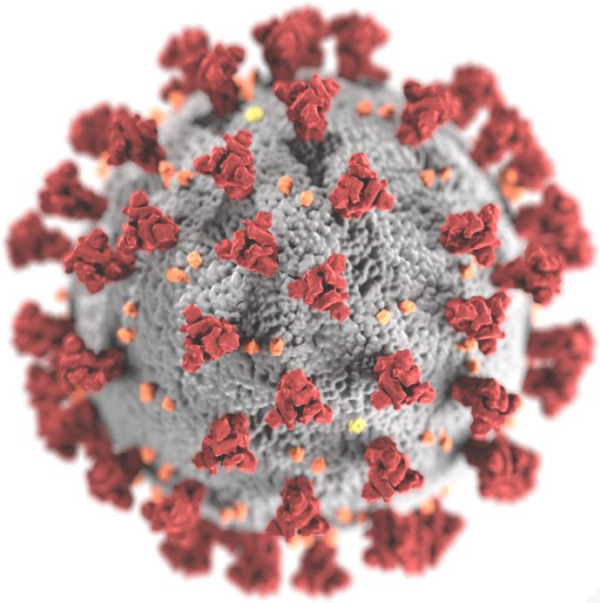

COVID-19 Vaccination Plan

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Georgia Department of Public Health
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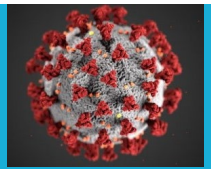
GEORGIA INTERIM COVID-19 VACCINATION PLAN



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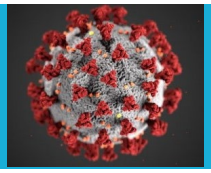

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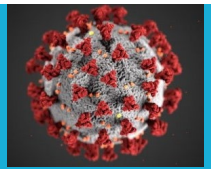

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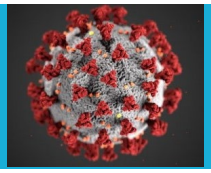

Record of Changes

Date of original version: October 2, 2020

Date Reviewed	Change Number	Date of Change	Description of Change	Name of Author
10/15/2020	1	10/16/2020	Transferred to CDC Template	S. Lovett
11/6/2020	2	11/05/2020	Added verbiage for Critical Populations	N. Dixon
11/6/2020	3	11/05/2020	Added verbiage for Vaccine Storage; Added verbiage for pharmacy enrollment	T. Dabbs
11/6/2020	4	11/06/2020	Added verbiage for LTCF enrollment; Added Appendix F	S. Lovett
11/6/2020	5	11/06/2020	Updates to Section 12 per CDC recommendations	E. Jens A. Tavarez
12/7/2020	6	12/7/2020	Rearranged and formatted Section 2 for better flow	S. Thomas
12/7/2020	7	12/7/2020	Added IMT Organization Chart in Section 2	S. Thomas
12/7/2020	8	12/7/2020	Added a clearer image in Appendix C	S. Thomas
12/7/2020	9	12/7/2020	Revised Phase 1 population section to reflect ACIP Phase 1a recommendation	S. Lovett
12/17/2020	10	12/20/2020	Verified, updated, added internal and external links	S. Thomas
12/17/2020	11	12/20/2020	Updated Phase 1 populations section to reflect ACIP Phase 1b and 1c recommendations	S. Thomas
01/05/20201	12	01/05/2021	Updated Phases populations to include GA's revised phase 1A+ populations	S. Lovett
01/05/2021	13	01/05/2021	Replaced Appendix C with the most current version	N. Nydam

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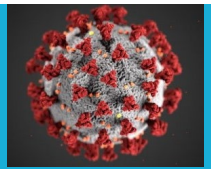

Executive Summary

The Georgia Department of Public Health (DPH) understands the development of a successful COVID-19 vaccination program requires a strong partnership between federal, state, and local clinical and non-clinical partners. Through these established partnerships and following guidance from the Centers for Disease Control and Prevention (CDC), DPH is working to ensure Georgia is prepared and ready to actively respond once vaccines become available.

The H1N1 pandemic demonstrated that well planned and executed mass vaccination efforts, are an effective method for addressing and slowing the spread of disease resulting from a naturally occurring pandemic. This statewide Mass Vaccination Distribution and Administration Plan will be used as a state protocol for the distribution and administration of the COVID-19 vaccine to public health districts and other enrolled COVID-19 pandemic vaccine providers.

Phased Approach to COVID-19 Vaccination

The main goal throughout this response will be to ensure vaccine distribution and administration processes are in place to begin rapid vaccine administration to Georgia residents once vaccines become available. Current assumptions include a possible imbalance between vaccine demand and supply. To address this, provider sites and vaccine shipments will be prioritized according to the populations those providers serve and the key populations who have been prioritized for the vaccination effort. Critical populations will be prioritized using a four-phased approach based on their level of risk for exposure to or complications from the disease.

Critical Populations

During limited vaccine availability, GIP will utilize CDC ACIP recommendations and the National Academy of Medicine's Framework for Equitable Allocation of COVID-19 Vaccine. DPH Immunization Program will utilize a combination of existing national, state-wide, and local data sources; engagement of community-based organizations, academic institutions, and state agencies; mapping, modeling, and forecasting; and surveillance data to identify critical and priority populations. Information collected on critical populations will be compiled into a Critical Populations database maintained by DPH.

COVID-19 Vaccination Provider Recruitment and Enrollment

DPH began the recruitment of COVID-19 providers, August 2020, with the release of a COVID-19 vaccine provider interest survey. The enrollment process will begin with the review of submitted surveys to place interested providers into three Phases. DPH will use a phased approach to enroll providers in the COVID-19 vaccine program. Active recruitment and enrollment of new providers will continue while the COVID-19 vaccine remains available. The Georgia Immunization Program (GIP) will lead the COVID-19 vaccine enrollment activities.

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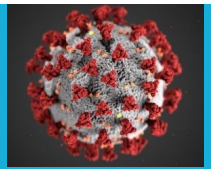

COVID-19 Vaccine Storage and Handling

Cold chain storage and handling requirements for each vaccine product will vary from refrigerated (2° to 8° C) to frozen (-20°C) to ultra-cold (-60° to -80°C) temperatures, and ongoing stability testing may impact these requirements. Vaccines must be stored appropriately from the time they are manufactured until the time they are administered to a patient. While providers are not being asked to purchase ultracold storage units, all providers will be required to follow the CDC, ACIP, and manufacturer's guidance regarding the proper storage and handling of each vaccine. Specific directions for storage temperatures are stated in the vaccine product monograph or on the vaccine product label, and checking vaccine product/package is necessary for required storage temperatures. For vaccine products being issued under a EUA, the storage information will be contained within the EUA.

The U.S. Pharmacopeia (USP) Chapter 659 "Packaging and Storage Requirements" provides examples of different temperature storage conditions. The following definitions have been provided and have been verified in the latest release of the USP <659> Chapter.

- FROZEN- Any temperature at -20°C (-5 degrees Fahrenheit). A freezer is a cold storage unit in which the temperature is maintained at −25°C and −10°C (−13°F and 14° F).
- Cold: Any temperature not exceeding 8°C. A refrigerator is a cold storage unit in which the temperature is maintained between 2°C and 8°C (36 to 46 °F).
- Cool: Any temperature between 8°C and 15°C (46°F and 59 °F)
- Controlled room temperature: The temperature maintained thermostatically that encompasses at the usual and customary working environment of 20°C-25°C(68°F-77 °F).
- Warm: Any temperature between 30°C and 40°C (86° and 104 °F).
- Excessive heat: Any temperature above 40°C (104 °F).

U.S. Pharmacopeial Convention. USP General Chapter <659> Packaging and Storage Requirements. https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/revisions/659_rb_notice_english.pdf

The CDC COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations describes ultra-cold vaccine storage temperature to be around -60°C to -80°C.

COVID-19 Vaccination Second-Dose Reminders

Many pharmacies and healthcare organizations have internal systems they use for patient notifications and reminders. Providers are encouraged to utilize these systems for second dose reminders to patients. DPH will implement a statewide reminder recall program to support local efforts and providing additional redundancy for second dose reminder methods.

Section 12: COVID-19 Vaccination Program Communication

Communication plans have been established within the state DPH Crisis and Emergency Risk Communication (CERC) plan. The plan has been vetted, updated, and approved for use in emergencies with an all-hazards approach. Coordination of communication efforts about vaccine development and availability will be led by the state DPH Division of Communications.

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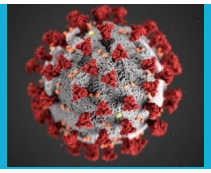

COVID-19 Vaccine Safety Monitoring

DPH has a policy and in place for reporting vaccine adverse events following immunization services. The Vaccine Adverse Event Reporting System (VAERS) policy is located in the GIP Manual (Chapter 4) which is accessible on the GIP website at https://dph.georgia.gov/immunization-section/immunization-publications. Providers authorized to administer vaccines are required by law to report to VAERS any adverse event following immunization including a vaccine administration error. GIP will include VAERS reporting procedure job aids and website information in provider training materials and resources.

Vaccine safety monitoring can also be conducted by COVID-19 vaccine recipients via VSAFE. Providers should inform COVID-19 vaccine recipients about VSAFE. VSAFE is a new voluntary, smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins for COVID-19 vaccine recipients. V-safe allows participants to report any side effects after the COVID-19 vaccination to CDC in almost real-time. It also gives them a convenient reminder to get their second COVID-19 vaccine dose if they need one. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html

COVID-19 Vaccination Program Monitoring

DPH will assume responsibility for continuous monitoring for vaccine-related situational awareness throughout COVID-19 vaccination response activities. GIP will use capacity maps to monitor access to COVID-19 vaccines and ensure the accessibility of these services for critical populations. GIP will review available CDC dashboards (e.g., Weekly Flu Vaccination Dashboard and COVID-19 Vaccination Response Dashboard), as additional monitoring tools. GIP will work with the Pandemic Vaccine Planning Team to share identified issues and update this plan to address these issues.

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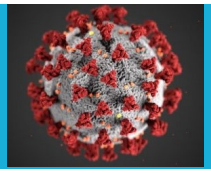

Section 1: COVID-9 Vaccination Preparedness Planning

Introduction

A safe and effective COVID-19 vaccine is a critical component in reducing COVID-19 related illnesses, hospitalizations, and deaths and will help restore a sense of normalcy nationally. The Georgia Department of Public Health (DPH) understands the development of a successful COVID-19 vaccination program requires a strong partnership between federal, state, and local clinical and non-clinical partners. Through these established partnerships, following guidance from the Centers for Disease Control and Prevention (CDC), DPH is working to ensure Georgia is prepared and ready to actively respond once a vaccine becomes available.

The H1N1 pandemic demonstrated that well planned and executed mass vaccination efforts, are an effective method for addressing and slowing the spread of disease resulting from a naturally occurring pandemic. DPH has developed this statewide COVID-19 vaccine administration and distribution plan using best practices learned from past H1N1 pandemic response activities, the Georgia "DPH Pandemic Response Plan – Support Annex K: Mass Vaccination Distribution Plan", and the CDC's "COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations", and other pandemic influenza planning guidance and tools. Understanding this is a situation that may continue to evolve, DPH will review, update, and share revised versions of this plan as additional information is received.

Purpose

This statewide Mass Vaccination Distribution and Administration Plan will be used as a state protocol for the distribution and administration of the COVID-19 vaccine to public health districts and other enrolled COVID-19 pandemic vaccine providers. This plan, in combination with the Georgia Immunization Program (GIP) Manual, Mass Vaccination Section, will serve as the framework and guidance for districts and counties to create their detailed plans, which should be tailored to meet the needs of individual communities.

Lessons Learned from H1N1

Lessons learned from DPH's H1N1 vaccination response will be used to inform the COVID-19 vaccination response. Some of these key lessons include:

- Vaccine supply and availability may be sporadic in the initial phases of a pandemic response
- Ensure DPH's ability to scale down plans based on the degree of community spread
- Communication with providers is as essential as communication with staff
- Staff cross-training is essential.
- The "push" method of vaccination was more effective during this event than the "pull" method. A higher portion of the population was served by establishing mass vaccination clinics in popular, high traffic areas, as opposed to holding the clinics in geographically unfamiliar, clinical settings.

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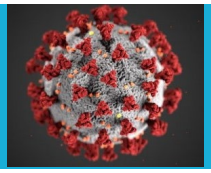

- Collaboration with the Department of Education provided for a higher rate of vaccination in Georgia's population.
- Full-scale mass vaccination sites would be more effective with additional human resources
- Need to be flexible and recognize the variability that is inherent in pandemics and to be able to plan and respond accordingly

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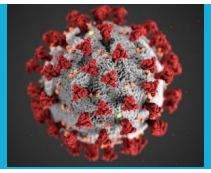

Section 2: COVID-19 Organizational Structure and Partner Involvement

Local and state agencies and organizations have specific roles and responsibilities during public health emergencies. A complete list of these roles and responsibilities can be found within the DPH, Emergency Preparedness and Response (EPR) Emergency Operations Plan (EOP). This plan further defines the roles and responsibilities related to mass vaccination distribution and administration response efforts.

Partner Involvement

Core COVID-19 Vaccination Planning Team Members

DPH has established a COVID-19 Vaccine Core Planning and Coordination Team. This team will be responsible for the annual review of state plans, updating plans during an active response, and distributing updated plans to partners and stakeholders.

A complete list of Georgia's COVID-19 Vaccination Planning Team members is included in the appendices (Appendix B). This list may be revised throughout this response. In addition to DPH's Immunizations and Emergency Preparedness staff, representation from each of the following offices are active participants of this team:

- **Office of General Counsel:** Office of General Counsel will provide legal guidance and counsel and assist in the application and adherence to state laws and regulations throughout the incident. ***Please see the Disease Exposure Control Plan (DEC), DPH EOP, Annex P***
- **Office of Emergency Medical Services and Trauma (EMS)**: EMS will communicate training requirements, information, data reporting requirements, etc. to EMS services throughout the state via the Regional EMS Directors.
- **Office of Nursing (OON):** OON will assist by coordinating with Georgia's County Nurse Managers and district Nursing Directors throughout the state to assist in the appropriate staffing of MVCs.
- **Office of Pharmacy:** Pharmacy will assist through collaboration with the districts and support for the Pharmacy Disaster Response Coordinator pharmacist as outlined under Roles and Responsibilities in the DPH, EOP.

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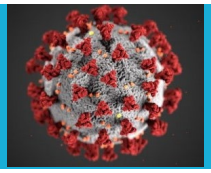

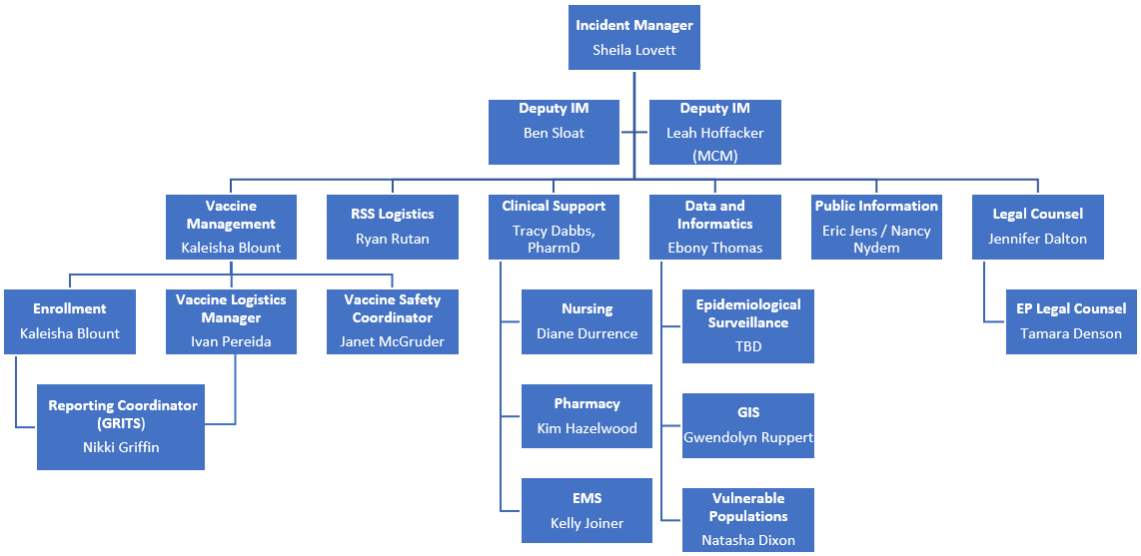

GDPH's COVID-19 Vaccine Core Planning & Coordination Organizational Chart

State and Local Partnerships

Collaboration between state and local public health, other state agency partners, private immunization providers, and immunization stakeholders is key to the success of vaccine response efforts. A comprehensive list of key collaborating partners for this response activity is included in the appendices (Appendix B). This list may be updated as additional collaborations are established.

DPH has identified staff to serve as primary and back-up for each of the roles outlined here. Each district will identify primary and back-up staff members responsible for each position:

- **Vaccine Safety Coordinator:** ensure public health staff is trained on the proper administration, storage, and handling of the vaccine. Also, train on treating adverse events and reporting them through the Vaccine Adverse Event Reporting System (VAERS) on-line.
- **Reporting Coordinator:** contact for reporting responsibilities as determined per state/federal requirements. The assumption should be that all doses administered will be submitted (via an interface or direct entry) into the Georgia Registry of Immunization Transactions and Services (GRITS).
- **Medical Countermeasures Coordinator:** Manages and coordinates receipt of supplies and medications at the RSS. Recruits and supports closed POD and MVC partners throughout their enrollment and administration activities.
- **Vaccine Logistics Manager:** Vaccine supply and documentation of inventory are the responsibility of the vaccine logistics manager. This position also coordinates shipments to other sites, if needed.

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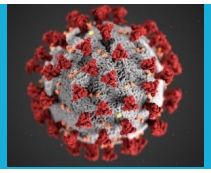

Tribal Communities

Collaboration with federally and state-recognized tribal communities is especially important for reaching one of this response's priority populations. While Georgia has no federally recognized tribes or Indian Health Service tribal (HIS) facilities within the state; response outreach will center on state-recognized tribes that are primarily informally organized. GIP has reached out to local tribal organizations for collaborative activities and will continue to make inroads to sustainable immunization partnerships.

In Georgia, there are no health care organizations primarily serving American Indian individuals, as most tribal members are not concentrated on reservations. This contributes to challenges faced when working to assess population estimates for this priority group. For example, one of Georgia's 3 tribal groups only has one member living within Georgia while the other members cross back and forth across the Georgia/Florida state line, living primarily in Florida. GIP will continue efforts to gather the number of populations served in tribal communities, as well as assess need and resources available to establish MVCs/PODs within these areas using the following methods:

- Work with regional health districts, local health departments, and tribal councils to gather data on the number of tribal members to better estimate the number of vaccines needed to support this population.
- Continue to support district and local county health departments with COVID-19 vaccine educational and vaccination outreach efforts targeting this population in the absence of tribal medical facilities.
- Continue to support private vaccination providers with COVID-19 vaccination and vaccine educational outreach serving Georgia's Native American populations and other rural populations.
- Continue to reach out to tribal partners, solidifying connections with local tribal leaders and supporting tribe-originated needs for the COVID-19 vaccine.

Roles and Responsibilities

DPH Planning and Coordination Team

The DPH COVID-19 Vaccine Core Planning and Coordination Team will be responsible for the annual review of state plans, updating plans during an active response, and distributing updated plans to partners and stakeholders. Primary responsibilities of this core team include:

- Ensuring Mass Vaccination Distribution and Administration Plan is in alignment with the current version of the GIP Manual and Nursing Protocols as well as current federal guidance so that all resources communicate a consistent message.
- Using cross-team collaboration (emergency preparedness, immunization, pharmacy, nursing, communications, and field operations) in the development of plans, protocols, and guidance.

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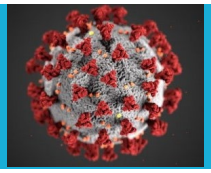

- Determine and communicate the priority populations based on Emergency Use Authorization (EUA) guidance, Advisory Committee on Immunization Practices (ACIP) recommendations, and CDC guidelines, contingent upon current issues and available guidance relative to those issues.
    - FDA authorized a EUA for the Pfizer-BioNTech COVID-19 vaccine on December 11, 2020, https://www.cdc.gov/vaccines/covid-19/eua/index.html. The CDC's ACIP released interim recommendations for the vaccine on December 12, 2020, https://www.cdc.gov/mmwr/volumes/69/wr/mm6950e2.htm.
    - FDA authorized a EUA for Moderna COVID-19 vaccine on December 18, 2020, https://www.modernatx.com/covid19vaccine-eua/. The CDC's ACIP released interim recommendations for the vaccine on December 20, 2020. https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e1.htm
- Communicate vaccination planning efforts and priority population specifications to the Governor, legislators, medical societies, other state agencies, state-level provider organizations, and other stakeholders as needed.
- Provide guidance and technical support on planning for COVID-19 vaccine-related activities to district and local public health partners and all other COVID-19 pandemic providers.
- Engage and facilitate registration of statewide provider networks, such as chain pharmacies, hospitals, long-term care facilities, correctional facilities, and other critical workforce employers.
- Provide training on vaccine storage and handling, data submission to the state's immunization registry, and adverse event reporting to non-public health providers. Conduct train-the-trainer sessions with identified public health district personnel for continued training of local-level public health staff.
- Develop a method for allocating vaccines to each public health district and other providers. This will depend on population density, level of disease endemic to each district, and the number of priority populations.
- Coordinate direct distribution of vaccine to at each district or county public health provider and registered non-public health providers with approved vaccine storage units and capacity.
- Use the proper method of cold chain transport when assisting with vaccine transport between vaccinating sites.
- Plan for receiving and reporting aggregate data back to the CDC through GRITS generated reporting mechanisms.
- Provide social distancing guidance for vaccination operations following the state Disease Exposure Control (DEC) plan and current CDC guidelines for the protection of staff and those participating in the vaccination campaigns.
- The DPH Communications Office will provide key guidance and talking points as well as disseminate public service announcement language to support statewide campaigns.
- Provide guidance for engaging with state partners working with the following populations: Refugees, Migrant Workers, Homeless populations, etc. utilizing the Emergency Preparedness

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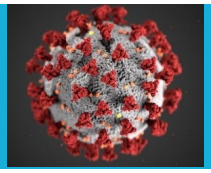

Underserved Populations Planning Document and affiliations through various coalitions. Public Health Districts

DPH District Responsibilities

Public Health Districts have developed plans to utilize Points of Distribution for Medical Countermeasures and Administration and Medical Material Management and Distribution. Public Health districts are to utilize Points of Distribution (PODs) as Mass Vaccination Clinics (MVCs) for the SARS-CoV2 (COVID-19) mass vaccination campaigns. Primary responsibilities include:

- Develop a COVID-19 Mass Vaccination Distribution and Administration Plan following state guidance that best meets the needs of each community within its geographical boundaries, maximizing efficiency in the use of resources.
- Engage and encourage registration of partner providers to assist in vaccinating all priority populations.
- Collaborate with community partners (local colleges, schools, and/or large childcare facility personnel) to ensure access to vaccination for priority populations.
- Develop and implement closed MVCs for internal vaccination clinics, as staffing and other resources allow.
- Explore other nontraditional venues for vaccine administration, such as retail settings, faith-based facilities, and occupational settings.
- Comply with all reporting requirements, including interim reports of vaccination planning and implementation activities specific to each event.
- Each district or county will have agreements and contracts with the local police department to help secure vaccines and maintain order at mass vaccination sites. Emergency Response plans will be in place at each location.
- Districts will have standing operating procedures (SOPs) for each vaccination site. The CDC recommends facilities develop and maintain clearly written, detailed, and up-to-date storage and handling SOPs. SOPs should be reviewed by all staff and updated by the vaccine coordinator. SOPs should contain plans and information for three major areas:

    - General information – include contact information for vaccine manufacturers, equipment service providers, and important facility staff, as well as job descriptions, regularly used forms, and staff training requirements.

    - Routine storage and handling – include information for all aspects of vaccine inventory management, from ordering to monitoring storage conditions.

    - Emergency vaccine storage, handling, and transport – outline steps to be taken in the event of equipment malfunctions, power failures, natural disasters, or other emergencies that might compromise vaccine storage conditions.

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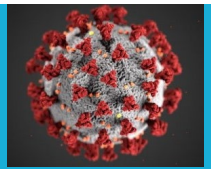

- Adhere to storage and return guidelines for manufactures' thermal shippers.
  - Pfizer: https://contlogo.s3.eu-central-1.amazonaws.com/Pfizer/Thermal%20Shipper%20Return%20Guidance.pdf
    - Video: https://www.cvdvaccine-us.com/product-storage-and-dry-ice
  - Moderna: More information to come.

More details regarding the development of SOPs are available in the CDC's Vaccine Storage and Handling Toolkit: https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html

- Each Public Health MVC will obtain informed consent for every patient before vaccination.
- Each public health district/county health department/partner provider will have access to and must distribute the COVID-19 EUA Fact Sheet or Vaccine Information Statement (VIS) document before administering each vaccine. This is following federal law.
  - It is the responsibility of the public health district/county health department/partner provider to obtain and distribute an approved EUA and VIS, as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representatives via electronic or printed materials.
- Each district is responsible for the advertising of priority populations and sites of the PODs/MVCs.

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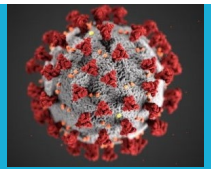

Section 3: Phased Approach to COVID-19 Vaccination

Early vaccine program assumptions support a phased implementation of COVID-19 vaccination response activities. During limited vaccine availability, GIP will utilize CDC ACIP recommendations and the National Academy of Medicine's Framework for the equitable allocation of COVID-19 Vaccine. As additional information is received, we will adjust our plan outlined below accordingly.

Situation

DPH will receive allocations of COVID-19 vaccines from the federal government. The vaccine will be distributed using the current Vaccines for Children (VFC) vaccine distribution infrastructure. This distribution mechanism will allow vaccines to be shipped directly to providers who have enrolled as COVID-19 vaccine providers. In the event a provider cannot store or administer minimum shipping quantities during the designated time frame, DPH will provide vaccines for these sites through an approved redistribution provider location for the smaller sites. As an additional backup to the VFC distribution method, the vaccine may be sent to Georgia's Receipt Stage and Store (RSS) warehouse. (Location will not be disclosed in the plan due to security).

General Assumptions for Program Implementation

The main goal throughout this response will be to ensure vaccine distribution and administration processes are in place to begin rapid vaccine administration to Georgia residents once vaccines become available. Current assumptions include a possible imbalance between vaccine demand and supply. To address this, provider sites and vaccine shipments will be prioritized according to the populations those providers serve and the key populations who have been targeted for the vaccination effort. A copy of the Georgia Priority Population Vaccination Allocation Matrix has been included in the appendices (Appendix C).

The State of Georgia will decide the amount of vaccine given to each of the 18 public health districts and enrolled COVID-19 providers based on population density, level of disease endemic to each area, and numbers of priority populations. Additional information related to the vaccine allocation method is included in Section 7 of this plan.

For mass vaccination, the state will follow recommendations from the ACIP. These recommendations are the most current guidelines regarding vaccine administration, storage and handling, and safety. The ACIP details guidance for the administration of all routinely administered vaccines for the civilian population. Recommendations for each vaccine are updated as needed. Current copies of recommendations of the ACIP for each vaccine are located on the following CDC website: https://www.cdc.gov/vaccines/covid-19/info-by-product. Each public health facility that administers vaccines must have a written copy of the ACIP recommendations or internet access to the above website.

DPH will also disseminate recommendations and guidance via the GIP Manual. This manual provides guidance for ordering, storing, handling and administration of vaccines routinely provided and the

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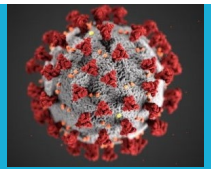

provision of immunization related services, including quality assurance standards and standard operating guidelines for conducting **mass vaccination clinics (MVCs).** The manual is updated at least annually. The GIP Manual can be accessed at https://dph.georgia.gov/immunization-publications. Georgia Public Health districts may use POD locations and plans to conduct MVCs.

Possession of Vaccines

In addition to the enrollment requirements included in Section 5 of this plan, partner providers or vaccinators must meet "one" of the following legal requirements to receive an allocation of vaccine:

- Must be able to possess dangerous drugs following O.C.G.A.§ 16-13-72 and must meet the definition of "pharmacist" or "pharmacy" as defined by O.C.G.A. § 26-4-5(28) or as defined by O.C.G.A §26-4-5(30).
- Must be able to possess dangerous drugs following O.C.G.A § 16-13-72 and must meet the definition of "practitioner" or "practitioner of the healing arts" as defined by O.C.G.A. § 26-4-5(33).
- A nurse acting pursuant to an influenza vaccine protocol agreement as provided by O.C.G.A. § 43-34-26.1 and meets the definition of a "nurse" as defined in 43-34-261 (a) (7). "The nurse (RN or LPN) must be regularly employed by a physician who is actively employed in private practice."
- Must be able to possess dangerous drugs following O.C.G.A § 16-13-72 and meet the definition of "advanced practice registered nurse" as defined by O.C.G.A.§ 43-34-25 and acting pursuant to an influenza vaccine "protocol agreement" following O.C.G.A. § 43-34-25.
- Must be able to possess dangerous drugs as defined by O.C.G.A. § 16-13-72 and meet the requirements of O.C.G.A. § 43-34-103, meet the definition of "Physician Assistant" as defined by O.C.G.A. §43-34-102 and be acting pursuant to an influenza vaccine "job description" following O.C.G.A. §43-34-102.

Authority to Vaccinate during a Public Health Emergency

Under Georgia's law, only certain licensed health professionals are authorized to administer vaccines. Currently, no provisions in the law state that Georgia's non-licensed health care professionals have the authority to vaccinate. "The Georgia Emergency Act of 1981 could be interpreted to provide the non-licensed health care professionals the authority to vaccinate by deeming such individuals as emergency management workers and volunteers that are engaged in emergency management activities."

Various health professionals are currently considered to have the authority to administer vaccines under the Georgia Code due to their job duties, job descriptions, protocols, or delegation from a physician. Some of these professionals may only administer medications/drugs while under the supervision of another. Georgia Code includes provisions for pandemic influenza vaccines, but it does not include vaccines that would protect against other pandemic diseases (i.e. COVID-19). Working with our legal team, the Core COVID-19 Vaccine Planning Team will explore changes in applicable statutory language. Discussions regarding the implementation of an emergency order

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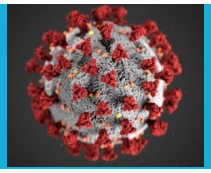

to provide an exception that would allow these health professionals to administer COVID-19 are currently underway.

In addition to physicians, the following is a list of currently authorized health professionals and statutes which provide authority to administer vaccines under an established protocol for a public health emergency:

- Pharmacists - O.C.G.A. § 26-4-4, 26-4-5(30)(A) and (31), O.C.G.A. §43-34-26.1 (influenza, pneumococcal disease, shingles, or meningitis vaccine)
- Licensed Practical Nurse (LPN) - O.C.G.A. § 43-26-3(6) and § 43-34-23(7)
- Registered Professional Nurse (RN) - O.C.G.A. § 43-26-3(6) and (8), O.C.G.A. § 43-34-26.1(c) and O.C.G.A. § 43-34-23(a)(6 - 8) and (b)(2)
- Advanced Practice Nurses: Certified Nurse Midwife, Certified Registered Nurse Anesthetist, Nurse Practitioner, and Clinical Nurse Specialist - O.C.G.A. § 43-26-3(1), (6) and (8) and § 43-34-23(b)(1)(B)
- Physician Assistant (PA) - O.C.G.A. § 43-34-105 and O.C.G.A. §43-34-23(b) (1-2)
- Medical Student, Intern or Resident - O.C.G.A. § 43-34-22(b)(9)(A) and O.C.G.A. § 43-34-26(a)(3)
- Certified Emergency Medical Technicians - O.C.G.A. § 31-11-53
- Paramedics - O.C.G.A. § 31-11-54
- Certified Cardiac Technicians - O.C.G.A. § 31-11-55

The Code does not give the following professionals authority to administer drugs:

- Acupuncturists - O.C.G.A. § 43-34-62 (1) and (4)
- Veterinarians - O.C.G.A. § 43-50-3 (5)
- Chiropractors - O.C.G.A. § 43-9-1 (2)
- Dentists - O.C.G.A. § 43-11-1 (5) and § 43-11-17

Vaccine Program Implementation Phases

The below phases are preliminary. A final description of all phases will be provided once additional information regarding priority populations have been defined by the ACIP and CDC. Section 4 of this plan will provide a defined description of each phased population mentioned in this section.

Based on available clinical trial data, COVID-19 vaccination is expected to cause systemic post-vaccination symptoms, such as fever, headache, and muscle pain at the injection site. While the incidence and timing of post-vaccination symptoms will be updated with available clinical trial data, strategies are needed to mitigate possible healthcare personnel absenteeism and resulting personnel shortages due to the occurrence of these post-vaccination symptoms. Considerations might include:

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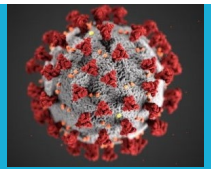

- Staggering of delivery of the vaccine to healthcare personnel in a facility so that personnel from a single department or unit are not all vaccinated at the same time. Based on greater reactogenicity observed following the second vaccine dose based on current clinical trial data, staggering considerations may be more important following the second dose.
- Planning for personnel to have time away from work if they develop systemic symptoms following COVID-19 vaccination.

For more specific details on the Georgia's Priority Population Groups please see Appendix C.

Phase 1: Limited COVID-19 Vaccine Availability

COVID-19 vaccine supply is expected to be limited during the initial implementation of vaccine response activities (Phase 1). During this phase, vaccine efforts will focus on reaching defined critical populations who meet DPH defined Phase 1 criteria. Vaccine administration will occur through closed POD sites, including, but not limited to, public health clinics, hospitals, long term care facilities (LTCFs), emergency medical services (EMS), etc.

The below list of Phase 1 populations is not all-inclusive and will be reviewed and updated throughout the response as needed:

1. Healthcare personnel likely to be exposed to or treat people with COVID-19
2. First Responders
3. People at increased risk for severe illness from COVID-19, including those with underlying medical conditions and people 65 years of age and older
4. Other essential workers

Initial vaccine supply may not be enough to maximize access for the entire Phase 1 population. ACIP recommends that healthcare personnel be prioritized in the earliest phase of COVID-19 vaccination (https://www.cdc.gov/mmwr/volumes/69/wr/mm6949e1.htm). However, in settings where the initial vaccine supply is insufficient to vaccinate all healthcare providers, sub-prioritization of vaccine doses may be necessary. Considerations for sub-prioritization, of equal importance, include but are not limited to:

1. Phase 1-A will include paid and unpaid persons serving in a healthcare setting who have the potential for direct or indirect exposure to patients or infectious materials. Hospital staff, public health clinical staff, EMS, and other first responders, long term care facility (LTCF) staff, and urgent care facility staff are examples of people who will be included in this Phase. Additional examples include:
    a. healthcare workers (e.g. physicians, nurses, pharmacists, EMS, laboratory staff, environmental services, etc.)
    b. LTCF staff and residents
    c. Adults 65 and older and their caregivers

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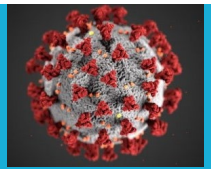

d. Law enforcement, fire personnel (e.g. volunteer fire departments), dispatchers, 9-1-1 operators, etc.)

2. Phase 1-B will include other essential workers and people at higher risk of severe COVID-19 illness. Examples of people that will be included in this Phase are listed below:
    a. Essential workers (non-healthcare) who perform job tasks across critical infrastructure sectors ensuring continuity of functions critical to public health, safety, economic and national security.

3. Phase 1-C will include persons aged 16-64 with medical conditions that increase the risk for severe COVID-19

Additional considerations regarding Phase 1a sub-population prioritization may be found on the CDC's website, here: https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html.

For more specific details on Georgia's Priority Population Groups please see Appendix C.

Phase 2: Increased COVID-19 Vaccine Availability

As vaccine availability increases, vaccine response efforts will also expand to ensure vaccination of Phase 1 critical populations not yet vaccinated, as well as members of the population for whom vaccine has been recommended. During this phase, DPH will also activate additional COVID-19 vaccination providers to expand access to vaccination services. Additional providers may include healthcare settings (physician offices, clinics, etc.), retail pharmacies, public health community clinics, mobile clinics, FQHCs, and other community settings. The following list of Phase 2 populations is not all-inclusive and will be reviewed and updated throughout the response as needed:

1. Phase 1 populations, not yet vaccinated, including non-clinical public health, hospital, and LTC facilities and their household members.
2. Critical populations as defined in Section 4 of this plan.
3. Other populations for whom vaccine has been recommended.

For more specific details on the Georgia's Priority Population Groups please see Appendix C.

Phase 3: Vaccine Supply Widely Available

COVID-19 vaccination activities will transition to Phase 3 response, once the vaccine becomes more widely available, and vaccine limits and allocations have been removed. During this phase, COVID-19 vaccination will be integrated into routine vaccination programs, and the release of additional ACIP and CDC guidelines and recommendations. Planning for this phase assumes that vaccine supply exceeds

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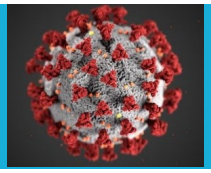

demand, and access to vaccination services are available through a broad vaccine administration network.

During this phase, DPH will enroll and activate providers as requests for vaccination program enrollment are received. As vaccination efforts become more routine, DPH will begin to phase out mass vaccination clinics and outreach where these services are no longer required. The following list of Phase 3 populations is not all-inclusive and will be reviewed and updated throughout the response as needed:

1. Phase 1 and Phase 2 populations that have not yet been vaccinated.
2. The general population includes all populations for which vaccines have been recommended.
3. Phase 1, Phase 2, and Phase 3 populations in need of additional doses to complete vaccination series (i.e. dose 2).

For more specific details on Georgia's Priority Population Groups please see Appendix C.

Phase 4: Recovery/Mitigation

The critical activities of recovery include, but are not limited to:

1. Ensure accurate documentation of reported adverse events and doses administered.
2. Return surplus vaccine following federal guidelines.
3. Follow the Strategic National Stockpile (SNS) and Medical Countermeasures Plane (MCM) Plan as needed.
4. Document lessons learned and adjust vaccination plans based on lessons learned.

Mitigation minimizes the adverse impact of an emergency and reduces vulnerability to future emergencies. Mitigation measures may be implemented at any time. Mitigation includes:

1. Continued vaccination campaigns to reduce the risk of infection.
2. Continued public information and education.
3. Regular training and exercises to improve public health's ability to respond to future outbreaks and pandemics.

For more specific details on the Georgia's Priority Population Groups please see Appendix C.

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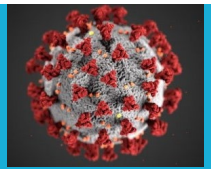

Section 4: Critical Populations

During limited vaccine availability, GIP will utilize CDC ACIP recommendations and the National Academy of Medicine's Framework for Equitable Allocation of COVID-19 Vaccine. To identify, estimate the numbers of, and locate critical populations for COVID-19 vaccine distribution, the DPH Immunization Program will utilize a combination of a) existing national, state-wide, and local data sources; b) engagement of community-based organizations, academic institutions, and state agencies and c) mapping, modeling and forecasting, and d) surveillance data. All information collected on critical populations (i.e., estimate and data source) will be compiled into a Critical Populations (Appendix D) database maintained by DPH. In addition to DPH identifying, estimating, and locating critical populations, each of the 18 health districts will be required to identify data sources to assess critical populations in their respective areas. The information from local public health will be collected at the state-level and compared to state estimates.

Data Sources

DPH will establish a list of currently available data sources that estimate the numbers of critical populations. The current data sources include, but are not limited to, the Cybersecurity and Infrastructure Security Agency (CISA), the U.S. Census, Medicare, and Medicaid. Additionally, Georgia's Online Analytical Statistical Information System (OASIS) will be used to estimate and locate critical populations. OASIS is a suite of interactive tools used to access the Georgia Department of Public Health's standardized health data repository. Additional data sources are described below.

Partnerships

1. **Professional Organizations/Societies, State Agencies, Academic Institutions, Licensing/Regulatory Boards, etc.**: DPH has established relationships with professional organizations/societies, state agencies (e.g., Department of Community Health, Georgia Emergency Management Agency), academic institutions, and licensing/regulatory boards. DPH will work with these organizations and groups to gather their current data on specified critical populations.

2. **Community-Based Organizations**: Community-based organizations (CBOs) traditionally commit to locate and reach vulnerable populations to provide services while accommodating language, cultural, and accessibility needs. They offer day-to-day services and often have earned the trust of the individuals they serve. Hence, they can also provide an accurate barometer of needs and mobilize the community and local resources. DPH has established relationships with CBOs at both the state and local levels. DPH will engage and work closely with CBOs to identify the population they serve and collect current data on the specified population. Additionally, some CBOs have begun utilizing neighborhood or geographic information systems (NIS or GIS) to locate their target population. Therefore, DPH will work with CBOs to collect this data to find critical populations.

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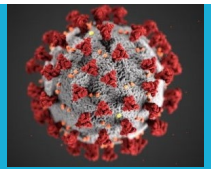


3. **COVID-19 Health Equity Team**: In response to the pandemic, DPH has established a COVID-19 Health Equity Team. The team has been engaging CBOs to address health inequities exacerbated by COVID-19. DPH will utilize the current partnerships created by this team to collect estimates on critical populations and locate them.

Mapping, Modeling, and Forecasting

DPH will partner with academic institutions to conduct risk assessments to identify and categorize subset groups. Assessments will include geospatial analysis, modeling, and mapping of communities, the burden of disease, access to testing, vaccine providers, and places of employment to identify groups at the highest risk for disease or severe illness and available resources. Additionally, DPH will partner with the Georgia Emergency Management Agency (GEMA) to map current vaccination providers to identify areas and communities where vaccination services are scarce.

Surveillance Data

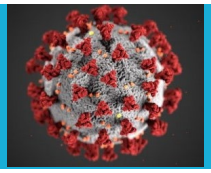
DPH will analyze COVID-19 surveillance data to identify, estimate, and locate critical populations in Georgia. Analyzing surveillance data will allow public health to identify vulnerable populations who are at the most significant risk for disease and more severe outcomes. Additionally, examining outbreak surveillance data will

Defining Populations

The GA DPH uses the U.S. Department of Homeland Security (https://www.cisa.gov/sites/default/files/publications/Version_4.0_CISA_Guidance_on_Essential_Critical_Infrastructure_Workers_FINAL%20AUG%2018v3.pdf) as guidance to define the essential critical infrastructure workforce. However, the final classification of a group as an essential critical infrastructure workforce in Georgia will be decided by state officials. To estimate the number of essential workers in Georgia, DPH will utilize a combination of, but not limited to, national (census), state, and local data sources, and data from professional organizations and licensing boards (Appendix D).

1. The definition of essential critical infrastructure workforce established by DPH will be provided to key stakeholders including, but not limited to, local public health departments, healthcare providers, professional societies/organizations, pharmacists, academic institutions, etc.
2. Based on data and disease burden, local public health, in consultation with DPH, may define additional essential critical infrastructure workforce to receive the vaccine.

If there is insufficient vaccine supply, GA DPH will utilize ACIP guidance, pre-established, evidenced-based priority categories and definitions, and state-specific COVID-19 surveillance data to identify different subset groups of critical populations in Georgia. Considerations for identifying subset groups include, but are not limited to, occupational risk, the burden of disease, vulnerability to severe illness, residential setting (i.e., congregate), geographical location, and equity. To ensure an equitable



framework for vaccination allocation, DPH will consider the following criteria proposed by CDC and the National Academy of Medicine:

- **Risk of acquiring infection**: Higher priority given to individuals who have a greater probability of being in settings where COVID-19 is circulating and exposure to the virus.
- **Risk of severe morbidity and mortality**: Higher priority given to individuals with a greater probability of severe disease or death if they acquire infection.
- **Risk of negative societal impact**: Higher priority is given to individuals with societal function, and upon whom other people's lives and livelihood depend directly and would be imperiled if they fell ill. It does not consider their wealth or income, or how readily an individual could be replaced in a work setting, given labor market conditions.
- **Risk of transmitting the disease to others**: Higher priority is given to individuals who have a higher probability of transmitting the disease to others.

Considering these factors, DPH will work with state officials to establish subset groups of critical populations. When a person is included in more than one group, they will be prioritized for vaccination in the highest Phase group in which they are included.

Additionally, DPH will partner with academic institutions to conduct risk assessments to identify and categorize subset groups. Assessments will include geospatial analysis, modeling, and mapping of communities, the burden of disease, access to testing, and vaccine providers to identify groups at the highest risk for disease or severe illness and available resources.

Through COVID-19 disease surveillance and working with various partners to develop COVID-19 guidance, the GA DPH has established relationships with academic institutions, government agencies, professional organizations, various industries (e.g., poultry plants, manufacturers, warehouse distribution companies), healthcare organizations, jails, and detention centers, employers, and community-based organizations (CBOs). To establish points of contact (POC) with critical populations, DPH will utilize existing relationships, state-based listservs, and POCs. Additionally, the established points of contact and listservs will be used to identify and engage supplementary POCs. DPH's COVID-19 Health Equity Team will assist in identifying additional POCs, focusing primarily on CBOs. An up-to-date communication distribution list of organizations, healthcare providers, agencies, and POCs will be maintained before and throughout vaccine distribution to ensure consistent communication with key stakeholders. When appropriate, essential COVID-19 vaccine information for critical populations will be provided on the DPH website; health advisory notices, communication materials, and relevant updates for critical populations will be placed on DPH's webpage and updated as necessary.

Health Districts and Local Public Health Departments

Georgia's 18 Health Districts and local public health departments have established relationships with local community partners, healthcare organizations, long-term care facilities, businesses, industries, and professional organizations. Each district will be required to establish points of contact for key critical populations to a) identify and locate critical populations in their geographic area and b) communicate

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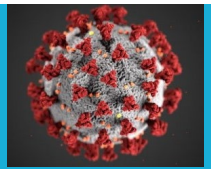

timely and effective COVID-19 vaccination messaging. Districts will be required to complete a district-specific "Population Group Worksheet" (Appendix E) and submit it to DPH.

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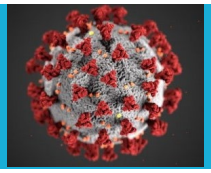

Section 5: COVID-19 Provider Recruitment and Enrollment

In partnership with Emergency Preparedness, GIP began the first phase of COVID-19 provider recruitment on August 12, 2020, by disseminating recruitment letters to external partners; Health Districts, currently enrolled Vaccines for Children (VFC) providers, and previous H1N1 mass vaccination providers. Each letter was tailored to address further recruitment instructions based on provider type and provided a link for providers to complete a *COVID-19 Vaccine Pre-Enrollment Questionnaire* through survey monkey was provided.

The recruitment process will include a review of submitted surveys to place interested providers into three Phases. GIP will extract and filter data from survey monkey into Excel format. Phases will be assigned based on providers' ability to store and handle vaccines with documented completed training, followed by their capability of being a mass vaccination site for each of the three population Phase phases outlined by the CDC. GIP will use a phased approach to enroll providers in the COVID-19 vaccine program. Active recruitment and enrollment of new providers will continue while the COVID-19 vaccine remains available.

COVID-19 Vaccine Program - Provider Enrollment

The GIP Program will lead the COVID-19 vaccine enrollment activities. COVID-19 vaccine providers may enroll by completing the Pre-Enrollment Survey, Provider Profile, Provider Agreement, Routine Emergency Vaccine Handling Plan. The Accountability Policy, and the Fraud and Abuse Policy should be reviewed for specific terms and conditions of enrollment. The organization's chief medical officer (or equivalent) and chief executive officer (or chief fiduciary) must complete and sign the CDC COVID-19 Vaccination Program Provider Requirements and Legal Agreement. CDC COVID-19 Vaccination Program Provider Profile Information must be completed for each vaccination location covered under the organization. The provider agreement and medical licenses must be submitted for each physician, physician assistant, and nurse practitioner signed to the provider list.

There must be a signed CDC COVID-19 Vaccine Redistribution Agreement for any facility/organization approved by DPH to conduct vaccine redistribution and a fully completed CDC COVID-19 Vaccination Provider Profile Information form (Section B of the CDC COVID-19 Vaccination Program Provider Agreement) for each receiving vaccination location.

The COVID provider enrollment period lasts approximately 3 weeks for program requirement review and for approval of your storage equipment (See Section 8 for specific vaccine storage and handling guidance).

Pharmacy Enrollment

Participation by pharmacy partners will be a key component during the second phase of vaccine distribution. Pharmacy partners not served directly by the CDC will receive information through the Office of Pharmacy with the Georgia Department of Public Health, the Pharmacy Disaster Response

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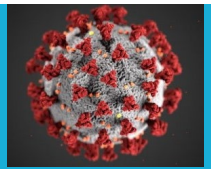

Coordinator pharmacist, the Georgia Board of Pharmacy, and respective state pharmacy associations regarding provider enrollment and vaccine guidance with support from the Office of Immunization.

Long Term Care Facility Enrollment

As part of a nationwide vaccination strategy, all long-term care facilities will have three options for ensuring vaccination coverage for staff and residents.

- Facilities with the capacity to facilitate vaccination clinics for staff and residents, without external assistance, should complete enrollment instructions as outlined above and register with the GIP to serve as a COVID-19 vaccination provider site.
- Enroll in the Pharmacy Partnership for Long Term Care Program. Through this program CDC has engaged two retail pharmacies, CVS and Walgreens, to secure the COVID-19 vaccine and provide onsite vaccination of residents, at no cost to the facility once the vaccine is recommended for them.
- Leverage existing partnerships with local pharmacies, county public health clinics, etc. to provide access to vaccines for facility staff and residents. LTCFs who choose this option should still register with GIP, either independently or in partnership with the agency that will facilitate vaccination clinics for their center.

COVID-19 Vaccine Program Requirements for Providers

1. The organization must administer COVID-19 Vaccine following all requirements and recommendations of the CDC and CDC's ACIP. Within 24 hours of administering a dose of COVID-19 Vaccine and adjuvant (if applicable), Organization must record in the vaccine recipient's record and report required information to the relevant state, local, or territorial public health authority. Details of the required information (collectively, Vaccine-Administration Data) for reporting can be found on CDC's website.

2. The organization must submit Vaccine-Administration Data through the Georgia Registry of Immunization Transaction and Services (GRITS). The organization must preserve the record for at least 3 years following vaccination, or longer if required by the state, local, or territorial law. Such records must be made available to any federal, state, local, or territorial public health department to the extent authorized by law.

3. The organization must not sell or seek reimbursement for COVID-19 Vaccine and any adjuvant, syringes, needles, or other constituent products and ancillary supplies that the federal government provides without cost to Organization.

4. The organization must administer the COVID-19 Vaccine regardless of the vaccine recipient's ability to pay COVID-19 Vaccine administration fees.

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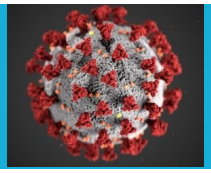

5. Before administering COVID-19 Vaccine, the Organization must provide an approved EUA fact sheet or VIS, as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representatives.

6. The organization's COVID-19 vaccination services must be conducted in compliance with CDC's Guidance for Immunization Services During the COVID-19 Pandemic for safe delivery of vaccines.

7. The organization must comply with CDC requirements for COVID-19 vaccine management. These requirements include the following:

    a. The organization must store and handle COVID-19 Vaccine under proper conditions, including maintaining cold chain conditions and chain of custody at all times following the manufacturer's package insert and CDC guidance in CDC's Vaccine Storage and Handling Toolkit, which has been updated to include a COVID Addendum.
    b. The organization must always monitor vaccine-storage-unit temperatures using equipment and practices that comply with guidance located in CDC's Vaccine Storage and Handling Toolkit
    c. The organization must comply with each relevant jurisdiction's immunization program guidance for dealing with temperature excursions
    d. The organization must monitor and comply with COVID-19 Vaccine expiration dates
    e. The organization must preserve all records related to COVID-19 Vaccine management for a minimum of 3 years, or longer if required by the state, local, or territorial law

8. The organization must report the number of doses of COVID-19 vaccine and adjuvants that were unused, spoiled, expired, or wasted as required by the relevant jurisdiction

9. The organization must comply with all federal instructions and timelines for disposing of COVID-19 vaccine and adjuvant, including unused doses

10. The organization must report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS).

11. The organization should provide the COVID-19 Vaccine recipient with VSAFE information. VSAFE is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins.

12. The organization must provide a completed COVID-19 vaccination record card to every COVID-19 Vaccine recipient, the adult caregiver accompanying the recipient, or other legal representatives. Each COVID-19 Vaccine shipment will include COVID-19 vaccination record cards.

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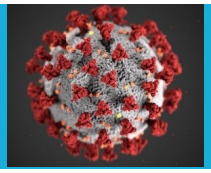

a. The organization must comply with all applicable requirements as set forth by the U.S. Food and Drug Administration (FDA), including but not limited to requirements in any EUA that covers the COVID-19 vaccine.
b. The organization must administer COVID-19 vaccines in compliance with all applicable state and territorial vaccination laws.

COVID-19 Provider Training

GIP has a list of training topics and a method for tracking provider training requirements through provider enrollment and quality assurance and improvement processes. Provider training requirements are located in the state GIP Manual in the Quality Assurance/Quality Improvement (QA/QI) section (Chapter 13). The learning expectations are based on the ACIP recommendations that outline the recommended Policies and Procedures for administering vaccines and providing immunization services by Registered Nurses (RNs) and Licensed Practical Nurses (LPNs) in a public health setting. The QA/QI tool is used to document the training/education expectations and the parameters of clinical practice for immunization services. The training tool is used to promote consistency in practice across programs on a statewide basis, provide an opportunity to identify excellence in practice and provide opportunities for improvement. The training list and learning expectations will apply to all enrolled COVID-19 vaccine providers. Under Georgia's authority to administer vaccines during a state public health emergency, the training list and the QA/QI section of the GIP manual will be updated to include CDC guidance for COVID-19 vaccine(s) administration.

List of Training Topics

Before administering the COVID-19 vaccine the learner will complete the following "You Call the Shots" CDC training modules: https://www2.cdc.gov/vaccines/ed/covid19/

1. **COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers Understanding the Basics:** The objective of this module is to provide healthcare providers with information about COVID-19 vaccine Emergency Use Authorization and safety, as well as general information about vaccine storage, handling, administration, and reporting

2. **Storage and Handling of COVID-19 Vaccines:** The Vaccine Storage and Handling (1.0hr) training module is under development and will include general COVID-19 vaccine storage, handling, and transport information. The addendum will be updated as COVID-19 vaccine products are approved. Fact sheets for storage and handling will be developed to use as job aids for each COVID-19 vaccine. More extensive information related to storage, handling, shipping, package, and transport will be provided when approved.

3. **COVID-19 Vaccine Administration:** Vaccine Administration (1.0hr) training module is under development and will include vaccine indications, contraindications/precautions, vaccine preparation, vaccine administration, and documentation for COVID-19. Fact sheets with COVID-19 vaccine indications, contraindications/precautions, vaccine preparation, vaccine administration, and documentation will be developed to use as job aids for providers.

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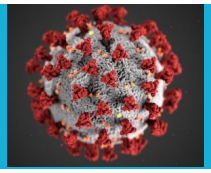

4. **Interim Guidance for Immunization Services During the COVID-19 Pandemic:** Each COVID-19 provider will be referred to the Interim Guidance for Immunization Services During the COVID-19 Pandemic. The CDC developed a website for providers to access web-based resources and FAQ document(s) to use as job aids and training material. These resources can be accessed at https://www.cdc.gov/vaccines/pandemic-guidance/index.html.

5. **Documentation and Tracking of Provider Training:** As part of the CDC COVID-19 Vaccination Program, each enrolled vaccination location will be required to submit training verification records for all providers covered under the organization as part of their Provider Agreement. Each COVID-19 provider will be required to sign the appropriate provider agreements, and then undergo training on how to utilize the functionalities of GRITS(IIS), how to monitor and manage vaccine inventory within GRITS, as well as how to submit data.

6. **Additional training and education materials for Healthcare Professionals and Jurisdiction** can be accessed from the CDC website at https://www.cdc.gov/vaccines/covid-19/index.html .

7. **Pfizer-BioNTech COVID-19 Vaccine Training Links:** https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html
    a. For additional information: https://www.pfizer.com/

8. **Moderna COVID-19 Vaccine Training Links:** https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html
    a. For additional information: https://www.modernatx.com/

9. **ACIP COVID-19 Vaccine Interim Recommendations:** https://www.cdc.gov/vaccines/covid-19/index.html

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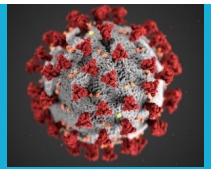

Section 6: COVID-19 Vaccine Administration Capacity

DPH's GIP and EPR began accessing vaccine administration capacity and vaccine provider interest, August 2020. In coordination with the Georgia Emergency Management Agency's (GEMA) Geographic Information System (GIS) Coordinator, we will use mapping as a method of assessing vaccine accessibility throughout the state. These maps will allow Georgia to assess current capacity and identify pockets of need across the state.

Data elements will include:

1. Provider type
2. Populations served as stated in the provider profiles
3. Vaccine storage capabilities
4. Number of vaccines on hand
5. Doses of vaccines administered

All maps will be shared with our public health partners and others to be used for situational awareness purposes and to assist with local vaccination efforts.

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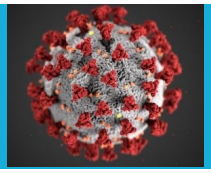

Section 7: COVID-19 Vaccine Allocation, Ordering, Distribution, and Inventory Management

The information provided in this section is based on current assumptions as provided by the CDC. This section will be reviewed, revised, or updated as the situation develops, and additional guidance and recommendations are shared.

COVID-19 Vaccine Allocation

When the COVID-19 vaccine first becomes available for allocation, GIP will utilize information collected from the *COVID-19 Vaccine Pre-Enrollment Questionnaire* (Appendix F). Data will be extracted and filtered to prioritize providers with high volumes of Phase 1: frontline workers/first responders (hospitals, EMS, etc.), long term care facilities (LTCs), and the capacity to vaccinate their staff, patients, and community. In partnership with state public health's Office of Emergency Preparedness and Response and the Georgia Emergency Management Agency (GEMA), GIP plans to utilize Geographic Information System (GIS) mapping as a method of assessing vaccine accessibility throughout the state. Provider type and populations served stated in the provider profiles will be added factors to determining allocation prioritization. As more COVID-19 vaccine becomes available, GIP will utilize the same method for allocating to providers of Phase 2: other essential workers and other vulnerable populations, and Phase 3: General Public (which would include children and other non-vulnerable adults).

COVID-19 Vaccine Cold Chain Management

A key component in GIP's plan to incorporate COVID-19 vaccine allotments is by assuring providers can maintain cold chain capabilities. This is accomplished by collecting providers' documentation of completed vaccine storage and handling training required during the enrollment process, and verification of proper working equipment for vaccine storage during physical and/or virtual site visits.

GIP will adhere to vaccine manufacturer, ACIP, and CDC guidance regarding proper storage and handling of the COVID-19 vaccine and share this information with COVID-19 providers once this guidance has been updated and made available.

COVID-19 Vaccine Ordering

GIP will initially mass upload provider information into the CDC Vaccine Tracking System (VTrckS) utilizing information collected from the GRITS and COVID-19 Provider Profiles. Mass uploads will continue as deemed necessary, and staff will individually upload/update a single provider's information in VTrckS on a case-by-case basis. Allocations will be processed via VTrckS *EXIS Provider Orders (Sales Orders) Interface,* similarly to how other seasonal Special Circumstance orders are processed such as influenza. A .CSV file indicating information of providers to receive the COVID-19 vaccine will be uploaded.

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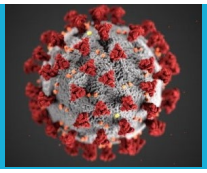

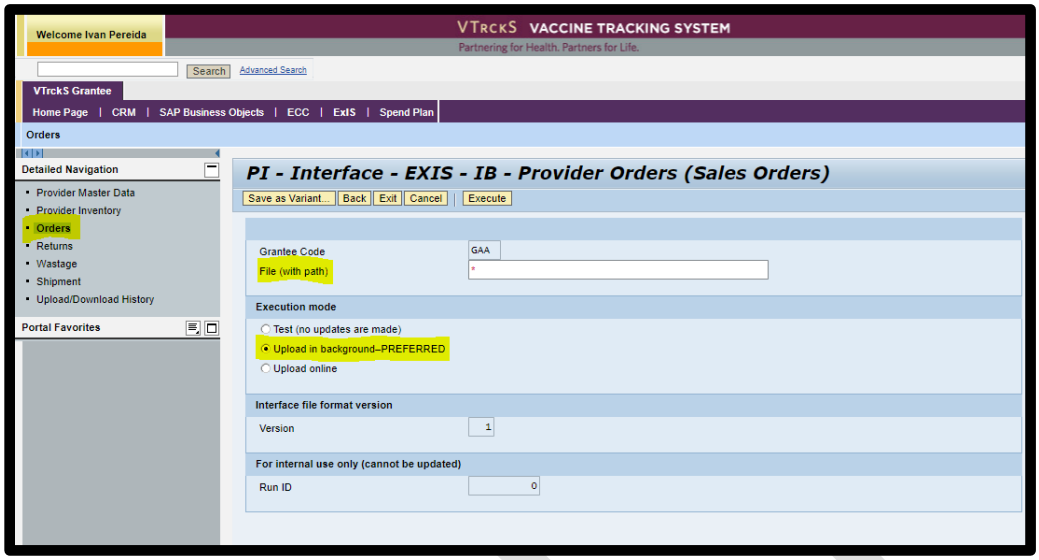

Transfer or Redistribution of Vaccine

The message of not allowing the frozen COVID-19 vaccine to be repositioned and limited transfers of refrigerated vaccines will be communicated to providers by email and newsletters. Proper communication of providers needing approval from GIP before a transfer will be portrayed. In addition to having a COVID-19 Redistribution Agreement on file, additional training as needed for transporting vaccine doses physically, and in the GRITS system will be executed, as needed. Providers will have an Immunization Regional Consultant assigned to their site who will coordinate with the Adult and Adolescent Immunization Coordinator to accomplish a proper transfer.

Vaccine Wastage and Inventory Levels

Tracking COVID-19 vaccine wastage/spoilage and inventory levels will be recorded through GRITS. To assure accurate levels of inventory, proper training and guidance of finding COVID-19 expiration dates by lot numbers through the US Department of Health and Human Services (HHS) website (pending link) will be provided. Additional training regarding best practices for conducting off-site clinics to minimize wastage will be part of the enrollment training. GIP plans to practice/adopt CDC's COVID-19 vaccine recovery plans once available.

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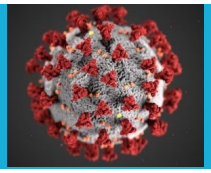

Section 8: COVID-19 Vaccine Storage and Handling

Cold chain storage and handling requirements for each vaccine product will vary from refrigerated (2° to 8° C) to frozen (-20°C) to ultra-cold (-60° to -80°C) temperatures, and ongoing stability testing may impact these requirements. Vaccines must be stored appropriately from the time they are manufactured until the time they are administered to a patient. Excessive heat or cold may reduce vaccine potency, thereby increasing the risk that recipients will not be protected against vaccine-preventable diseases. Complying with state and federal laws and regulations relating to the storage, security, and distribution of vaccines is a requirement to ensure quality pharmaceutical services consistent with attaining high standards of pharmaceutical integrity for all recipients of COVID-19 Vaccine. Failure to maintain vaccine product integrity can result in patients inadvertently receiving a compromised vaccine, facilities unable to gain access to and/or replace limited vaccine inventory, re-vaccination having to occur for patients, and loss of patient confidence.

Individual Provider Locations Responsibilities

1. **COVID vaccine locations should ASSIGN** responsibility for handling vaccines to a primary and secondary point of contact.
2. **CHECK** vaccine shipments immediately upon arrival.
3. **STORE** vaccines in a pharmaceutical-grade, commercial-grade, stand-alone unit, or ultra-cold storage unit. More information on proper COVID-19 vaccine storage can be found in the CDC's Storage and Handling Toolkit: https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html
   The receiving facility will be responsible for tracking the vaccine product and maintaining cold-chain documentation for **any** verification purposes. The facility will agree to provide digital data logger files and temperature logs upon request from the Office of Immunization within 1 business day of the request.
4. **RECORD** temperatures at the beginning of the day using a digital data logger with a current certificate of calibration. Refrigerator temperatures should remain between 36- 46° Fahrenheit and 2°-8° Celsius. Freezer temperatures should remain between 5° or colder Fahrenheit and -15° or colder Celsius. Ultra-cold (-60° to -80°C): Temperature excursions outside of the required range should be reported to dph-gavfc@dph.ga.gov within 24 hours. All providers are required to have at least one backup digital data logger in the event the primary data logger malfunctions.
5. **ROTATE** vaccine stock to ensure short-dated vaccines are administered before the expiration date.
6. **REPORT** short-dated vaccines 30 days before expiration to GIP.
7. **RETURN**
   a. Thermal Shippers
      i. Pfizer-BioNTech: https://contlogo.s3.eu-central-1.amazonaws.com/Pfizer/Thermal%20Shipper%20Return%20Guidance.pdf
         1. Video: https://www.cvdvaccine-us.com/product-storage-and-dry-ice
   b. Wastage / Expired.
   c. Additional COVID-19 Vaccine Processes

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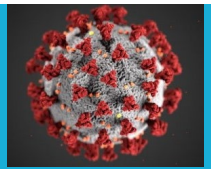

i. Pfizer-BioNTech
ii. Moderna

8. **MAINTAIN** a completed Routine and Emergency Vaccine Handling Plan in an accessible location in the event of refrigerator/freezer malfunctions, natural disasters, etc. This plan should be reviewed monthly and updated as often as needed.

Satellite, Temporary, or Off-Site Settings

To increase equitable vaccine access to the COVID-19 vaccine, providers may conduct satellite, temporary, or off-site clinics in collaboration with community stakeholders. Providers involved with off-site locations should ensure that the vaccine cold chain is maintained and follow COVID vaccine storage and handling practices.

Resources for off-site vaccination clinics that should be reviewed include but are not limited to the following:

1. CDC's Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Location https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html
2. CDC's COVID-19 Addendum to CDC's Vaccine Storage and Handling Toolkit https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html
3. CDC's Guidance for Vaccination During a Pandemic https://www.cdc.gov/vaccines/pandemic-guidance/index.html

Additional considerations for off-site vaccination clinics

- The number of vaccines transported to an off-site or mass vaccination clinic should be based on the anticipated number of individuals to be served.
- Vaccines may be transported—not shipped—to a clinic site using vaccine transportation procedures outlined in CDC's Vaccine Storage and Handling Toolkit. This includes transporting vaccines to and from the site at appropriate temperatures and using appropriate equipment, as well as monitoring and documenting temperatures using a digital data logger with a probe in buffered material.
- Upon arrival at the clinic site, vaccines must be stored correctly to maintain appropriate temperature throughout the clinic day. This includes reviewing temperatures every hour using a digital data logger with a digital display and a probe in a buffered material. At the end of the clinic day, the temperature data must be downloaded from the data logger and printed out. Make sure to document the date, location where the clinic was conducted, start time of transportation of vaccines, and end time of transportation of vaccines.
- If vaccines are exposed to out of range temperatures at any time, vaccines are to be labeled **"do not use"** until steps are taken to ensure vaccines are viable. This includes following the steps in the vaccine incident report (https://www.gritstest.state.ga.us/docs/Blank_Vaccine_Incident_Report_Rev_09132017.pdf),

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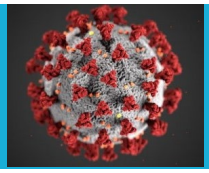

and following up with the designated manufacturers. Even if vaccines are deemed viable, it is required that you keep all documentation related to the incident

- Place a data logger in each portable storage unit containing an off-site vaccine.
- Monitor the temperature in each portable storage unit every hour from the time it is placed in the cooler(s) until it is returned to the refrigerator. There is an hourly temperature log for this purpose. Download the data logger at the end of the off-site clinic and print a copy of the report.

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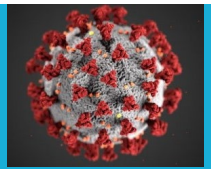

Section 9: COVID-19 Vaccine Administration Documentation and Reporting

DPH will use the Georgia Registry of Immunization Transactions and Services (GRITS) to collect COVID-19 vaccine doses administered data from providers. GRIST is an Internet-based IIS operated by the GIP. As a birth to death registry, GRITS was developed in 2003 to comply with Georgia Law (OCGA 32 12 3.1). GRITS Enables providers to determine whether patients are due or overdue for an immunization; Clarifies immunization schedules and emerging vaccine combinations; as well as, manage vaccine inventory.

Reporting using IZ Gateway Connect

Once it becomes available, GRITS plans to participate in the 'Connect' component of IZ Gateway and send COVID-19 related data, in real-time, or scheduled upload, through an HL7 exchange. In the intervening time, the COVID-19 Vaccination Reporting Specifications and Submission (CVRS) will be the method used to report COVID records to CDC. Manual uploads of the CVRS will be made directly to the Data Clearinghouse, daily.

Through the online Pandemic Enrollment feature in GRITS, each COVID-19 provider will be required to complete and sign the designated provider agreement. Proof of online training (CDC's You Call the Shots - Storage and Handling Module, CDC's COVID-19 training module, and GRITS Manage Orders Online Training) will also be required. Training can be given to new GRITS users by Immunization Regional Consultants (IRCs) field staff in a train-the-trainer setting as deemed necessary. Written 'walkthrough' tutorials will also be available for distribution.

Providers will test all data exchange connections with an IIS analyst to ensure smooth data submission. Once all training and testing have taken place, providers will be reminded that adherence to the binding agreements is pertinent. Consistent, timely reporting must be completed within 24 hours of administration.

GRITS, in collaboration with Gainwell partners and Wisconsin Immunization Registry (WIR) Consortium members, is working to develop a mobile IIS app for out-of-office use. Users will be able to submit vaccine administration data records from off-site and temporary clinic settings by manual input. Records will either immediately be retained in the IIS or be uploaded upon returning to their office when outside the internet is not available.

Data Entry and Reporting Monitoring

Districts received GIA funds, and some plan to use these funds to hire additional staff, such as temp EMS staff qualified to provide vaccines during an emergency response. All staff members, new and old, will follow data submission processes.

As a method of assessing current reporting times, off-site and drive-thru flu clinics will be monitored to determine the estimated interval of time between vaccine administration and reporting the

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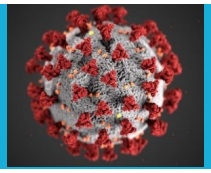

administered dose through GRITS. Resolutions to tighten any gaps will be built based on the evaluation of these estimates.

GRITS will instruct each user how to monitor data submissions with the "Check Status" function, which allows providers to review a log of all data records sent through data exchange including percentages of error within each completed submission. As well as review the monthly generated provider report card, which shows the target percentage of what GRITS expects to receive vs. the percentage of what is received, per data field.

Coverage Reports

GRITS has implemented easy-to-use immunization assessment reports to offer clinic-based and county-based immunization rates to assist in monitoring immunization coverage and quality improvement activities. Development of the assessment reports as part of the CDC's efforts to transition from the Comprehensive Clinical Assessment Software Application (CoCASA) to Registry-based assessment reporting. The assessment reports generate baseline immunization rates and identify areas for improvement. The reports condense various information into one summary report. Reports are divided into three basic areas: Childhood, Adolescent, Adult. Currently, the assessment reports help monitor immunization rates for vaccines recommended by the ACIP. GRITS will add the upcoming COVID-19 vaccines to that list of assessment reports, which can help serve as the foundation of childhood, adolescent, or adult COVID-19 immunization rate improvement activities.

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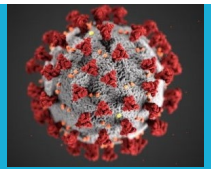

Section 10: COVID-19 Vaccination Second-Dose Reminders

GIP program will utilize the IIS, GRITS, to enforce the use of the three following methods in conducting COVID-19 vaccine second dose reminders:

1. **Encourage COVID-19 vaccine providers to have patients place a reminder on their cell phone:** GIP will encourage COVID-19 vaccine providers to complete the vaccination record cards that will be included in every ancillary kit. Once accurate vaccination record card information is documented (i.e., vaccine manufacturer, lot number, date of first dose administration, and second dose due date), the provider will be encouraged to ask recipients to take a photo of the vaccine record card and place a reminder for the 2nd dose due date in their smartphone calendar (when applicable). Providers will be reminded to ask recipients to bring vaccination cards with them when they return for their second dose.

2. **Encourage COVID-19 vaccine providers to utilize their internal systems for second dose reminders:** Many pharmacies and healthcare organizations have their systems for patient notifications and reminders, some using functionality within their electronic health record (EHR). Providers will be encouraged to use automated patient phone calls, emails, and text-message based systems for second dose reminders.

3. **GIP will contract with a reminder recall vendor:** GIP, through a contracted vendor, will conduct reminder recalls supporting statewide efforts. The contract will outline the utilization of GRITS data to send second dose reminders for COVID-19 vaccine recipients. GIP is aware of potential health plans assisting in notifying their enrollees about second doses based on filed COVID-19 vaccine claim information, and therefore providing additional redundancy for second dose reminder methods.

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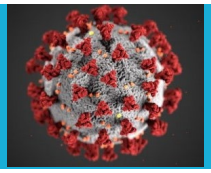

Section 11: COVID-19 Requirements for IISs or Other External Systems

GRITS, in collaboration with Gainwell partners and WIR Consortium members, is working to develop a mobile IIS app for out-of-office use. Users will be able to submit vaccine administration data records from off-site and temporary clinic settings by manual input. Records will either immediately be retained in the IIS or be uploaded upon returning to their office when outside the internet is not available.

Description of Vaccine Related Data Elements

In addition to the required data elements listed in the CDC IIS Data Requirements for COVID-19 Vaccine Administration (Administered at a location, Administered at location: type, Administration address: city, Administration address: county, Administration address: state, Administration address: street, Administration address: zip code, Administration date, CVX (Product), Dose Number, IIS Recipient ID, IIS Vaccination Event ID, Lot Number: Unit of Sale, MVX, Recipient address: county, Recipient address: city, Recipient address: state, Recipient address: street, Recipient address: zip code, Recipient date of birth, Recipient name, Recipient sex, Sending Organization, Vaccination Complete, Vaccine administering site, Vaccine expiration date, and Vaccine route of administration), GRITS is also able to provide: race, ethnicity, and serology comments.

Data Exchange and Reporting GRITS Capabilities

All GRITS users have the option of sending that data to the system electronically. GRITS accepts client/immunization files in either a batch flat file, batch HL7, or real-time HL7 (version 2.5.1) upload. Batch uploads are manual processes. Real-time interfacing is automated through WSDL web service or PHINMS connection. Most GRITS users utilize the interface functionality. As of September 1, 2020, GRITS has run 5,822,216 total data exchange jobs.

Server consolidation will take place within the 4th quarter of 2020, which will move GRITS to a cloud-based environment. This will essentially give GRITS an unlimited amount of storage capacity.

GRITS Provider Access – Registration

Enrollment in the GRITS database is a requirement for all vaccinating providers in Georgia. Providers who are not currently registered may begin this process by initiating an enrollment request via the GRITS online enrollment application (add link/web address). Onboarding registration can be handled within 24hrs or less. Registration includes gaining login credentials, scheduling training, and ascertaining needed functionalities (i.e. VFC enrollment, electronic data exchange, etc.).

GRITS and IZ Gateway Connect

GRITS will participate in the 'Connect' component of IZ Gateway and send COVID-19 related data, in real-time, or scheduled upload, through an HL7 exchange. Submissions will be made following the CDC IIS Data Requirements for COVID-19 Vaccine Administration. The data use agreement (DUA) required to

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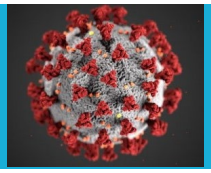

establish GRITS connection with the IZ Gateway was signed and fully executed as of 9/23/2020. DPH leadership, GIP, and GRITS staff continue to explore efforts related to:

1. The establishment of a DUA between GRITS and CDC for national coverage analysis; and
2. Memorandum of Understanding (MOU) to share data with other jurisdictions via the IZ Gateway Share component.

Loss of System or Internet Connectivity

DPH continues to explore options to ensure backup solutions are in place in the event system or internet connectivity issues occur. Discussions have included possible collaborations with other jurisdictions to develop a viable system-based solution; financially supported through a collective effort.

GRITS, in collaboration with DXC partners and WIR Consortium members, is working to develop a mobile IIS app for out-of-office use. Users will be able to submit vaccine administration data records from off-site and temporary clinic settings by manual input. Records will either immediately be retained in the IIS or be uploaded upon returning to their office when outside the internet is not available.

Data Quality Monitoring

GRITS developed the GRITS Provider Report Card to highlight the completeness of an organization's electronic reporting fields. The report card provides a visual of the target percentage of what GRITS expects to receive vs. the percentage of what is received, per data field. Currently, the report is automatically generated for each health department, monthly. COVID-19 providers, not already included as part of another vaccine program, will be added to that list.

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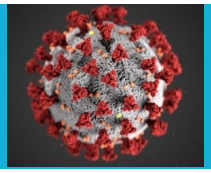

Section 12: COVID-19 Vaccination Program Communication

Communication plans have been established within the state DPH Crisis and Emergency Risk Communication (CERC) plan. The plan has been vetted, updated, and approved for use in emergencies with an all-hazards approach. Spokespersons for news conferences and media inquiries will be selected from within the GIP and DPH leadership that may include, but are not limited to, the GIP Director and other Subject Matter Experts within the program, DPH leads including the Commissioner, the Health Protection Director, and the Communications Director. Every Communications endeavor outlined in this plan will be conducted with considerations to maximize health equity, providing information and vaccine services to those in the greatest need for the information and services.

Coordination of communication efforts about vaccine development and availability will be led by the state DPH Division of Communications.

- The public will receive this information from the state DPH website, media reports and additional marketing campaigns as funding allows. Information will be promoted through social media and updated as more information and resources become available from the CDC. The state DPH website includes an icon specifically for the use of public COVID-19 questions and concerns. There is also a statewide COVID-19 hotline number listed on the website and promoted elsewhere to address public questions and concerns. The public also has the option of having questions and concerns addressed by phone, e-mail, or in-person where possible, at all state and local DPH offices.
- Healthcare providers will be informed through regular communications, as established with the Regional Coordinating Hospital system, and directly through DPH Communications' constant contact list-serve.
- Partner agencies informational updates on vaccine development and availability will be coordinated through the Joint Information Center (JIC) operations, and redundantly through communications with the 18 Public Health districts and their communicators.

The DPH Division of Communications has and will continue to, update media contacts with a variety of media outlets. This includes tv, radio, newspaper, and on-line news services locally and statewide throughout Georgia.

Vaccine public education will be coordinated through the GIP and DPH Division of Communications. Key audiences have been and will continue to be, identified by the GIP and the state DPH Division of Communications. Key audiences will receive targeted messages in an effective and timely fashion as set forth by the three anticipated phases of vaccine availability. Such key audiences will include but are not limited to employers, essential workers, those with limited access to vaccine services, and other major stakeholders in the healthcare system.

Plain language will be used in social media messages, infographics, news releases, and other methods of promoting Public Health messages throughout Georgia, as part of a coordinated effort to ensure a consistent approach, as it relates to COVID-19 vaccination communication. Further educational outreach will be conducted through targeted marketing campaigns as funding allows. This will be accomplished in

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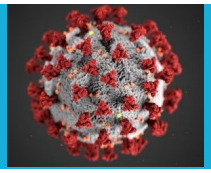

phases including 'Limited' vaccine supply, 'Increased Availability,' and 'Widely Available.' Communication plans for the phases of vaccine availability are outlined in the timed response actions established in the state DPH CERC plan.

Clear, concise, and consistent communication activities, taking into account social, economic, and demographical determinants, will be conducted to ensure the highest possible public confidence in the efficacy of the COVID-19 vaccine. This will include, information on what is known and what is still being researched, in a transparent fashion. Messaging to ensure the highest public health and safety as it relates to COVID-19 vaccination will follow the same pattern established through the first nine months of 2020. This includes frequent updates to the website and posted information in the virtual JIC housed within WebEOC. This may include further development of infographics, fact sheets, and other communication tools available to all DPH and external partners.

The GIP and DPH Division of Communications has and will continue, collaborative efforts to identify talking points and key considerations associated with COVID-19 vaccination endeavors. This includes identifying populations of focus who are at the greatest risk of negative outcomes related to contracting COVID-19. The DPH Division of Communications will coordinate with local Public Health districts specifically to identify the at-risk populations and determine the most effective mediums to use in messaging to those key audiences. This may include, but is not limited to, language consideration, spokesperson selection, and other facets of effective messaging. Plans are in place to expand such considerations externally though the DPH led Joint Information Center (JIC). The JIC was established on March 2, 2020, and as of September 26, 2020, includes 148 members from more than 50 local, state, and federal government and stakeholder agencies partnered for Communications in response to COVID-19 in Georgia.

The DPH Emergency Preparedness Limited English Proficiency/Sensory Impairment database identifies languages and communication means within each of the 18 health districts. Additionally, the database provides contact information on Phased levels for interpretation, translation, and other resource services. Additionally, local Public Health offices can provide resource capacity in the form of trusted community leaders and other partnerships to reach all audiences effectively.

Vaccine administration locations will be posted on the state DPH website in a timely, accurate fashion, and/or on the digital properties maintained by the 18 Public Health districts within Georgia. This will be shared with the public, media, and partners to reach the largest audience, with a focus on making the information available to those targeted audiences that are the most vulnerable, and thereby in the greatest need of receiving a vaccination. Similar strategies were developed and improved statewide to promote COVID-19 Specimen Point of Collection (SPOC) locations. The uptake of the COVID-19 vaccine will be tracked and monitored by GIP and information shared internally. External information may be shared through Communications as deemed necessary by the Division of Communications, GIP, and DPH leadership.

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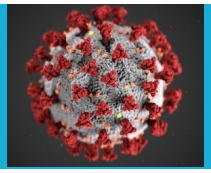

Section 13: Regulatory Considerations for COVID-19 Vaccination

Current assumptions suggest the initial COVID-19 vaccine may be authorized for use under a EUA issued by FDA or approved as licensed vaccines. DPH will continue to monitor this development and share the below plans with COVID-19 providers to ensure preparedness under both scenarios. To ensure proper vaccine administration and patient care, DPH will observe ACIP COVID-19 vaccine recommendations before the administration of a EUA approved vaccine product.

Scenario 1: Emergency Use Authorization (EUA)

The EUA authority allows FDA to authorize either (a) the use of an unapproved medical product (which includes vaccine) or (b) the unapproved use of an approved medical product during an emergency based on certain criteria. If the COVID-19 vaccine is released under a EUA, the EUA will provide specific guidance regarding how the COVID-19 vaccine should be used and any conditions that must be met to use the vaccine. The "condition of authorization" will be discussed and confirmed between the FDA and CDC. Conditions are expected to cover distribution requirements, reporting requirements, and safety monitoring requirements. EUAs are authorized for a specific period and will expire at the end of the defined period. While the COVID-19 vaccine remains under and EUA, COVID-19 providers will be required to provide a copy of the EUA fact sheet to each patient, parent, or guardian before the vaccine is administered.

Scenario 2: Licensed Vaccine

VISs are required after a vaccine has been licensed and added to the Vaccine Injury Table. Planning for developing VIS for the COVID-19 vaccine is still being discussed at the federal level. Once made available, COVID-19 providers will be required to provide a copy of the VIS to each patient, parent, or guardian before the vaccine is administered. DPH will continue to monitor this situation and update this plan as additional guidance is received.

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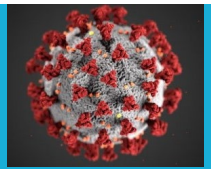

Section 14: COVID-19 Vaccine Safety Monitoring

GIP has a policy and in place for reporting vaccine adverse events following immunization services. The Vaccine Adverse Event Reporting System (VAERS) policy is located in the GIP Manual (Chapter 4) which is accessible on the GIP website at https://dph.georgia.gov/immunization-section/immunization-publications. Providers authorized to administer vaccines are required by law to report to VAERS any adverse event following immunization including a vaccine administration error. GIP will include VAERS reporting procedure job aids and website information in provider training materials and resources. CDC has developed a website and an Interim Guidance for Providing Vaccinations Safely During A Pandemic which will also be shared with providers. The website will be updated as appropriate to include COVID-19 infection control resources. GIP will share all CDC COVID-19 safety monitoring information on the GIP website to assure that providers understand the process and protocols for VAERS.

CDC is also working to expand COVID-19 vaccine safety surveillance through new systems and additional information sources as well as by scaling up existing safety monitoring systems. This will give the CDC and FDA the ability to evaluate vaccine safety and make sure COVID-19 vaccines are as safe as possible.

V-Safe
A new voluntary, smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins for COVID-19 vaccine recipients. V-safe allows participants to report any side effects after the COVID-19 vaccination to CDC in almost real-time. It also gives them a convenient reminder to get their second COVID-19 vaccine dose if they need one.
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html

National Healthcare Safety Network (NHSN)
An acute-care and long-term care facility monitoring system that will promote reporting to VAERS. The new COVID-19 vaccine safety surveillance systems and any additional information sources will be shared with providers as it becomes available. https://www.cdc.gov/nhsn/index.html

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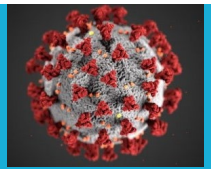

Section 15: COVID-19 Vaccination Program Monitoring

The GIP will assume responsibility for continuous monitoring for vaccine-related situational awareness throughout COVID-19 vaccination response activities. GIP will use capacity maps to monitor access to COVID-19 vaccines and ensure the accessibility of these services for critical populations. GIP will review available CDC dashboards (e.g., Weekly Flu Vaccination Dashboard and COVID-19 Vaccination Response Dashboard), as additional monitoring tools. GIP will work with the Pandemic Vaccine Planning Team to share identified issues and update this plan to address these issues. GIP will use the COVID-19 vaccine e-mail to provide an open-communication stream between COVID-19 vaccine providers and our office. GIP will adapt current VFC monitoring processes and guidance from the CDC to ensure the successful outcome of the COVID-19 vaccine program and response activities.

Monitoring COVID-19 Vaccination Program Implementation:

The GIP will continue to follow federal vaccination program guidelines to ensure providers enrolled in the COVID-19 vaccination program meet and continuously comply with program federal and state requirements as applicable. GIP and EP will continue collaborations with GEMA to update GIS maps as additional vaccine providers are enrolled in the program. This will aid us in identifying geographical areas in need of additional access points, educational outreach, etc.

GRITS staff will continue to monitor system activity to ensure any connectivity issues are quickly identified and remedied. GRITS staff will also work with providers to ensure reporting requirements are might and provide training and technical assistance upon enrollment or request.

Monitoring Resources

The Core Vaccine Planning Team will work with state and local partners to ensure the resources needed to perform vaccine response activities are maintained at levels necessary to respond. This will include the monitoring of budgets, staffing capacity, and supplies (e.g. ancillary supplies necessary to administer vaccines and appropriate personal protective equipment). The Core Vaccine Planning Team will provide support to address needs as they are identified.

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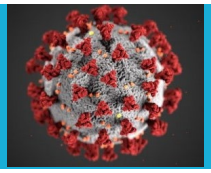

Appendix

Appendix A: Acronyms

Appendix B: Core COVID-19 Vaccine Planning Team and List of State and Local Partners

Appendix C: Georgia Priority Populations Vaccine Allocation Matrix

Appendix D: Critical Populations Data

Appendix E: Population Group Worksheet

Appendix F: COVID-19 Vaccine Pre-Enrollment Questionnaire

Appendix G: Georgia COVID-19 Vaccine Planning Frequently Asked Questions

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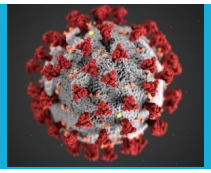

Appendix A: Acronyms

ACIP: Advisory Committee on Immunization Practices

CDC: Center for Disease Control and Prevention

DPH: Georgia Department of Public Health

EUA: Emergency Use Authorization

FDA: Federal Drug Administration

GEMA: Georgia Emergency Management Agency

GIP: Georgia Immunization Program

GRITS: Georgia Registry for Immunization Transactions and Services

IIS: Immunization Information System (GRITS in Georgia)

MCM: Medical Countermeasures

MVC: Mass Vaccination Clinic

POD: Point of Distribution

SNS: Strategic National Stockpile

SOP: Standard Operating Procedures

VAERS: Vaccine Adverse Event Reporting System

VIS: Vaccine Information Statements

VTrckS: CDC Vaccine Tracking System

NHSN: National Healthcare Safety Network

WIR: Wisconsin Immunizations Registry

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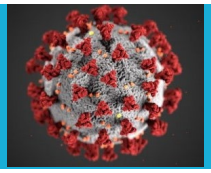

Appendix B: Core COVID-19 Vaccine Planning Team and List of State and Local Partners

Georgia Vaccine Task Force

- Office of the Governor
- Office of Insurance and Safety Fire Commissioner
- Georgia Department of Public Health
- Georgia Emergency Management and Homeland Security Agency

Georgia DPH Core COVID-19 Vaccine Planning Team

- **Division of Medical and Clinical Services**
  - Immunization Program
  - Office of Nursing
  - Office of Pharmacy

- **Division of Health Protection**
  - Emergency Preparedness Program
  - Office of Emergency Medical Services

- **Office of General Counsel**

State and Local Partners

- Georgia Public Health Districts (18)
- Georgia Chapter of American Academy of Pediatrics
- Georgia Hospital Association
- Georgia Health Care Association
- University System of Georgia
- Emory University
- Morehouse School of Medicine
- Georgia Primary Care Association
- Georgia Pharmacy Association
- Georgia Department of Community Health
- Georgia Department of Behavioral Health Disorders and Disabilities
- Georgia Alliant Quality – Quality Improvement for Alliant Health Solutions

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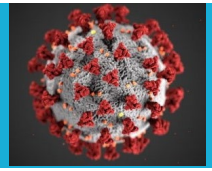
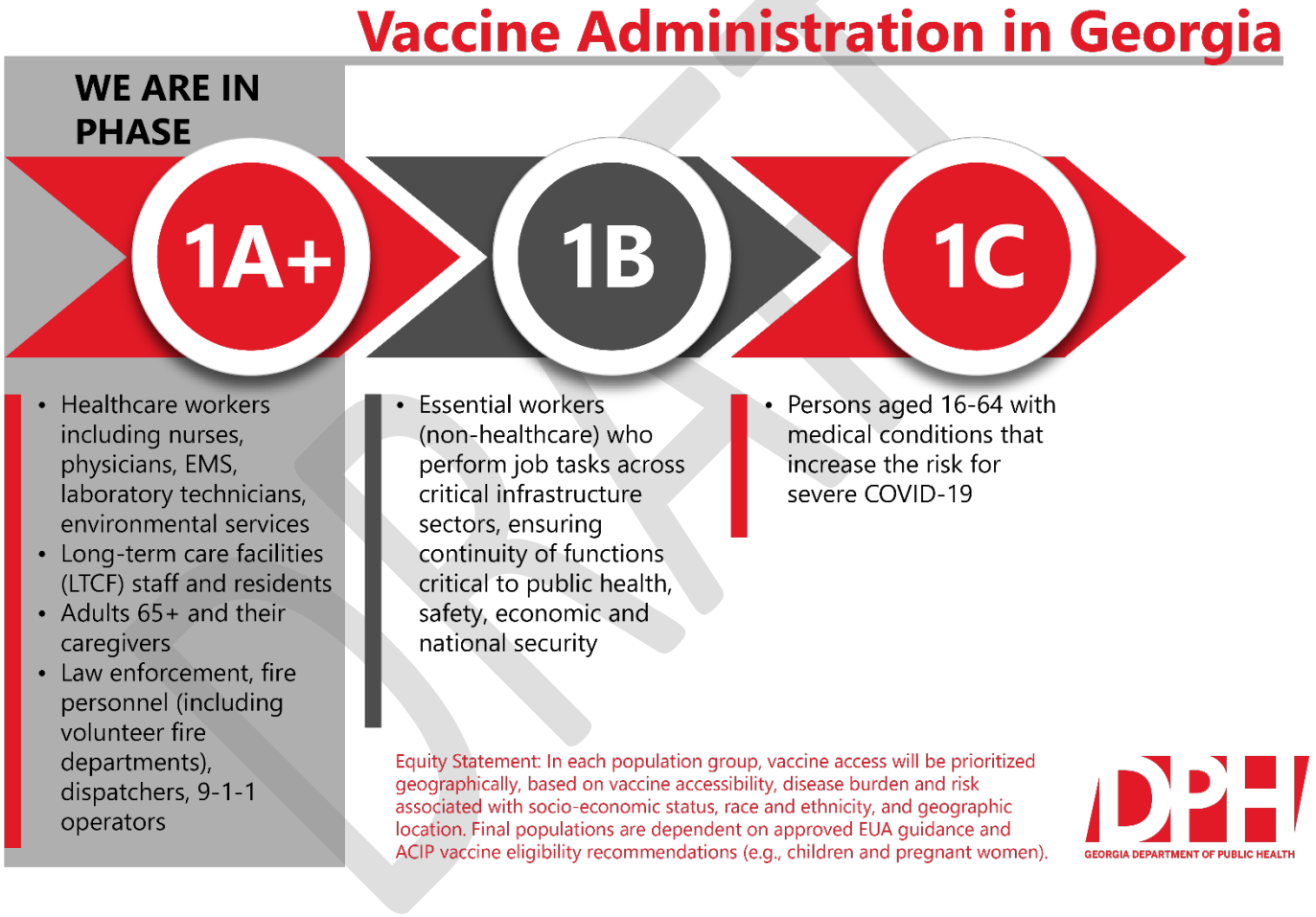
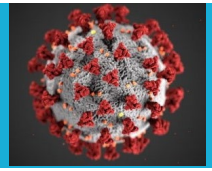


Appendix C: Georgia Priority Population Vaccine Allocation Matrix





Appendix D: Estimating Critical Populations in Georgia

Healthcare Personnel			
Subpopulation	Identify	Estimate	Data Sources
Practicing Physicians	Georgia Board of Health Care Workforce (https://healthcareworkforce.georgia.gov/)	22,471	• https://healthcareworkforce.georgia.gov/document/publication/distribution-physicians-practice-settings-2015/download • https://healthcareworkforce.georgia.gov/main-publications-reports/data-publications/counties-without-pcps • https://healthcareworkforce.georgia.gov/physician-workforce-data
Practicing Physician Assistants	Georgia Board of Health Care Workforce (https://healthcareworkforce.georgia.gov/)	3,810	• https://healthcareworkforce.georgia.gov/physician-workforce-data • https://healthcareworkforce.georgia.gov/physician-assistant-workforce-report
Practicing Nurses	Georgia Board of Health Care Workforce (https://healthcareworkforce.georgia.gov/)	141,117	• https://healthcareworkforce.georgia.gov/physician-workforce-data
Psychiatrists	Georgia Board of Health Care Workforce (https://healthcareworkforce.georgia.gov/)	1,097	• https://healthcareworkforce.georgia.gov/document/publication/psychiatry-distribution-georgia-2015/download
Dentists	Georgia Board of Health Care Workforce (https://healthcareworkforce.georgia.gov/)	5,143	• https://healthcareworkforce.georgia.gov/dentistry-workforce-reports
List of Providers (Physicians, Pharmacies, Nursing Services, Behavioral Health…etc.)	Georgia Department of Community Health (https://dch.georgia.gov/)	60,000 providers listed (some are facility-level)	• https://dch.georgia.gov/providers/provider-directory
Directory of Pharmacists	Georgia Department of Community Health (https://dch.georgia.gov/)	TBD	• https://gadch.mylicense.com/verification/Search.aspx
Critical Infrastructure Workers			

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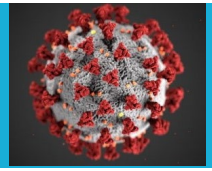

Subpopulation	Identify	Estimate	Data Source
Law Enforcement	US Census Bureau Annual Survey of Public Employment & Payroll (https://www.census.gov)	2,706 (police) 15,689 (corrections)	https://www.census.gov/data/datasets/2019/econ/apes/annual-apes.html
First Responders			
Public Safety			
Education	U.S. Census Bureau Annual Survey of Public Employment & Payroll (https://www.census.gov)	105,442	• https://www.census.gov/data/datasets/2019/econ/apes/annual-apes.html
Food & Agriculture			
Energy Sector			
Water & Wastewater			
Transportation & logistics	US Census Bureau Annual Survey of Public Employment & Payroll (https://www.census.gov)	3,828 (Highways)	https://www.census.gov/data/datasets/2019/econ/apes/annual-apes.html
Public Works & Infrastructure			
Long-term Care Facilities			
Subpopulation	Identify	Estimate	Data Source
	Georgia Department of Community Health (https://dch.georgia.gov/)		• https://dch.georgia.gov/announcement/2020-09-22/long-term-care-facility-covid-19-report
	Center for Medicaid and Medicare Services (https://data.cms.gov)	~27,000	• https://data.cms.gov/Special-Programs-Initiatives-COVID-19-Nursing-Home/COVID-19-Nursing-Home-Dataset/s2uc-8wxp
	Kaiser Family Foundation (https://www.kff.org/)	22,894	• https://www.kff.org/other/state-indicator/number-of-nursing-facility-residents/?activeTab=map&currentTimeframe=0&selectedDistributions=number-of-nursing-facility-residents&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D
Other Vulnerable Populations			

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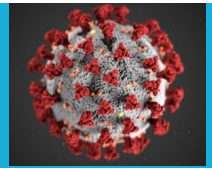

Subpopulation	Identify	Estimate	Data Source
People 65-years of age and older	Georgia Online Analytical Statistical Information System (https://oasis.state.ga.us)	1,516,954	• https://oasis.state.ga.us/oasis/webquery/qryPopulation.aspx
Homeless Population			
Refugees			
Migrant Workers			

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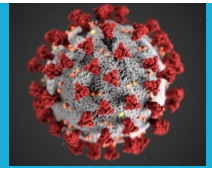

Appendix E: Population Group Worksheet Example

Health District: _____	Completed By: _____	Date: _____

Critical Population Group A: Healthcare Workers						
Sub-Group	**Agency/Organization**	**Point of Contact (POC)**	**POC Number**	**Contact e-mail**	**Key Group**	**Estimate # in Key Group**
Long Term Care						
Hospitals						
Public Health						
Pharmacists						
Other Healthcare						

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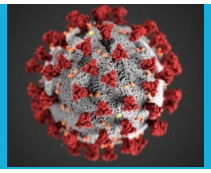

Appendix F: COVID-19 Vaccine Pre-Enrollment Questionnaire

COVID-19 Vaccine Pre-Enrollment Questionnaire

Please discuss the following questions with members of your facility/clinic. The questions asked here are for planning and preparation for the availability and distribution of the Novel COVID-19 vaccine. Completing the survey does not guarantee that your facility will be enrolled as a COVID-19 vaccine provider. Rather survey responses will be used to comprise a list of providers who are interested in becoming a COVID-19 vaccine provider.

1. Provider Contact Information:

   Name of Office:

   Address:

   County:

   Phone Number:

   Email:

   Person Completing the Questionnaire:

   Primary Contact Person:

2. The Best way to reach primary contact:

   ☐Phone

   ☐Email

3. Are you currently or have you ever been a Vaccines for Children (VFC) provider?

   ☐Yes

   ☐No

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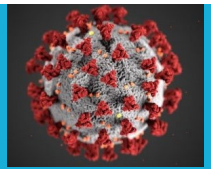

4. What is or was your VFC Provider Identification Number (PIN)?

5. Are you currently or have you ever been a GA Adult Vaccine Program (AVP) provider?

☐Yes

☐No

6. What is or was your AVP Provider Identification Number (PIN)?

7. Are you currently using GRITS to document vaccines administered in your office?

☐Yes

☐No

8. Do you enter vaccines for both pediatric and adult * patients in GRITS?

☐Yes

☐No

9. What is your GRITS organization code? (the capital letters you use to log into GRITS)

10. Do you manage your vaccine inventory in GRITS?

☐Yes

☐No

11. Please provide an approximate number of individuals who work or are clients of your practice, placing them in the appropriate category below:

Phase 1: Frontline Workers/First Responders:

Phase 2: Long Term Care facilities and other vulnerable populations:

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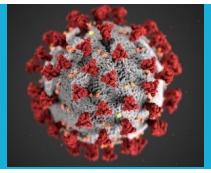

Phase 3: General Public (which would include children and other non-vulnerable adults):

12. What data source was used to provide your response to the question above (Question 11)? (Select all that apply)

- GRITS
- EMR/EHR
- Billing Data
- Other (please specify)

13. Do you currently have storage units that meet the CDC's minimum requirements for storing vaccines? (Information for vaccine storage units can be found in CDC's Vaccine Storage and Handling Toolkit located at this website:

https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html

☐Yes

☐No

14. Please provide information on the type of storage unit(s) (stand-alone refrigerator, stand-alone freezer, combination household unit, pharmaceutical-grade combination unit, etc.)

15. Do you currently have calibrated digital data loggers that can monitor storage units where the vaccine is stored? (Information for digital data loggers can be found in CDC's Vaccine Storage and Handling Toolkit located at this website:
https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html

☐Yes

☐No

16. When is the calibration expiration date? (Please enter expiration date in the following format: MM/DD/YYYY)

17. How often are you downloading the data from the data logger(s)?

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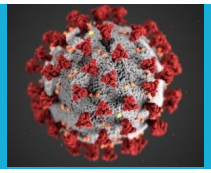

Please respond to each of the following statements:

18. Our clinic has the staff/capacity to serve as a mass vaccination pandemic site and will be willing to serve our patients following normal business practices, as well as our staff and members of our community during scheduled mass vaccination events.

☐Yes

☐No

19. Our clinic only has the staff/capacity to serve as a vaccination pandemic site for our current patient population and staff.

☐Yes

☐No

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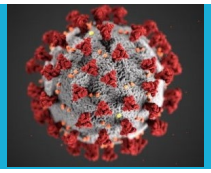


Appendix G: Georgia COVID-19 Vaccine Frequently Asked Questions

1. What does mass vaccination mean?

   Answer: A mass vaccination pandemic site is a site willing to serve their patients following normal business practices, as well as all members of the community during scheduled mass vaccination events.

2. How much will the vaccine cost?

   Answer: There is no charge for the COVID-19 vaccine. The vaccines have been paid for with federal funds at no cost to the patient nor provider, which means that no one may be charged a fee for the vaccine itself.

3. If given to providers free of charge, can we charge patients an administration fee?

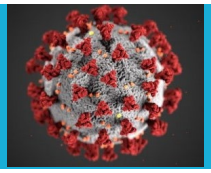
   Answer: Providers may charge a set fee of up to $21.93 to administer each dose. If the family cannot afford the fee, the fee must be waived, and vaccines administered free of charge.

4. Are we agreeing to vaccinate the general population, not just our clinic's patients?

   Answer: You have two options when expressing interest. You can either be a "*mass*" vaccination pandemic site or a "private" pandemic vaccination site:
   - **a. If your clinic has the staff/capacity to serve your patients following normal business practices, as well as, members of your community during scheduled mass vaccination events, you will be designated as a *mass* vaccination pandemic site and eligible to receive vaccine supply to serve your patient population and members of your community.**
   - **b. If your clinic *only* has the staff/capacity to serve your current patient population, you will be designated as a *private* pandemic vaccination site, and only receive vaccine supply to serve your patient population.**

5. In what ways may hospitals, urgent care facilities, emergency medical services, and other facilities assist in the state's vaccination efforts?

   Answer: You have three options when expressing interest. You can either be a closed point of dispensing (POD) site, *"mass"* vaccination pandemic site, or a "private" pandemic vaccination site:
   - **a. If your facility *only* can serve your staff, members of your staff's immediate household, and your admitted patient population, you will be designated as a closed POD and eligible to receive vaccine supply to serve these populations.**
   - **b. If your facility has the staff/capacity to serve your in-patients and out-patients following normal business practices, as well as, members of your community during**



scheduled mass vaccination events, you will be designated as a *mass* vaccination pandemic site and eligible to receive vaccine supply to serve your patient population and members of your community.

c. **If your facility *only* has the staff/capacity to serve your current patient population, you will be designated as a *private* pandemic vaccination site, and only receive vaccine supply to serve your patient population.**

6. If we are agreeing to vaccinate the population, what hours are required from us? Would this be after our normal business hours? During business hours? Are weekends required?

   Answer: Your clinic will be responsible for setting your mass vaccination clinic hours and reporting these hours to the Georgia Immunization Program. Clinics should account for the needs of your patient population and the community when establishing hours.

7. What compensation will our employees receive for vaccinating the population?

   Answer: While vaccine and ancillary supplies will be provided to participating providers at no cost to the provider or recipients, funding is not available to provide compensation for participating sites or your employees. Participation is voluntary.

8. Will supplies such as needles, syringes, Band-Aids, alcohol preps, and gauze be provided as they were when the H1N1 vaccine was released?

   Answer: Yes, providers will receive two different types of kits based on the vaccine supply received:

   a. **Administration Kits with needles, syringes, alcohol prep pads, facemasks, and face shields (all vaccines).**
   b. **Mixing Kits with needles/mixing syringes to support vaccines that require field mixing (as applicable).**
   c. **Sharps containers will not be supplied.**

9. If you complete the survey, are you committed to the program?

   Answer: No, Survey responses will be used to comprise a list of providers who have expressed interest in becoming a COVID-19 vaccine provider. Providers will be enrolled using a phased approach according to vaccine availability, and target populations served/willing to serve. (Please see the response to question 9 for more information regarding phases.)

10. For pediatric clinical sites, does the vaccine logistics include administering to adults, as well?

    Answer: Yes. If your clinic decides to be a mass vaccination pandemic site, you are agreeing to serve your patients and members of your community, including adults.

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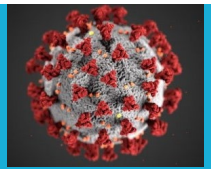

11. For adult clinical sites, does the vaccine logistics include administering to children, as well?

    Answer: Yes. If your clinic decides to be a mass vaccination pandemic site, you are agreeing to serve your patients and members of your community, including children.

12. Please explain how the program will roll out (logistics/planning type questions).

    Answer: Vaccines will be released in a phased approach:

    a. **Phase 1: Vaccines will be available in limited quantities and provided to closed points of dispensing (POD) partners to ensure vaccination of our Phase 1 targeted populations (First Responders, Emergency Personnel, Front-line Essential Workers, etc.)**
    b. **Phase 2: Vaccine will be available in higher quantities and provided to pandemic vaccination providers who agree to serve as mass pandemic vaccination sites, providers who serve members of Phase 2 targeted population (senior adults, patients with chronic medical conditions, etc.)**
    c. **Phase 3: Vaccine will be widely available and provided to providers mentioned above, as well as providers who agreed to serve as a pandemic vaccine site. Vaccines will be available for general administration to the general public based on vaccine recommendations.**

13. We only want to provide to our patients, if we do not participate, will we still have the vaccine to administer?

    Answer: If you only want to provide the vaccine to your patients, your clinic will need to sign up as a "private" pandemic vaccination site. We will ship the vaccine to your site once available and based on the phases outlined above.

14. Do all health departments need to complete a survey?

    Answer: Yes, every Health Department clinic that would like to be a vaccination site needs to complete a survey.

15. Will the allotment to Long Term Care Facilities (LTCF) include vaccination for staff family members?

    Answer: This will be dependent on vaccine availability, but we intend to supply vaccines to facility workers and their families. To assist us in preparing accordingly, please provide numbers for both facility staff, staff family members, and facility residents under separate categories.

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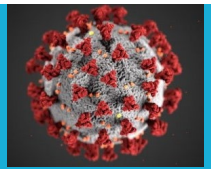

Answer: There is limited funding to support vaccine storage units and other supplies for district and county public health sites. However, private facilities will need to support their cold chain requirements.

16. Will there be a single-dose vaccine, or will a second dose be required at some point after the 1st dose?

    Answer: CDC has shared that vaccines may be available as both single-dose and 2 dose series. There will likely be different brands and preparations with varying administration schedules.

17. What procedures will be followed for the administration of the vaccine for children?
    Answer: Information for the pediatric vaccine(s) is currently not available. We will share that information once received.

18. Will the vaccine(s) go through the same FDA process as other vaccines, or have special considerations been made given due to the pandemic?

    Answer: The FDA process has been streamlined for Project Warp Speed (The Federal COVID-19 vaccine development project). The vaccines will undergo a review and approval process with FDA, but the exact form of approval is still pending, e.g., standard approval, emergency use authorization (EUA), etc.

19. Will ancillary supplies be provided with the vaccine to local health departments?

    Answer: Yes, ancillary supplies will be provided with the vaccines. Please refer to the response to Question 6 for more detailed information regarding anticipated supply kits.

20. Will our current contractual agency staffing be able to assist in giving the vaccine?

    Answer: Yes, if it is within their scope of practice to administer vaccines and within the scope of the DPH contract.

21. Who will give the injections at the closed POD locations?

    Answer: Staff within the closed POD may administer a vaccine based on their clinical scope.

22. After reviewing the slide (trying to read between the lines), it appears that we may have two or more different manufacturers of vaccines, and if you start with one, the second dose must be the same brand. When shipping out the vaccine to the closed pods will someone make sure that they get the same brand each time they receive a shipment?

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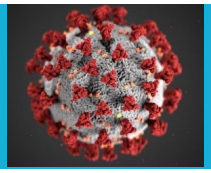

Answer: The allocations of vaccines will go through the DPH Office of Immunization and the CDC Distribution site. The CDC has indicated that you should receive enough vaccine in the first shipment to provide the second dose from the same brand. However, inventory management at the vaccination clinic site will play an important role in tracking this information and ensuring the vaccine is available to complete the patient vaccine series. Staff should also use GRITS as a resource for confirming previous doses administered if the first dose was received at an alternate location.

23. What kind of paperwork will closed PODs complete, and how will the information get into GRITS?

    Answer: Closed PODs should use electronic medical records and/or GRITS for data collection/submission. If a closed POD does not have access to GRITS, or their EMR does not interface with GRITS, please reach out to the Office of Immunization to work on a solution.

24. How will you make sure that closed PODs have digital data loggers and Koolatrons in place with a contact person to receive the vaccine?

    Answer: Determining whether a location can support the cold chain requirements for the vaccine and having designated staff to oversee vaccine management practices within each location is part of the enrollment process for becoming a provider. These items must be confirmed before marking a site as an active provider.

25. Does the vaccine follow the same regulations for temperature monitoring as other vaccines the state provides?

    Answer: Yes. Temperature monitoring requirements will be the same as other vaccines.

26. Are you developing just in time training with regards to the administration of the vaccine as well as storage and handling?

    Answer: Yes. Just in Time Training will be developed and shared with all vaccine providers.

27. Will vaccines be shipped to jails/ correctional institutions once the critical workforce has been vaccinated?

    Answer: No. Federal correctional institutions will receive guidance and vaccine directly from the CDC. If local public health would like to vaccinate at their county or local jails and are trying to develop a relationship, we have contacts with the 'Sheriff's Association to help establish the relationship, if needed. Additionally, the state vaccination planning team will work with the Georgia Department of Corrections to address their vaccination needs.

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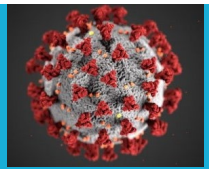

28. Should DPH Health Districts plan for the distribution of vaccines to EMS?

    Answer: Vaccines will be shipped to EMS sites directly from CDC's distribution center if they are actively enrolled as pandemic vaccine providers with the Office of Immunizations. If a district would like to support the storage of the vaccine to help its EMS partners, they may do so but need to ensure they have the capability/capacity to do so.

29. Do we need to plan for the cold chain for pre-filled syringes?

    Answer: This is a possibility, so please prepare for all presentation types (multidose vials, single-dose vials, and pre-filled syringes).

30. Can a closed POD plan for vaccination of targeted partners? For example, EMS vaccinating other first responders in the county.

    Answer: Yes, they should be able to administer the vaccine to other public safety agencies. Please make sure the EMS service provider consults their medical director for approval and coordinate with the DPH Office of EMS.

31. When will community engagement communication strategy documents be made available to begin education?

    Answer: The CDC recently released guidance that includes communication strategies. The DPH COVID-19 Planning Committee is working to develop a state plan that will include these strategies and provide a guide to vaccination partners once finalized.

32. How much education will be given to the public before vaccine administration?

    Answer: Our goal is to provide as much education as possible before the vaccines' availability. As we receive information from the CDC regarding education and guidance, we will work with DPH Communications, our state public health partners, and the districts to develop appropriate education strategies.

33. Does the State know the cold chain requirements for each of the products yet?

    Answer: We were briefed on three different parameters (but final requirements are not yet known):
    1. **Refrigerated: 2-8C**
    2. **Frozen: -20C**
    3. **Ultracold: -80C**

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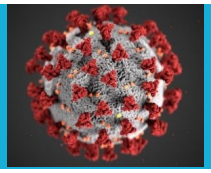

34. If given "free," how will we know if someone goes to another source to get the vaccine and then chooses to come to PH to receive an additional vaccine?

    Answer: All vaccinations should be recorded in GRITS following administration. This will allow clinical staff to view the recipient's record to determine vaccine history if this is suspected of an individual.

35. Can closed PODs get assistance with expanding cold chain capacity?

    Answer: If it is a public health county/district-based closed POD, yes. Please contact the Office of Immunization for further guidance. If it is a private provider, they should procure their cold chain management.

36. How do we dispose of the expired vaccine?

    Answer: Continue to provide a vaccine until it has reached its expiration date. If a vaccine expires, it may be returned to the manufacturer. We will provide more information regarding expired vaccines as we receive them.

37. What is the definition of "front-line workers"?

    Answer: The ACIP (Advisory Committee for Immunization Practices) is meeting next week (August 26) to discuss front-line workers based on risk exposure. A link will be posted on the morning of the meeting. These meetings generally begin at 8:00 AM. We will look for this link and share it with our partners once available. We will also have staff attend the meeting and provide additional information once received. The link for the recording of the July meeting is below:
    https://www.cdc.gov/vaccines/acip/meetings/live-mtg-2020-07.html

38. Where can I find information regarding liability immunity for covered persons during an emergency response event?

    The Declaration Under the Public Readiness and Emergency Preparedness Act (PREP Act) for Medical Countermeasures Against COVID-19 provides liability immunity to covered persons. The third amendment to the declaration defines "covered persons".

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