical Medicine / Epidemiology
- Tulane Virology Department

Organizations Represented on the Logistics/Operations Work Group / Relevant Expertise

- Lead: Louisiana Office of Public Health / Immunization Program
- Acadian Ambulance
- Governor's Office of Homeland Security and Emergency Preparedness / Fusion Center
- Louisiana Board of Pharmacy
- Louisiana Department of Health / Bureau of Emergency Medical Services
- Louisiana Department of Health / Bureau of Health Information
- Louisiana Hospital Association
- Louisiana National Guard / Planning
- Louisiana Nursing Home Association
- Louisiana Primary Care Association
- Louisiana Office of Public Health / Epidemiology
- Louisiana Office of Public Health / Community Preparedness
- Louisiana Department of Health / Office of Emergency Preparedness
- Tulane University / State & Federal Regulations, Government & Community Relations



Coordination with State and Local Authorities

The Unified Command Group (UCG) is the strategic decision-making body for emergency and disaster response in the state with the governor serving as the unified commander. The UCG provides a unified and coordinated approach to emergency incident management, enabling institutions and agencies with different legal, geographic and functional responsibilities to coordinate, plan and interact effectively.

The UCG coordinates and manages the activities of the State Emergency Operations Center (SEOC). The Louisiana Department of Health representative on the UCG is the Secretary and State Health Officer.

This COVID-19 Vaccination Playbook is created using a cooperative management concept. While there is a single point (State Health Officer or designee) to obtain and disseminate key medical-related information, many of the other requirements of the program are supported by other State and local agencies at various stages of the pandemic. Planning, emergency management, prevention, preparedness, response, recovery, and mitigation discussions are facilitated by LDH OPH and use subject matter experts for relevant contributions.

A trained workforce within OPH carries out the public health emergency response when the LDH Emergency Operation Plan is activated. The established Regional structure continues during public health emergencies. The various operations required for response may or may not parallel normal activities, depending on the response action required.

The head of each Section, Bureau, and Region has designated an emergency coordinator and an alternate to act on him/her behalf during an emergency. Each of these areas has a Continuity of Operations Plan (COOP) Coordinator to prepare and maintain plans, procedures, arrangements and agreements related to maintaining core/essential public health services during an emergency response. Sections, Bureaus, and Regions are responsible for remaining current on state and federal guidance, formulating and updating plans, procedures, arrangements and agreements, and for coordinating emergency operations within their area of responsibility.

OPH engages with jurisdictional business, educational, and social service sectors to support the mitigation of future incidents formally at the State level through the Emergency Support Function (ESF) responsibilities. A network of Designated Regional Coordinators (DRC) exists within Louisiana for coordination of ESF 8 activities at the Regional level. DRCs are generally not State employees, but professionals employed in the area of their DRC responsibility. These DRC networks include but are not limited to public health, hospitals, home health, nursing homes, emergency medical services, coroners, and behavioral health services. Activities include coordination of response activities as well as community planning, outreach, and preparedness exercises.

Tribal Engagement

The Governor's Office of Indian Affairs and the LDH Office of Minority Health Access staff have established relationships with tribes and tribal communities. In addition, the OPH Regions, Bureau of



Community Preparedness and Immunization Program have established relationships with routine contact.

Louisiana has four federally recognized tribes with a limited provision of healthcare on tribal lands. In 2009, two tribes, Chitimacha and Coushatta provided H1N1 vaccine to their members. Currently, only the Chitimacha Tribal clinic participates in the Louisiana Vaccines for Children (VFC) Program. In 2019, the OPH Immunization Program mapped the healthcare providers where families reported being American Indian for the VFC Program and developed a fact sheet.

In addition to the federal tribes, there are 11 state recognized tribes, for a total of 15 Tribal nations. Overall Tribal health considerations are integrated into the strategic plan of the OPH with documented of ongoing communication and outreach.

For the current Tribal health centers and clinics, the OPH has completed the CDC's *Tribal and Urban Indian Program Engagement Tool for COVID-19 Vaccine Distribution*:

Tribe	Chitimacha Tribe of Louisiana	Coushatta Tribe of Louisiana	Jena Band of Choctaw Indians	Tunica-Biloxi Indian Tribe of Louisiana
Population	1,300 members + general public	~865	327	~1,226
Distribution Method	 Chitimacha Tribe of Louisiana Health Clinic IHS LINKS Enrolled Pending 	 Coushatta Tribe of Louisiana Department of Health IHS LINKS Enrolled Pending 	 Jena Band of Choctaw Indians Health Department Pending 	 Tunica-Biloxi Health Department LINKS Enrolled Pending

Table 2.1: Federally Recognized Tribal Nations of Louisiana

While the decisions for vaccine distribution will be made by the Tribe, both parish and regional planning includes the Coushatta, Jena Band of Choctaw, and Tunica-Biloxi Tribes, in their healthcare infrastructure and planning for COVID-19 vaccine distribution and dispensing. The Chitimacha Tribe has closed POD planning developed in coordination with OPH Region 3. The above chart provides a list of IHS direct service sites, Tribal Health facilities, and Urban Indian facilities located in Louisiana.

In addition to federal and state tribes in Louisiana, there are communities that are included in the planning of the Bureau of Minority Health.



Key Partnerships for Critical Populations

The Governor established a Health Equity Task Force early in COVID-19 response asking universities and research institutions to lead this effort. The groups that participate in the task force include:

- Southern University's Nelson Mandela School of Public Policy
- Xavier University's Department of Public Health Services
- Health Science Centers at LSU and Tulane
- LDH Office of Public Health
- LDH Bureau of Minority Health Access
- Pennington Biomedical Research Center
- Schools of Nursing all Louisiana universities

The immediate assignment to the Health Equity Task Force is to make sure communities with health disparities are blanketed with good information on COVID-19 safety and prevention; provide the medical community with best practices and protocols for treating communities with underlying medical conditions and health disparities; and ensure testing availability and ease of access for all communities. This Task Force began work immediately in April 2020 and their research will result in the creation of a Dashboard on Health Equity. The OPH Immunization Program has established a relationship for COVID-19 vaccination coordination. This collaborative effort has recognized concerns that have been shared by Louisiana with national organizations. The Health Equity Task Force will direct outreach activities, and risk/crisis response communication messaging and delivery. Task Force membership includes leadership from the State's COVID-19 Vaccination Action Collaborative.

Seven of the COVID-19 testing contractors are interested in participating in COVID-19 vaccination efforts. These contracts are being amended and several operational documents have been developed for these Mobile Vaccination Teams. These teams will be deployed to address vulnerable and rural populations of Louisiana.

Regional and Local POD plans include provisions for the identification, notification, and vaccination of vulnerable populations including and homeless, people with disabilities (both physical and cognitive), people who speak limited English or languages other than English, etc.). To assist local health officials in providing for special populations in their emergency preparedness planning efforts, OPH has developed Special Populations Guidance in the Local Point of Dispensing planning. This guidance has the OPH Regions go through a process of identifying community based outreach organizations to assist in the identification, education, contact, and vaccination of each of these special population groups. In addition, COVID-19 vaccination planning has included targeted outreach.

 Residential/Occupational Locations - Many residential/occupational locations in Louisiana are capable of self-prophylaxis during a pandemic. These facilities have occupational health or trained medical staff. Providing these locations with vaccine not only benefits the community by keeping residents and workers at their location, but also relieves some of the total burden on the public PODs. The State of Louisiana has therefore prepared the Residential/Occupational



POD Workbook to prepare these locations to be their own POD. This guide helps these institutions set up Point of Dispensing sites for their employees, families, and accessory staff. This guidance is appropriate for hospitals, nursing homes, residential living facilities, large occupational locations (chemical plants, large industry), military facilities, residential schools (Universities), etc. Vaccine for a pandemic immunization campaign would be direct shipped to these predetermined locations, or picked up by these pre-qualified institutions at the local Health Unit or other site meeting storage and security requirements.

- 2. Correctional Facilities LDH OPH has developed a plan with the Louisiana Department of Corrections to have correctional facilities provide vaccinations to their residents and staff in the event of a pandemic. Most correctional facilities with medical staff are trained and competent in providing care to their residents. Correctional facilities will have their vaccine direct shipped to their pharmacy, or pick up their vaccine from their local Health Unit.
- 3. Louisiana has many ICE Detention Facilities. There are occasional challenges, but recent response to varicella and mumps outbreaks among detained persons have demonstrated the ability of the state to work with these facilities. Many of these facilities are coordinated with local sheriff's offices. Local law enforcement in Louisiana is engaged in parish POD planning with well established relationships with Louisiana Office of Homeland Security and Emergency Preparedness.
- 4. Nursing Homes and Assisted Living Facilities In addition, OPH is working with the Louisiana Nursing Home Association to address the issue of delivering and administering vaccine to nursing homes, behavioral health centers, and assisted living centers by using the Residential/Occupation Point of Dispensing planning. These facilities can vaccinate both residents and employees individually or work with community pharmacies as is their usual process for influenza vaccination. Facilities which do not participate in this program or have a very independent population will access vaccine at the public PODs.
- 5. The Louisiana Home Health Association participates on the VAC and provides a communication network for Home Health agencies in Louisiana and homebound persons. This relationship will identify the specific needs of COVID-19 vaccine response.
- 6. The on-going Hepatitis A outbreak in Louisiana that began in December 2018 has strengthened relationships and established a vaccination infrastructure that continues to provide hepatitis A vaccine during the pandemic. Behavior Health Centers and Substance Abuse Treatment Facilities across the state have established processes for requesting vaccine that will be appropriate for
- COVID-19 vaccine response when appropriate. This Mobile Vaccination Team planning will transition to include influenza vaccine by mid-November when state purchased flu vaccine is available. In addition to the homeless and substance abuse populations reached by the Mobile Vaccination Teams for hepatitis A, these Teams will also include hard-to-reach populations as determined by the OPH Flu Dashboard. Additional federal funding will be used for Mobile Vaccination Team outreach with COVID-19 vaccine.
- 7. Community Preparedness has established networks for engagement and communication with the faith-based community. Information regarding the importance of seasonal flu vaccination has been provided in past years, along with inserts for bulletins and advertising campaign



posters to add local faith-based event information. This season's planning is in development with the Roll Up Your Sleeves, Louisiana media campaign beginning in mid-October 2020. Contact information and details for off-site vaccine providers in Louisiana is located on the LDH Fight the Flu LA web page.

- 8. Within LDH, the Office of Citizens with Developmental Disabilities and the Office of Community Partnerships & Health Equity coordinate Emergency Preparedness planning and response. The Association of State and Territorial Health Officers (ASTHO) has selected Louisiana to embed an ASTHO Persons with Disabilities Champion for COVID-19 Vaccination. This addition will enhance existing planning focused on the challenges of this community.
- 9. The LDH OPH has well established emergency planning by both GOHSEP and BMAC for people with language disabilities or limited proficiency with English. The OPH Flu and COVID-19 vaccination promotion media campaigns include activities directed to hard-to-reach populations. Print materials are routinely provided in both English, Spanish and Vietnamese developed through an existing contract.

To further address health equity, the LDH OPH recognizes that an extensive array of partnerships already exists throughout Louisiana, and that through collaborating with community partners embeds ethics, equity, and cultural competence into their activities. Some are considered "traditional" public health partners, such as federally qualified health centers, hospitals, and pharmacies (including community pharmacies). Providers in the community can play a valuable role in reaching community members, but their own potential fragility in the context of the pandemic needs to be taken into account. Other entities that serve as community partners in the vaccination campaign include community centers, schools, universities, Historically Black Colleges and Universities, Hispanic Association of Colleges and Universities, Tribal Colleges and Universities, faith-based organizations, public safety organizations, philanthropic organizations, and employers.



Section 3: Phased Approach to COVID-19 Vaccination

Phase 1	Phase 2	Phase 3	Phase 4		
 Phase 1a "Jumpstart Phase" High-risk health workers First responders Phase 1b People of all ages with comorbid and underlying conditions that put them at significantly higher risk Older adults living in congregate or overcrowded settings 	 K-12 teachers and school staff and child care workers Critical workers in high-risk settings—workers who are in industries essential to the functioning of society and at substantially higher risk of exposure People of all ages with comorbid and underlying conditions that put them at <i>moderately</i> higher risk. People in homeless shelters or group homes for individuals with disabilities, including serious mental illness, developmental and intellectual disabilities or in recovery, and staff who work in such settings People in prisons, jails, detention centers, and similar facilities, and staff who work in such settings All older adults not included in Phase 1 	 Young adults Children Workers in industries and occupations important to the functioning of society and at increased risk of exposure not included in Phase 1 or 2 	 Everyone residing in the United States who did not have access to the vaccine in previous phases 		
Equity is a crosscutting consideration:In each population group, vaccine access should be prioritized for geographic areas identified through CDC's Social Vulnerability Index or another more specific index.					

To address and ensure health equity, within each phase, **all groups have equal priority**. LDH OPH will assess the program's ability to reach key populations identified by working to reduce health disparities, use data-driven approaches, engage with community partners and diverse leaders, lead culturally responsive outreach, and reduce stigma. Through collaborations, community organizations and immunization administrators can ensure that vaccination initiatives are based on the best available evidence and that initiatives are culturally and linguistically appropriate for the people and communities who need them. All community partners will embed ethics, equity, and cultural competence into their activities.

The LDH OPH will focus on being culturally and linguistically appropriate to improve communication about COVID-19 vaccine and its benefits among people and their families. This will help to build trust in care providers and public health authorities; it also supports informed decision making and may help reduce vaccine hesitancy. LDH OPH will use existing systems, structures, and partnerships to ensure equitable allocation, distribution and administration of the COVID-19 vaccine.



Planning for the Three Phases of Vaccine Administration

Phase 1: Potentially Limited Doses Available

The LDH OPH has the flexibility within the structure for COVID-19 vaccination response to range from two to several phases of vaccine availability. The Louisiana Allocation Tool uses a four phased response, but is easily adaptable to three phases as described in Playbook guidance.

The Point of Dispensing (POD) planning will be the framework for the COVID-19 vaccine response. Social distancing and infection control procedures will be required at POD sites. Vaccine will be administered at the local level to priority groups determined by the Incident Commander, the Louisiana Governor in collaboration with the State Health Officer or designees, epidemiologic evidence and guidance from CDC, and the OPH Infectious Disease Epidemiology Section. Local communities, in partnership with the nine Louisiana OPH Regions, have the responsibility to plan and implement PODs for administration of COVID-19 vaccine to priority groups in their jurisdictions. Louisiana will follow the CDC's Advisory Committee on Immunization Practices guidance on priority groups and will likely focus primarily on healthcare and congregate care setting facilities (see prioritization of tier groups). Distribution of vaccines to sites within priority groups may also be based on geographic positivity rate or hospitalization rate in order to protect those in greatest need or at most risk.

These groups are ranked together at the top of the order of prioritization because they meet at least two criteria listed in the decision-making goals. Both groups are considered to be at an equal prioritization level, and therefore if the initial supply is inadequate to provide to both groups, it is recommended that a proportionate distribution based on the number of staff in each group (for example, if there are combined 100,000 personnel in both groups, and of that 30,000 are from the Congregate Care Setting Facilities, it is recommended to give 30% of available vaccine to the Congregate Care Setting Facilities personnel).

If the initial supply of vaccine is inadequate to cover all hospitals, it is proposed that the vaccine be distributed to various hospitals based on their COVID-19 hospital census (for example, those who in the past month have had higher census would get more vaccine). Acknowledging that even using this method will likely leave many hospitals with inadequate vaccine for all workers, the principle of subsidiarity is invoked to allow each hospital to decide at the local level which of their personnel should receive the vaccine. However, local recognition is encouraged of the important contributions and possible exposure of all staff, including housekeeping, custodial, transport, and any others who may not be considered clinical but nonetheless have exposure and may be at higher risk due to other demographic variables.

In addition, Louisiana will approve orders based on the likely populations served by a vaccination provider, the provider's capability to store and handle various COVID-19 vaccine products, and existing inventory. The Immunization Program has developed a COVID-19 Vaccine Dose Allocation Tool and comprehensive list of POD sites to assist in these efforts. Given that the minimum order size and increment for centrally distributed vaccines will be 100 doses per order for one planned product, and 1,000 doses for another planned product, most Phase 1 POD sites will have larger volumes of patients



maximize the utilization of those doses within those orders. Distribution to smaller POD sites is described in the Distribution and Transport sections of these plans.

When a vaccine against COVID-19 becomes available, it will be ordered through LINKS, the established immunization information and management system of the Louisiana Department of Health Office of Public Health (LDH OPH) Immunization Program. McKesson, the CDC's vaccine distribution vendor, will distribute vaccine to sites throughout the state that have had orders approved by the Program. Contingency plans for storage, alternate distribution options, transport, and security for vaccines will follow the Louisiana Strategic National Stockpile planning with key response partners. A strict chain of custody for pandemic vaccine will be followed and documented. Each dose of vaccine must be accounted for to ensure continued receipt of vaccine from the federal government as well as continued distribution from LDH OPH to vaccine providers.

Whenever possible, vaccine will be shipped to the location where it will be administered to minimize potential breaks in the cold chain. There will be scenarios for smaller POD sites where vaccine will be shipped to a central depot and redistributed to additional locations. Since the federal government does not redistribute product, this will be the responsibility of the state.

Since initial COVID-19 vaccines are anticipated to be authorized under an EUA, they will contain slight variations from approved Food and Drug Administration (FDA) products, the most distinct being that vaccines will not have expiration dates on them. Current expiration dates by vaccine lots for all authorized COVID-19 vaccines will be posted on the US Department of Health and Human Services (HHS) website, accessible to all COVID-19 vaccination providers in Louisiana through a barcode scanner. All POD sites will have the ability to scan and/or manually enter these codes to get the current expiration date of the product upon arrival and mark the product with that date using a temporary card. The expiration date will be verified daily and any changes to the expiration date will be updated.

Each vaccine will also have a QR code that allows vaccine providers to access FDA-authorized, vaccine product-specific EUA fact sheets for COVID-19. POD sites will print out these facts sheets and distribute them to every person who receives the vaccine.

According to The Framework, Phase 1a individuals—who are themselves unable to avoid exposure to the virus—play a critical role in ensuring that the health system can care for COVID-19 patients. In considering those health care workers who are at an elevated risk of transmitting the infection to patients at higher risk of mortality and severe morbidity, it is also important to note that nursing home residents and staff have been at the center of the pandemic since the first reported cases. In addition to their occupational and community exposures, these workers are statistically at a higher risk of contracting COVID-19 and experiencing severe health effects because they come from populations with higher rates of comorbid conditions. A notable proportion of nursing home workers are Black (27.8 percent), as are home care workers (Black: 29.7 percent and Latinx: 17.5 percent). A sizable proportion of such workers are over 65 as well (Black: 9.1 percent and Latinx: 11.3 percent).



For Phase 1b vaccinating all individuals with these comorbid conditions is not possible, because the group includes hundreds of millions of people in the United States. In a highly constrained vaccine scenario, the initial group of recipients with comorbid and underlying conditions could focus specifically on individuals with two or more of these designated conditions. The combination of the risk of severe disease due to advanced age and the higher risk of acquiring infection and transmission among older adults included in this population group makes it among the highest priority groups for receiving the COVID-19 vaccine.

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

As large number of doses become available in Phase 2, administration of vaccine to priority groups will continue to occur through registered vaccine providers in LINKS, such as hospitals, private physicians, and pharmacies. Vaccination providers/sites will be enrolled in the United States Government (USG) COVID-19 vaccination program.

Vaccine will be distributed to the public through multiple possible mechanisms, including a combination of private providers, hospitals, clinics, and public health units. As part of an overall distribution and dispensing plan for Louisiana, communities, working with their Regional Office of Public Health and Local Office of Homeland Security and Emergency Preparedness, have plans in place to implement these PODs for residents in their community. This strategy may be used in part for the administration of pandemic vaccine during Phase 2. Louisiana Regional Offices of Public Health are an integral planning partner in PODs. The State of Louisiana Point of Dispensing Plan, the Louisiana Regional Point of Dispensing Plan, the Louisiana Local Point of Dispensing Site Plan, and the Residential/Occupational Point of Dispensing provide guidance to the local OHSEP office and Public Health Regions, the individual public POD sites, and Residential and Occupational facilities on planning and implementing emergency point of dispensing sites.

Staffing at the PODs will be through a combination of Public Health employees, state and parish agency employees, and both medical and non-medical volunteers. POD staffing is the responsibility of the local Parish organizers, supplemented with public health and government workers. Though it may be time and staff intensive as some vaccines may require reconstitution with diluent or mixing adjuvant at point of administration.

Vaccines need to be centrally controlled via GOHSEP/LDH distribution as a logistical control as with all other items. Vaccine may be direct shipped to providers, as was done for the 2009 H1N1 event. Additionally, as in the 2009 H1N1 event, there may be a need to receive vaccine at a central site, with the ability to break down and repackage/reship vaccine to local providers from a central site at the Louisiana Office of Public Health Immunization Program in New Orleans, and possibly through the nine Regional Offices.

According to The Framework, Phase 2 individuals and a population may fit into multiple phases; for example, a group of critical workers in high-risk settings may also belong to a population with significant comorbid conditions, and an older adult may live in a congregate multi-generational setting. When individuals within a group fall into multiple phases, the higher phase will take precedent. In each



population group, OPH will use CDC's Social Vulnerability Index (SVI) or another more specific index, as needed to prioritize for geographical areas for vaccine access.

Phase 3: Likely Sufficient Supply, Slowing Demand

LDH OPH will work with their partners to identify and monitor the supply and demand during this phase. If providers are ordering too much product and encountering inappropriate levels of waste, the Immunization program will help edit their order size to meet demand. The Immunization program will also scale up or scale down provider orders, within their vaccine capacity.

If vaccine being stored has expired and/or has otherwise been deemed unusable (for example, through temperature excursions) it will be discarded and documented in LINKS. If vaccine is going to expire soon, POD sites will contact the Immunization Program if they believe they will not utilize all of their supply before the expiration date. The Immunization program will instruct them to either adjust the schedule of their POD vaccination activities or transport vaccine to another POD to ensure as much vaccine is administered as possible.

COVID-19 vaccination providers will report inventory of COVID-19 vaccines, and Louisiana's Immunization program will ensure this inventory information is submitted with each order. Vaccine orders will not be approved by the Immunization Program without this inventory information.

A detailed inventory will be kept at every POD site. This inventory will be updated regularly as vaccines come in and out.

If the vaccine cold chain becomes too challenging to maintain through redistribution, larger POD sites will be prioritized. POD Sites who have increased amounts of vaccine waste will be evaluated and complete corrective actions before additional vaccine is allocated.

Vaccine will be delivered through a process that ensures the availability of vaccines to all individuals, whatever their social and economic resources, employment, immigration or insurance status. OPH may have to make final decisions on refining and applying the priorities identified in the plan and will modify for situations when prioritization has to be adapted mid-process. This will be dependent on real-time surveillance of all aspects of the program and will maintain an emphasis on equity in the vaccine distribution strategy. In doing so, OPH will refer to the principles and allocation criteria in the Framework for Equitable Allocation of COVID-19 Vaccine. OPH will ensure that the prioritization process does not obstruct or slow down vaccination. Within phases, OPH may adapt the priority population groups to their specific conditions. OPH will consider new information on key vaccine characteristics emerging from vaccine trials and other sources such as the number of vaccine courses to be made available, considerations for special populations (e.g., pregnant women or individuals previously infected with COVID-19), anticipated vaccine efficacy, and anticipated vaccine safety as it becomes available.



Section 4: Critical Populations

Louisiana developed a COVID-19 Vaccination Action Collaborative (VAC) Prioritization-Allocation Work Group. These members have been tasked with identifying critical populations and creating guidelines to distribute COVID-19 vaccine in a manner that is consistent with the goals, values and needs of the State. The numbers of critical populations have been a collaborative effort of the Governor's Office of Homeland Security and Emergency Preparedness and the Louisiana Department of Health Office of Public Health. This information is detailed on the Louisiana COVID-19 Vaccine Dose Allocation Tool. Mapping of these populations is a collaborative effort that remains in progress.

The definitions of critical populations align with the terms used by the LDH Health Standards for licensing. Louisiana is a centralized public health system, other than the parishes of Orleans and Plaquemines. Planning has been inclusive of the City of New Orleans which compromises Orleans parish. Plaquemines is a rural parish near New Orleans. These health departments work closely with LDH OPH on a routine basis and successfully during the COVID-19 pandemic. The estimated numbers of persons in the critical workforce, does vary greatly by jurisdiction. Extensive listings of organizations are maintained by GOHSEP. This information has been updated and verified by OPH through established points of contacts within the critical population groups. Communication methods for organizations, employers, systems and communities have been expanded for COVID-19 vaccination response. The COVID-19 Vaccine Allocation Tool identifies subset groups of critical populations if there is insufficient vaccine supply.

Knowing that the initial supply will not be adequate for all, the Work Group has used three recommended goals to form decisions:

- Protect those needed in the ongoing fight against COVID-19
- Protect those at most risk from the disease
- Protect those workers essential to maintaining societal function

The work below will help prioritize vaccination of those who meet one of the listed descriptions. Justification for the decision-making of the VAC Prioritization Work Group is included.

There will be some persons who are included as critical population groups, but don't obviously qualify as at-risk or essential. It is recognized that within some groups there are persons who may be working from home and therefore should not be included in the priority list, or have already had COVID-19 and possibly have immune protection. It is impractical to address those questions and the principle of subsidiarity allows these decisions to be made with local level input. These decisions will also allow recognition of ancillary and critical patient support personnel who may not be typically thought of as clinically important, but are none the less at risk of exposure, essential for continued operation of patient services, and deserving of prioritization.

Deciding priority among these groups involved difficult ethical decisions and these guidelines are meant to be a fluid living document that changes as information changes. "Good ethics begins with good facts"



and the facts around this disease and the vaccine are still incomplete. Ethical principles are provided and indicated in the text (*).

Phase 1A

HOSPITAL PERSONNEL – DIRECT COVID EXPOSURE AND CARE

Definition: Includes paid and unpaid personnel serving in healthcare settings who have the potential for direct or indirect exposure to COVID-19 patients or COVID-19 infectious materials and are unable to work from home. Includes personnel providing critical services (both direct and support) to COVID-19 patients at the following licensed facilities:

- Tier one hospitals (medical hospitals providing acute medical services, medical emergency services, surgeries, intensive care, etc.)

- Tier two hospitals (hospitals where patients have been transported to continue receiving healthcare services while recovering from COVID-19 until well enough to be released)

Examples of "other" critical roles provided to COVID-19 patients in the hospital setting include services involving patient room and board, medical and nursing, laboratory, radiology, pharmacy, and physical therapy.

Justification: Hospital personnel are needed to treat COVID-19 patients, but also to treat other health conditions that normally affect society. They are at high risk of exposure while caring for patients with COVID-19. They qualify for higher prioritization under the ethical principles of reciprocity* and narrow social utility*. If the initial supply of vaccine is inadequate to cover all hospitals, it is proposed that the vaccine be distributed to various hospitals based on their COVID-19 hospital census (for example, those who in the past month have had higher census would get more vaccine). Acknowledging that even using this method will likely leave many hospitals with inadequate vaccine for all workers, the principle of subsidiarity* is invoked to allow each hospital to decide at the local level which of their personnel should receive the vaccine. However, local recognition is encouraged of the important contributions and possible exposure of all staff including housekeeping, custodial, transport and any others who may not be considered clinical, but nonetheless have exposure and may be at higher risk due to other demographic variables.

CONGREGATE CARE SETTING PERSONNEL – NURSING FACILITIES/HOMES AND ADULT RESIDENTIAL CARE FACILITIES

Definition: Includes paid and unpaid personnel serving in congregate nursing and residential care settings who have the potential for direct or indirect exposure to COVID-19 positive residents/patients or COVID-19 infectious materials and are unable to work from home. Includes personnel providing services to COVID-19 patients and residents at the following licensed facilities: - Nursing facilities/homes, including Skilled Nursing Facilities

- Adult Residential Care Facilities (includes "assisted living" facilities)

Examples of services provided by these personnel include: nursing and related services, specialized rehabilitative services (treatment and services required by residents with mental illness or intellectual disability, not provided or arranged for by the state), medically-related social services, pharmaceutical services (with assurance of accurate acquiring, receiving, dispensing, and



administering of drugs and biologicals), dietary services individualized to the needs of each resident, professionally directed programs of activities to meet interests and needs for the wellbeing of each resident, emergency dental services (and routine dental services to the extent covered under the state plan), room and bed maintenance services, and routine personal hygiene items and services.

Justification: Nursing Facilities/Homes and Adult Residential Care Facilities personnel care for patients who are at high risk and have suffered the greatest burden of morbidity and mortality thus far in the pandemic. The patients they care for live in a congregate setting, thus increasing the likelihood for spread. By vaccinating these workers early on, community spread into Nursing Facilities/Homes and Adult Residential Care Facilities can be prevented. Doing so is supported by the ethical principle of protecting the most vulnerable. The greatest concern here is not the number of cases in the Nursing Facilities/Homes and Adult Residential Care racilities, but the incidence in the community, since the concern is workers bringing the disease into work. Therefore, it is proposed that if the initial supply is inadequate to provide COVID-19 vaccine to all Nursing Facilities/Homes and Adult Residential Care Facilities personnel, those with highest community positivity rate should be prioritized.

Phase 1B

HOSPITAL PERSONNEL

Definition: Includes paid and unpaid personnel serving in healthcare and care settings who have the potential for direct or indirect exposure to patients or infectious materials and are unable to work from home. Includes personnel providing critical services (both direct and support) to patients at the following licensed facilities:

- Tier one hospitals (medical hospitals providing acute medical services, medical emergency services, surgeries, intensive care, etc.)

- Tier two hospitals (hospitals where patients have been transported to continue receiving healthcare services until well enough to be released). This includes rehabilitation hospitals as well as behavioral health hospitals where patients are staying at the facility for more than one day

Examples of "other" critical roles provided to patients in the hospital setting include services involving patient room and board services, medical and nursing services, laboratory services, radiology services, pharmacy services, and physical therapy services.

Justification: Hospital personnel are needed to treat COVID-19 patients, but also to treat other health conditions that normally affect society. They are at high risk of exposure while caring for patients with COVID. They qualify for higher prioritization under the ethical principles of reciprocity* and narrow social utility*. If the initial supply of vaccine is inadequate to cover all hospitals, it is proposed that the vaccine be distributed to various hospitals based on their COVID-19 hospital census (for example, those who in the past month have had higher census would get more vaccine). Acknowledging that even using this method will likely leave many hospitals with inadequate vaccine for all workers, the principle of subsidiarity* is invoked to allow each hospital to decide at the local level which of their personnel should receive the vaccine. However, local



recognition is encouraged of the important contributions and possible exposure of all staff including housekeeping, custodial, transport and any others who may not be considered clinical, but nonetheless have exposure and may be at higher risk due to other demographic variables.

CONGREGATE CARE SETTING PERSONNEL

Definition: Includes paid and unpaid personnel serving in healthcare and care settings who have the potential for direct or indirect exposure to patients/residents or infectious materials and are unable to work from home. Includes personnel providing services to patients and residents at the following licensed facilities:

- Nursing facilities/homes, including Skilled Nursing Facilities
- Adult Residential Care Facilities (includes "assisted living" facilities)
- Intermediate Care/Developmentally Delayed Facilities
- Forensic Supervised Transitional
- Psychiatric Residential Treatment Facilities
- Therapeutic Group Home Facilities (younger behavioral)
- Adult Brain Surgery Facilities (residential and community levels of care)

Examples of services provided by these personnel include: nursing and related services, specialized rehabilitative services (treatment and services required by residents with mental illness or intellectual disability, not provided or arranged for by the state), medically-related social services, pharmaceutical services (with assurance of accurate acquiring, receiving, dispensing, and administering of drugs and biologicals), dietary services individualized to the needs of each resident, professionally directed programs of activities to meet interests and needs for the wellbeing of each resident, emergency dental services (and routine dental services to the extent covered under the state plan), room and bed maintenance services, routine personal hygiene items and services.

Justification: Congregate Care Setting Facility personnel care for patients who are at high risk and have suffered the greatest burden of morbidity and mortality thus far in the pandemic. The patients they care for live in a congregate setting, thus increasing the likelihood for spread. By vaccinating these workers early on, community spread into the Congregate Care Setting Facility can be prevented. Doing so is supported by the ethical principle of protecting the most vulnerable. The greatest concern here is not number of cases in the Congregate Care Setting Facility, but the incidence in the community, since the concern is workers bringing the disease into work. Therefore, it is proposed that if the initial supply is inadequate to provide COVID-19 vaccine to all Congregate Care Setting Facility personnel, those with highest community positivity rate be prioritized.

EMERGENCY MEDICAL SERVICES PERSONNEL

Definition: Includes Emergency Medical Services (EMS) personnel performing direct patient care, support, and transport.

Justification: EMS Personnel are frequently the first responders to emergency and thus are critical to societal function. They also may be the first to evaluate a person suffering with COVID-19 who



requires transport to the hospital and thus are at risk of disease. Providing them vaccination early on is again supported by the ethical principle of reciprocity* and narrow social utility*.

END STAGE RENAL DISEASE FACILITY PERSONNEL

Definition: Includes End Stage Renal Disease Facility personnel performing direct dialysis care and support services to patients.

Justification: End Stage Renal Disease Facility Personnel provide care for persons who are at high risk for COVID-19. The service they provide is lifesaving and thus an essential function. The patients they care for are at high risk of disease and at higher risk of dying from COVID-19. If these employees are vaccinated early on, they will be enabled to continue their work which is an important societal function, and protecting the patients they care for by preventing these personnel from spreading the disease to their patients.

URGENT CARE FACILITY PERSONNEL

Definition: Includes Urgent Care Facility personnel performing direct patient healthcare and patient support services at urgent care type outpatient facilities.

Justification: Urgent Care Facility personnel are often the first providers to evaluate patients with minor illness such as cough or cold. As such, they have treated and diagnosed a large majority of COVID-19 cases thus far in the pandemic. This makes them an essential element in the continued fight against COVID-19 and eligible for early vaccination based on the principles of reciprocity* and narrow social utility*.

PUBLIC-TYPE OUTPATIENT HEALTH FACILITIES PERSONNEL

Definition: Includes personnel performing direct patient healthcare and patient support services within the following facilities:

- Federally Qualified Health Centers (FQHCs)
- Parish Health Unit Clinics
- Rural Health Clinics
- Tribal Clinics

Justification: Public-type outpatient health facilities personnel typically provide care to citizens who are either marginalized or economically disadvantaged and thus at higher risk of disease. To that end, these personnel are both necessary to the function of society, and at high risk of exposure. Therefore, they are ranked higher than their private sector counterparts in vaccine priority.

NON-PUBLIC TYPE PRIMARY CARE

Definition: Includes personnel performing direct "primary care type" patient healthcare and patient support services. This includes personnel working within primary care facilities that act as the first contact and principal point of continuing care for patients within a healthcare system. These facilities coordinate other specialist care that the patient may need.



Justification: Primary care provider facilities are often the first providers to evaluate patients with minor illness such as cough or cold. As such they have treated and diagnosed a portion of COVID-19 cases thus far in the pandemic. This makes them an essential element in the continued fight against COVID-19 and eligible for early vaccination based on the principles of reciprocity* and narrow social utility*.

CORRECTIONS OFFICERS AND JAILERS

Definition: Includes state corrections officers, as well as parish and local jailers with direct exposure to the inmate/prisoner population.

Justification: Corrections officers and jailers are eligible for early vaccination for reasons similar to Congregate Care Facility personnel. They perform a job that is essential for continued societal function and care for a group of citizens who are in close quarters in a congregate setting. While not typically as at risk as their elderly counterparts in Congregate Care Facilities, many prisoners have underlying diseases that put them at increased risk as well. Similar to the rationale for distribution of limited vaccine in the Congregate Care Facility personnel, assuming inadequate supply for all personnel who fall in this category, prioritization based on community positivity rate is recommended, since the goal is to prevent personnel bringing the disease into the facility.

FIREFIGHTERS – MEDICAL RESPONSE ROLE

Definition: Includes firefighters in the state performing first response medical services in the community setting.

Justification: Firefighters often fill a similar role as EMS in regards to response to 911 calls and to that end would be included at a similar level of prioritization. However, in cases where they do NOT provide this service they would not be included in this ranking. (It is unclear to the prioritization committee if this role of EMS is statewide or varies by locale, and this should be taken into consideration in allocation of vaccine.)

INPATIENT BEHAVIORAL HEALTH FACILITY/HOSPITAL PERSONNEL

Definition: Includes personnel performing direct inpatient healthcare and support care at the following licensed facilities:

- Acute Behavioral Health Facilities
- Critical Access Behavioral Health Facilities
- Long Term Care Acute Behavioral Health Facilities (up to 30 days)
- Other Behavioral Health Hospitals

Justification: Inpatient Behavioral Health Facility Personnel provide care to patients who are in a congregate community setting and thus at high risk of spread. These include inpatient treatment for substance abuse as well as for depression and other psychiatric conditions. The social effects of the COVID-19 pandemic may have increased the number of patients needing such assistance, and because these patients live in a congregated setting, preventing employees from bringing COVID-19 into the facility protects them and should be a priority.

CONGREGATE CARE FACILITY RESIDENTS/PATIENTS

Definition: Includes residents/patients receiving care at the following licensed facilities:



- Nursing facilities/homes, including Skilled Nursing Facilities
- Adult Residential Care facilities
- Intermediate Care/Developmentally Delayed Facilities
- Psychiatric Residential Treatment Facilities
- Therapeutic Group Home Facilities
- Forensic Supervised Transitional
- Adult Brain Surgery Facilities (residential and community levels of care)

Justification: Congregate Care Facility residents have suffered the greatest percentage of cases and deaths from COVID-19 and should be prioritized as early as possible due to this. Many of them suffer from multiple comorbid conditions that put them at increased risk of death should they become infected with COVID-19. They live in a congregate setting with increased risk of spread from one person to another. Thus, early vaccination fulfils the obligation to protect the vulnerable, as well as the utilitarian principle* of saving the most lives. (Because of their isolation during the pandemic, most Congregate Care Facility patient cases are coming from exposure to workers, and thus vaccinating the Congregate Care Facility personnel was ranked above the patients as a protection for the patients who have been most vulnerable.)

STATE COVID-19 RESPONSE PERSONNEL

Definition: Includes the Unified Command Group, GOHSEP Incident Command Staff, and other staff serving an emergency support function. Doses are planned for the nine regional medical health directors.

Justification: State COVID-19 Response Personnel includes Governor Office personnel, GOHSEP and other emergency support staff. Protecting them early on can help continue the essential function of society, thus fulfilling the principles of public order* and narrow social utility*.

HOME CARE PERSONNEL

Definition: Includes personnel performing direct patient care within patient homes through the following licensed health entities:

- Home and Community Based Care
- Home Health
- Hospice

Justification: Home Care Personnel can allow patients to be discharged from the hospital early, thus easing overload of hospital resources (Home health care). They also allow those who are in need of some level of help to remain independent at home (Home and Community based care) and help those who are at the end of life die comfortably at home (Hospice). Protecting them enables continuation of these essential services to vulnerable populations.

OTHER OUTPATIENT HEALTHCARE PERSONNEL



Definition: Includes personnel performing direct patient care at the following outpatient facilities: (Listed in alphabetical order)

- Ambulatory Surgical Centers
- Community Mental Health Centers
- Dental Offices
- Outpatient Behavioral Health Facilities
- Outpatient Physical Therapy
- Outpatient Specialty Clinics
- Pain Management Clinics
- Pediatric Day Health Care Facilities
- Specialty Medical Offices

Justification: Other Outpatient Personnel is a large and diverse category. While the list below is somewhat hierarchical, there was not general agreement on what group should be prioritized over the others. It is the second largest grouping of early prioritization, and includes the following:

Community Mental Health & Outpatient Behavioral Health Facilities. The personnel in this category are important in helping patients deal with COVID-19 and the socioeconomic consequences it has entailed. The pandemic has resulted in a marked increase in symptoms of depression and anxiety, substance abuse, and suicidal ideation (<u>CDC</u>).

Pediatric Day Health Care Facilities. The personnel in this category provide service to Medicaid recipients ages 0 through 20 who have a medically fragile condition and who require nursing supervision and possibly therapeutic interventions all or part of the day. They care for a vulnerable population and provide a valuable service, and thus should be offered the vaccine early on in order to protect both them and the patients they serve.

Dentists and Dental Clinics. In order to continue dental care, providers in this field must subject themselves to close exposure to patients and occasional aerosol generating procedures. Thus, including them in the early stages of vaccination allows protection of this group.

Ambulatory Surgical Centers. Many surgical procedures are performed today in an outpatient setting and thus take a burden off of the hospital by allowing them to care for sicker patients. Protecting the staff of these facilities allows them to continue this function and to prevent the spread of COVID-19 to the surgical patients they care for.

Pain Management Clinics. With the awareness of the danger of narcotics, these clinics have in a large part taken over the prescribing of chronic pain medication for many patients. It is possible some of this task could be accomplished via virtual visits, but it is important to not allow this professional relationship to be interrupted. Thus, this group of providers should be offered vaccination early on.

Outpatient Physical Therapy is a service that allows patients recovering from stroke, surgery, or other conditions to return to normal function. While not at highest risk, personnel providing this


service are at some risk due to close interactions and deserve protection. The patients they interact with are often elderly and vulnerable, with comorbidities.

Specialty Medical Offices provide services that allow patients to receive important medical care and recover from other conditions.

FEDERALLY DEPLOYED COVID-19 RESPONSE PERSONNEL

Definition: Includes federally deployed personnel already in the state conducting work associated with COVID-19 outbreak response.

Justification: This group includes federally deployed personnel who are doing work associated with the COVID response and thus qualify for vaccination on the principles of narrow social utility* and reciprocity*.

LAW ENFORCEMENT PERSONNEL

Definition: Includes all state-, parish-, and city-level law enforcement officers and deputies performing direct law enforcement activities in the community.

Justification: Law Enforcement Officers and Deputies are high priority for both their importance to continued function of society and frequent involvement with first response to emergencies. Thus, they qualifying for early vaccination based on the narrow social utility*, public order*, and reciprocity* principles.

MEDICAL AND PUBLIC TRANSPORTATION SERVICES PERSONNEL

Definition: Includes personnel providing non-emergency transportation services that enable a client or patient to access core medical and support services.

Justification: Many patients are unable to get to doctors' offices for non-emergency problems without the use of either medical or public transportation. Keeping these personnel safe from COVID-19 is important to the continued function of society.

PHARMACISTS

Definition: Includes all licensed pharmacists residing in the state, regardless of medication administration privileges.

Justification: These professionals provide a valuable service in enabling patients to get the medication they need. They also serve as a possible source for distribution and administration of the COVID-19 vaccine.

FOOD PROCESSING AND PACKING PERSONNEL



Definition: Includes personnel engaged in the packing or processing of agricultural crops, animals, seafood, and their byproducts, which entails cutting, sorting, boxing, crating, canning, rendering, tanning, and so forth.

Justification: Food processing and packing personnel are at high risk, and as of July, there were at least 11 outbreaks of COVID-19 at these facilities in Louisiana, leading to over 423 cases. Food production is an essential service to maintain societal function, and the workers in this sector are often from a demographic that is high risk.

PERSON 65 YEARS OF AGE OR OLDER WITH EXISTING HEALTH CONDITIONS

- Definition: Persons over the age over 65 with one or more of the following conditions:
 - Cancer
 - Chronic kidney disease
 - COPD (chronic obstructive pulmonary disease)
 - Immunocompromised state (weakened immune system) from solid organ transplant
 - Obesity (body mass index [BMI] of 30 or higher)
 - Serious heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies
 - Sickle cell disease
 - Type 2 diabetes mellitus

Justification: In the attempt to protect the most vulnerable, accurate information is needed on who is most at risk of death and disease. Current CDC guidelines list the following (in addition to age) as risk factors for COVID.

(updated July 17, 2020, <u>https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-</u>

<u>conditions.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fneed-extra-precautions%2Fgroups-at-higher-risk.html</u>)

Phase 2

K-12 SCHOOL AND DAYCARE PERSONNEL

Definition: Includes all personnel at public and private schools in Louisiana, Grades K-12. Includes personnel at all licensed daycare/early learning centers in Louisiana.

Justification: K-12 school and daycare personnel are at risk through their exposure to large numbers of students who may be asymptomatic carriers. These personnel are essential to societal function due to the need to provide education. In addition, if schools and daycares are unable to operate, many parents would be forced to leave children at home unattended or to miss work to provide childcare.

GROCERS AND FOOD DISTRIBUTORS



Definition: Includes personnel at all grocery stores in Louisiana. A grocery store is any retail store that sells food. Includes all personnel involved in transport and delivery of food to grocery store locations from food distribution centers.

Justification: Grocers and Food Distributors are highly exposed to the general public and hence at risk of contracting COVID-19. Their service is essential in order for society to obtain food and other essential items; hence, they should receive early vaccination.

The prioritization of the following groups is more difficult and involves balancing the preservation of certain necessary societal functions with preventing illness in high-risk groups of populations. It is believed that the two groups listed above deserve special consideration as described. The remaining are similar in importance and thus are not listed in any hierarchical fashion. Doses made available in Phase 2 of the vaccine response are expected to be adequate to cover all priority groups listed.

UTILITY AND GOVERNMENTAL MAINTENANCE PERSONNEL

Definition: Includes personnel involved in the maintenance and delivery of utility services made available to the public. Included in this group are personnel working to provide public water services, public electricity services (including nuclear generated), public gas/oil services, public trash services, and public communications services. Also included in this group are workers responsible for maintaining sewer and water systems and drainage/pumping systems, as well as governmental workers responsible for maintaining the operation of streets, highways, and bridges.

GOVERNMENTAL SUPPORT SERVICES and COMMUNITY PROGRAM PERSONNEL

Definition: Includes all personnel from the Louisiana Department Children and Families and the Department of Health.

POSTAL WORKERS

Definition: Includes public and private personnel who handle, sort, and deliver mail and postal packages.

LABORATORY PERSONNEL

Definition: Includes personnel working in public and private laboratories, including certified labs testing drinking water.

MORTUARY PERSONNEL

Definition: Includes personnel working in mortuary, cremation, and funeral services, including funeral directors.

DEPARTMENT OF HOMELAND SECURITY PERSONNEL, NATIONAL GUARD, FEDERAL INTELLIGENCE AND SECURITY PERSONNEL, MILITARY PERSONNEL

Definition: Includes any personnel involved in state and federal level security, military, intelligence, and counterterrorism services.

ADULTS 18-64 WITH EXISTING HEALTH CONDITIONS

Definition: Persons between the ages of 18-64 with one or more of the following conditions:



- Cancer
- Chronic kidney disease
- COPD (chronic obstructive pulmonary disease)
- Immunocompromised state (weakened immune system) from solid organ transplant
- Obesity (body mass index [BMI] of 30 or higher)
- Serious heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies
- Sickle cell disease
- Type 2 diabetes mellitus

INCARCERATED ADULTS

Definition: Includes all incarcerated adults in Louisiana.

Phase 3

General Public – Open Access

Definition: Includes all Louisiana residents if recommended by the CDC's ACIP.

Ethical Principles Used in the Deliberation of the Louisiana Vaccination Action Collaborative Prioritization Workgroup*

The **Utilitarian Principle** is most commonly quoted as "the most good for the most people". This can be argued from the standpoint of *most lives saved, most life years saved* (prioritizing younger citizens) or even *the best outcome for society as a whole*, including such goals as societal function and economic benefits.

The **Public Order Principle** refers to the concept that in order to keep society functioning and prevent widespread chaos in a pandemic, government officials, police, firemen, and other protectors of the public order will be needed.

Narrow Social Utility refers to the concept of prioritizing a group not because of their hypothetical social worth, but because that person or group of people can provide a valuable benefit for society. Hence, for instance, it is not the fact that a person is a doctor that makes them valuable, but the fact that they can provide a valuable service to society that is needed during the pandemic or crisis.

Reciprocity refers to the principle that if someone puts their life at risk to provide services to society, society should reciprocate and help care for and protect that person.

Subsidiarity is an organizational principle that certain matters should be handled at the local level rather than by a central authority. This principle is invoked when recognizing that each community has different needs and thus may decide to offer the vaccine to different subsets in its population.

Louisiana will comply with critical population guidance from the Advisory Committee on Immunization Practices approved by the CDC Director. Louisiana will fully comply with national guidance. Final recommendations from the Louisiana State Health Officer or designee will be made to the Louisiana Governor. The Governor will make the ultimate decision on critical populations for the State.



Section 5: COVID-19 Provider Recruitment and Enrollment

In Louisiana, most COVID-19 vaccine providers are current vaccine providers due to state regulations enacted in April 2020 requiring all vaccinations administered in the state be reported to LINKS, the Louisiana Immunization Network, via electronic means. Potential additional new vaccine providers (process underway) for the COVID-19 vaccination campaign will be recruited for enrollment through direct communications from OPH disseminated through established communication networks. All interested COVID-19 vaccination providers will be required to complete the CDC Provider Agreement along with the appropriate LINKS enrollment documents, including credentials. Pharmacies not served directly by the CDC will be recruited utilizing partnerships developed via the biweekly meetings of OPH IP, Independent Pharmacy Association, and the LA Board of Pharmacy. Interested pharmacies in this group will enroll as providers via LINKS as with all other COVID-19 vaccine program providers.

Enrollment Documents		
LINKS View Only Reference Card	Download/View	
Requirements for Participation Checklist	Download/View	
HIPAA Requirements	Download/View	
Site Enrollment Agreement	Download/View	
Confidentiality Policy	Download/View	
User Agreement	Download/View	
Individual User Removal Form	Download/View	
Prevent Sharing	Download/View	

During Phase 1, first available COVID-19 vaccine will be prioritized for distribution to large provider settings with high numbers of Tier 1a personnel, and provider recruitment and enrollment activities will primarily focus on vaccination providers currently practicing at healthcare facilities, such as hospitals, and congregate care setting facilities, such as nursing homes, where staff have a high risk of exposure to COVID-19. Providers must complete LINKS enrollment agreement forms to verify the ability to administer vaccines approximately prior to gaining LINKS system access (most are already enrolled in LINKS). Verification of credentials will be required on the CDC Provider Agreement form and verified by automated cross-reference in LINKS. For the Phase 2 campaign, the Immunization Program has and will continue to contact high priority sites for enrollment through email and telephone communications. Verification of providers with required credentials will occur through a manual review process conducted within the OPH. Sites determined to be "high priority" in Phase 1 will be identified from a directory developed by LDH and GOHSEP with input from respective boards, and professional organizations and associations.



POD specific planning is coordinated by the nine Regional Office of Public Health (OPH) Community Preparedness Response Coordinators. These Coordinators are currently reaching out to parish Office of Homeland Security and Emergency Preparedness (OHSEP) programs within their respective regions for mass vaccination exercise planning in anticipation of a COVID-19 vaccination response. COVID-19 preparatory vaccination exercises (using influenza vaccine) will occur mid-October through mid-November 2020. OPH through the Bureau of Community Preparedness provides a template for POD planning developed in collaboration with GOHSEP for the parish OHSEPs and with the Louisiana State Police who serve as ESF 13 State Lead for local law enforcement. POD planning includes , but is not strictly limited to, site security, site-specific traffic flow plans, and space utilization for a floor plan of the facility.

Generally, emergency medical services maintain a presence on-site while PODs are operational to manage any medical emergencies. Local parishes are familiar with and routinely perform similar operations for sheltering and evacuation response.

POD planning (both open and closed) is evaluated annually via HSEEP table-top exercise or full-scale exercises by OPH with the nine OPH Regions. Increased guidance specific to COVID-19 vaccine operations has been provided to Regional OPH staff at recent Regional Leadership and Regional Medical Director meetings in anticipation of COVID-19 POD operations. An update on POD planning focused on appropriately maintaining social distancing among clients and staff was provided during the September Regional Leadership call.

The OPH Immunization Program will collect, compile, and transmit provider enrollment data electronically to CDC twice weekly, using a CDC-provided Comma Separated Values (CSV) via LINKS. If this is unavailable, then data will be transmitted manually in an excel spreadsheet to the CDC. In order to be enrolled through LINKS, providers will certify that training in the following COVID-19 vaccine-specific topics provided by OPH and CDC have been completed:

- Awareness of Emergency Use Authorization (EUA) fact sheets
- Location of EUA fact sheets
- Understanding of the EUA
- Vaccine information statements (VISs), as applicable, and required information to be distributed at the time of vaccine administration to vaccinates
- The Vaccine Adverse Event Reporting System (VAERS)
- Vaccination informed consent requirements and procedures
- COVID-19 vaccine handling and storage guidelines

Every effort will be made by OPH to avoid any need for vaccine redistribution. If redistribution becomes necessary, OPH IP will evaluate and approve requests for redistribution of vaccine among sites based on target population to be served. All sites seeking to redistribution of excess supply will alert OPH IP of the need and OPH IP will direct any redistribution based on existing criteria for current Phase of response, maintaining equitable access, and likelihood of reaching a hard to reach population.



Vaccine Administration to Critical Population Groups

The provider types and settings will be determined based on CDC and state guidelines to determine priority groups and provider types that will participate in Phase 1 of the COVID-19 vaccination response. Extensive work has been done by the VAC Prioritization Work Group to align the terminology. The Governor will authorize which sites will receive vaccine doses first, after recommendations are made by the State Health Officer. For instance, hospitals will be a primary site because employees (for example, physicians, nurses, first responders) will be directly exposed to COVID-19 in their line of work.

Collection and Compilation of Provider Enrollment Data

Provider enrollment data will be collected and compiled through the IIS (LINKS). This information will be sent to CDC on days predetermined by CDC and the state. Louisiana has participated in the Public Health Immunization Hub since 2015 and is currently exchanging data with the Immunization Gateway.

Provider Credentialing

Providers will list their credentials on the CDC provider agreement form. Credentials will be verified through a review process occurring within the state's Immunization Program. The LDH Emergency Operations Center has strong existing relationships and processes to verify licensure with state boards and credentialing organizations.

Provider Training

Most of the Phase 1 providers are currently enrolled and using LINKS. Training and education will be provided by the Immunization Program through written materials, videos, and virtual trainings. Supplemental funding is being utilized for a COVID-19 Vaccine Training Coordinator along with 9 Regional COVID-19 Vaccination Specialist positions. The Training Coordinator position will work with the Tri-Regional LINKS Outreach Coordinators promoting vaccination, providing and tracking training. The Immunization Program maintains a workforce development training tool along with a calendar to document outreach activities and which sites have completed training. Over 20 short trainings for routine LINKS activities are on the LDH YouTube channel. This resource is prominent on the LINKS Homepage. Individualized training are conducted by Zoom.

Planned Redistribution of COVID-19 Vaccine

OPH and the Louisiana Board of Pharmacy conducts pharmacy-public health COVID-19 vaccine collaboration Zoom meetings every other week since August 2020. This is an opportunity to share information during this rapidly evolving situation. More than half of the pharmacies in Louisiana are independent pharmacists. Louisiana is also in communication with the three largest pharmacy vaccine providers in the state, CVS, Walgreens and Walmart for participation in the earliest phases of vaccine outreach. Current processes may be adapted to individualized listings of critical infrastructure personnel to supplement closed POD operations. Opportunities for large chain pharmacies and health system pharmacies with the ability to redistribute vaccine are being explored. Accountability and inventory



management discussions are on-going. Generally, vaccination providers will not be allowed to redistribute the COVID-19 vaccine on their own without prior pre-planning. Providers must go through the OPH Immunization and Pharmacy Services Programs if they seek to redistribute vaccines. This will allow the management of every dose of COVID-19 vaccine.

OPH has a very successful partnership with a distributor, Morris & Dickson for emergency response. These activities have focused on shelter pharmaceutical needs. There have been several discussions with this wholesaler on how they can support redistribution, if needed as more details about COVID-19 vaccine candidates are learned.

Equitable Access to COVID-19 Vaccination Services

The OPH Immunization Program will track locations of all vaccine administration sites and the volumes of vaccine available at these locations, statewide. Through geospatial mapping to the zip code level, the state will continue to ensure the sites providing vaccine are appropriately located geographically and meeting the needs of the communities in which they are located. If there are areas identified as needing additional vaccine availability, OPH will further recruit and enroll sites as needed. Additionally, the state will have the capacity to deploy Mobile Vaccination Teams to provide vaccination services in areas where any gaps in access are identified. Targeted messaging may also be directed to areas with low vaccine update. The network and engagement of the Governor's Health Equity Task Force, along with the OPH Office of Community Outreach & Health Equity, will engage with Tele-Town Hall meetings and community workers will be utilized. Priority recruitment along with the nine Regional Field staff can help identify populations in the state that are hard to reach for vaccination services.

Louisiana response to addressing health equity during COVID-19 vaccine distribution is based on the principles of: Fairness, Transparency and Evidence-based distribution.

Thus, limited vaccine supplies will be deployed equitably and transparently using pre-established, evidence-based criteria to prioritize allocation. Vaccine allocation will be based on:

- 1. Risk of acquiring infection
- 2. Risk of severe morbidity and mortality
- 3. Risk of negative societal impact
- 4. Risk of transmitting infection to others

Louisiana will adhere to the ACIP recommendations for initial populations of focus and critical populations for prioritized vaccination.

Recruitment and Enrollment of Pharmacies

Louisiana will recruit and enroll pharmacies not served directly by CDC in the same manner as other COVID-19 provider sites. The Louisiana Pharmacists Association, the Louisiana Independent Pharmacy Association and the Louisiana Chapter of the National Association of Chain Drug Stores have participated in the every-other-week Pharmacy-Public Health COVID-19 Vaccine Collaboration meetings



conducted by the Louisiana Board of Pharmacy and the OPH Immunization and Pharmacy Services Programs.



Section 6: COVID-19 Vaccine Administration Capacity

Estimation of Vaccine Administration Capacity

The vaccine administration capacity of Point of Dispensing (POD) sites will be crucial for COVID-19 vaccine roll out. The Bureau of Community Preparedness (BCP) and State and local Offices of Homeland Security and Emergency Preparedness (OHSEPs) can already accurately estimate vaccine administration capacity of POD sites based on hypothetical planning scenarios provided previously. These include real-opt–computer modeling programs to validate POD throughput, previous real-world exercises AARs (H1N1)., and previous vaccine POD exercises (i.e. Mass Vaccination Exercises [MVEs]). POD trainings and MVEs are conducted on a yearly basis. These trainings can be webinars, or face-to-face sessions, and are geared toward both state agencies and volunteers. Each of Louisiana's nine regions are conducting an MVE in October or November of this year; with most electing to do a drive through POD exercise.

All nine OPH regions already have POD sites secured (Total ~571). The formula used to determine the number of PODs needed is provided below and encompasses the above planning:

(TP/ (HPI-S))/ PPH = # of PODs required

TP = Total Population HPI = Hours to Provide Immunization S = Setup Time PPH = Patients per Hour

The Louisiana Office of Public Health (OPH) Immunization Program staff is also very familiar with guidance, tools and modeling to estimate vaccine administration capacity. In 2019, Immunization staff reviewed national pandemic influenza preparedness guidance, including the CDC's Updated Planning Guidance on Allocating and Targeting Pandemic Influenza Vaccine during an Influenza Pandemic, and the Community Mitigation Guidelines to Prevent Pandemic Influenza and updated the OPH Pandemic Influenza Plan Vaccination Annex in 2019. The Program work group met four times, collected data to model the vaccination capacity for the state of Louisiana using the CDC Pandemic Flu Response Planning tool. Projections were made with population specific data and estimates for weekly throughput. This information was compiled into a report using charts and graphs generated by the tool and custom created. The OPH Immunization Program shared this report within OPH at that time and more recently as COVID-19 vaccine planning reminders. Louisiana provided feedback to the CDC as a pilot project participant in utilizing the Pandemic Flu Response Planning tool. The *Modeling Pandemic Influenza Vaccination Capacity, Louisiana Report* was completed in March 2019. A lot of this modeling data was able to be extrapolated for COVID-19 vaccination and was used to develop the State's COVID-19 planning.

The CDC's COVID-19 Provider Enrollment Form and Redistribution Form include storage, handling and administration questions that will confirm providers at POD sites are equipped to vaccinate. The Immunization Program has also developed a supplemental questionnaire, surrounding vaccine administration capacity, which will be sent out with Provider Enrollment forms to verify every location



that receives allocated vaccine will be able to effectively handle the product. CDC's forms and Louisiana's questionnaire will give a complete picture of storage capacity (including dry ice capacity), and the number of vaccinators at POD site.

The LDH is working closely with pharmacists in the state to ensure they will have the capacity to vaccinate for COVID-19. The Louisiana Immunization program spearheads the national public health and pharmacy collaboration team, called Navigators (see Appendix 7). This national collaboration meets weekly to address issues and concerns and then monthly to engage key stakeholders. In addition to national collaboration efforts, OPH established the Louisiana Pharmacy-Public Health Collaboration that meets every other Wednesday at 1 pm to share information, address concerns and work through solutions for COVID-19 vaccination.

The LDH also has planned a Table Top Exercise to test out its COVID-19 vaccination plans in late October. This exercise, along with MVEs, will identify any unforeseen gaps in COVID-19 POD site's ability to vaccinate that can be bolstered to ensure complete capacity by COVID-19 vaccine rollout.

Evaluation of Provider Suitability

Louisiana will only approve vaccine orders from CDC enrolled COVID-19 providers, who have the storage and capacity to vaccinate and reach target populations for each phase of COVID-19 distribution. Louisiana will use the information provided on the CDC provider enrollment form (and Redistribution Form if needed), along with the Vaccine Capacity Questionnaire, to help determine which POD sites will be approved to receive vaccine. Regions have used a detailed process to work with partners to determine appropriate vaccination POD sites, including developing a planning team, emergency notification system, population assessments, security measures, staffing needs, and trainings. The Immunization Program will work closely with BCP to ensure all POD sites that are able to reach target populations have the capacity to vaccinate, and enroll as COVID-19 vaccine providers, for an equitable distribution of the vaccine.

Any organization, including RSS sites, who are approved to redistribute vaccine will meet the minimum training and storage requirements provided by the State and the CDC. They will also sign and agree to conditions in the CDC COVID-19 Vaccine Redistribution Agreement for the sending facility/organization and have a fully completed and signed CDC COVID-19 Vaccination Provider Profile form for each receiving location.

All of the above vaccine administration capacity information in Louisiana has informed the need for vaccine provider recruitment to quickly engage pharmacy providers. Discussions with the three large chain pharmacy providers are ongoing. Independent pharmacies which routinely use McKesson are reaching out to this distributer along with coordinating their efforts through the Louisiana Independent Pharmacists Association.

Recruitment of nursing homes for LINKS reporting was in process prior to COVID-19 vaccine response by the Immunization Program's Tri-Regional LINKS Outreach Coordinators. While nursing homes will likely be vaccinated by pharmacists, LDH is still surveying their capacity.



Outreach to FQHCs and RHC to strengthen relationships and improve electronic health record and LINKS interfaces was an Immunization Program Priority for 2020. The preliminary discussions with the Louisiana Primary Care Association prior to the pandemic facilities the success with 100% LINKS participation by the states 258 FQHCs. RHC participation in LINKS is ongoing.

If PODs don't have the capacity to vaccinate, Louisiana can utilize Mobile Immunization Strike Teams to assist with vaccine distribution and administration, as needed. Mobile Immunization Strike Team contracts are being finalized with six corporations in Louisiana who have previously been contracted to execute COVID-19 testing. Collectively, they will be able to send mobile vaccination teams to every Parish in Louisiana. Regional health officers and Louisiana's Immunization Program will identify locations to send these teams, which could include Closed PODs without staff who can vaccinate, hard to reach locations in Louisiana, and more as needed. They will order COVID-19 vaccine through Louisiana and all have the capacity to store, transport and administer COVID-19 vaccine anywhere in the State.

According to the Framework, it is important to emphasize that, whenever they become available, COVID-19 vaccines will be added to an already complex (and evolving) mix of public health strategies that include (1) non-pharmaceutical interventions (NPIs) such as mask usage, physical distancing, hand washing, and others; (2) expanded diagnostic testing linked to contact tracing, isolation, and quarantine strategies aimed at containing transmission, suppressing outbreaks, and interrupting super-spreading events; and (3) the deployment of therapeutic measures that mitigate morbidity and mortality and, ultimately, curtail transmission from those who do become infected (CDC, 2017, 2020a,b). The principle that public policy should be evidence based is essential to guiding the allocation of scarce countermeasures.



Scenario	Change in Allocation Framework
Number and Timing of Vaccine Doses	
Fewer vaccine courses available than	Allocation framework is unchanged. Some individuals
expected by Operation Warp Speed.	receive vaccination later than they would otherwise.
Vaccine requires two doses, rather than one.	Allocation framework is unchanged, but some individuals receive vaccination later. Vaccination should use strategies and systems (e.g., use of established providers or use of federally qualified health centers) to ensure continuity of care between the first and second dose. Both doses would need to be the same type of vaccine, so this would complicate the second dose if several types are available.
Vaccine Efficacy	
Low vaccine efficacy among older adults or other population subgroup.	Only allocate to this population subgroup if vaccine benefits outweigh the risks.
Vaccine Safety	
Unanticipated vaccine side effects.	Continuously monitor vaccine safety as the vaccine is rolled out. Only allocate to individuals for whom vaccine benefits outweigh the risks.
Significant vaccine side effects among	Continuously monitor vaccine safety as the vaccine is rolled
older adults or other population	out. Only allocate to this population subgroup if vaccine
subgroups.	benefits outweigh the risks.
Vaccine Uptake	
Vaccine uptake is lower than expected.	Allocation framework is unchanged. The communication campaign accompanying the vaccine must outline the risks and benefits of the vaccine in a factual way that members of the population can understand.
Number of Vaccine Types	
More than one vaccine type available.	Allocation framework is unchanged, but which vaccines are allocated to which population groups must. Consider the benefits and harms of the vaccine for each population group.
Epidemic Conditions and Immune Status	
Epidemic spread is continuing across much of the United States when the vaccine becomes available.	Allocation framework is unchanged. Public health messages must continue to stress the need for personal protective measures (e.g., masks, social distancing).
Epidemic is spreading most rapidly in particular hot spots when the vaccine becomes available.	A certain fraction of vaccine courses (e.g., 10 percent) is reserved for vaccinating individuals in hot spots. Public health messages must continue to stress the need for personal protective measures (e.g., masks, social distancing).



Vaccine Distribution and Administration	
States are required to follow federal guidelines for vaccine allocation.	Allocation framework is unchanged.
States have some leeway in the extent to which they follow federal guidelines for vaccine allocation.	States adapt the allocation framework to their needs (e.g., they may set aside a certain number of doses for particularly vulnerable populations in their state).
Social, Economic, and Legal Contexts	
Some states mandate vaccination of schoolchildren.	Allocation framework is unchanged, but states mandating vaccination of schoolchildren might allocate the vaccine in a manner different from the committee's proposed allocation framework (i.e., prioritize schoolchildren).
Some employers require proof of vaccination.	Allocation framework is unchanged, but such requirements could change rates of vaccine uptake, and would pose hazards for those individuals for whom the vaccine is medically contraindicated and could raise issues around discrimination against those unable to obtain the vaccine, and therefore unable to work.
Some states do not provide free vaccine access to people without documentation of legal status.	Allocation framework is unchanged. Other sources of financial support (e.g., philanthropy, health systems, pharmaceutical companies) should be sought to provide vaccination for those individuals.

Table 6.1: Summary Table of the Application of the Committee's Framework in Various Scenarios



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

Allocation and Assignment of Vaccine

The Louisiana COVID-19 Dose Allocation Tool allows allocating vaccine by percentages based on the Advisory Committee on Immunization Practices and CDC guidance for priority groups. This tool includes planning by Phases. Louisiana has identified groups using the terminology of the Louisiana Department of Health (LDH) Health Standards.

According to the Framework, for an initial period when demand exceeds supply, the Office of Public Health (OPH) should utilize a phased approach, guided by evidence to maximize societal benefit by reducing morbidity and mortality caused by the transmission of the novel coronavirus. Limited supply scenarios are referenced in Section 6, Table 1, "Summary Table of the Application of the Committee's Framework in Various Scenarios."

Cold Chain Capability of Individual Providers

As described in Section 6, the CDC's COVID-19 Provider Enrollment Form and Redistribution Form includes cold chain questions that will confirm providers at POD sites are equipped to vaccinate. The OPH Immunization Program's supplemental questionnaire will also verify provider's storage and dry ice capacity. Only providers with cold chain capacity will be approved to receive COVID-19 vaccine.

Ordering of COVID-19 Vaccine

COVID-19 vaccination providers enrolled by the state of Louisiana will order COVID-19 vaccine through Louisiana's Immunization Information Network, LINKS. LINKS integrates with the CDC's Vaccine Tracking System (VTrckS) for provider direct order entry.

Most providers already have experience with LINKS, and there are multiple trainings available on the LINKS homepage website. The OPH Immunization program is developing new training modules for providers on COVID-19 Vaccine Ordering. The training will be found on the LINKS homepage and will describe all aspects of enrolling as a COVID-19 provider and ordering vaccines. The state has also increased the STC Help Desk services from two to three full-time equivalents in anticipation of increased use. Providers have chat, email or telephone call options for assistance. More detailed information about vaccine ordering can be found in Appendix 9.

Coordination of Unplanned Repositioning

The OPH Immunization Program has at least two staff in each OPH Region for vaccine strategic planning and quality improvement. These staff occasionally have to transport vaccine to avoid vaccine loss. Additional transport coolers are being purchased. Nine staff, one per OPH Region are being hired to assist with additional COVID-19 vaccine activities, including unplanned repositioning of vaccine. All COVID-19 vaccinators will be equipped to transport vaccine in the event of emergency weather or



power outage. The need for emergency redistribution will be reported to the Immunization Program who will assist sites in determining where to transport vaccine and ensuring they have the supplies to do so effectively. Large POD sites will have a backup generator.

COVID-19 vaccines would be transported during an emergency using vaccine transportation procedures outlined in the upcoming COVID-19 addendum to CDC's Vaccine Storage and Handling Toolkit. OPH could call upon ESF 1: Transportation, the Louisiana Department of Transportation and Development, the Louisiana National Guard, or the Louisiana State Police to provide transportation of vaccines to supplement the Immunization Program, if needed. OPH could also use existing SNS transportation plans for COVID-19 vaccine transport. More detailed information on emergency, and planned, transport can be found in Appendices 9 and 10.

Every effort will be made to avoid the need for vaccine repositioning. Should unplanned repositioning become necessary, OPH IP will coordinate any unplanned repositioning of vaccine assets in order to minimize loss, maintain cold-chain, while working to target vulnerable populations and maintain equitable access to vaccines. POD sites in need of unplanned repositioning will notify OPH IP immediately once the need is identified and follow direction of OPH IP. Repositioning will be done strategically to most appropriate and closest operating POD site. Monitoring of COVID-19 vaccine wastage and inventory levels will be performed in real time via the LINKS inventory management component by OPH IP.

Monitoring COVID-19 Vaccine Wastage and Inventory Levels

COVID-19 vaccination providers will report inventory of COVID-19 vaccines, and Louisiana's Immunization program will ensure this inventory information is submitted with each order. Vaccine orders will not be approved by the Immunization Program without this inventory information.

Vaccine monitoring is already routinely completed in LINKS and will remain so for COVID-19 vaccine. Regional staff and the STC Help Desk are able to assist with inventory management issues. Vaccine wastage will be evaluated, and corrective measures, including increased vaccination activities or redistribution, will be implemented. Compliance with requirements will be necessary before additional requests for COVID-19 vaccine is allocated.

Inventory management will also identify excess vaccine, either by the Regional Immunization staff or vaccine ordering staff. Solutions are implemented at the local level whenever possible, then within the region. All Parish Health Units are VFC Providers in compliance with vaccine storage and handling, along with vaccine emergency relocation plans. Each OPH Regional Office has vaccine transport and storing equipment and experience. The OPH Immunization Program has increased vaccine storage capacity in anticipation of COVID-19 vaccine. Many healthcare systems have also reported increasing their vaccine storage space. More detailed Inventory Management information is available in Appendix 9.



Section 8: COVID-19 Vaccine Storage and Handling

Note: Please see Appendix 8: Louisiana's Comprehensive Point of Dispensing Plan for COVID-19 Vaccine and Appendix 9: Louisiana's Plan to Securely Order, Distribute, Receive, Store and Transport COVID-19 Vaccine for more detailed information about the planning presented in this section.

Adherence to COVID-19 Vaccine Storage and Handling Requirements (Cold and Ultra-cold)

Louisiana has developed plans to ensure adherence to COVID-19 vaccine storage and handling requirements at every level. These plans will be further operationalized when more specific information becomes available in the upcoming COVID-19 addendum to CDC's *Vaccine Storage and Handling Toolkit*. Current planning is described in Appendix 9, with key aspects highlighted below.

• Individual provider locations

Healthcare providers in Louisiana are responsible for maintaining vaccine quality as soon as a vaccine shipment arrives at their respective sites. Each provider will have a designated staff member to receive, unpack, examine, and store COVID-19 vaccine shipments. This person will have undergone specific COVID-19 vaccine storage and handling training provided by the CDC. Backup staff members who have undergone the same training will also be available to unpack and store the product. Facilities will ensure at least one qualified staff member is on site during all operating hours in case a COVID-19 vaccine shipment arrives. Louisiana will provide virtual Just-In-Time Training (JITT) to all POD staff involved in COVID-19 vaccination activities.

Any potential vaccine storage issues found will be reported to the Immunization Program, and the product will be stored according to the manufacturer guidelines. The vaccine will be marked "DO NOT USE" until guidance is provided. Regional LDH staff will visit provider sites to ensure vaccine is being stored correctly throughout vaccination activities.

• Satellite, temporary, or off-site settings

COVID-19 vaccines will be transported (not shipped) to a satellite, temporary, or off-site COVID-19 vaccination clinic using vaccine transportation procedures outlined in the upcoming COVID-19 addendum to CDC's *Vaccine Storage and Handling Toolkit*. Ancillary supply kits will be transported with their corresponding vaccines to avoid any separation of the two.

Upon arrival at the COVID-19 vaccination clinic site, vaccines will immediately be stored correctly by the designated staff member at the mobile clinic site to maintain appropriate temperature throughout the clinic day. Staff at these sites will undergo the same training as individual provider locations. Sites will review CDC's revised *Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations* as well as *Vaccination Guidance During a Pandemic*. They will complete a "Vaccinating at Satellite, Temporary, and Off-Site Locations"



checklist for every mobile clinic conducted to ensure vaccine administration is not compromised.

Planned redistribution from depots to individual locations and from larger to smaller locations
Whenever possible, vaccine will be shipped to the location where it will be administered to
minimize potential breaks in the cold chain. There may be scenarios where vaccine will be
shipped to a central depot (like RSS sites or a large POD) and be redistributed to smaller PODS.
Since the federal government does not redistribute product, this will be the responsibility of the
state. Louisiana's Immunization Program will provide guidance to those involved in
redistribution to ensure validated cold-chain procedures are in place in accordance with the
manufacturer's instructions and CDC's guidelines. Detailed information about potential RSS site,
and large POD site, redistribution is provided in Appendix 8.

Any organization, including RSS sites, who are approved to redistribute vaccine will meet the minimum training and supply requirements provided by the State and the CDC. They will also sign and agree to conditions in the CDC COVID-19 Vaccine Redistribution Agreement for the sending facility/organization and have a fully completed and signed CDC COVID-19 Vaccination Provider Profile form for each receiving location.

• Unplanned repositioning among provider locations Unplanned emergency redistribution is described in Section 7 of these plans. Additional Storage and Handling planning can be found in Appendix 9.

Redistribution Depot COVID-19 Vaccine Storage and Temperature Monitoring Capabilities

As described in Section 6, the CDC's COVID-19 Redistribution Form includes questions that will confirm POD sites have the capacity to redistribute vaccine. The Immunization Program's supplemental questionnaire will further verify this capacity. RSS sites are all being equipped to handle COVID-19 vaccine storage (including ultra-cold storage), as described in Appendix 9. Louisiana will provide training to redistribution depots that includes COVID-19 vaccine transport information outlined in the upcoming COVID-19 addendum to CDC's *Vaccine Storage and Handling Toolkit*.

Louisiana response to addressing health equity during COVID-19 vaccine distribution is based on the principles of:

- Fairness
- Transparency
- Evidence-based Distribution



Thus, limited vaccine supplies will be deployed equitably and transparently using pre-established, evidence-based criteria to prioritize allocation. Vaccine allocation will be based on:

- 1. Risk of acquiring infection
- 2. Risk of severe morbidity and mortality
- 3. Risk of negative societal impact
- 4. Risk of transmitting infection to others

Louisiana will adhere to the ACIP recommendations for initial populations of focus and critical populations for prioritized vaccination.



Section 9: COVID-19 Vaccine Administration Documentation and Reporting

Collection of COVID-19 Vaccine Administered Doses

The Louisiana Immunization Network, LINKS will be used to record vaccine doses administered. Providers will have access to LINKS through their organizational/facility-level account access. Individual facility-level accounts will be created for vaccinators who do not have access to LINKS. This will allow vaccinators to log each vaccine they administer into the system. Individual facility-level accounts for vaccinators will allow tracking of vaccines and follow-up with vaccinators as necessary.

Submission of COIVD-19 Vaccine Administration Data via the Immunization Gateway

COVID-19 required vaccine information will be collected via LINKS and sent to the CDC via the IZ Gateway, using current HL7 standards. If this method is not available, a CSV file will be compiled of the required data elements and sent to CDC via established methods of transfer (SFTP site).

Reporting the Required COVID-19 Vaccine Administration Data Elements to the IIS or Other External System Every 24 Hours

COVID-19 vaccination providers will be trained through LINKS training videos, accessible 24/7 on the homepage. These videos teach organizations and facilities how to use MyIR, administer vaccines, create and print patient records, add and search for patients, and create reports. Regional consultants will also provide support and training as needed through Zoom conference calls, supplemental documents, materials, and resources. Since the IIS was implemented in 2001, most of the COVID-19 providers have experience using it and are familiar with the system. Providers can use and access the immunization information system 24/7. User support is also provide through the help desk via chat, email, and phone. It will be verified that each facility has the ability to provide and store vaccines properly before becoming a COVID-19 vaccine provider.

Real-time Documentation and Reporting of COVID-19 Vaccine Administration Data from Satellite, Temporary, or Off Site Clinic Settings

COVID-19 vaccine providers will be required to enter vaccine administration data into LINKS within 12 hours of administration. If Internet access is not available, providers are required to complete the Vaccine Administration Record (VAR) form during the vaccination event and record it in LINKS within 12 hours.

Monitoring Provider-Level Data and Non-Compliance

Provider-level data will be monitored through daily immunization reports for each site. If reporting is not accurate, it will be addressed with the organization or facility's point of contact for correction. The



process of accountability for COVID-19 will be the same as the process of accountability for VFC. Ultimately, providers who do not comply can be terminated as COVID-19 vaccine providers.

Generation of COVID-19 Vaccine Coverage Reports

COVID-19 vaccination coverage reports will be generated in LINKS. These reports will be used to track and monitor COVID-19 vaccination rate and coverage across Louisiana, as well as determine pockets of need (PON).

Louisiana response to addressing health equity during COVID-19 vaccine distribution is based on the principles of:

- Fairness
- Transparency
- Evidence-based distribution

Thus, limited vaccine supplies will be deployed equitably and transparently using pre-established, evidence-based criteria to prioritize allocation. Vaccine allocation will be based on:

- 1. Risk of acquiring infection
- 2. Risk of severe morbidity and mortality
- 3. Risk of negative societal impact
- 4. Risk of transmitting infection to others

Louisiana will adhere to the ACIP recommendations for initial populations of focus and critical populations for prioritized vaccination.



Section 10: COVID-19 Vaccination Second-Dose Reminders

Second Dose Reminders

In Louisiana, there are several options to remind COVID-19 vaccine recipients of the need for a second dose. At the provider level, the clinic facility is able to use the Louisiana Immunization Network, LINKS to generate a reminder list/postcards/mailing labels/auto dialer files specifically for the second dose of COVID-19 vaccine. Instructions on how to use this function in LINKS will be provided through training videos and quick reference guides. At the state level, COVID-19 vaccine recipients can be reminded of the need for a second dose through the consumer access portal, MyIR Mobile which uses the recipient's email address and/or mobile phone number. Patients that are scheduled to receive COVID-19 vaccines will be registered with MyIR Mobile. This will provide the ability to automatically send reminders via text messaging or email. In addition to reminders, patients can also receive vaccine specific information to make sure they receive the correct vaccine presentation second dose. Vaccine recipients will also have the ability to text questions via MyIR Mobile.

Louisiana's response to addressing health equity during COVID-19 vaccine distribution is based on the principles of:

- Fairness
- Transparency
- Evidence-based Distribution

Thus, limited vaccine supplies will be deployed equitably and transparently using pre-established, evidence-based criteria to prioritize allocation. Vaccine allocation will be based on:

- 1. Risk of acquiring infection
- 2. Risk of severe morbidity and mortality
- 3. Risk of negative societal impact
- 4. Risk of transmitting infection to others

Louisiana will adhere to the ACIP recommendations for initial populations of focus and critical populations for prioritized vaccination.



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

Vaccine Administration in Temporary or High-Volume Vaccination Settings

In the event of network outages or in high-volume vaccination settings, COVID-19 providers are required to complete the Vaccine Administration Record (VAR) form during the vaccination event and record it in the Louisiana Immunization Network, LINKS within 12 hours.

Variables of Data Capture for Recipients of COVID-19 Vaccine

LINKS can capture the following variables: administration location (facility name/ID, type), administration address, administration date, CVX (product), dose number, IIS recipient ID, IIS vaccination event ID, lot number (unite of use, unit of sale), MVX (manufacturer), recipient address, recipient date of birth, recipient name, recipient sex, sending organization, vaccine administering provider suffix, vaccine administrating site, vaccine expiration date, vaccine route of administration.

Louisiana response to addressing health equity during COVID-19 vaccine distribution is based on the principles of:

- Fairness
- Transparency
- Evidence-based distribution

Thus, limited vaccine will be deployed equitably and transparently using pre-established, evidencebased criteria to prioritize allocation. Vaccine allocation will be based on:

- 1. Risk of acquiring infection
- 2. Risk of severe morbidity and mortality
- 3. Risk of negative societal impact
- 4. Risk of transmitting infection to others

Louisiana will adhere to the Advisory Committee on Immunization Practices (ACIP) recommendations for initial populations of focus and critical populations for prioritized vaccination.

Louisiana's Current Capacity for Data Exchange, Storage, and Reporting to accommodate the COVID-19 Vaccination Program

LINKS is capable of capturing all patient vaccination data. This provides the ability to track and monitor when patients receive vaccines, the number of doses received, and when and where doses were received. LINKS also has the capability to run coverage reports and manage vaccine inventory. Online pandemic registration is scheduled to be implemented in mid-October. The first responder module (iCAT) is scheduled to be implemented at the end of October, which will allow organizations to maintain their cohort of facilities to track who has and has not been vaccinated. It also allows organizations to see the professions of people in their cohort to administer the vaccine during the appropriate phase.



Rapid Enrollment and Onboarding to the IIS of Provider Facilities and Healthcare Personnel

Online pandemic enrollment is scheduled to be implemented during the second or third week of October, which would include the CDC COVID-19 Vaccination Program Provider Agreement. Hospitals and long term care facilities have been contacted in preparation for COVID-19 pandemic registration.

If online pandemic enrollment is unavailable, providers will complete the CDC COVID-19 Vaccination Program Provider Agreement, located in the document center of the LINKS homepage. Once the form has been completed, providers will email the agreement to <u>la.links@la.gov</u>. The team will process completed agreements, then update LINKS to indicate the organization and facilities as COVID-19 providers. Finally, the facility will be notified to let them know that they are COVID-19 providers via email within 72 hours. Providers who are new to LINKS will be required to complete the LINKS enrollment documents found on the LINKS web page. The Requirements for Participation Checklist, Site Enrollment Agreement, and User Agreement must be completed and sent to <u>la.links@la.gov</u>.

IZ Gateway Connect and Share

Since 2015, Louisiana has participated with the Immunization Gateway, which was known as the Public Health Immunization (PHIZ) project. Louisiana has gone through numerous data exchange tests and is currently connected to the IZ Gateway Connect and Share components.

Data Use Agreements and Memoranda

The APHL Data Use Agreement and the Memorandum of Understanding between Jurisdictions to Exchange Data are in review by the Louisiana Department of Health (LDH) Legal Department. The LINKS and STCHealth staff, the LINKS vendor have successfully tested with the Immunization Gateway. The privacy preserving record linkage option will be presented to LDH Legal when written information is available.

Backup Solutions for Offline Use

COVID-19 vaccine providers will be required to enter vaccine administration data into LINKS within 24 hours of administration. If Internet access is not available, providers are required to complete the Vaccine Administration Record (VAR) form during the vaccination event and record it in LINKS within 24 hours.

Monitoring Data Quality

Staff will work with the LINKS vendor, STC Health to ensure high data quality standards and complete and accurate data input through various data quality reports and system monitoring. Provider-level data will be monitored through daily immunization reports for each site. If reporting is not accurate, it will be addressed with the organization or facility's point of contact for correction. The process of accountability for COVID-19 will be the same as the process of accountability for Louisiana Vaccines for



Children (VFC) Program. Ultimately, providers who do not comply can be terminated as COVID-19 vaccine providers.



Section 12: COVID-19 Vaccination Program Communication

The Framework for Allocation of COVID-19 Vaccine (2020) states to ensure an effective and equitable national COVID-19 vaccination program, the ethical principles, implementation processes, and expected outcomes must be transparently communicated. Those communications also must be easily accessible, given people's normal sources of information. In the committee's Statement of Task, the federal government and the state, tribal, local, and territorial authorities responsible for COVID-19 vaccine allocation, distribution, and administration must "communicate to the American public [so as] to minimize perceptions of lack of equity." As noted in Chapter 3, the "[COVID-19 vaccine allocation] framework must not only be equitable, but also be perceived as equitable by audiences who are socioeconomically, culturally, and educationally diverse, and who have distinct historical experiences with the health system."

Communication is key during these uncertain times. For this reason, the State of Louisiana has developed a comprehensive and clear communication plan surrounding the COVID-19 vaccine. It is a combination of leveraging existing communication channels and working with partners to develop new tactics while educating the people of Louisiana on vaccine safety, availability and dispelling myths. Existing channels will become available as they are completed while a new media plan will be rolled out in distinct phases. This effective plan meets the CDC communication objectives, while broadly building vaccine confidence, ensuring vaccine uptake.

All messaging will be as culturally sensitive and tailored to each diverse population as possible, with a focus on health equity. The language will be clear and easy to understand. This focus on inclusivity and understanding of different populations will help avoid any unintentional misinformation, errors or loss of credibility and instead help build trust between communities and the vaccine.

Existing Communication Methods

The Governor's Office and Homeland Security and Emergency Preparedness (GOHSEP) maintains a Joint Information Center (JIC). Throughout COVID-19 response the LDH Public Information Officers (PIOs) have with GOHSEP to keep Louisiana residents current on the pandemic. This established communication structure will be appropriate for COVID-19 vaccine response.

A specific COVID-19 Vaccine web page is in development for the Louisiana Department of Health (LDH) <u>COVID-19 website</u>. This web page will provide information about the vaccine, its development, Emergency Use Authorization (EUA) or licensure, Vaccine Information Statements (VIS) and more. This web page, advertised through a media campaign with Feigley Communications, will allow COVID-19 vaccinators and the public to easily locate current vaccination information.

Communications to COVID-19 vaccination providers will ensure these providers are informed of and follow all conditions that must be met to use the vaccine. The Food and Drug Administration (FDA) will coordinate with the CDC to confirm these "conditions of authorization". These conditions are expected to include distribution and reporting requirements, along with safety and monitoring requirements. Upon enrollment for providing the COVID-19 vaccine, providers will receive EUA fact sheets, VIS



statements and web page links to further information in their enrollment packet. Providers in Louisiana will be able to monitor changes and receive information from the above-mentioned COVID-19 website. They will also receive mass emails and faxes from the LDH Office of Public Health (OPH). OPH currently has the capability to send mass email and fax information to Louisiana Vaccine for Children Providers. This capability is being configured to include COVID-19 vaccine providers.

The LDH OPH routinely provides talking points to the OPH Regional Medical Directors or their designees for their role as local spokespersons. These trained spokespersons are trusted resources for accurate information in their communities. Information about vaccine safety and availability, and Emergency Use Authorization, Vaccine Information Statements, and VAERS reporting will be included in their talking points. LDH also has Public Information Officers (PIO) whom routinely collaborate with the GOHSEP PIO to ensure consistent and current COVID-19 information. The PIOs have discussed the ability to disseminate accurate and timely information, including frequently asked questions from the FDA website. This process is well established and will continue for COVID-19 vaccination communication.

Louisiana has partnered with the "211" Statewide system to assist with communications. 211 is manned 24/7, and provides scripted responses to frequently asked questions. Frequently asked questions and answers are reviewed and updated daily by the LDH communications team. Calls that are beyond general knowledge (such as a person asking a question about an adverse event) are triaged for higher level response within OPH.

The Louisiana Department of Education has established a COVID-19 communication contract with the Louisiana Children's Medical Center Health (LCMC Health) for responses for children beyond the 211 system's ability. The LCMC or OPH staff will provide guidance to any caller questioning the vaccine and an adverse event following COVID-19 vaccination, including clinical referral and completing a VAERS form.

OPH is monitoring the CDC's website for any communication resources that the CDC develops, particularly for minority and tribal organizations. This monitoring includes reviewing CDC's COVID-19 Communication Resources and One-Stop Shop Toolkits. These communications will be tailored and shared as needed for Louisiana.

Through this comprehensive communication plan, Louisianans will understand the safety of the vaccine and its availability, while being encouraged to receive the vaccine.

New Media Campaign

The State of Louisiana is proud to partner with <u>Feigley Communications</u> to expand COVID-19 vaccination communication. Feigley Communications is a Louisiana-based media company with a strong background in health communication and experience in COVID-19 communications. Feigley's COVID-19 communication plan, entitled "Phase Out COVID", features specific ways to target vulnerable and harder-to-reach populations during the distribution process. The plan also features communication tactics to emphasize the safety of a potential vaccine, as well as clear and accessible language that will permeate across large swaths of the state's population. While the plan targets key populations, this media campaign will also be visible to all of Louisiana, educating the general public about the vaccine



and building confidence in the vaccine. Through these tactics, "Phase Out COVID" will reach vulnerable populations, providing key information about the COVID-19 vaccine to all, thus ensuring health equity.

This campaign will be unified by design theme, but will offer a range of phrasing and language tailored to target audiences. Each medium of communication will work together as a comprehensive package to help promote the vaccine, increase awareness of its availability, and influence community perception of its safety. These mediums include:

Digital/Online

Since digital display advertising can target narrow audience segments, including job titles and interests, specific micro-targets will be able to receive messages directly, including healthcare workers, racial and ethnic minorities, rural populations, vaccine hesitant groups, essential workers, and staff and residents of long-term care facilities throughout the campaign. The plan will include tactics such as behavioral targeting to reach specific users, mobile device ID targeting to reach specific areas, and multiple methods of online advertising.

Social Media

Social media advertising, or social media targeting, are advertisements served to users on social media platforms like Facebook, Instagram and Twitter. Social networks utilize user information to serve highly relevant advertisements based on interactions within a specific platform. The plan will utilize a mixture of monthly ads with specific targeting options and promoted posts.

Radio

The Feigley plan has identified specific radio networks and stations that will assist with harder to reach populations. These channels include the Louisiana Agriculture Radio Network, Hispanic/Latinx stations, and urban stations. Radio ads will be played on these stations to reach key populations.

Digital Newspapers

Ads will be placed within 46 Community Online Newspapers across the state. Ads are delivered on desktop and mobile and are positioned on Home and News pages.

Minority Print

In addition to major newspapers across the state, the plan will also place ads in ethnic and minority publications, specifically those that serve the Vietnamese, Hispanic and African American communities.

Television

The plan has identified local news stations in large cities across the state, including Alexandria, Baton Rouge, Lafayette, Lake Charles, Monroe, New Orleans, and Shreveport. These stations will allow the state of Louisiana to easily reach a wide, diverse audience in these cities and surrounding areas.

Virtual Town Hall Meetings

In addition to the media campaigns, the state of Louisiana will also be hosting three virtual town hall meetings during this phase to promote initial vaccine distribution information at a local level. These meetings will feature state health administrative officers, as well as various faith leaders and community



members from the specific regions in which the meetings will take place. The dates for these town halls will coincide with the state's push to encourage residents to receive their annual influenza vaccine. The dates and regions for the virtual town halls are as follows:

Town Hall 1 (Regions 6, 7, & 8): Thursday, October 15, 2020, 10:30 a.m.–12:00 p.m. Town Hall 2 (Regions 3, 4, & 5): Thursday, October 22, 2020, 11:00 a.m.–12:30 p.m. Town Hall 3 (Regions 1, 2, & 9): Wednesday, October 28, 2020, 2:00 p.m.–3:30 p.m.

Phase 1

Target Dates: Late October – November

Key Audience: Primary Target Audience; high priority (health care workers, long-term care facility staff and residents, racial and ethnic minorities, rural populations, vaccine-hesitant groups, and essential workers that include police and firefighters)

Phase 1 will kick off the campaign with a comprehensive Digital/Online strategy to target the Primary Target Audience. The message of the campaign during this phase will focus on the theme that a vaccine is coming soon. Only this audience will receive impressions during this phase of the campaign. This audience is the most vulnerable to COVID-19 and needs to be aware of the vaccine's availability, importance and the safety measures being practiced as outlined by the CDC.

Because of the newness of the vaccine and the needs of this micro-targeted audience, it is important to spend some time explaining the safety measures of the vaccine through 60-second radio spots and full-page ads. Messaging will then be adjusted through subsequent phases to reflect the vaccine availability and target demos.

Phase 2

Target Dates: Late November – Late December

Key Audience: Same as Phase 1

In Phase 2, the Digital/Online Campaign will continue to target the Primary Target Audience, although with a different message to indicate the vaccine's wider availability. Phase 2 will also increase print ads in minority newspapers.

Phase 3

Target Dates: Early January 2021 – June 2021

Key Audience: General Public (adults 18+), not excluding Primary Target Audience

Phase 3 is a continuation of Phase 1 and 2 digitally but will include tactics to reach a broader and more general audience to inform them that the vaccine is available and safe. Television ads will be increased at this point to reach an even larger audience. The Primary Target will not be excluded in this stage; however; some specific targets will be phased out towards the end of the campaign. They will continue to receive messaging through the general audience tactic. Additionally, second dose reminders can be



developed and targeted at population subgroups, through minority print or radio, who may have received the first dose of the vaccine but need a general reminder to receive the second dose. This broad reminder will be in addition to individual reminders people will receive when they complete the first dose.

Feigley Communications' comprehensive and targeted plan will reach all parts of Louisiana's population, from disproportionately affected populations to hard to reach groups to the general population. Providing information on the COVID-19 vaccine, its availability and its safety will help ensure health equity throughout the distribution of the vaccine.

Expedited Procedures for Risk/Crisis Emergency Communication

Along with regular communication, emergency and crisis communication is key during this time. The Office of Public Health (OPH) and its partners, including other members of the Louisiana government and Feigley Communications, have developed several plans for handling emergency communication and disseminating new information.

The OPH is hoping to utilize a pre-existing text alert system that was launched by the Office of the Governor in April 2020. By texting "LACOVID" to 67283, Louisiana residents are able to receive timely COVID-19 updates and other critical guidance directly from the governor's office. The system also encourages residents to create a profile through Smart911, an independent company that uses patient profiles to alert emergency responders to a patient's medical needs in the event of a crisis.

In addition, Feigley Communications and OPH will monitor the campaign, its reception and COVID-19 vaccine updates. They will collaborate to respond to any changes and adapt quickly.

The LDH Emergency Operations Center (EOC) maintains a state-level Health Alert Network (HAN). Each of the nine OPH Regions has Alert Network capacity. There are several groupings within the Alert Network that will be appropriate for COVID-19 vaccination information sharing. This information can be shared generally to all partners or directly to a certain group. Coordination to prepare the LDH EOC for these eventualities has begun. Communication documents follow an established review process to ensure information is clear and understandable.

According to the Framework, the discipline of risk communication involves an iterative process with four steps:

- 1. Summarize the evidence relevant to the decisions that members of the intended audience face.
- 2. Describe their current beliefs.
- 3. Create communications designed to close critical gaps in understanding.
- 4. Test to ensure that they can make informed choices; repeat as necessary.



Section 13: Regulatory Considerations for COVID-19 Vaccination

Emergency Use Authorization

Every Louisiana COVID-19 vaccination provider will be informed of Emergency Use Authorization (EUA) fact sheets for both providers and patients, as well as a Vaccination Information Statement (VIS). The COVID-19 vaccine providers will be informed using both print materials and web page links in their enrollment packet, educational campaigns and then continuously educated, as information changes through mass email, mass fax, and Health Alerts.

The OPH Immunization Program web page describes vaccine communication and oversight. The steps to ensuring safety are depicted as on the a <u>Vaccine safety</u> navigational tab. General information about <u>Vaccine Information Statements</u> (VISs) requirements along with links to the latest versions of VISs are also on the LDH Immunization Program web page. COVID-19 vaccine information will be included in LDH COVID-19 website navigational tabs.

A specific COVID-19 Vaccination tab is in development for the <u>LDH COVID-19</u> web page. The FDA's *What is an EUA?* YouTube link will be on the new web page and on the LINKS Home Page with Training Videos. Additional information about Emergency Use Authorization (EUA) and VISs will be added to the tab and home page when available. This web page will allow COVID-19 vaccinators to easily locate current information.

Communications will be directed to ensure COVID-19 vaccination providers are informed of and follow all conditions that must be met to use the vaccine. The FDA will coordinate with CDC to confirm these "conditions of authorization". Vaccine conditions of authorization are expected to include distribution requirements, reporting requirements, and safety and monitoring requirements.

The OPH Immunization Program has the ability to send mass email and fax information to Louisiana VFC Providers. This capability is being configured to include all the COVID-19 Vaccination Providers with information from provider enrollment. This mass communication capacity will include groups and subgroups to ensure COVID-19 vaccine providers in Louisiana are aware of current information including EUA fact sheets and VISs.

Additionally, the LDH Emergency Operations Center (EOC) maintains a state-level Health Alert Network (HAN). Each of the 9 OPH Regions has Alert Network capacity. There are several groupings within the Alert Network that will be appropriate for COVID-19 vaccination information sharing. First, COVID-19 vaccination information can be sent generally to all healthcare and educational partners in the State. Second, COVID-19 specific HAN group for communications can be sent directly to these providers. These systems are tested on a routine basis. Coordination to prepare the LDH EOC for these eventualities has begun. Communication documents will follow an established review process to ensure information is clear and understandable.

The LDH Public Information Officer (PIO) routinely collaborates with the GOHSEP PIO ensuring consistent and current COVID-19 information. This process will continue for COVID-19 vaccination



communication. These PIOs have discussed the ability to disseminate accurate, timely information on EUAs, including guidance and frequently asked questions from the FDA website.

Louisiana has an extensive system of both closed and open Points of Dispensing (PODs). POD Managers and COVID-19 vaccination providers will be provided EUA fact sheets for vaccine recipients from the FDA/CDC. The LDH COVID-19 vaccine tab will include this information as well, for easy lookup and printing. Just-In-Time Training (JITT) and Checklists have been developed for POD positions. Additional JITTs and Checklists for social distancing in the POD setting are in development. JITT for personnel on the EUA is being considered and awaiting additional national guidance. A series of 17 mass vaccination exercises providing influenza vaccine while social distancing will be conducted from mid-October through mid-November 2020. These exercises are to evaluate and improve POD planning in advance of a COVID-19 vaccination campaign.

Enrolled COVID-19 Vaccination Providers to Provide Emergency Use Authorization (EUA) and Vaccine Information Statements (VISs)

Each COVID-19 Vaccination provider will be educated on the terms of being a provider in their enrollment packet, thorough the provider navigational tab on the COVID-19 web page, and through frequent communications using email, mass fax, and the HAN COVID-19 provider system. Within these communications will be the requirement to provide each vaccine recipient with any appropriate EUA fact sheet and VIS. Links to these documents will be directly embedded in each communication.

POD Managers and COVID-19 vaccination providers will be provided EUA fact sheets for distribution to vaccine recipients from the FDA/CDC. The LDH COVID-19 vaccine tab will include this information as well for easy access for printing and display. By utilizing the LINKS program to enroll COVID-19 vaccine providers, OPH ensures that appropriate training has been completed by all providers and tracks training course completion.

In order to be enrolled through LINKS, providers will certify that training in the following COVID-19 vaccine-specific topics provided by OPH and CDC have been completed:

- Awareness of Emergency Use Authorization (EUA) fact sheets
- Location of EUA fact sheets
- Understanding of the EUA
- Vaccine information statements (VISs), as applicable, and required information to be distributed at the time of vaccine administration to vaccinates



Section 14: COVID-19 Vaccine Safety Monitoring

Reporting of Adverse Events to the Vaccine Adverse Event Reporting System (VAERS)

Each COVID-19 Vaccination provider in Louisiana will be educated on the need to and the mechanism to report any adverse event following vaccination with the COVID-19 vaccine. The OPH Immunization program has added a COVID-19 Vaccination Training Coordinator to identify training materials, which will include Vaccine Adverse Event Reporting System (VAERS). This staff will develop a training plan, conduct and direct the nine regional staffs in providing a COVID-19 vaccine provider educational campaigns throughout the pandemic.

The Louisiana Department of Health (LDH) Immunization web page includes information on <u>Reporting</u> <u>adverse events</u> along with the importance of reporting. A link to the HHS CDC <u>Vaccine Adverse Event</u> <u>Reporting System</u> and the phone contact is provided on the web page. The importance of reporting for identification of "signals" that may indicate possible safety problems will promptly initiate investigations.

A COVID-19 Vaccination web page is in development for the LDH COVID-19 website. Information about adverse events and a link to VAERS will be added to both the "for the public" and "for providers" tabs. This web page will allow COVID-19 vaccinators and the public to easily locate current vaccination information, including adverse event reporting.

Within the CDC COVID-19 Vaccination Program Provider Agreement, vaccine providers will be required to report adverse events following vaccination and should report clinically important adverse events even if they are not sure if the vaccination caused the events. This information will be included in the enrollment packet and on the COVID-19 Vaccination navigation tab, along with the procedures for reporting adverse events to VAERS to ensure providers understand this obligation.

The OPH Immunization Program has the ability to send mass email and fax information to Louisiana VFC Providers. This capability is being configured to include all the COVID-19 Vaccination Providers. This mass communication capacity will ensure groups and sub-groups are educated about adverse events, and to ensure vaccine adverse events are reported by COVID-19 vaccine providers in Louisiana.

The LDH Emergency Operations Center (EOC) maintains a state-level Health Alert Network (HAN). Each of the nine OPH Regions has Alert Network capacity. There are several groupings within the Alert Network that will be appropriate for COVID-19 vaccination information sharing. First, COVID-19 adverse event information can be sent generally to all healthcare and educational partners in the State. Secondly, COVID-19 specific HAN group will be created for communications directly to these providers, which would include vaccine adverse events and reporting. These systems are tested on a routine basis. Coordination to prepare the LDH EOC for these eventualities has begun. Communication documents will follow an established review process ensure information is clear and understandable.



LDH routinely provides talking points to the Office of Public Health (OPH) Regional Medical Directors and their designees for their role as local spokespersons. These spokespersons are trusted resources for accurate information in their communities. Information about reports to VAERS will be included in their talking points.

Louisiana has also partnered with the "211" Statewide system to assist with communications. 211 is manned 24/7, and provides scripted responses to frequently asked questions. Frequently asked questions and answers are reviewed and updated daily by the LDH communications team. Calls that are beyond general knowledge (such as a person asking a question about an adverse event) are triaged for higher level response by OPH staff.

In addition, the Louisiana Department of Education (LDOE) has also established a COVID-19 communication contract with the Louisiana Children's Medical Center Health (LCMC Health) for responses for children beyond the 211 system's ability. LCMC is a nonprofit network of healthcare providers including academic centers, acute care facilities, and research hospitals. The LCMC and the RMD will provide guidance to any caller questioning an adverse event following COVID-19 vaccination, including clinical referral and completing a VAERS form.

OPH staff are familiar with the Vaccine Safety Datalink active surveillance systems and the Clinical Immunization Safety Assessment Project, which conducts clinical research and assesses complex adverse events following vaccination. A reminder will be provided to appropriate LDH OPH staff of this opportunity to consult on a complex vaccine safety issue for an individual patient.



Section 15: COVID-19 Vaccination Program Monitoring

Methods and Procedures for Monitoring Progress in COVID-19 Vaccination Program Implementation

- Provider enrollment
 - i. Provider enrollment will be performed through LINKS and monitored daily or weekly, as needed by Louisiana Department of Health (LDH) Office of Public Health (OPH) staff to ensure provider engagement is adequate in areas where critical populations are located. This monitoring will gather data on which to base Point of Dispensing (POD) Sites or Mobile Vaccination Team locations for later Phases of vaccine response. The status of provider enrollment and related activity will be provided by OPH Immunization staff to CDC and the larger response team via daily or weekly submission of situational reports as determined necessary during each Phase of COVID-19 vaccine response.
 - ii. COVID-19 vaccination providers should be aware there will likely be additional requirements from the Centers for Medicaid and Medicare (CMS) in addition to CDC requirements. This information will be made available through the usual CMS communication networks along with information on the LDH COVID-19 website.
 - iii. The LDH staff are aware providers should enroll with the Centers for Medicaid and Medicare (CMS). Collaboration with Louisiana CMS for COVID-19 response will include vaccination as national guidance becomes available. The actions of CMS in exercising its 1135 waiver authority to assist in provider enrollment and the CMS toll-free hotlines at each of the Medicare Administrative Contractors (MACs) will allow certain providers and suppliers to initiate temporary Medicare billing privileges.
- Access to COVID-19 vaccination services by population in all phases of implementation
 - i. Access to COVID-19 vaccination services by population in all phases of implementation will be monitored by OPH staff through LINKS. Providers will enter vaccine administration data directly into LINKS daily and OPH staff will monitor and report any gaps in population coverage to LDH OPH Leadership to target additional provider enrollment or local health authority engagement to provide additional vaccine access.
 - ii. In accordance with CDC recommendations, access to vaccination must be assured. The following methods will be used to ensure population access in Louisiana:
 - 1. Review and strengthening of vaccine distribution networks to reach target groups,
 - 2. Communications strategies to promote vaccination in target groups,
 - 3. Expanded engagement of stakeholders along with communications strategies promoting vaccination in target groups,
 - 4. Microplanning for vaccine implementation, and
 - 5. Plan evaluations to rapidly monitor vaccine safety, effectiveness, and coverage as referenced in *COVID-19 Vaccine Prioritization: Work Group Considerations*.



(https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-08/COVID-08-Dooling.pdf).

• *IIS or other designated system performance* Submitting vaccination information to the LDH, as required in statute, must be done through the Louisiana Immunization Network, LINKS.

The first step is contacting a Regional Immunization Consultant who will provide guidance on getting enrolled in LINKS and trained on how to use LINKS. Current information is maintained at https://lalinks.org/linksweb/ and will be added to the LDH COVID-19 vaccination web page.

• Data reporting to CDC

Data related to COVID-19 vaccination response will be collected via LINKS, by working with the immunization information system vendor, STC Health, on enhancing LINKS functionalities to collect, manage, and report required data elements to LDH OPH Leadership and CDC. Being one of the early adopters of the Public Health Immunization (PHIZ) project in 2015, Louisiana currently has the ability to report LINKS data to CDC via the IZ Gateway and is also able to report to CDC through the Secure Access Management System (SAMS) and/or alternate SFTP site, designated by CDC. At the present time, seven staff have access to several areas in SAMS, with key staff being granted access to new areas related to COVID-19 vaccination. In addition to collaborating with the LINKS vendor and other STCHealth Consortium states in building a state and local level COVID-19 dashboard, LINKS to support CDC COVID-19 dashboards that are being developed by CDC.

• Provider-level data reporting

Provider-level data reporting will be conducted via LINKS and monitored by LINKS staff to assure fair and transparent distribution and administration of vaccine at all phases of vaccine response.

• Vaccine ordering and distribution

Vaccine ordering and distribution will be performed by enrolled providers through LINKS and all vaccine requests approved by OPH staff before vaccine is shipped directly to providers from CDC or the manufacturer.

• 1- and 2-dose COVID-19 vaccination coverage

All data related to COVID-19 vaccine administration (manufacturer, lot number, expiration date, etc.) must be documented in LINKS. If a second dose is required, there are several options to remind COVID-19 vaccine recipients. At the provider level, the clinic facility is able to use LINKS to generate a reminder list/postcards/mailing labels/auto dialer files specifically for the second dose of COVID-19 vaccine. Instructions on how to use this function in LINKS is provided through training videos and quick reference guides. At the state level, the consumer access portal, MyIR


Mobile which uses the recipient's email address and/or mobile phone number, is able to remind COVID-19 vaccine recipients of the need for a second dose. Patients that are scheduled to receive COVID-19 vaccines will be registered with MyIR Mobile. This gives the ability to automatically send reminders via text messaging or email. In addition to reminders, patients can also receive vaccine specific information to make sure they receive the correct vaccine presentation second dose. Vaccine recipients will also have the ability to text questions via MyIR Mobile.

Each enrolled provider is responsible for assuring request of second dose vaccine, if necessary, from CDC, for each vaccine recipient as appropriate. Providers are responsible for communication with vaccine recipients regarding the need for a second dose of COVID-19 vaccine, as well as, the administration of the dose. Ancillary supply kits for administration of second doses will be ordered at time of second dose vaccine request via LINKS.

Monitoring Resources

• Budget

The LDH OPH will follow existing budget tracking processes to monitor expenditures related to COVID-19 vaccination distribution, dispensing, and administration.

• Staffing

The Louisiana Employees Online, LEO allows staff tracking of time for specific response events. COVID-19 is currently designated as CV19. A designation will be made if distribution, dispensing and administration monitoring is required.

Staffing of COVID-19 Vaccination PODs will require many persons, representing many professions, disciplines, agencies, and backgrounds (Nurses, MDs, Behavioral Health, EMS, etc.). POD staff will come from the POD site itself, public health and hospital staff members, first responders and Louisiana Volunteers in Action (LAVA). The LAVA staff and system recruit, register, credential, train, and exercise individuals for public health disaster response. Staff positions will be assigned at each step of the POD dispensing process and may be omitted or combined as determined by the size and status (Open vs. Closed) of the POD.

In Louisiana, the POD Manager has the ultimate responsibility for evaluating POD movement and adjusting the flow to increase throughput. The POD Manager is responsible for opening more express lanes and has the discretion to inform LDH and/or OPH leadership of the need to open more PODs. The POD Managers coordinate response to health incidents during POD operations. Planning includes a POD assistant manager to supplement this workload.

The Facility Supervisor will provide facility access, ensure building maintenance, and address housekeeping issues in the POD setting.



The POD Medical (Operations) Lead is responsible for management of the "clinic" operations, including screening and vaccination. This includes managing the Screening, Vaccinating, First Aid, Translator, and Behavioral/Mental Health Staff.

The POD Non-Medical (Logistics) Lead is responsible for management of the "non-clinical" POD operations. This includes managing the Registration/Training/Break Room staff, Supply Supervisor, POD Runners and Facility Supervisor. The POD Line Lead (and Line Staff) are responsible for management of the POD flow. Communications/IT Support Staff provide communication to and within the POD site.

The POD Screening Staff, under the direction of the screening supervisor, are responsible for review of the screening form and direction to appropriate area for vaccination. For COVID-19 vaccination PODs, there will be up to twenty-eight (28) vaccination staff available to be notified to work, depending on the size of the POD. Vaccination staff will be working in pairs. They will review the screening form to determine which vaccine/dose to administer, sign the screening form, administer vaccine, give the client a vaccine information sheet and add COVID-19 vaccination information in LINKS. Vaccination Staff Assistants will draw vaccine, complete paperwork/vaccine documentation if needed and instruct the vaccinated individual about next steps (i.e. second dose of vaccine).

The POD Vaccination Staff will all work under the POD Vaccination Supervisor. The Supply Supervisor organizes, monitors, and controls the POD supplies, including the vaccines. POD Runners are responsible for supporting POD operations by delivering these supplies to POD functional areas as needed.

The First Aid Staff will attend to the needs of injured or ill persons at the POD. The First Aid Staff will evaluate whether persons reporting they are ill need evaluation at a medical facility. Trained Behavioral Health staff will provide immediate support to all persons at a POD who may be in emotional distress as observed, identified, or reported, either by any Emergency Operations or Behavioral Health staff members. If more intense Behavioral Health support is necessary to stabilize responders, Behavioral Health staff will work with the IC to help maintain a safe environment and make appropriate recommendations for service referrals when indicated. Behavioral Health staff will work with the Emergency Command Operations to address specific recommendations that may be implemented to reduce incident-related behavioral health reactions in responders as applicable.

Emergency care, or treatment, for minors allows licensed practitioners the ability to treat minors who are allowed to receive treatment without parental consent, if such treatment is performed under emergency conditions and in good faith.



The POD Security Manager and staff are responsible for overall POD security, including POD Staff, vaccine security, crowd and traffic control. LAVA volunteers will be assigned to various POD roles, based on their expertise, at the discretion of the POD manager and MCM Volunteer Coordinator.

Upon arrival, the volunteer will check-in and present photo identification. The volunteer will have a photo taken, if applicable, by the Volunteer Coordinator and given a temporary badge. If the ability to create a photo badge is not available, the MCM Volunteer Coordinator will provide a generic badge with a unique identifying number assigned to the volunteer.

Registration/Training/Break Room Staff are responsible for the registration of POD Staff/volunteers. They provide general POD Training and keep up the Break Room at the POD. Each POD will have staff providing translator services to offer assistance to non-English speaking persons in the POD setting and works to assure smooth POD screening operations. Detailed job descriptions, qualifications and trainings for all the positions described above are available in each individual's POD site planning, maintained in a database by BCP.

Louisiana's *POD Guidance 2020* utilizes a POD Volunteer Staff Contact Information, a formalized JITT process, and a process to document and track time in/time out and total hours worked by staff and volunteers assigned to a POD.

Private sector dispensing sites such as chain and independent pharmacies, FQHC, Clinics, and Primary Care Physicians will utilize existing practices and processes to track staffing within their own facility.

• Supplies

The LDH EOC has processes and systems in place to procure supplies and equipment. The LDH EOC has been coordinating with the State EOC for personal protective equipment. Discussions are ongoing in LDH OPH for items that may be unique to the COVID-19 vaccination effort.

Communications Monitoring

Message delivery

OPH has over 20 staff receiving messages from the CDC EpiX system. Internal communication has increased during the pandemic with many staff teleworking. LDH Bureau of Media and Communications develops and coordinates messaging with subject matter experts, then collaborates with GOHSEP for timely consistent messaging. Each OPH Region has several staff that have completed risk communication training. The LDH EOC and nine OPH Regions maintain the Health Alert Network. OPH is able to communicate with vaccine provider groups, such as Louisiana Vaccines for Children Providers, hospitals, and pharmacies. Information from the Louisiana COVID-19 online provider enrollment is being configured as an additional resource.



• Reception of communication messages and materials among target audiences throughout jurisdiction

Each state agency, that is responsible for the well-being of a segment of society will have a published call line with trained personnel on staff 24/7 to field and disseminate information.

Maintaining Local Level Situational Awareness

The LDH EOC has established situational awareness reporting by the OPH Regions and Sections. Emergency managers at the local level also coordinate situational awareness and report back to the State EOC at established intervals. Reports can be done through an incident specific conference call schedule or electronically via WEBeoc.

COVID-19 Vaccination Program Metrics

The OPH Flu Dashboard information was established to inform decision-making to the zip code level. Since that inception, the need for online public-facing information was recognized. Public Health Informatics have provided an exceptional level of detail on the LDH COVID-19 website. Discussions are continuing. The current OPH flu dashboard is being built to incorporate data that can reflect COVID-19 vaccination response activities.

Appendix 1: LDH OPH Organizational Chart





Appendix 2: OPH Regional Map for the State of Louisiana

Appendix 3: Legal Authorities and References

Authorities

In recent years, emergency preparedness has become a focus for public health and public health law. Natural disasters (such as hurricanes and floods); man-made disasters (such as terrorism and oil spills); and communicable disease outbreaks (such as Ebola and Zika). Since 2005, more than a dozen incidents have warranted presidential emergency declarations because the severity of Louisiana's hurricanes, storms, tornadoes, and flooding have exceeded state resources.

From these, the Louisiana Department of Health birthed the Louisiana Public Health Emergency Law Bench Book in 2018. The "Bench Book", which provides a detailed, comprehensive overview of Louisiana public health laws implicated before, during, and after crises, addresses public health infrastructure (roles and responsibilities), jurisdictions, emergency declarations, evacuation and sheltering, disease surveillance, detention of individuals, and medical countermeasures. For access to the Bench Book, contact the LDH-OPH-Bureau of Community Preparedness.

Homeland Security Presidential Directive #7, "Critical Infrastructure Identification, Priority and Protection" officially designated the public health systems of the nation as critical infrastructure. As a result, Homeland Security Presidential Directive #8, "National Preparedness" assigned the public health profession the role of "first responder" in the event of a disaster or catastrophic health event resulting from either natural or man-made causes.

Under the guidelines of the GOHSEP State of Louisiana Emergency Operations Plan, public health is required to establish procedures for responses to heath, environmental, and medical needs of the State of Louisiana. LDH has primary responsibility and is required to coordinate with the Federal government for assistance provided under the National Response Framework's Emergency Support Function-8, Public Health and Medical Services, and Emergency Support Function-12, Energy and Utilities. In Louisiana, LDH has support responsibilities in most of the remaining Emergency Support Functions.

Any emergency or disaster may present health concerns requiring public health to respond. Executive Order BJ 08-32 requires each Agency to prepare and maintain plans, procedures, arrangements and agreements to ensure that the organization can carry out its mission.

The State Health Officer, the Secretary of the Louisiana Department of Health, the LDH Medical Director and the Assistant Secretary of the Office of Public Health are responsible for State health and medical services during an emergency. The scope of the service is adjusted to the size and type of disaster. Response planning in LDH OPH is both modular and scalable. LDH collaborates with a variety of State agencies and medical care provider partners for planning, exercises and real-world response.

The Louisiana Revised Statutes 29: 761-762, 769; 40:5, 7-10 and the Louisiana Administrative Code, June 2004, Public Health Sanitary Code (5), Part 2: The Control of Diseases provides the Louisiana State Health Officer with the authority to take actions to control diseases and procure needed assets. The Sanitary Code mandates reporting of diseases of major public health concerns because of the severity of disease and the potential for epidemic spread. This is to be done by telephone reporting immediately upon recognition that a case, a suspected case, or a positive laboratory result is known. In addition, all cases of rare or exotic communicable diseases, unexplained deaths, unusual clusters of diseases, and all outbreaks shall be reported. It further mandates reporting duties of physicians, health care providers,

laboratories, parents, schools and day care centers. The State Health Officer is empowered, and it is their duty to investigate and promptly institute necessary control measures whenever a case of communicable disease occurs and may carry on such measures to prevent the spread of disease.

The Louisiana Emergency Powers Act 2003 grants the State Health Officer, the Louisiana Department of Health (LDH) and LDH OPH jurisdiction, control and authority to isolate or quarantine and to take such action as is necessary to accomplish the subsidence and suppression of diseases of all kinds in order to prevent their spread. This Act provides the authority to issue standing orders, develop protocols for dispensing sites, allow personnel to dispense medications and suspend administrative policies and procedures to the extent necessary for the protection of life and controlling the spread of human disease.

Revised Statute 40.5 describes the "general powers and jurisdiction (of) the State health officer and the Office of Public Health of the Louisiana Department of Health shall have exclusive jurisdiction, control, and authority:

(1) To isolate or quarantine for the care and control of communicable disease within the State.

(2) To take such action as is necessary to accomplish the subsidence and suppression of diseases of all kinds in order to prevent their spread."

The authority to issue standing orders and protocols for disease control and suppression is inherent with the stated charge to the State Health Officer or designee.

Revised Statute 29:766 describes "A State of public health emergency may be declared by executive order or proclamation of the governor, following consultation with the public health authority, if he finds a public health emergency as defined in R. S. 29:762 has occurred or the threat thereof is imminent.

Revised Statute 29:762 defines: "A 'public health emergency' as an occurrence or imminent threat of an illness or health condition that:

(a) Is believed to be caused by any of the following:

(i) Bioterrorism.

(ii) The appearance of a novel or previously controlled or eradicated infectious agent or biological toxin.

(iii) A disaster, including but not limited to natural disasters such as hurricane, tornado, storm, flood, high winds, and other weather related events, forest and marsh fires, and man-made disasters, including but not limited to nuclear power plant incidents or nuclear attack, hazardous materials incidents, accidental release or chemical attack, oil spills, explosion, civil disturbances, public calamity, hostile military action, and other events related thereto.

(b) Poses a high probability of any of the following harms:

(i) A large number of deaths in the affected population.

(ii) A large number of serious or long-term disabilities in the affected population.

(iii) Widespread exposure to an infectious or toxic agent that poses a significant risk of substantial future harm to a large number of people in the affected population."

Revised Statute 29:766 describes, "During a state of public health emergency, in addition to any powers conferred upon the governor by law, he may do any or all of the following: (1) Suspend the provisions of any regulatory statute prescribing procedures for the conduction of State business, or the orders, rules, or regulations of any State agency, if strict compliance with the provisions of any statute, order, rule, or regulation would in any way prevent, hinder, or delay necessary action in coping with the emergency. (2) Utilize all available resources of the State government and of each political subdivision of the State as reasonably necessary to cope with the disaster or emergency. (3)Transfer the direction, personnel, or functions of State departments and agencies or units thereof for the purpose of performing or facilitating emergency services. (4) Subject to any applicable requirements for compensation, commandeer or utilize any private property if he finds this necessary to cope with the disaster or emergency."

Section E of Revised Statute 29:769 and the Uniform Emergency Volunteer Act discusses the temporary registration of health care professionals. "Any board or commission placed within the Louisiana Department of Health by R.S. 36:259 [®], (R), (EE), and (GG) may exercise during such period as the declared State of public health emergency exists, the power reasonably necessary to issue temporary registrations to health care providers licensed, certified, or registered in another jurisdiction of the United States whose licenses, certifications, or registrations are current and unrestricted and in good standing in such jurisdictions."

Specific professions define authority to dispense medications. The Statutory Definition for Registered Nurse Scope of Practice R.S. 27:913 includes, "Implementing nursing care through such services as case finding, health instruction, health counseling, providing care supportive to or restorative of life and wellbeing, and executing health care regimens as prescribed by licensed physicians, dentists, optometrists, or other authorized prescribers."

519. State of Emergency states, "A pharmacist may work in the affected Parish(es) and may dispense a one-time emergency prescription of up to thirty-day supply of a prescribed medication if: a. in the pharmacist's professional opinion the medication is essential to the maintenance of life or to the continuation of therapy. A pharmacist not licensed in Louisiana, but currently licensed in another State, may dispense prescription medications in those affected Parish(es) during the time that a State of emergency exists if: a. the pharmacist has some type of identification to verify current licensure in another State; and b. the pharmacist is engaged in a legitimate relief effort during the emergency period." The authority provided for in this section shall cease with the termination of the State of emergency.

Procurement of private property is discussed in Revised Statute 29:769, "In accordance with R.S. 40:10 and as may be reasonable and necessary to respond to a State of public health emergency, the State health officer may employ any means to control the use of food, fuel, clothing, and other commodities. The following meanings shall apply: (a) 'Any means' includes rationing, quotas, allocations, prohibitions of shipments, or other means. (b) 'Control' includes inspect, restrict or regulate. (c) 'Use' includes sale, dispensing, distribution and transportation."

OPH Policy 401 and Human Resource Policy 0011-83 describe staff compensation and provides information on workers compensation. La. Revised Statutes 29: 735.1 provides that during declared emergency anywhere in the State, any health care provider who in good faith voluntarily renders emergency care or first aid to assist persons in the disaster shall not be civilly liable for causing injury, death or damage to property unless it is by gross negligence or willful misconduct. The statute may also protect an organization from vicarious liability under Louisiana Law. The Public Readiness and Emergency Preparedness (PREP) Act has liability protection for medical countermeasure development, distribution and administration protection and provides national guidance.

Appendix 4: Vaccine Action Collaborative Work Group Charters and Members

Prioritization & Allocation Work Group Charter		
Purpose	Objectives	
 The VAC Prioritization & Allocation Work Group consists of members from various health agencies who will develop plans/approaches associated with the following key aspects of the Louisiana COVID-19 vaccination response: Identify and estimate sizes of critical populations. Describe and identify where critical populations are located, including places of employment for critical workforce. Determine allocation method of vaccine to COVID-19 vaccination providers for identified critical populations in constrained vaccine supply for 3 scenarios. 	 Discuss critical populations and workforce populations for prioritization in Louisiana within the CDC framework (pending) and verify the populations of each group by September 25, 2020. Define critical populations (with exclusions) by October 2, 2020. Refine existing dose allocation tool to reflect accurate allocations to prioritized populations by October 9, 2020. Develop an inventory of all sites, with points of contact, to reach the critical populations and workforce populations by October 16, 2020. 	
Member Involvement Detail	Work Group Members	
Work Group members can expect to participate in one meeting each week, from September 1, 2020 through November 1, 2020 (2 months). Meetings will generally last one hour and occur via phone teleconference. Group members may be tasked with performing additional Work Group related activities outside of regular meetings, and the time spent conducting these activities will vary.	Team Leads: Office of Public Health LSU Health Sciences Center Members: GOHSEP Ochsner Louisiana Board of Pharmacy Louisiana Hospital Association Louisiana Nursing Home Association Louisiana Public Health Institute LPCA, FQHC or RHC LSU Health Sciences Center Tulane SPHTM Tulane Virology	

	Prioritization & Allocation Work Group Charter		
Projected Deliverable Timeline			
Deliverable	Projected Start Date	Projected End Date	
1. Document that includes definitions critical populations and workforce populations, and populations of each group.	September 1, 2020	October 2, 2020	
2. COVID-19 Allocation Tool ready for COVID- 19 vaccine response to 3 scenarios.	September 1, 2020	October 9, 2020	
3. A completed inventory of all sites, with points of contact, to reach the critical populations and workforce populations.	September 1, 2020	October 16, 2020	
4. Identify temporary clinic locations for prioritized populations and develop logistical plans for each.	September 1, 2020	October 16, 2020	
6. Listing of vaccination providers' storage capacity by volume at routine refrigerated (2 to 8C), frozen (-20C), and ultra-cold (-60 to - 80C) temperatures.	September 1, 2020	October 16, 2020	

Logistics / Operations Work Group Charter		
Purpose	Objectives	
The VAC Logistics/Operations Work Group consists of members from	1. Determine IIS enrollment and data collection protocols for	
various health agencies who will develop approaches associated with		
the following key aspects of the Louisiana COVID-19 vaccination	2. Modify existing planning for the receipt, storage and	
response:	transport of vaccine by September 25, 2020.	
 Identify vaccination providers and settings for rapid vaccination of early populations of focus. 	 Detail the process to work with OHSEP and OPH Regions for COVID-19 vaccine appropriate POD sites by October 16, 2020 	
 Target vaccination providers for immediate enrollment in LINKS and the US Government's COVID-19 vaccine program. 	4. Complete LINKS security assessment by September 30, 2020.	
 Determine IIS enrollment and data collection protocols for doses administered. 		
 Determine points of contact for each priority population group to be vaccinated and establish methods of communication and coordination. 		
 Develop primary, alternate and contingent planning for vaccine receiving, storing and transport. 		
 Review and modify the process to work with parish Office of Homeland Security and Emergency Preparedness (OHSEP) and Region Office of Public Health to identify locations for temporary clinics and develop logistical plans for each, building on Point of Dispensing (POD) planning for COVID-19 vaccine response based on existing Strategic National Stockpile planning. 		

Logistics / Operations Work Group Charter		
Member Involvement Detail		Work Group Members
Work Group members can expect to participate in one meeting each week, from September 1, 2020 through November 1, 2020 (2 months). Meetings will generally last one hour and occur via phone teleconference. Group members may be tasked with performing additional Work Group related activities outside of regular meetings, and the time spent conducting these activities will vary.		Team Leads: Office of Public Health Members: Acadian Ambulance GOHSEP LANG LDH EMS Louisiana Board of Pharmacy Louisiana Hospital Association Louisiana Nursing Home Association Louisiana Primary Care Association Office of Public Health
	-	erable Timeline
Deliverable	Projected Start Date	Projected End Date
1. An updated multi-layered Receiving, Storage, and Transport Plan for COVID-19 vaccine response including security.	September 1, 2020	September 25, 2020
2. A LINKS security assessment document.	September 1, 2020	September 30, 2020
3. IIS enrollment and data collection protocols for doses administered.	September 1, 2020	October 2, 2020
4. A comprehensive POD Plan for COVID-19 vaccine response, including security.	September 1, 2020	October 16, 2020

Planning Work Group Charter		
Purpose	Objectives	
 The VAC Planning Work Group consists of members from various health agencies who will develop plans with the following key aspects of the Louisiana COVID-19 vaccination response: Solicit edits for the Draft Louisiana COVID-19 Vaccination Plan Develop a Louisiana COVID-19 Playbook based on possible scenarios along with experience of recent response With the assistance of a contractor, develop and conduct a tabletop exercise plan. Conduct a Hot Wash and develop After Action Report. Revise and finalize the Plan and Playbook based on the exercise and follow up. Inform VAC, key partners and OPH LDH Leadership for planning 	 Gather input from VAC, OPH LDH Leadership and COVID-19 Incident Command to the Louisiana COVID-19 Vaccination Plan by September 25, 2020. Develop response plans as a Louisiana COVID-19 Playbook by October 23, 2020. Conduct a tabletop exercise of the Plan and Playbook by October 16, 2020. Complete an After Action Report to revise and finalize Plan and Playbook by October 23, 2020. Provide an overview of the finalized Plan and Playbook to OPH, LDH Leadership and COVID-19 Incident Command by October 30, 2020. 	
Member Involvement Detail	Work Group Members	
Work Group members can expect to participate in one meeting each week, from September 1, 2020 through November 1, 2020 (2 months). Meetings will generally last one hour and occur via phone teleconference. Group members may be tasked with performing additional Work Group related activities outside of regular meetings and the time spent conducting these activities will vary. This will include Plan, Playbook, Exercise, Reports and presentation.	Team Leads: Office of Public Health Members: GOHSEP Planning Office of Public Health Louisiana Board of Pharmacy Louisiana Department of Health LSU Health Sciences Center Xavier College of Pharmacy	

Communication & Outreach Work Group Charter		
Purpose	Objectives	
 The VAC Communication & Outreach Work Group consists of members from various health agencies who will develop plans and approaches associated with the following key aspects of the Louisiana COVID-19 vaccination response: Guidance and method of vaccination provider enrollment for both LINKS and the United States Government (USG) COVID-19 vaccination program. Education and training of enrolled providers on vaccination. Gather community input, prioritizing populations most impacted by COVID-19. Information sharing planning. Collection and reporting of vaccines and vaccinations given. Messaging to providers and the public (including VAERS process). Provide input for a COVID-19 vaccine media campaign. 	 Detail a communication process for frequent communication and data sharing within Incident Command with key partners, participating COVID-19 vaccination providers, and the public by October 16, 2020. Develop plans for provider enrollment, training, and education by September 25, 2020. Determine culturally and linguistically responsive communication approaches for critical populations and the general public, based on CDC messaging and Louisiana community input by September 30, 2020. Team Leads will share media campaign details with this Work Group and gather input to inform the vaccine media campaign by September 30, 2020. Determine methods and systems to provide second-dose reminders for vaccine recipients as warranted by October 16, 2020. Determine data sharing processes and plans for sharing data with officials throughout vaccination response by October 16, 2020. 	
Member Involvement Detail	Work Group Members	
Work Group members can expect to participate in one meeting each week, from September 1, 2020 through November 1, 2020 (2 months). Meetings will generally last one hour and occur via phone teleconference. Group members may be tasked with performing additional Work Group related activities outside of regular meetings, and the time spent conducting these activities will vary.	Team Leads: Office of Public Health Members: Balentine/Willis Knighton Governor's Office of Indian Affairs LDH Bureau of Media and Communication Louisiana State Nurses Association Office of Public Health Urban League of Louisiana Xavier University	

Communication & Outreach Work Group Charter		
Projected Deliverable Timeline		
Deliverable	Projected Start Date	Projected End Date
1. Communication Annex for the Louisiana COVID-19 Vaccine Plan.	September 1, 2020	October 16, 2020
2. Vaccination Provider Annex including enrollment, training, and education.	September 1, 2020	September 25, 2020
3. A culturally and linguistically responsive COVID-19 Communication Toolkit for critical populations and the general public.	September 1, 2020	September 30, 2020
4. Comprehensive social marketing/media campaign that includes messaging to multiple audiences (high-risk populations, providers, etc.) in various forums (print, tv/radio, social media).	September 1, 2020	September 30, 2020
5. Detailed second-dose reminder processes for vaccine recipients within the Communication Annex.	September 1, 2020	October 16, 2020
6. Detailed data sharing information with intervals in the Communication Annex.	September 1, 2020	October 16, 2020

Appendix 5: Overviews of Exercises Referenced in Section 1

Louisiana Office of Public Health Pandemic Flu Full Scale Exercise 2015 (example provided)

Pandemic Flu Full Scale Exercise 2015 (October 16–November 5, 2015)

This exercise was a functional exercise, planned for one day involving eight parishes in Louisiana's Region 6 during the following dates:

- October 16, 2015–October 16, 2015 (Winn Parish Health Unit)
- October 29, 2015–October 29, 2015 (Grant Parish Health Unit)
- October 30, 2015 October 30, 2015 (Avoyelles, Concordia, LaSalle, Rapides, Vernon, Winn Parish Health Units)
- November 5, 2015–November 5, 2015 (Avoyelles (Bunkie) Parish Health Unit)

Capability 3: Emergency Operations Coordination

Capability 4: Emergency Public Information and Warning

Capability 6: Information Sharing

Capability 8: Medical Countermeasure Dispensing

Capability 14: Responder Safety and Health

Scenario: The scenario involves the emergence of a new strain of bird flu H2N25. The new strain has now migrated globally including the United States. 45 states have identified cases, and a vaccine has been developed and is ready for distribution. DHH has initiated POD distribution. Louisiana's Region 6 is located in central Louisiana and is designated as a rural area of the state.

Louisiana Office of Public Health Mass Vaccination Campaign 2018-After Action Report (example)

The 2018 Mass Vaccination Campaign was designed to test several capabilities related to developing media campaigns, community outreach, vaccination clinics, and response partner collaboration. This sustained campaign identified several lessons learned used to influence the development of this initial plan. Those lessons learned include the documentation of vaccines, vaccination supplies, and the effectiveness of the media and outreach campaign. The below synopsis outlines those key findings obtained from the Mass Vaccination Campaign.

Documentation of Vaccinations

The State of Louisiana uses a number of electronic systems for maintaining data on different public health activities. Immunizations are tracked through the Louisiana Immunization Network for Kids Statewide (LINKS). LINKS is a web-based application used by healthcare providers across the state to document vaccines given to their patients. Despite the name, LINKS contains immunization records on people of all ages. As a matter of policy, all vaccinations provided at an OPH health unit are entered into LINKS. Public health units also utilize an electronic health records (EHR) system to document all client encounters (including immunizations). The EHR system collects detailed information on each client.

During the vaccination campaign, both electronics systems, LINKS and EHR were utilized to document vaccinations given. Many people who came to the health unit seeking vaccination had not been seen at

the health unit previously, so new records had to be created for each person. The initial creation of a client record is not purely electronic and requires some manual steps.

The creation of new records created bottlenecks in some clinics where the line for registration was long, but the nurses had no one in line to be vaccinated. Observers noted that this was often caused by the involved process for entering first-time clients into the EHR system or by using two systems at once to document vaccinations. Less often observers stated that more clerical staff was needed to handle the associated paperwork and data entry tasks. One specific instance noted a lack of clerical oversight as a cause of the slowdown.

In most of the cases described, throughput was increased by two methods:

- Administering vaccine to the client while they filled out paperwork and then afterward having the client return to the clerical desk to complete the process.
- Doing only manual record keeping during the clinic and completing data entry tasks later that day or the next day.

Previous experience in mass vaccination operations have shown that vaccination itself takes very little time; the most time consuming part of the process has always been documentation. While these processes can be streamlined, the major limiting factor can usually be traced to a lack of staff available for client registration and data entry.

Vaccination Supplies

Vaccination supplies include vaccine, alcohol pads, gloves, and adhesive bandages. Health Units always have a cache of these on hand and additional supplies were ordered by each health unit in anticipation of the vaccination campaign.

Additional supplies, above and beyond what was located at each health unit, were available upon request either through the OPH Regional Office or directly from the OPH Immunization program.

Supplies in the situations described by observers generally meant syringes and vaccine. At no point did supply issues interrupt clinic operations, however, most observations described shortages caused by greater-than-anticipated demand from the public. This demand was sometimes linked to the expansive reach of the media campaign.

Overall, acquisition of needed supplies was not a limiting factor for vaccination operations, though some opportunities for improvement were identified. Some observers reported a slightly complex method of requesting additional supplies. A noteworthy observation included the fact that several different people were charged with handling supply orders, which may have caused confusion or possible duplication of orders. Another observer noted that there was a significant delay in acquiring supplies that had to be transported from the regional office.

For most of these observations, the observer could not determine the cause of the issue from their standpoint. No parallel observations were collected from the staff actually fulfilling the supply orders. Nonetheless, it appears as though the re-supply procedures suffered from at least some inefficiency, possibly because the need for additional supplies was not anticipated. This again might relate to the increased public demand for vaccination.

Media Campaign Effectiveness

The media outreach portion of the mass vaccination campaign played a critical role in making the public aware of the risks of influenza, but also the importance of vaccination and the availability of the influenza vaccine. It is worth noting that this public awareness campaign also included outreach by regional OPH staff (summarized in an appendix) in addition to the traditional media and social media activities of the Bureau of Media and Communications (BMAC).

Feedback from clinic staff in regard to the effectiveness of the media campaign was positive. Several observers described how members of the public specifically mentioned the media spots as the reason for their coming to be vaccinated.

Both of the lessons learned mentioned above could logically be attributed to the success of the media campaign surrounding the flu vaccination clinics. It is highly likely that the large number of people seeking flu vaccination would not have been made aware of the availability of vaccine if not for the extensive media activities.

Appendix 6: Acronyms, Definitions and Terms

Acronyms

ACIONYINS	
AAR	After-Action Review
ACIP	Advisory Committee on Immunization Practices
ВСР	Bureau of Community Preparedness
CDC	Centers for Disease Control and Prevention
CERC	Crisis and Emergency Risk Communication
СООР	Continuity of Operations Plan
EOC	Emergency Operations Center
EOP	Emergency Operations Plan
FEMA	Federal Emergency Management Agency
FQHC	Federally Qualified Health Centers
GOHSEP	Governor's Office of Homeland Security and Emergency Preparedness
HAN	Health Alert Network
ICS	Incident Command System
JIC	Joint Information Center
JITT	Just-In-Time Training
LANG	Louisiana National Guard
LAVA	Louisiana Volunteers in Action
LDH	Louisiana Department of Health
LINKS	Louisiana Immunization Network for Kids Statewide
MVE	Mass Vaccination Exercise
NIMS	National Incident Management System
NRF	National Response Framework
OHSEP	Office of Homeland Security and Emergency Preparedness
ОРН	Office of Public Health
POD	Point of Dispensing
SHO	State Health Officer
UCG	Louisiana's Unified Command Group

VAC Vaccine Action Collaborative

VFC Vaccines for Children

Definitions

Disaster: Any occurrence or imminent threat of widespread or severe damage, injury, or loss of life or property resulting from a natural, technological, and/or national security incident, including earthquake, explosion, fire, flood, high water, hostile military actions, hurricanes, landslide, mudslide, storms, tidal wave, tornadoes, or wind-driven water.

Emergency Operations Center (EOC): A protected site from which personnel exercise direction and control during an emergency or disaster. It is equipped and staffed to provide support in coordinating and guiding emergency and disaster operations.

Emergency Operations Plan (EOP): A written framework guiding and directing emergency operations.

Emergency Support Function (ESF): That portion of a comprehensive emergency management plan that describes a grouping of similar or interrelated support activities necessary for managing the impacts of a disaster.

Evacuation: The removal of potentially endangered, but not yet exposed, persons from an area threatened by an emergency or disaster incident.

Executive Leadership: Includes the LDH Secretary, State Health Officer, LDH Medical Director, LDH Office of the Secretary Deputy Secretary, Office of Management and Finance Undersecretary, LDH Executive Director of Emergency Preparedness, OPH Assistant Secretary, OPH Deputy Assistant Secretary, OPH Medical Director and OPH Center Directors.

Governor's Office of Homeland Security and Emergency Preparedness (GOHSEP): The Governor of Louisiana is responsible for the coordinated delivery of all emergency resources during a natural, technological, and/or national security emergency or disaster situation. The Governor has delegated the authority to develop and implement an emergency operations plan and to coordinate all-hazard response efforts to GOHSEP.

HIPAA Privacy Rule: National standards protecting the privacy of individually identifiable health information which authorizes public health activities to identify, monitor, and respond to disease, death, and disability.

Incident: An event involving a hazardous material or a release or potential release of a hazardous material.

Incident Command: A disciplined method of management established for the specific purpose of control and direction of resources and personnel.

Incident Command System (ICS): The combination of facilities, equipment, personnel, procedures, and communications operating within a common organizational structure with responsibility for the management of resources to effectively accomplish stated objectives pertinent to an incident.

Incident Commander (IC): The individual responsible for overall management of the incident at the field level.

Incident Management System (IMS): A standardized management system designed for control and coordination of field emergency response operations under the direction of an Incident Commander through the allocation and utilization of resources within pre-defined functional and/or geographic areas.

LDH OPH Executive Leadership: Includes the LDH Secretary, State Health Officer, LDH Medical Director, LDH Office of the Secretary Deputy Secretary, Office of Management and Finance Undersecretary, LDH Executive Director of Emergency Preparedness, OPH Assistant Secretary, OPH Deputy Assistant Secretary, OPH Medical Director and OPH Center Directors.

Medical Countermeasures: Medications such as antibiotics, antivirals or antitoxins and the vaccines for treatment or prophylaxis of persons in an identified population in accordance with public health guidelines and recommendations.

Operations: The coordinated tactical response of all operations in accordance with the Incident Action Plan.

Pandemic: An epidemic of infectious disease that is spreading through human populations across a large region; for instance, multiple continents, or even worldwide.

Personal Protective Equipment (PPE): Equipment provided to shield or isolate a person from the chemical, physical, and thermal hazards that may be encountered at a hazardous materials incident. Adequate personal protective equipment should protect the respiratory system, skin, eyes, face, hands, feet, head, body, and hearing. Personal protective equipment includes-personal protective clothing, self-contained positive pressure breathing apparatus, and air purifying respirators.

Public Health Authority: A person or entity authorized to respond to a public health emergency in accordance with the plan for emergency responses to a public health emergency prepared in accordance with section 8 of this act, including, but not limited to, licensed health care providers or local and district health directors.

Public Health Emergency: An occurrence or imminent threat of a communicable disease, except sexually transmitted disease, or contamination caused or believed to be caused by bioterrorism, an epidemic or pandemic disease, a natural disaster, a chemical attack or accidental release or a nuclear attack or accident that poses a substantial risk of a significant number of human fatalities or incidents of permanent or long-term disability.

Public Information Officer (PIO): An individual from an organization or jurisdiction participating in the event that is designated to prepare and release public information regarding the situation and the response.

Response: That portion of incident management where personnel are involved in controlling and/or mitigating an emergency or disaster.

Treatment: Any method, technique, or process which changes the physical, chemical, or biological character or composition of any hazardous waste, or removes or reduces its harmful properties or characteristics for any purpose.

Unified Command: An adaptation of the Incident Management System in which all key local, Regional, State, and/or Federal agencies cooperatively participate in planning, decision making and resource coordination in support of the designated Incident Commander.

Vulnerability: The susceptibility of life, the environment, and/or property, to damage by a hazard.

Appendix 7: Navigators

NAVIGATORS



Who Are We?

Our Mission

Collaborating across sectors to improve upon and expand the existing pharmacy – public health infrastructure by Investigating opportunities to reduce barriers and leverage resources to increase immunization rates, protect individuals, empower consumers, and prevent disease in communities.

The Navigators, established in the Spring of 2020, is a grass roots organization that started with a casual conversation between two friends, one from the public sector and one from the private sector. It has become abundantly clear that no one group can do the work that needs to be done to build lasting partnerships and collaborations.

The Navigators are a group of subject matter experts from both the public and private sectors that represent various organizations within the healthcare system. We are pharmacies, state immunization programs, national membership organizations, and much more.

Member Organizations

AIM • NASPA • NACDS • APhA • NCPA • NABP • ASCP

What Do We Do?

We focus on topics that have a national Impact, identify barriers, gather information, and then work diligently to implement solutions. **We Take Action!**

Navigator Activities

- Community Vaccinator Map, a collaboration with the Association of Immunization Manager's
- "Vaccinate Now!" Media Toolkit (under development)
- □ Shared Resources
- □ Navigating VFC
- Adult Influenza



www.navigatehealthnow.com navigatorinfo@stchome.com

Appendix 8: Louisiana's Comprehensive Point of Dispensing Plan for COVID-19

Louisiana's Comprehensive Point of Dispensing Plan for

COVID-19 Vaccine

Louisiana's Vaccine Action Collaborative

Operations and Logistics Workgroup

October 2020

Introduction

The following document contains a comprehensive Point of Dispensing (POD) plan for COVID-19 vaccine response in Louisiana. This plan reflects the most current vaccine assumptions provided by the CDC and will be adjusted as more specific information about COVID-19 vaccine, and its distribution, becomes available. This planning is designed to ensure every resident of Louisiana is able to receive the COVID-19 vaccine in multiple locations, through a collaborative effort between Louisiana's Immunization Program, Bureau of Community Preparedness (BCP), Office of Homeland Security and Emergency Preparedness (OHSEP) and Regional Offices of Public Health.

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Distribution of COVID-19 Vaccine Products

As described in Louisiana's COVID-19 Vaccine Storage and Handling Plans, COVID-19 vaccines, and ancillary supplies, will be procured and distributed by the federal government at no cost to enrolled COVID-19 vaccination providers in Louisiana. Louisiana is ensuring accurate and complete shipping information for all these enrolled providers is available in CDC's Vaccine Tracking System (VTrckS). The vast majority of these providers are already designated as Points of Dispensing (PODs) by BCP and OSHEP, which means this information has already been collected. BCP allocation models include latitude, longitude, staff population, resident population, and POD planning information for each site. The models will be used to help determine how many vaccines to distribute to providers at each POD. Based on current assumptions, either McKesson or the manufacturer will distribute the determined amount of vaccine directly to the provider, by shipping them through FedEx or UPS.

COVID-19 vaccine (and diluent or adjuvant, if required) will be shipped to vaccination POD Sites enrolled by the State's Immunization Program within 48 hours of order approval. McKesson, or the manufacturer if shipped directly, will be responsible for maintaining COVID-19 vaccine cold chain and minimizing the likelihood of vaccine loss or damage during shipment.

Whenever possible, vaccine will be shipped to the location where it will be administered to minimize potential breaks in the cold chain. There may be scenarios where vaccine will be shipped to a central depot (like RSS sites or a large POD) and be redistributed to smaller PODs. Since the federal government does not redistribute product, this will be the responsibility of the state. In these instances, vaccination provider organizations/facilities, third-party vendors, and other vaccination providers would be approved by Louisiana's Immunization Program to redistribute COVID-19 vaccine. The Immunization Program will also distribute and/or coordinate the distribution of vaccine products internally with GOSHEP, as needed. The Immunization Program has also coordinated pricing with FedEx Custom Critical, as a secure backup option for vaccine delivery. Louisiana's Immunization Program will provide guidance to ensure validated cold-chain procedures are in place in accordance with the manufacturer's instructions and CDC's guidelines.

Any organization who is approved to redistribute vaccine will meet the minimum training and supply requirements provided by the State and the CDC. They will also sign and agree to conditions in the CDC COVID-19 Vaccine Redistribution Agreement for the sending facility/organization and have a fully completed and signed CDC COVID-19 Vaccination Provider Profile form for each receiving location.

If the State needs to take a more active role in vaccine distribution, current Strategic National Stockpile (SNS) plans have been amended to allow Receipt, Store, and Stage (RSS) sites to centrally distribute COVID-19 vaccine. Centralized distribution through RSS sites could occur if the ability to ship directly to providers becomes unavailable and/or in later stages of COVID-19 vaccine roll out when large numbers of the general public need to be vaccinated. The primary RSS vendor has 4 transport hubs located within Louisiana that may be utilized to expedite distribution within the regions to those sites designated by the Immunization Program. RSS site's will have cold chain capacity, and a system is currently being set up to supply these sites with dry ice.

The Louisiana National Guard (LANG) can provide a Distribution Supervisor, tracking and monitoring of vehicles and shipments, and access to ten (10) trucks and ten (10) drivers with ten (10) additional ride-along attendants per shift. This staffing level is with the expectation that deliveries will

continue on a 24-hour basis using two 12-hour shifts for a total personnel requirement of twenty (20) drivers and twenty (20) attendants, but will be adjusted based on the quantity of COVID-19 vaccine Louisiana is allocated.

BCP has developed maps for each RSS site. As a benchmark for time and distance, the agency has identified all OPH Health Units located in each region. By mapping the time and distance beforehand, the state has been able to identify the estimated driving time and total estimated driving distance from the point of origin to the destination point from each designated RSS site. The Logistics section uses the 9 regional allocation models and Tour Solver software to calculate the distribution routes to designated dispensing sites in each region from three RSS sites to determine times, type, and number of vehicles needed to perform distribution of SNS assets.

In the supporting agency response, LANG is the primary support for RSS operations for receiving, packaging, picking, and distribution, if needed. As a back-up to LANG, the Louisiana Department of Transportation and Development (DOTD) along with ESF-7 (GOHSEP) can serve as a resource for trucks and drivers. Additional drivers and trucks may be requested through DOTD and GOHSEP, as described in the DOTD concept of operations. The SNS team has compiled a LDH list of vehicles and drivers that can be used during transport. The LDH Logistics Section has developed contingency contracts with three private businesses to provide four different types of vehicles with qualified drivers. These vehicles and drivers will be used to augment distribution efforts. The primary method of transporting SNS materials to the delivery sites will be ground transportation.

Louisiana will ensure adequate distribution assets (people, vehicles, and equipment) are available to move COVID-19 vaccine products throughout the SNS distribution system if needed. Louisiana has a cold chain policy that outlines procedures for cold chain management, which is being updated to account for all potential COVID-19 vaccine temperatures.

COVID-19 Vaccine POD Site Determination

COVID-19 vaccine administration sites will be locations where CDC enrolled COVID-19 providers, who have the storage and capacity to vaccinate, reach target populations for each phase of COVID-19 distribution. Target populations, and their location, for each phase of COVID-19 vaccination, have been determined by Louisiana's COVID-19 Prioritization and Allocation Workgroup, informed by ACIP recommendations.

All nine OPH regions already have POD sites secured (Total ~571). The formula used to determine the number of PODs needed is as follows:

(TP/ (HPI-S))/ PPH=# of POD's required

TP= Total Population HPI= Hours to provide Immunization S=Setup time PPH=Patients per hour Regions have used a detailed process to work with partners to determine appropriate POD sites, including developing a planning team, emergency notification system, population assessments, security measures, staffing needs, and training.

The Immunization Program will work closely with BCP to cross reference the list of COVID-19 Target Population sites with preexisting POD sites. Extensive preparation is already underway to ensure POD sites have the capacity to effectively vaccinate all target populations for COVID-19, as described in these plans.

All vaccination providers in the state who wish to provide COVID-19 vaccines will submit a CDC provider enrollment form (and Redistribution Form if needed) along with a Vaccine Capacity Questionnaire. LDH is currently developing information on target populations for each phase, what locations they can be vaccinated at, and the capacity of those locations to vaccinate. Louisiana will use this information to determine which POD sites will be approved to receive vaccine.

Closed POD Sites

Based on current assumptions, Closed Point of Dispensing Sites (PODs) will be the POD method of choice, at least initially, given the specific target populations in each Phase of COVID-19 vaccination. Closed POD sites will receive specific allotments of COVID-19 vaccine based on the number of members of each target population they can vaccinate.

To facilitate initial COVID-19 target populations, nine (9) planning regions for private and public hospitals, EMS, nursing homes, home health agencies, and coroners have been identified. These regions correspond with those used by LDH OPH. All hospitals and health care facilities are assigned to a Region and have participated in the development of regional POD planning in the past.

Hospitals and health care facilities have been asked to identify a point of contact, known as the Designated Regional Coordinator (DRC) as well as several people to serve as back-ups for the identified DRCs. These individuals will complete COVID-19 Provider Enrollment forms so they have the authority to request COVID-19 vaccine on behalf of their facilities. Nursing Homes, Home Health agencies, EMS and Mass Fatality DRCs are essential participants in regional response planning. The DRC networks will work with LDH and the State Health Officer (SHO) for authority, leadership, and guidance during COVID-19 vaccination.

Facilities participating in residential POD planning would include hospitals, nursing homes, military installations, universities, federally recognized Native American reservations, homeless shelters and prisons. These institutions or organizations can be thought of as individual small "communities" with defined populations and will be target populations in various phases of COVID-19 vaccination. Many residential facilities employ or contract health care services for routine vaccination; therefore, many of these facilities are a natural fit to be enrolled COVID-19 vaccination providers themselves. For facilities without vaccinating staff, vaccine administrators will be contracted to come in and vaccinate the population. Pharmacy chains are already being contracted federally to vaccinate long term care facilities. Louisiana has also contracted Mobile Vaccination teams that can vaccinate Closed PODs who don't have the ability to vaccinate.

During COVID-19, residential facilities could become a residential POD for their patients/residents/students, the facilities' employees, and the employees' families. They allow vaccination to occur in a familiar setting and limit the transportation to Open PODs. These POD sites already have extensive planning in place and will be provided with information and specific guidelines for the use of approved COVID-19 vaccines when available.

Following the determination to provide COVID-19 vaccinations by state and national health authorities, health care professionals in these PODs will be responsible for receiving, storing, and administering COVID-19 vaccines. The residential POD will provide health information, including copies of Vaccine Information Statements, to all individuals receiving COVID-19 Vaccination at their facility. Given many employees are working from home and the storage and handling requirements of COVID-19 vaccine, it is unlikely Non-Medical Closed PODs (large businesses, corporations, or entities that have a structural framework in place) will be used for COVID-19, at least initially.

All Closed PODs submit extensive, POD plans annually to BCP and OSHEP. These plans include everything needed to operate a successful POD, including staffing, POD Incident Command Systems, POD Layout and more. These plans, RSS plans and Louisiana's Cold Chain Policy are all being updated in accordance with COVID-19 vaccine assumptions.

Open POD Sites

Open Point of Dispensing (POD) sites are unlikely, at least initially, given the distribution assumptions of the COVID-19 vaccine, but remain an option for vaccinating the general public in Phase 4. At least one large Open POD site for COVID-19 vaccination has been identified in each of Louisiana's 9 regions to handle their region's population.

Open POD sites will require staffing that far exceeds the LDH OPH or local medical communities' abilities. Therefore, Louisiana OPH and OSHEP staff members have worked with local communities to coordinate and identify volunteers to staff PODs in their areas. These individuals will be supported by health care professionals, who would actually administer the COVID-19 vaccine, as described in the Staffing section of these plans.

The Open POD sites are local operations in a setting that is familiar and accessible to all members of the public to provide vaccines. Examples of Open POD sites include high schools, health units, auditoriums and civic centers, since hospitals will likely be busy caring for ill individuals. However, given the storage and handling requirements of COVID-19 vaccine, hospitals and other medical facilities may be the sites of Open Drive-Through PODs. BCP, OSHEP, and the Immunization Program all have ample guidance and planning templates for large scale Drive Through PODs. Louisiana is working to determine the interest/ability of medical facilities to operate these PODs and will make sure they have the resources to do so effectively.

Open POD sites require an onsite survey by LDH and supplemental security planning from the POD site. This planning documents required equipment and resources, procedures to acquire these resources, current contact lists for the site/facility, and MOAs signed by the site. Plans with the above noted documentation are accessible by the Regions, BCP, the SNS Coordinator, and the SNS Pharmacist.

Uniformity of Open PODs is extremely important. All PODs will follow state guidance for hours of operation, the information provided, and policies. Failure to enforce uniformity could lead to public disorder. Uniformity of PODs will also prevent the negative perception by the public of different levels of service. Consistency of operations allows for ease of personnel movement between different PODs if necessary.

LDH OPH, through the OPH Regions and local communities, have pre-established numerous possible POD sites and have signed MOAs with these sites that are renewed every four (4) years. Current contact information for Open POD sites can be found within their planning documentation and the BCP Allocation Spreadsheets. This information is updated at least once a year. Facility information is up-to-date with addresses and 24-hours-a-day/7days-a-week contact information. All personnel who are able to work at POD sites, and their current contact information, can be found in Region-specific Open POD folders. Personnel are identified and pre-assigned according to EED, region-specific 48-hour plans, operational position, and geographical location.

In the event that a POD is disabled or unprepared to provide vaccination in the jurisdiction during COVID-19 response, the POD Manager will notify Regional leadership and begin demobilizing the POD. A secondary POD within the jurisdiction, with the capacity to vaccinate, will be opened/utilized to accommodate those individuals in need. All POD facilities which have MOAs are listed on detailed spreadsheets kept by BCP. Every effort is being made to ensure all potential PODs are equipped for COVID-19 vaccine ahead of time.

POD Site Vaccine Administration Capacity

The Vaccine Administration capacity of POD sites will be crucial for COVID-19 vaccine roll out. BCP and OSHEP can already accurately estimate vaccine administration capacity of POD sites based on hypothetical planning scenarios provided previously. These include real-opt-computer modeling programs to validate POD throughput, previous real-world exercises AARs (H1N1) and previous vaccine POD exercises (i.e. Mass Vaccination Exercises [MVEs]). POD trainings and MVEs are conducted on a yearly basis. These trainings can be webinars, or face-to-face sessions, and are geared toward both state agencies and LAVA volunteers. Each of Louisiana's 9 regions are conducting an MVE in October or November of this year; with most electing to do a drive through POD exercise.

The CDC's COVID-19 Provider Enrollment Form and Redistribution Form include storage, handling and administration questions that will confirm providers at POD sites are equipped to vaccinate. The Immunization Program has also developed a supplemental questionnaire, surrounding vaccine administration capacity, that will be sent out with Provider Enrollment forms to verify every location that receives allocated vaccine will be able to effectively handle the product. CDC's forms and Louisiana's questionnaire will give a complete picture of storage capacity (including dry ice capacity), and the number of vaccinators at POD site. LDH has planned a Table Top Exercise to test out its COVID-19 vaccination plans, which will identify any unforeseen gaps in COVID-19 POD site's ability to vaccinate, in late October.

If PODs don't have the capacity to vaccinate, Louisiana can utilize Mobile Immunization Strike Teams to assist with vaccine distribution and administration, as needed. Mobile Immunization Strike Team contracts are being finalized with six corporations in Louisiana who have previously been contracted to execute COVID-19 testing. Collectively, they will be able to send mobile vaccination teams to every Parish in Louisiana. Regional health officers and Louisiana's Immunization Program will identify locations to send these teams, which could include Closed PODs without staff who can vaccinate, hard to reach locations in Louisiana, and more as needed. They will order COVID-19 vaccine through Louisiana and all have the capacity to store, transport and administer COVID-19 vaccine anywhere in the State.

Layout of COVID-19 Vaccination PODs

The layout of COVID-19 PODs is designed to facilitate accurate and rapid dispensing of vaccine. POD floor plan templates have been provided to POD sites, who developed their own layout plans with variation based on local circumstances. These layout plans are being updated to account for social distancing as a result of COVID-19, including Drive-Through POD plans.

There are five steps of the dispensing process that are detailed in each POD site's plan. First, there is a Greeting and Triage station where symptomatic individuals will be directed to a designated area to be evaluated. Upon evaluation, the individual will be referred to their health care provider or a designated treatment facility. Second, there is a Screening Station where Screening staff will assist individuals in completing forms and will review the paperwork for legibility and completeness. Screening staff will direct individuals needing specialized assistance to the appropriate location and will determine whether the patient meets the criteria for COVID-19 vaccination at the POD. Next, patients will be directed to the Vaccine Administration Site. Here vaccine administrators will administer COVID-19 vaccines, and document the administration in LINKS. Foot traffic in the area where vaccine is being administered will be kept to a minimum.

Vaccinated individuals will need to be observed for immediate adverse reactions in a nearby area (which may be a designated parking area if a drive through clinic). There will also be a designated emergency treatment area for any adverse events. Symptomatic individuals will be sent to this area to be evaluated. Upon evaluation, the individual will either be referred to their health care provider or a designated treatment facility. If needed, staff will call 911 for transport to a medical facility via ambulance. Depending on the size and status (Open vs. Closed) of the POD, a location for behavioral health counseling may be provided.

Entry and Exit points at the POD will be made large enough to account for the number POD patients and social distancing, utilizing multiple lanes and appropriate signage/barriers as needed. Drive-through PODs will be located close to major roads, highways, or freeways in order to prevent traffic jams. Entry and exit points will be large enough to allow multiple lanes of traffic, and multiple lanes for vaccinating, to ensure a high throughput and to prevent the overflow of traffic onto neighboring streets. Traffic control and security plans will also be executed to prevent traffic overflow, and to prevent road rage that could severely disrupt the process. The Immunization Program, BCP and OSHEP have numerous planning resources and checklists in place to ensure drive-through PODs can run smoothly.

Staffing of COVID-19 Vaccination PODs

It takes many people to run a POD; representing many professions, disciplines, agencies, and backgrounds (Nurses, MDs, Behavioral Health, EMS, etc.). POD staff will come from the POD site itself, public health and hospital staff members (regional), first responders and Louisiana Volunteers in Action (LAVA). The LAVA staff and system recruit, register, credential, train, and exercise people for public

health disaster response. Staff positions will be assigned at each step of the POD dispensing process and may be omitted or combined as determined by the size and status (Open vs. Closed) of the POD.

In Louisiana, the POD Manager has the ultimate responsibility for evaluating POD movement and adjusting the flow to increase throughput. The POD Manager is responsible for opening more express lanes and has the discretion to inform LDH and/or OPH leadership of the need to open more PODs. The POD Manager will be notified of any adverse reactions from vaccinations. There will also be a POD assistant manager to supplement this workload. The Facility Supervisor will provide facility access, ensure building maintenance and address housekeeping issues in the POD setting.

The POD Medical (Operations) Lead is responsible for management of the "clinic" operations, including screening and vaccination. This includes managing the Screening, Vaccinating, First Aid, Translator and Behavioral/Mental Health Staff.

The POD Non-Medical (Logistics) Lead is responsible for management of the "non-clinical" POD operations. This includes managing the Registration/Training/Break Room staff, Supply Supervisor, POD Runners and Facility Supervisor.

The POD Line Lead (and Line Staff) are responsible for management of the POD flow. Communications/IT Support Staff provide communication to and within the POD site. The POD Screening Staff, under the direction of the screening supervisor, are responsible for review of the screening form and direction to appropriate area for vaccination.

For COVID-19 vaccination PODs, there will be up to twenty-eight (28) vaccination staff available to be notified to work, depending on the size of the POD. Vaccination staff will work in pairs. They will review the screening form to determine which vaccine/dose to administer, sign the screening form, administer vaccine, give the client a vaccine information sheet and add COVID-19 vaccination information in LINKS. Vaccination Staff Assistants will draw vaccine, complete paperwork/vaccine documentation if needed and instruct the vaccinated individual about next steps (i.e. second dose of vaccine). The POD Vaccination Staff will all work under the POD Vaccination Supervisor.

The Supply Supervisor organizes, monitors, and controls the POD supplies, including the vaccines. POD Runners are responsible for supporting POD operations by delivering these supplies to POD functional areas as needed.

The First Aid Staff will attend to the needs of injured or ill persons at the POD. The First Aid Staff will evaluate whether persons reporting they are ill need evaluation at a medical facility. Trained Behavioral Health staff will provide immediate support to all persons at a POD who may be in emotional distress as observed, identified, or reported either by any Emergency Operations or Behavioral Health staff members. If more intense Behavioral Health support is necessary to stabilize responders, Behavioral Health staff will work with the IC to help maintain a safe environment and make appropriate recommendations for service referrals when indicated. Behavioral Health staff will work with the Emergency Command Operations to address specific recommendations that may be implemented to reduce incident-related behavioral health reactions in responders as applicable. Emergency care, or treatment, for minors allows licensed practitioners the ability to treat minors who are allowed to receive treatment without parental consent if such treatment is performed under emergency conditions and in good faith.

The POD Security Manager and staff are responsible for overall POD security, including POD Staff, vaccine security, crowd and traffic control.

LAVA volunteers will be assigned to various POD roles, based on their expertise, at the discretion of the POD manager and MCM Volunteer Coordinator. Upon arrival, the volunteer will check-in and present photo identification. The volunteer will have a photo taken, if applicable, by the Volunteer Coordinator and given a temporary badge. If the ability to create a photo badge is not available, the MCM Volunteer Coordinator will provide a generic badge with a unique identifying number assigned to the volunteer. Registration/Training/Break Room Staff are responsible for the registration of POD Staff/volunteers. They provide general POD Training and keep up the Break Room at the POD.

Each POD will have one or more translators to offer assistance to non-English speaking persons in the POD setting and work to assure smooth POD screening operations. Detailed job descriptions, qualifications and trainings for all the positions described above are available in each individual POD site planning, maintained in a database by BCP.

Security

Security is an integral piece of POD planning. As described in Louisiana's COVID-19 Storage and Handling Plans, all vaccine storage units at the Immunization Program and the Regional Offices are locked and monitored by security staff. During COVID-19 vaccination, security at these sites, and additional COVID-19 vaccine storage locations, will be supplemented as required based on local law enforcement expertise.

A security system for all COVID-19 vaccine storage units will have an alarm system in place to give a local and a remote warning if there are problems with the power or temperature. The alarm system will alert a guard, or call a certain phone number in case of a power failure or temperature problem. All clinic/program staff will be trained on how the system works, and how to reach someone responsible for the vaccines, if needed. A written emergency plan will also be posted, so staff know what to do if the power is out in the facility or there is a mechanical failure. Each site will also have a backup alarm system available.

If vaccine is sent to local community PODs (outside the Louisiana public health system), local authorities (OHSEP) are responsible for security of vaccine during transport between the regional offices and the local distribution sites, and during vaccine storage and distribution at the local distribution sites. They are also responsible for safety of the volunteers and patients. Local health units and PODs have memoranda of understanding with their local public safety departments to ensure adequate security for vaccine at the PODs, as detailed in the Local Point of Dispensing Site Plan's Security. Each local POD is required to have at least one armed security officer, with accessory security staff as appropriate. These could include, unarmed security personnel, exterior patrol, storage patrol, roaming patrol, outside security, inside security and traffic control.

Parish OHSEPs will coordinate with local law enforcement to provide protection and security for the COVID-19 vaccine from the RSS to health care facilities and/or POD sites, if needed. POD sites and staff may require crowd control and protection. The ESF2 lead, in coordination with LDH staff, has the responsibility for communications during asset transport. Every vehicle and mode of transportation used for delivery will have a LWIN radio/communications equipment and/or cell phone to communicate with

the Distribution Manager. Verification of effective communications prior to departure from the RSS facility will be performed by the RSS Communications Manager. Security escorts will be coordinated through the LSP SNS Security Officer, if needed.

All PODs have a security section in their plans, with Open PODs requiring a separate supplemental security plan and site surveys (that address safety and security) as a part of their approval process. Security plans are inclusive of procedures to identify, acquire, and maintain security measures at all PODs. They include site information, chain of command, staffing requirements, specific assignments, patrol zones, rules of engagement, administration information, and contingency planning.

GOSHEP Security Desk, State Police, Parish Police, Louisiana National Guard, and Marshals are also all involved in current COVID-19 vaccine planning and able to play a larger role if needed.
Appendix 9: Louisiana's Plan to Securely Order, Distribute, Receive, Store and Transport COVID-19 Vaccine

Louisiana's Plan to Securely Order, Distribute, Receive,

Store and Transport COVID-19 Vaccine

Louisiana's Vaccine Action Collaborative

Operations and Logistics Workgroup

October 2020

Introduction

The following document contains an updated multi-layered plan to order, distribute, receive, store, and transport Louisiana's allotment of COVID-19 vaccine. This plan reflects the current vaccine assumptions provided by the CDC and will be adjusted as more specific information about COVID-19 vaccine becomes available. There is planning that accounts for the possibility of an ultra-frozen (-70°C), frozen (-20°C), and refrigerated (2-8°C) vaccine product. For each section, primary and contingent planning is provided.

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Ordering COVID-19 Vaccine Products

COVID-19 vaccination providers enrolled by the state of Louisiana will order COVID-19 vaccine through LINKS. LINKS integrates with the CDC's Vaccine Tracking System (VTrckS) for provider direct order entry.

Depending on the available vaccine supply and Louisiana's allocation of vaccine product, the Louisiana Immunization Program will approve or deny providers vaccine orders. The Immunization Program will draw down vaccine and allocate following the guidance of the Incident Commander and the State Health Officer or their designees. Facilities ordering outside of Louisiana's allocation (i.e., commercial and federal entities with federal MOUs in place) will order directly from CDC, and CDC will be responsible for approval of those orders.

During Phase 1 of the vaccination program, when there is limited vaccine supply for critical populations, Louisiana will approve orders based on the likely populations served by a vaccination provider, the provider's capability to store and handle various COVID-19 vaccine products, and existing inventory. The Immunization Program has developed a Dose Allocation tool and comprehensive list of potential administration sites (using existing Point of Dispensing [POD] plans) to assist with these efforts. Given the minimum order size and increment for centrally distributed vaccines will be 100 doses per order, most Phase 1 providers will have at least 100 patients. Distribution to smaller facilities is described in the Distribution and Transport sections of these plans.

Ancillary supplies will be packaged in kits and will be automatically ordered in amounts to match vaccine orders in VTrckS. Each kit will contain supplies to administer 100 doses of vaccine. For COVID-19 vaccines that require reconstitution with diluent or mixing with adjuvant at the point of administration, mixing kits with syringes, needles, and other needed supplies will also be included automatically in provider's orders. Providers will be responsible for ordering second doses of vaccine, if COVID-19 vaccines require two doses. A reminder will be sent to providers through LINKS regarding the need to order second doses.

Contingency Plans

Louisiana is actively enrolling providers to vaccinate for COVID-19 and updating LINKS to accommodate COVID-19 vaccine. LINKS has undergone an extensive security assessment, as described in Louisiana's COVID-19 Security Plan. As part of an overall distribution and dispensing plan for Louisiana, communities already have plans in place to implement emergency dispensing sites (PODS) for residents in their community that overlap extensively with Louisiana's anticipated COVID-19 administration sites. The Louisiana SNS Program maintains a database of the PODs site locations, contact persons, and anticipated clinic throughput for each POD in every community, which the Immunization program will enroll as COVID-19 Providers, if applicable. The Immunization Program will work to ensure every resident of Louisiana has at least two potential locations/methods to receive a COVID-19 vaccine.

The Immunization program is developing new training modules for providers on COVID-19 Vaccine Ordering. The training will be found in LINKS and will describe all aspects of enrolling as a COVID-19 provider and ordering vaccines. If providers cannot effectively enroll and order vaccine, they will be able to contact the Louisiana Immunization Program with any questions. FAQs are also being developed to assist with troubleshooting. LINKS built-in Pandemic Module can be used if any setbacks or unforeseen challenges arise with COVID-19 specific modules.

Since it is anticipated that some people will not come in for a second dose, the Louisiana Immunization program will provide guidance to vaccine providers about the quantity of second dose to request and/or when allocated second doses should be transitioned to first doses when this information is available.

Some ultra-cold (-60°C to -80°C) vaccine (if authorized for use or approved) may be shipped directly from the manufacturer in larger quantities (1,000 doses). If larger orders are required, the Immunization program's dose allocation tool can be adjusted to accommodate larger POD sites. Large hospital systems with the capacity to store and administer this high quantity of doses would be utilized. Hospital capacity in the state is currently being surveyed and various allocation models are being constructed to account for different potential quantities of allocated doses and order sizes.

As of now, ancillary supply kits will not include sharps containers, gloves, and bandages. Vaccine providers will need to order these materials separately, which the State will assist with. Because of cold chain requirements, ancillary supply kits (and diluent, if applicable) will ship separately from vaccine but should arrive before or on the same day as vaccine. If possible, regional locations throughout the state will have additional ancillary supplies for vaccine providers, in case the kits do not arrive at the same time as the vaccine or are missing materials. Each entity administering vaccine will request these supplies through normal EOC/LDH channels in the COVID response protocol. If needed materials are not available, providers must notify the Immunization Program.

If there are multiple COVID-19 vaccine products available at the same time, the Immunization Program will ensure LINKS and VTrckS only allow the ordering (and administration) of the same vaccine product for a patient's second dose.

The COVID-19 Vaccine Action Committee will determine if there needs to be a small proportion of vaccine held for administration to essential State personnel, based on the Priority Group List. In respect with the tier system established, the State Health Officer, in coordination with the State Epidemiologist and the Immunization Program, may make allocation adjustments to this scheme based on areas of differential impact, higher proportion of target group individuals, and vaccine availability.

If there are any major problems with the COVID-19 vaccine ordering system, the Immunization Program will temporarily coordinate all COVID-19 vaccine ordering for POD sites while the ordering system is fixed. The Immunization Program has a detailed list of all providers and can coordinate the ordering internally if needed.

Distributing COVID-19 Vaccine Products

COVID-19 vaccines and ancillary supplies will be procured and distributed by the federal government at no cost to enrolled COVID-19 vaccination providers in Louisiana. Some vaccine products, such as those with ultra-cold temperature requirements, will be shipped directly from the manufacturer to the vaccination provider site. Louisiana is ensuring accurate and complete shipping information for all POD sites is available in VTrckS. The vast majority of these providers are already designated as Points of Dispensing (PODs) by BCP and OSHEP, which means this information has already been collected. BCP

allocation models include latitude, longitude, staff population, resident population, and POD planning information for each site. The models will be used to help determine how many vaccines to distribute to providers at each POD. Based on current assumptions, either McKesson or the manufacturer will distribute the determined amount of vaccine directly to the provider, by shipping them through FedEx or UPS.

COVID-19 vaccine (and diluent or adjuvant, if required) will be shipped to vaccination provider sites enrolled by the State's immunization program within 48 hours of order approval. McKesson, or the manufacturer if shipped directly, will be responsible for maintaining COVID-19 vaccine cold chain and minimizing the likelihood of vaccine loss or damage during shipment.

Whenever possible, vaccine will be shipped to the location where it will be administered to minimize potential breaks in the cold chain. There may be scenarios where vaccine will be shipped to a central depot (like RSS sites or a large POD) and be redistributed to smaller PODS. Since the federal government does not redistribute product, this will be the responsibility of the state. In these instances, vaccination provider organizations/facilities, third-party vendors, and other vaccination providers would be approved by Louisiana's immunization program to redistribute COVID-19 vaccine. The Immunization program will also distribute and/or coordinate the distribution of vaccine products internally if needed, as described in Louisiana's Comprehensive Point of Dispensing Plan for COVID-19 Vaccine. The Immunization Program has also coordinated pricing with FedEx Custom Critical, as a secure backup option for vaccine delivery. Louisiana's Immunization program will provide guidance to ensure validated cold-chain procedures are in place in accordance with the manufacturer's instructions and CDC's guidelines.

Any organization, including RSS sites, who are approved to redistribute vaccine will meet the minimum training and supply requirements provided by the State and the CDC. They will also sign and agree to conditions in the CDC COVID-19 Vaccine Redistribution Agreement for the sending facility/organization and have a fully completed and signed CDC COVID-19 Vaccination Provider Profile form for each receiving location. Based on current assumptions, Louisiana will only redistribute refrigerated COVID-19 vaccine.

Contingency Plans

If the vaccine cold chain becomes too challenging to maintain through redistribution, larger administration sites will be temporarily prioritized. Providers who have increased amounts of vaccine waste will be discontinued and/or have vaccine product redistributed.

If the system and distribution process becomes significantly delayed/more than 48 hours, the Louisiana Immunization Program will encourage providers to order vaccines earlier so they have enough time to make scheduled vaccination dates. If providers are ordering too much product and encountering a lot of waste, the immunization program will help edit their order size to meet demand. The Immunization program will also scale up or scale down provider orders, within their vaccine capacity, to ensure appropriate quantities of target populations are being vaccinated in each phase.

If a shipping address is wrong, the POD site will be contacted to obtain a correct shipping address. If a correct address is not able to be obtained, vaccine will be redistributed to the next closest POD site, or a central distributor, with the capacity to store and administer additional vaccine. The same procedure is applicable if directions to the POD site are wrong and/or the route is not available through traditional mapping programs (i.e. rural locations). All POD addresses, and directions to these addresses, are currently being verified/cross referenced with existing POD site plans.

While the State is only able to redistribute refrigerated vaccines, the frozen and ultra-frozen products (based on current assumptions) can kept thawed for 5-7 days. If possible, these frozen products will be redistributed refrigerated to smaller administration sites.

If there are problems with vaccine distribution with McKesson and/or FedEx and UPS, the Immunization Program will assist them in solving the problem to the best of their ability. Depending on demand, certain security measures may be needed throughout the COVID-19 vaccine distribution process. These are presented in the COVID-19 Vaccine Security Considerations section of these plans, as well as Louisiana's COVID-19 Vaccine Security Plan and Comprehensive Point of Dispensing Plan for COVID-19 Vaccine.

Receiving COVID-19 Vaccine Products

Louisiana and vaccination providers are responsible for maintaining vaccine quality as soon as a vaccine shipment arrives at a vaccination provider site. Depending on the product, the provider will receive the vaccine directly from the manufacturer or from a central distributer. Either way, receipt of the product will be largely the same.

Each provider, will have a designated staff member to receive, unpack, analyze and store COVID-19 shipments. This person will have undergone specific COVID-19 vaccine storage and handling training, provided by the CDC.

The designated staff person will notify the manufacturer of all the times their facility is able to receive vaccine, through the provider enrollment form. They will sign and receive the vaccine shipment from FedEx/UPS upon arrival. Then, in accordance with the manufacturer's guidelines, the designated staff person will make sure the shipment is correct. They will ensure the quantity of product matches the amount ordered and will check the product for any deficiencies or signs of temperature excursions. The designated staff person will then update their vaccine inventory within LINKS.

If the shipment container is to be utilized as the storage container (ultra-frozen and possibly frozen products), the designated staff member will repack the product in the shipping container. They will replenish dry ice as needed; moving the shipping container to the designated secure vaccine storage space. If the product is to be stored within a refrigerator or freezer in the facility, the designated staff member will transfer the product to store in these locations.

Ancillary supply kits, and possibly diluents, will be shipped/received separately. The same designated staff member will inventory these supplies and check for any potential problems.

Contingency Plans

In case the designated staff member is not on location to receive the product, backup staff members who have undergone the same training, will be available to unpack and store the product. Facilities will ensure at least one qualified staff member is on site during all operating hours in case a COVID-19 vaccine shipment arrives.

If the vaccine shipment is not correct, any potential issues found will be reported to the Immunization Program and the product will be stored according to the manufacturer guidelines. The Immunization Program will help determine whether the issue was with McKesson or FedEx/UPS and notify them of the problem. The vaccine will be marked "DO NOT USE" until guidance is provided. If the shipment container itself is damaged but the product appears ok, the facility will contact the manufacturer (if shipped directly) or McKesson (if shipped from a central distributer) for guidance before using the shipping container to store vaccine. Sites will be provided with specific criteria for when vaccine product, and the shipping container, should not be used when this information is available.

If, upon receipt of the product, the facility does not have sufficient or effective storage capacity and the shipment container cannot be used for storage, the site must contact the Immunization Program for possible redistribution. Any additional problems that arise with vaccine, or ancillary supply receipt will be reported to the manufacturer or Immunization program as the facility deems appropriate. The Immunization Program will ensure facilities are able to effectively receive and store vaccine before being approved.

Storing COVID-19 Vaccine Products

Vaccine products will be stored differently depending on their temperature. The following vaccine storage plan is based on current assumptions and will be adjusted to fit the storage criteria described in CDC's updated Storage and Handling Toolkit when available.

Ultra-frozen vaccine products will be stored in their original shipping containers. The containers will be replenished with dry ice within 24 hours and again five days later (to be used within 10 days of shipment arrival). Louisiana has identified seven dry ice manufacturers in the state and will help coordinate dry ice purchasing and distribution to POD sites/providers, if needed. Some facilities, like hospitals already purchase and/or produce dry ice. The Immunization Program is currently surveying all POD sites about their dry ice capacity and BCP is doing the same for RSS sites. Shipping containers will be stored in a secure temperature controlled room. (At room temperature; room can't be too hot.) Diluent and ancillary supply kits will also be securely stored at room temperature, ideally in the same location as the shipping containers.

Frozen vaccine products will also be stored in their original shipping container, replenished with dry ice within 24 hours and then again every five days. These products must be used within 14 days. Both frozen and ultra-frozen vaccine products will be kept in their shipping containers until the day they are to be administered. On that day, vaccine will be stored and prepared in a secure location near, but not at, the vaccine administration site. Any unused vaccine after six (6) hours at room temperature will be discarded.

Refrigerated vaccine products will be stored in on-site refrigerators in accordance with CDC guidelines. Ultra-frozen vaccine products and frozen vaccine products, assumed to last five days and 14 days refrigerated respectively, may also be stored in refrigerators. Refrigeration of these frozen products will be used for products redistributed to smaller providers who can't access dry ice.

Facilities are responsible for ensuring they have the capacity to effectively store all COVID-19 vaccine they are ordering in accordance with CDC guidelines. Louisiana will not approve POD sites that don't meet the appropriate requirements to store or administer vaccine. This includes having appropriate

space, designated staff and equipment. POD sites will provide this information to Louisiana in their POD plans and CDC Provider Enrollment Forms. All potential COVID-19 vaccine administration sites are also currently being surveyed to determine their capacity to administer vaccines. The Louisiana Immunization Program will ensure the COVID-19 vaccine is accessible to every resident of Louisiana. Therefore, the Immunization Program will assist rural/undersupplied providers in meeting the appropriate requirements to store or administer vaccine to ensure the State is covered.

All staff members involved in vaccination must complete all COVID-19 vaccine storage and handling training when it becomes available, which will be verified by the Immunization Program. Louisiana's immunization program will assist POD sites with any identified storage shortcomings or storage problems that arise throughout COVID-19 vaccination activities. The state health department will regularly visit POD sites to ensure appropriate storage and handling procedures are being upheld.

Contingency Plans

Should additional storage be necessary, emergency storage containers would be used as well as refrigerated tractor-trailer truck obtained to store additional vaccine. The addition of one refrigerated trailer at the Immunization Program would provide adequate storage capacity for the New Orleans (Region 1), Baton Rouge (Region 2), Thibodeaux (Region 3), Region 4 (Lafayette) and Mandeville (Region 9) Public Health Regions. Shreveport (Region 7) probably has enough capacity to temporarily store vaccine for Lake Charles (Region 5), Alexandria (Region 6), and Monroe (Region 8). RSS sites are also currently being equipped to handle COVID-19 vaccine product cold chain and can be used if needed.

If there is a problem with ultra-frozen and frozen vaccine shipping containers, these products will be stored in refrigerators. Facilities will store vaccine in accordance with CDC guidelines and expedite/reschedule vaccination activities to use vaccine in the new refrigerated timeline. Undamaged shipping containers from previous vaccine shipments, replenished with dry ice, may also be used if available/approved by CDC.

If there is any problem with dry ice acquisition for ultra-frozen or frozen vaccine shipping containers, refrigeration will be utilized, if possible. The Immunization Program will assist sites with acquiring dry ice and emergency transport measures if refrigeration is unavailable.

It is possible that multiple COVID-19 vaccine products could be made available at once, and that facilities could be storing (and administering) two different products. If this is the case, products will be clearly marked and differentiated (if they have the same storage requirements). If products have different storage requirements, two appropriate storage locations will be used.

In case there is any problem with the room temperature where vaccine shipping containers and supplies are stored, a back-up room will have been pre-identified and available for immediate use. If there is any problem with the refrigerator vaccines are stored in, sites will utilize emergency transport coolers, or original shipping containers, if possible, to transport vaccines to the nearest POD site or location with available vaccine storage.

Facilities will all be equipped to transport vaccine in the event of emergency weather or power outage. The need for emergency redistribution will be reported to the state immunization program who will assist sites in determining where to transport vaccine and ensuring they have the supplies to do so effectively. Large POD sites will have a backup generator.

If vaccine being stored has expired and/or has otherwise been deemed unusable (for example temperature excursions) it will be discarded and documented in LINKS. If vaccine is going to expire soon, providers will contact the Immunization Program if they believe they will not utilize all of their supply before the expiration date. The Immunization program will instruct them to either adjust the schedule of their vaccination activities or transport vaccine to another location to ensure as much vaccine is administered as possible. Any additional storage issues that come up during COVID-19 vaccine activities will be reported by the facility to the manufacturer or Immunization program as appropriate.

Inventory Management of COVID-19 Vaccine Products

COVID-19 vaccination providers will report inventory of COVID-19 vaccines, and Louisiana's Immunization program will ensure this inventory information is submitted with each order. Vaccine orders will not be approved by the Immunization Program without this inventory information.

A detailed inventory will be kept at every facility storing COVID-19 vaccine. This inventory will be updated regularly as vaccines come in and out. The inventory, along with any and all relevant COVID-19 vaccine storage training materials, will be easily accessible to all designated staff members working in the facility in both paper and electronic copies.

Since anticipated COVID-19 vaccines will initially be authorized under an EUA, they will contain slight variations from approved Food and Drug Administration (FDA) products. The most distinct variation being that vaccines will not have expiration dates on them. Current expiration dates by vaccine lots for all authorized COVID-19 vaccines will be posted on a US Department of Health and Human Services (HHS) website, accessible to all COVID-19 vaccination providers in Louisiana through a barcode scanner. All facilities will have the ability to scan and/or manually enter these codes to get the current expiration dates. The designated staff member who receives vaccines should determine the current expiration date of the product upon arrival and mark the product with that date using a temporary card. The expiration date will be verified daily and any changes to the expiration date will be updated.

Each vaccine will also have a QR code that allows vaccine providers to access FDA-authorized, vaccine product-specific EUA fact sheets for COVID-19. Vaccine providers will print out these facts sheets and distribute them to every person who receives the vaccine.

Contingency Plans

All discrepancies in the inventory record of vaccine and the actual quantity of vaccine will be immediately investigated and reported to the Immunization Program if major or prolonged issues arise. If sufficient product is lost or unaccounted for, additional security measures will be taken and/or the provider will no longer be able to order COVID-19 vaccines.

The Immunization Program will update all COVID-19 vaccination PODS with any major changes to vaccine inventory management or expiration dates. The Immunization Program will ensure facilities have access to, and utilize, all relevant COVID-19 inventory management trainings.

If vaccine providers have any other problems scanning a barcode or interpreting COVID-19 vaccine information, they will reach out to the manufacturer or Immunization Program as appropriate. Facilities will be expressly required to report all aspects of their inventory, including temperature excursions, regularly to the State Immunization Program.

Transporting COVID-19 Vaccine Products to Satellite, Temporary, and Off-Site Clinics

COVID-19 vaccine products are temperature-sensitive so they must be stored and handled correctly throughout transport to ensure efficacy and maximize shelf life. Satellite, temporary, or off-site clinics in collaboration with community or mobile vaccinators may be used in Louisiana to provide equitable access to COVID-19 vaccines.

The quantity of COVID-19 vaccine transported to a satellite, temporary, or off-site COVID-19 vaccination clinic will be based on the anticipated number of COVID-19 vaccine recipients and the ability of the vaccination provider to store, handle, and transport the vaccine appropriately. This information is being determined in advance of COVID-19 vaccination activities to ensure a smooth roll out. Louisiana already has a detailed information on Closed POD sites capacity, which is being updated for COVID-19.

COVID-19 vaccines will be transported, not shipped, to a satellite, temporary, or off-site COVID-19 vaccination clinic using vaccine transportation procedures outlined in the upcoming COVID-19 addendum to CDC's Vaccine Storage and Handling Toolkit. Ancillary supply kits will be transported with their corresponding vaccines to avoid any separation of the two.

Upon arrival at the COVID-19 vaccination clinic site, vaccines will immediately be stored correctly by the designated staff member at the mobile clinic site to maintain appropriate temperature throughout the clinic day. The sites will collect and review temperature data throughout the day in accordance with CDC's Vaccine Storage and Handling Toolkit. At the end of the clinic day, only vaccines that have stayed in temperature range will be transported back to the primary facility. The vaccines that were exposed to out-of-range temperatures will be labeled "DO NOT USE" and stored at the required temperature until further information on usability can be gathered or further instruction on disposition or recovery is received.

Sites will review CDC's revised *Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations,* as well as *Vaccination Guidance During a Pandemic.* They will complete a "Vaccinating at Satellite, Temporary, and Off-Site Locations" checklist for every mobile clinic conducted to ensure vaccine administration is not compromised.

As with distribution, any organization who is approved to transport vaccine must meet the minimum training and supply requirements set by the CDC and State. They must also sign and agree to conditions in the CDC COVID-19 Vaccine Redistribution Agreement for the sending facility/organization and have a fully completed and signed CDC COVID-19 Vaccination Provider Profile form for each receiving location. Based on current assumptions, only refrigerated vaccine can be transported.

Contingency Plans

OPH could call upon ESF 1: Transportation, the Louisiana Department of Transportation and Development, the Louisiana National Guard, or the Louisiana State Police to provide transportation of vaccines to supplement the Immunization Program contracted courier services, if needed. OPH could also use existing SNS transportation plans for COVID-19 vaccine transport.

If the satellite/off clinic site is operated by an organization with a larger facility/adequate storage, that organization will be responsible for effectively transporting the vaccine. If the satellite/offsite clinic is a stand-alone location, Louisiana's Immunization Program, in coordination with GOSHEP and BCP, will be responsible for effectively transporting the vaccine. Vaccine will be transported in contracted government vehicles, ambulances and/or pick up by the satellite location will be coordinated at a central facility.

If the vaccine administration capacity of a site is unknown, the site will be contacted to obtain that information. Only approved sites with the appropriate temporary storage/administration capacity will receive transported COVID-19 vaccine. If vaccine arrives to a satellite location and proper storage capacity or supplies are not available, the vaccine will be transported back to the original site. Every effort is being taken to ensure this capacity is met prior to vaccine order/transport, and redistribution will not be approved unless capacity is evident.

If there is a problem during the transportation process, it is the responsibility of the transporting party to ensure the vaccine supply effectively reaches its intended destination. Extra vehicles, transport coolers, dry ice and other necessary supplies will be available in the event a transport vehicle breaks down/supplies are lost. These emergency protocols are described in more detail in the CDC COVID-19 Vaccine Redistribution Agreement.

COVID-19 Vaccine Security Considerations

Security is extremely important for every step of the vaccination process, from ordering to administration. Depending on the vaccine product used and the demand for the vaccine product, different security procedures will be implemented. The State SNS Plan lists in detail the processes and mechanisms for maintaining positive control of emergency assets in Louisiana, including vaccines. Security during vaccine storage, transport and distribution will be coordinated with GOHSEP's EOC, if OPH is unable to provide adequate security for COVID-19 vaccine.

For ordering, LINKS has undergone an extensive security assessment, described in Louisiana's COVID-19 Vaccine Security Plan, to ensure it has the capacity to securely document all vaccinations. Only designated and approved providers will be able to log into the system and order vaccine. Those orders must also be approved by the Immunization Program.

Distribution security will be the responsibility of the vaccine manufacturer and McKesson. For redistribution efforts, the state will use unmarked vehicles, ambulances or contracted GOSHEP vehicles. When the vaccine arrives at the administration location, it must be signed for by a designated staff member.

Upon arrival, the vaccine will be unpacked and analyzed for deficiencies in a secure area. It must then be secured in a locked storage area; only to be accessible by trained designated staff. Sign in sheets will be utilized any time the storage room is accessed. Vaccine will stay in these secured storage areas unless the inventory/temperature is being checked or the product is ready to be administered.

Currently, all vaccine storage units at the Immunization Program and the Regional Offices are locked. The central units at the Immunization Program are monitored 24 hours per day, 7 days per week. There is 24/7 Security at the Immunization Program. Security is 7 a.m.-6 p.m. at the Regional

Offices. Currently, security of vaccine at each Parish Health Unit is ensured through the locking of each refrigerator each night. This will be bolstered during a pandemic to secure vaccine at all Regional sites. Temperature logs are kept for documentation and assurance that the vaccine cold-chain is maintained. RSS sites are unknown to the public and also have security. During COVID-19 vaccination, security at these sites, and additional COVID-19 vaccine storage locations, will be supplemented as required based on BCP, GOSHEP and local law enforcement expertise.

Local health units and PODs have memoranda of understanding with their local public safety departments to ensure adequate security for vaccine at the PODs, as detailed in the Local Point of Dispensing Site Plan's Security section. Each local POD is required to have at least one armed security officer, with accessory security staff as appropriate. At the administration site, the vaccine will be kept in a secure area close by and under the watch of a staff member/security guard. Facilities will pick locations to store vaccine that are not readily accessible to the general public.

Contingency Plans

For local crowd control, local law enforcement will be responsible for traffic flow, maintaining perimeter control of the vaccination location, for immunization staff, and protecting vaccine assets. Additional security procedures can be introduced by the POD site as they see fit, or at the discretion of the Immunization Program and GOSHEP at any time. Potential increased security measures include, but are not limited to, police escort of vaccine during distribution/transport, security guard for POD site vaccine storage area, and additional police presence at administration sites. The state has the capacity to implement these increased security measures if needed and will monitor demand of the vaccine product and safety of administrators throughout vaccination activities. If there is ever a breach in security or providers have individual safety concerns, they will contact the Immunization Program for next steps. GOSHEP Security Desk, State Police, Parish Police, Louisiana National Guard, and Marshals are also all involved in current COVID-19 vaccine planning and able to play a larger role if needed. Additional security information can be found in Louisiana's COVID-19 Vaccine Security Plan.

Appendix 10: Louisiana's COVID-19 Vaccine Security Plan

Louisiana's COVID-19 Vaccine Security Plan

Louisiana's Vaccine Action Collaborative

Operations and Logistics Workgroup

October 2020

Introduction

The following document summarizes COVID-19 security measures mentioned in other Louisiana COVID-19 planning documentation, and elaborates on these measures with more operationalized details. This plan reflects the current vaccine assumptions provided by the CDC and will be adjusted as more specific information about COVID-19 vaccine becomes available. Extensive contingency planning is provided.

Ordering COVID-19 Vaccine

COVID-19 vaccination providers enrolled by the state of Louisiana will order COVID-19 vaccine through LINKS. LINKS integrates with the CDC's Vaccine Tracking System (VTrckS) for provider direct order entry. Only designated and approved providers, that have filled out CDC's COVID-19 Provider Enrollment Form, will be able to request COVID-19 vaccine. The program has a password protected log in, and their orders must be approved by the Immunization Program.

The security of vaccine ordering is of utmost importance to the Louisiana Immunization program. Louisiana's IIS system, LINKS, has several layers of administrative, technical, and physical safeguards to ensure the integrity and confidentiality of health information that is transmitted to and from the system.

State law defines all information in LINKS as confidential. LINKS was developed under the authority of Louisiana Revised Statutes 40:31.11-16. Patient or provider specific information in LINKS is only available to the authorized users, including clinic/office managers, nurses, physicians, medical assistants, and medical clerks. Patient or provider information is only available to participating immunization providers, the Louisiana Department of Health, schools and licensed daycare providers.

STChealth is the vendor that has run LINKS since its inception. The Security Protocols that STChealth adheres to, current process for assessing risk, and current plans for addressing known vulnerabilities are outlined below. They completed an additional security assessment of LINKS in July 2020 at the request of the Immunization Program.

STC has established cybersecurity requirements set forth by the National Institute of Standards and Technology (NIST) 800-53, for "moderate" controls. STC uses an inherited controls methodology to document the security of the system and surrounding infrastructure under STC enterprise's Common Controls Security Plan (CCSP). It addresses the selection and implementation of the security controls that are common to all information systems operated by STC. LINKS has several layers of security to protect information that is transmitted to and from the system and State law defines all information in LINKS as confidential.

The LINKS application is scanned during every release cycle using Veracode Static Analysis. The Veracode software scans the LINKS code by comparing the updated codebase against all known patterns and their associated vulnerability potential from a global database.

This scan provides a complete view of any and all issues in the application, rating them from high risk to low risk. Vulnerabilities discovered using blackbox or penetration testing only represent a subsegment of the issues that are able to be identified by this static scanning, due to the inclusion of

mitigation efforts outside of the application to protect attack vectors in the codebase. The scan will identify any problem in upstream layers or infrastructure.

STChealth attacked every vulnerability found that was identified as "High Risk" in August 2020. They use the common strategy and development approach of "Net Negative Delta". Specifically, they continue to regularly include security vulnerability tickets to ensure an ongoing decrease in vulnerabilities. While they prioritize vulnerabilities by category to eliminate the highest risk vectors first, they are continually mitigating all vulnerabilities that are found.

In addition to the Veracode Static analysis, LINKS has numerous other security measures in place to protect Louisiana's immunization data. These include SOC2 certification, addition of Web application firewalls, penetration testing, and additional static scanning built into LINKS CI/CD process.

STChealth is working to modernize its Legacy Code as quickly as the feature functions can be converted to new architectures and designs. Their long-term product development has always adhered to strict security guidelines, and Louisiana has never had a security problem with LINKS. STChealth will continue to provide quarterly security updates to the Immunization Program. They will perform an additional Security Assessment prior to COVID-19 vaccine rollout, to ensure issues found in July have all been effectively mitigated.

Transporting COVID-19 Vaccine

Given the direct to provider shipment method, distribution security will be the responsibility of the vaccine manufacturer, McKesson, FedEx and/or USPS. OPH could also call upon ESF 1: Transportation, the Louisiana Department of Transportation and Development, the Louisiana National Guard, or the Louisiana State Police to provide transportation of vaccines to supplement the Immunization Program contracted courier services, if needed. For redistribution efforts, the state will use unmarked vehicles or ambulances. If vaccine is sent to local community PODs (outside the Louisiana public health system), local authorities (OHSEP) are responsible for security for vaccine during transport between the regional offices and the local distribution sites.

The State Strategic National Stockpile (SNS) Plan lists, in detail, the processes and mechanisms for maintaining positive control of emergency assets in Louisiana, including vaccines. Current SNS plans have been amended to allow Receipt, Store, and Stage (RSS) sites to centrally distribute COVID-19 vaccine if any problems arise with the direct to provider shipment method. If this is the case, security during vaccine storage, transport and distribution will be coordinated with GOHSEP's EOC.

The primary RSS vendor has four transport hubs located within Louisiana that may be utilized to expedite distribution within the regions to those sites designated by the Immunization Program. The Louisiana National Guard (LANG) can provide a Distribution Supervisor, tracking and monitoring of vehicles and shipments, and access to ten (10) trucks and ten (10) drivers with ten (10) additional ridealong attendants per shift. This staffing level is with the expectation that deliveries will continue on a 24hour basis using two 12-hour shifts for a total personnel requirement of twenty (20) drivers and twenty (20) attendants, but will be adjusted based on the quantity of COVID-19 vaccine Louisiana is allocated. LANG will be the primary support for RSS operations for receiving, packaging, picking, and distribution, if operationalized. As a back-up to LANG, the Louisiana Department of Transportation and Development (DOTD) along with ESF-7 (GOHSEP) can serve as a resource for trucks and drivers. The ESF2 lead, in coordination with LDH staff, has the responsibility for communications during asset transport. Every vehicle and mode of transportation used for delivery will have a LWIN radio/communications equipment and/or cell phone to communicate with the Distribution Manager. Verification of effective communications prior to departure from the RSS facility will be performed by the RSS Communications Manager. Security escorts, by police or marshals, will be coordinated through the LSP SNS Security Officer if needed.

The Immunization program will plan to use elements of SNS transport planning, even if RSS sites are not used, to ensure all COVID-19 vaccine is transported safely. The Immunization program will initially rely on standard vaccine shipment security measures, but will follow the guidance of the CDC and GOSHEP for any additional transport security measures needed, such as LANG or police escort of shipments. GOSHEP Security Desk, State Police, Parish Police, Louisiana National Guard, and Marshals are all involved in current COVID-19 vaccine planning and able to play a larger role in COVID-19 transport if needed.

COVID-19 POD Sites

When the vaccine arrives at the administration location, it must be signed for by a designated staff member. Upon arrival, the vaccine will be unpacked and analyzed for deficiencies in a secure area. It must then be secured in a locked storage area; only to be accessible by trained designated staff. Sign in sheets will be utilized any time the storage room is accessed. Vaccine will stay in these secured storage areas unless the inventory/temperature is being checked or the product is ready to be administered. At the administration site, the vaccine will be kept in a secure area close by and under the watch of a staff member. POD sites will pick locations to store vaccine that are not readily accessible to the general public.

A security system for all COVID-19 vaccine storage units will have an alarm system in place to give a local and a remote warning if there are problems with the power or temperature. The alarm system will alert a guard, or call a certain phone number in case of a power failure or temperature problem. All clinic and program staff will be trained on how the system works, and how to reach someone responsible for the vaccines, if needed. A written emergency plan will also be posted, so staff know what to do if the power is out in the facility or there is a mechanical failure. Each site will also have a backup alarm system available.

All PODs have a security section in their plans, with Open PODs requiring a separate supplemental security plan and site survey (that addresses safety and security) as a part of their approval process. Security plans are inclusive of procedures to identify, acquire, and maintain security measures at all PODS. They include site information, chain of command, staffing requirements, specific assignments, patrol zones, rules of engagement, administration information and contingency planning. The plan also includes a designated POD Security Manager and staff in their planning who are responsible for overall POD security, including POD Staff, vaccine security, crowd and traffic control.

Local health units and PODs have memoranda of understanding with their local public safety departments to ensure adequate security for vaccine at the PODs. Each local POD is required to have at least one armed security officer, with accessory security staff as the POD site deems appropriate. These could include, unarmed security personnel, exterior patrol, storage patrol, roaming patrol, outside security, inside security and traffic control.

For local crowd control, local law enforcement will be responsible for traffic flow, maintaining perimeter control of the vaccination location, for immunization staff, and protecting vaccine assets. Additional security procedures can be introduced by the POD site/provider at the recommendation of GOSHEP and BCP, or at the discretion of the Immunization Program. Potential increased security measures include, but are not limited to, a security guard for the vaccine storage area, and additional police presence at administration sites.

Traffic control and security plans will also be executed to prevent traffic overflow, and to prevent road rage that could severely disrupt the vaccination process. POD sites and staff may require crowd control and protection. GOSHEP and BCP will ensure every location receiving and administering COVID-19 vaccine is secure.