



# COVID-19 Vaccination Plan

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MASSACHUSETTS

Massachusetts Department of Public Health  
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# MASSACHUSETTS COVID-19 VACCINATION PLAN

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INTERIM DRAFT



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## Section 1: COVID-9 Vaccination Preparedness Planning

### Planning and Preparedness Activities

Early in the COVID-19 pandemic, the Massachusetts Department of Public Health (MDPH) recognized the need to prepare a statewide vaccine strategy to ensure capacity and mount a campaign once a vaccine is approved by the U.S. Food and Drug Administration (FDA) and doses become available.

As part of this early planning, MDPH reviewed the lessons learned and improvement planning from the 2009 H1N1 vaccination campaign. At the conclusion of that pandemic, MDPH held an after-action conference and developed a formal After Action Report/Improvement Plan (AAR/IP), with areas of improvement highlighted for particular offices and bureaus.

In the summer of 2019, MDPH participated in the federal level pandemic planning exercise Crimson Contagion. Massachusetts was the lead state for the U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) Region I. Given that the scenario of the exercise was built around an influenza pandemic, the AAR/IP from Crimson Contagion was reviewed to further guide the planning for the upcoming COVID-19 vaccination campaign.

Several items highlighted between the two AAR/IP documents are currently being used to strengthen planning efforts. These include:

- Considering ways to expand the pool of individuals who can provide vaccinations — this includes commercial vaccinators
- Reviewing internal processes to streamline or adjust guidance to allow for changes to be communicated to health care providers in a timely manner
- Reviewing both existing and new platforms/sources of data to support identification of population groups by traditional demographic data points, as well as by geography

### Exercises and Continuous Improvement Activities

The MDPH Office of Preparedness and Emergency Management (OPEM) will coordinate ongoing assessment and maintenance of the Massachusetts COVID-19 Vaccination Plan through a series of discussion-based exercises. All MDPH exercises will be planned and evaluated following Homeland Security Exercise and Evaluation Program (HSEEP) guidelines. We will develop an AAR/IP and disseminate it following each exercise, and track completion of corrective actions by the OPEM Planning and Exercise Unit to support continuous improvement activities.

To assess what components of the plan need to be operationalized and to align appropriate resources, MDPH will work with exercise and training staff and vendors to develop a Tabletop Exercise (TTX) for each of the three phases of vaccine availability, as well as the vaccine-based scenarios, as described in the Centers for Disease Control and Prevention (CDC) Interim Playbook. Each TTX will include the appointment of a planning team that has representation from multiple agencies and sectors, including those who serve/support individuals within the identified critical populations to support the design, development, conduct, evaluation, and improvement planning of each exercise. The first exercise will occur in Calendar Year (CY) 2020 fourth quarter (Q4) and subsequent exercises will occur in CY 2021 Q1 and Q2. As appropriate, plan updates will be made to address identified corrective actions.

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## Section 2: COVID-19 Organizational Structure and Partner Involvement

### Massachusetts Department of Public Health Organizational Structure

The Massachusetts Department of Public Health (MDPH) is one of 12 agencies, in addition to two soldiers' homes and the MassHealth program, within the Executive Office of Health and Human Services (EOHHS), the largest secretariat in state government. MDPH promotes the health and well-being of all residents by ensuring access to high-quality public health and healthcare services, and by focusing on prevention, wellness, and health equity in all people. Led by the Commissioner of Public Health, MDPH regulates, licenses, and provides oversight of a wide range of healthcare-related professions and services, and focuses on preventing disease and promoting wellness and health equity for all people.

The Commissioner oversees a public health workforce of nearly 3,000, and a department comprised of eight bureaus and six offices responsible for a range of programs, including environmental health, surveillance and prevention of diseases dangerous to the public health, injury prevention, and maternal and child health. In addition, the department licenses health professionals and facilities that impact public health, and operates the state public health laboratory and four public health hospitals.

### Bureau of Infectious Disease and Laboratory Sciences

The Bureau of Infectious Disease and Laboratory Sciences (BIDLS) works to protect everyone in Massachusetts from over 90 infections and associated human disease by providing infectious disease prevention and surveillance, health information and education, promotion of immunizations and distribution of vaccines, and laboratory testing to medical professionals, hospitals, local health departments, other state agencies, community-based organizations, schools, correctional facilities, first responders, and the general public.

The BIDLS Immunization Division is the lead for COVID-19 vaccination planning, distribution, and implementation efforts hereinafter referred to as Massachusetts COVID-19 Vaccination Program (MCVP).

Five units make up the Immunization Division, and each unit will be integral to the success of the MCVP:

- Outreach Unit collaborates with stakeholders and partner organizations to promote immunization, as well as overseeing educational programs, trainings, conferences, and web and social media postings
- Nursing Unit follows up on cases of Perinatal Hepatitis B, provides clinical education, delivers training and technical assistance on immunizations, and conducts quality assurance visits with providers to increase immunization rates
- Vaccine Unit enrolls providers to receive state supplied vaccines, manages state supplied vaccine supplies and orders, and responds to vaccine storage and handling issues
- Assessment Unit cleans, analyzes, and reports immunization data both internally and externally — Quality Assurance Analysts in the Assessment Unit conduct site visits at provider offices to ensure compliance with state and federal vaccine requirements
- Massachusetts Immunization Information System (MIIS) Unit registers users for the MIIS (allowing providers to electronically report immunization data via their Electronic Health Record [EHR] system), and provides technical and programmatic assistance to providers

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The Immunization Division Director manages the entire Division and directly oversees the Vaccine, Nursing, and Outreach Units. The Immunization Division Director is responsible for the MCVP. The Associate Director directly oversees the MIIS and Assessment Units, and will support the Immunization Division Director in running the MCVP. Each Unit is led by a member of the Immunization Division's senior management team.

In addition to the Immunization Division, the following MDPH offices and bureaus have critical roles and responsibilities for the successful implementation of the MCVP.

## Bureau of Community Health and Prevention

The Bureau of Community Health and Prevention (BCHAP) promotes the health, safety, and well-being of the people in Massachusetts with programs that serve individuals, communities, and organizations in four main areas: chronic disease prevention and wellness; violence and injury prevention and services; access to quality health services; and surveillance of disease and injury. BCHAP will support the Immunization Division with communications planning.

## Bureau of Health Care Safety and Quality

The Bureau of Health Care Safety and Quality (BHCSQ) serves as the primary regulator of health care facilities (including hospitals, long-term care facilities, clinics, rest homes, adult day health, and other licensed facilities) in the Commonwealth. BHCSQ manages several large programs and data initiatives, including the data collection and analysis of Serious Reportable Events, Health Care Associated Infections, the Office of Emergency Medical Services (OEMS), and Health Care Personnel Influenza Vaccination. BHCSQ will support the Immunization Division, providing outreach and coordination with health care facilities in support of MCVP implementation activities.

## Bureau of Health Professions Licensure

The Bureau of Health Professions Licensure (BHPL) oversees and supports the Drug Control Program (DCP) and 10 boards of registration and certification in health professions. BHPL assesses the qualifications of applicants for health care professional licensure, registration, and certification. Standard rules and regulations set by the boards ensure the integrity and competence of all health care professionals in Massachusetts, and promote public health, wellness, and safety. BHPL will support the Immunization Division with outreach and coordination with health care professionals and the Board of Registration in Pharmacy.

## Office of Communications

The Office of Communications supports the MDPH mission to promote the health and well-being of all residents by ensuring access to high-quality public health and health care services, and by focusing on prevention, wellness, and health equity in all people. The Office of Communications, with support from other state agencies and offices, will develop and implement the MCVP Communications Plan.

## Office of Local and Regional Health

The Office of Local and Regional Health (OLRH) provides regular, timely communication of information and data from MDPH to local public health, and develops resources for local public health in response to identified needs. OLRH will support the Immunization Division with outreach and coordination with local boards of health in support of MCVP implementation activities.

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## Office of Population Health

The Office of Population Health (OPH) manages the contract with Boston University School of Public Health (BUSPH) for Social Vulnerability Index (SVI) analysis and related mapping support. Within OPH, the Office of Health Equity (OHE) works to address social determinants so all Massachusetts residents can attain their full health potential. OHE promotes principles and policies that inform the way health services are designed and delivered, and serves as an agency-wide resource by providing technical help to MDPH programs to address health inequities. OHE will support the Immunization Division by providing guidance to assure the MCVP addresses health inequities.

## Office of Preparedness and Emergency Management

The Office of Preparedness and Emergency Management (OPEM) provides planning and preparedness resources for disasters, outbreaks, and other large-scale public health emergencies and will support the Immunization Division with COVID-19 Vaccination Plan development expertise, as well as the development of exercises in support of plan implementation and post-incident debriefs. OPEM provides situational awareness on health and medical issues to the public health and healthcare communities, and is responsible for coordination of health and medical resources during a public health emergency, as needed. OPEM works with the Massachusetts Emergency Management Agency (MEMA) and federal partners to request deployment of state and federal assets.

## Massachusetts COVID-19 Vaccination Program Structure

Governor Baker established the COVID-19 Response Command Center, led by the Massachusetts Health and Human Services Secretary, on March 14, 2020. The Command Center serves as the single point of strategic decision-making and coordination for the Commonwealth's comprehensive COVID-19 response. The Command Center holds regular briefings with the Governor, and key secretariats and agencies, and communicates regularly with other stakeholders, such as municipalities and local boards of public health. The Command Center will provide strategic guidance for the MCVP, and coordinate information exchange and planning across state secretariats and agencies.

In order to coordinate the requirements for the MCVP, MDPH formally launched its internal COVID-19 Vaccine Planning Structure on August 13, 2020, to engage critical partners across MDPH (and identified external partners as required) in the planning, development, and implementation of the MCVP. A team of experts from across MDPH offices and bureaus serve on three work groups. There are primary and back-up representatives for each office and bureau on each of the relevant work groups to ensure continuity in the planning and implementation of the MCVP.

## Massachusetts COVID-19 Vaccine Advisory Group

The Baker-Polito Administration announced on October 7, 2020, a COVID-19 Vaccine Advisory Group to advance its efforts to prepare to distribute a safe and effective COVID-19 vaccine once it becomes available. Comprised of medical professionals, public health experts, elected officials, community leaders and infectious disease specialists, the COVID-19 Vaccine Advisory Group will advise the Administration, on communication, distribution, and equity issues relating to a COVID-19 vaccine.

The Commonwealth has actively been working on preparedness and planning for a COVID-19 vaccine since early August. This work builds on and enhances the state's experience in distributing approximately 3 million vaccine doses each year. The group will help inform the planning and

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preparedness work already underway and further strengthen efforts to successfully and equitably allocate, distribute and administer a safe and effective COVID-19 vaccine.

Representatives from the following organizations are participating in the working group:

- Mass General Brigham (Chair)
- Beth Israel Lahey Health
- Boston Children's Hospital
- Boston Medical Center
- City of Lawrence
- CVS Health
- Franklin Regional Council of Governments
- Harvard T.H. Chan School of Public Health
- Massachusetts League of Community Health Centers
- Massachusetts Medical Society
- Massachusetts State House of Representatives
- Massachusetts State Senate
- Roxbury Presbyterian Church
- South Shore Hospital
- University of Massachusetts Medical School

## Leadership Group

- Provides leadership guidance for development of the Massachusetts COVID-19 Vaccination Plan
- Reviews federal guidance to align state planning and implementation activities with federal orders and policies
- Makes recommendations for policy, surveillance, and clinical considerations to support the implementation of the Massachusetts COVID-19 Vaccination Plan
- Provides recommendations to the MDPH Commissioner who recommends to the Governor's COVID Command Center

Membership includes representatives from the following MDPH offices/bureaus, state agencies, and external partners:

- MDPH Bureau of Infectious Disease and Laboratory Sciences (BIDLS) (Lead)
- MDPH Bureau of Health Care Safety and Quality (BHCSQ)
- MDPH Bureau of Health Professions Licensure (BHPL)
- MDPH Commissioner's Office

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- Legislative Affairs Office
- Office of Communications
- Office of the General Counsel (OGC)
- Office of Health Equity (OHE)
- Office of Preparedness and Emergency Management (OPEM)
- Regulatory Affairs
- Massachusetts Emergency Management Agency (MEMA)

The Leadership Group has Legal and Clinical Sub-Groups

## **Logistics and Operations Group**

- Coordinates development of the Massachusetts COVID-19 Vaccination Plan and requisite implementation planning activities
- Makes recommendations for policy, operational and communications updates to facilitate seamless distribution of the vaccine

Membership includes representatives from the following MDPH offices/bureaus:

- MDPH Commissioner's Office
  - Office of Preparedness and Emergency Management (OPEM) (Lead)
- MDPH Bureau of Infectious Disease and Laboratory Sciences (BIDLS)
- MDPH Drug Control Program (DCP)
- MDPH Office of Emergency Medical Services (OEMS)
- MDPH Office of Local and Regional Health (OLRH)
- MDPH State Office of Pharmacy Services (SOPS)

## **Communications Group**

- Develops communication goals and priorities for the MCVP
- Develops and implements the MCVP communications plan structured around the audiences, the messages, tools, delivery channels, and the time/phases
- Coordinates internal messaging for MDPH

Membership includes representatives from the following MDPH offices/bureaus, state agencies, and external partners:

- MDPH Commissioner's Office
  - Office of Communications (Lead)
  - Legislative Affairs Office
  - Office of the General Counsel

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- Office of Health Equity (OHE)
- Regulatory Affairs
- MDPH Bureau of Community Health and Prevention (BCHAP)
- MDPH Bureau of Health Care Safety and Quality (BHCSQ)
- MDPH Bureau of Health Professions Licensure (BHPL)
- MDPH Bureau of Infectious Disease and Laboratory Sciences (BIDLS)
- Executive Office of Health and Human Services (EOHHS)
- Massachusetts COVID-19 Command Center
- Massachusetts Emergency Management Agency (MEMA)

## Coordination with Regional, State and Local Authorities

Massachusetts is one of six New England states. Although geographically small (45th in area among the 50 states), 2010 Census data ranks the Commonwealth 14th in population (6,547,629), and fifth in terms of population density. There are 49 cities and 302 towns in the Commonwealth. More than half of the state's residents live in the area bounded on the west by Interstate Highway 495, and on the east by the Atlantic Ocean.

### Federal Regional Coordination

As part of the U.S. Department of Homeland Security (DHS)/Federal Emergency Management Agency (FEMA) and U.S. Department of Health and Human Services (HHS) Region I (along with Maine, New Hampshire, Vermont, Rhode Island, and Connecticut), Massachusetts participates in standing weekly calls hosted by FEMA and the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) to discuss response coordination with public health and emergency management agencies across the six New England states. Massachusetts participates in the planning and contributes to the development of the COVID-19 Regional Federal Support Plan for vaccination planning within Region I.

### Massachusetts Local and Regional Coordination

Massachusetts has a decentralized public health system, with each of its 351 cities and towns having its own governing body and health board with authority to provide public health services to its residents. This has resulted in a significant range of capacity with respect to staffing at the local level.

MDPH's Office of Local and Regional Health (OLRH) provides leadership in collaboration with internal and external public health stakeholders to strengthen the capacity of Massachusetts local boards of health to protect the health of their communities and to deliver essential public health services. OLRH strengthens partnerships with municipalities through the Massachusetts Large Cities Project and Massachusetts Rural Local Public Health Project. OLRH coordinates its efforts with external stakeholder including the Coalition for Local Public Health, Local Public Health Institute, Western Massachusetts Public Health Association, and the Massachusetts Public Health Regionalization Working Group.

OLRH has been instrumental in coordinating with local boards of health throughout the COVID-19 response and will leverage existing communications and outreach mechanisms in support of the MCVP. These existing mechanisms include:

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- Conducting MDPH-led bi-weekly conference calls with boards of health on Tuesdays and Fridays to provide critical COVID-19 updates and an opportunity for questions and answers
- Conducting MDPH-led weekly conference calls with the largest cities, public health district leadership, and leads of affiliate organizations for critical updates, networking, and sharing of experiences and best practices
- Sending regular, timely email updates to the 351 cities and towns with critical news, updates, guidance, and other information — we number the updates for accessibility and tracking purposes
- Amplifying MDPH risk communication messages by posting information on partners' websites and social media and referring residents to Massachusetts' non-emergency service telephone number, Mass 211, for support
- Fostering regional collaboration for more effective and efficient delivery of services through new funding-driven relationships, or long-standing formal and informal inter-municipal collaborations

## Health and Medical Coordinating Coalitions

There are currently six regional Health and Medical Coordinating Coalitions (HMCCs) in Massachusetts that conduct capabilities-based, cross-disciplinary planning and support for public health and provide medical response during emergencies and disasters. Core disciplines are acute care hospitals, community health centers, emergency management, emergency medical services, long-term care, and local public health.

HMCCs support integrated planning and capacity-building across the six core disciplines. As part of the prior cooperative agreement, each HMCC developed an Emergency Coordination Plan and annex to support resource sharing and coordination. During an emergency, each will work within their regions to coordinate information gathering, situational awareness, and resource requests. HMCCs have the capacity to stand-up a multi-agency coordination center to support regional response and recovery activities, and can be leveraged to support vaccine planning and coordination among their stakeholders.

HMCCs work closely with other health and medical partners and build strong connections with emergency management and public safety/first responder organizations within the region, as well as other public and private organizations with a role under Emergency Support Function 8 (ESF8), public health and medical services. HMCCs participate in mitigation activities as identified through planning and response activities and in cooperative training, including National Incident Management System (NIMS) and Homeland Security Exercise and Evaluation Program-compliant exercising of regional plans.

## Public Health Preparedness Planning Coalitions

Within each HMCC are public health preparedness planning coalitions, accounting for a total of 15. Each coalition is funded with Centers for Disease Control and Prevention Public Health Emergency Preparedness (CDC PHEP) funds to build jurisdictional-level capacity to prepare for, respond to, and recover from public health emergencies, and mitigate the impacts. Included in their scope is the development and testing of Emergency Dispensing Sites (EDS). There are more than 500 primary and secondary sites identified in Massachusetts.

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## Coordination with Tribal Nations

Massachusetts is home to two federally recognized tribal nations, the Wampanoag Tribe of Gay Head (Aquinnah) and the Mashpee Wampanoag Tribe. With a combined enrollment of 3,903 members, both tribes are located in southeast Massachusetts and receive CDC PHEP funding.

There is one tribal health center, which is a Vaccines for Children (VFC) program enrolled provider. In addition, each tribal nation has an EDS plan and community centers that can serve as vaccine administration sites.

Outreach and coordination to the Wampanoag Tribe of Gay Head (Aquinnah) and the Mashpee Wampanoag Tribe is part of the vaccination community and stakeholder engagement planning process.

## Coordination with Key Partners for Critical Populations

MDPH is developing engagement strategies with key partners in support of the vaccination strategy for critical populations. Key partners include, but are not limited to:

- Community-based organizations
- Community health centers
- Correctional facilities
- Councils on Aging
- Shelters serving vulnerable populations
- Local education authorities
- 24/7 congregate care settings
- Higher education institutions
- Long term care facilities
- Acute Care Hospitals
- Meals programs
- Pharmacies
- Substance use disorder treatment programs
- Mental and Behavioral Health treatment programs
- Urgent care clinics

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## Section 3: Phased Approach to COVID-19 Vaccination

The Massachusetts COVID-19 Vaccination Plan is aligned with the three phases of vaccine availability, as well as the vaccine-based scenarios, as described in the U.S. Centers for Disease Control and Prevention (CDC) COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations Version 1.0, dated September 16, 2020 (Interim Playbook). The goal is to maximize vaccine acceptance and public health protection, while minimizing waste and inefficiency. The Massachusetts COVID-19 Vaccination Program (MCVP) will monitor vaccine inventory, distribution, and any repositioning of the vaccine to ensure end-to-end visibility of vaccine doses throughout all phases of the MCVP. As outlined in Section 5, the MDPH Immunization Division will be engaging in active recruitment and enrollment of all immunizing provider sites to fully support all three phases of the COVID-19 vaccination effort outlined below.

### Phase 1: Potentially Limited Supply of COVID-19 Vaccine Doses Available

Based on the scenarios provided by the CDC in the Interim Playbook, Massachusetts can expect initial allocations of between 20,000 and 60,000 doses of COVID-19 vaccine. Based on this scenario, MDPH anticipates prioritizing the following populations:

- Healthcare personnel (HCP) likely to be exposed to or treat people, with COVID-19
- People at increased risk for severe illness from COVID-19, including those with underlying medical conditions and people 65 years of age and older
- Other essential workers

CDC guidance as outlined in the CDC Interim Playbook further refines the target groups for when vaccine is very limited as follows:

- **Phase 1a:** Paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials and are unable to work from home
- **Phase 1b:** Other essential workers and people at risk for severe COVID-19 illness, including people 65 years of age and older

Because the first doses of the vaccine are likely to be targeted to HCP in contact with COVID-19 patients, MDPH is prioritizing hospitals, long term care facilities, including skilled nursing facilities (SNF), emergency medical services (EMS), and other health care providers for recruitment and enrollment in the MCVP. MDPH is coordinating with commercial vaccinators to register them in the Massachusetts Immunization Information System (MIIS), if they are receiving COVID-19 vaccine through federal agencies. Commercial vaccinators may assist hospitals and other entities to maximize throughput at vaccination clinics, while maintaining infection control procedures.

Initial allocations of the vaccine will depend on the following factors:

- The provider's ability to reach the populations targeted
- The provider's ability and readiness to manage cold chain requirements, and to meet reporting requirements for vaccine administration
- The provider's predicted immunization throughput

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- The available vaccine's/vaccines' characteristics, including the age group for which each vaccine is recommended by the ACIP

MDPH knows that this initial allocation of vaccine will be insufficient to immunize all providers associated with health care institutions and long-term care facilities. Within each participating facility prioritized by MDPH, prior identification of clinical providers and non-clinical staff with anticipated direct contact with COVID-19 patients, patients over 65, and those with specific co-morbid conditions will be identified and flagged for prioritized vaccine allocation. Strict allocation management by facility and specificity of eligible recipients at the facility level will be required to ensure complete and equitable distribution of vaccine in this initial phase.

Hospitals and large medical centers providing care to COVID-19 patients have existing emergency preparedness plans that include strategies for the rapid and structured delivery of needed immunizations to direct-case clinical and non-clinical staff. It will be expected that facilities will utilize their EP systems to allocate vaccine according to the protocols as outlined.

Given the constrained clinical and administrative capacity of some skilled nursing facilities (SNFs) and the successful deployment of SARS-CoV-2 testing to skilled nursing, assisted living, other LTCFs and congregate care settings, Massachusetts intends to seek deployment the Massachusetts National Guard to provide supplementary support for immunization of their staff and residents and for reporting of immunizations to the MIIS.

## Phase 2: Large Number of Vaccine Doses Available

In Phase 2, MDPH ensure continued access to vaccine for the populations listed above in Phase 1 and begin to provide vaccine for the broader population. To prepare for this phase, MDPH is broadening its vaccine provider network. In addition to the local health departments, hospitals, community health centers (CHCs), and pediatric providers who are the mainstay of the current Vaccine Program, MDPH is reaching out to a broader range of health care providers in the state who currently are not reporting immunization data to the MIIS and asking them to register with the MIIS. The MDPH Immunization Division will send an email to all licensed physicians and advanced practice nurses in the state specializing in internal medicine, family medicine, obstetrics, and gynecology, via the Health and Homeland Alert Network (HHAN). These physicians will receive information on how to enroll in the MCVF. See *Section 5: COVID-19 Vaccination Provider Recruitment and Enrollment*.

This broad network of vaccine providers will enable the timely distribution of doses in anticipation of a surge in demand for the vaccine. MDPH will continually monitor vaccine usage and adjust allocation strategies to minimize vaccine wastage in the event demand for the vaccine in certain areas is lower than expected.

During this phase of allocation MDPH will be highly reliant on the capacity of its community-based health system, in particular its over 52 community health centers (CHCs, comprised of Federally Qualified Health Centers [FQHCs] and look-alike members of the Mass League of Community Health Centers), in over 280 sites which have deep, prior relationships with communities of color and African American, Latinx, Asian/Pacific Islander, LGBT, and non-US born communities, considerable cultural and linguistic capacity, a substantial community health worker staff complement, and health care accessibility at the local level.

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Supplementary, targeted immunization access will also involve the extensive network of commercial and clinic-based pharmacies. Ongoing coordination with pharmacies continues; their registered pharmacists and supervised pharmacy interns are authorized under Massachusetts regulation and policy to administer the full range of vaccines for individuals age 3 and older.

Depending on the volume of vaccine over the course of this phase and on the analysis of immunization capacity and population need outlined in Sections 4 and 6 of this Plan, activation of locally organized Emergency Dispensing Sites (EDS) may be necessary to ensure timely local immunization access in some geographic areas, particularly those with limited hospital/health center capacity.

Close and ongoing analysis of vaccine allocation and administration in clinical facilities and pharmacies throughout this phase will be needed to ensure equitable access by geography and affected community, and the nimble ability to adjust allocations to prevent and address immunization inequity.

### Phase 3: Sufficient Supply of Vaccine Doses for the Entire Population (Surplus of Doses)

When there is an adequate supply of COVID-19 vaccine for everyone, the MCVP will focus on ensuring equitable vaccination across the entire population. The MCVP will continuously monitor vaccine uptake and coverage to identify underserved areas or populations in the state.

When areas of low vaccine uptake are identified, the MCVP will more aggressively recruit and enroll providers in those areas and/or direct vaccinators to those communities. MDPH will partner and collaborate with local communities to identify informational, attitudinal, and resource obstacles and barriers to COVID-19 vaccination and develop culturally appropriate strategies to address them, including the engagement of trusted community leaders and influencers within identified communities.

Throughout all phases of the MCVP, MDPH will continue to broaden its provider network to expand access to the vaccine and, where necessary, partner with vaccinators to fill identified gaps. Training of COVID-19 vaccine providers will continue throughout the program (See *Section 5: Provider Recruitment and Enrollment*).

During this phase of vaccine access, the full complement of hospital, CHCs, pharmacies, EDS, and locally organized immunization clinic capacity will be needed to manage the volume of vaccine administration and meet community demand. Careful planning for ancillary supplies, appointment management, social distancing strategies/masking sufficiency, MIIS data entry, and post-vaccination patient observation will need to be performed, with MDPH guidance, at each point of vaccine access.

Clear and reinforced communication will be needed to reach all residents of Massachusetts about the broad, free availability of vaccine, vaccine safety and efficacy, the mechanisms for accessing vaccine, and the urgency to seek timely immunization through this network of trusted immunization sites. Targeted communications to individuals and communities anticipated and observed to be more hesitant to COVID-19 immunization will need to come from local providers and organizations, including the growing corps of culturally competent community health workers, to address concerns and misinformation and support making appointments and making plans for safe travel to local immunization sites.

During this phase, paramedics working with local Emergency Medical Services providers, who have been active in delivering SARS-CoV-2 testing statewide with the practical support of Emergency Medical Technicians, will be useful adjuncts to Phase 3 immunization plans, as they can be deployed responsively to observed gaps in immunization coverage, set up neighborhood-level access points, and

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support clinical and non-clinical institutions facing greater-than-anticipated demand. Locally organized Mobile Integrated Health (MIH) programs can be the organizing framework for these providers, directed by city/town governments, and coordinated with local health department immunization plans.

In order to ensure that the cost of administering COVID-19 vaccine is not a barrier to providers enrolling in the program, the federal Health Services and Resources Agency (HRSA) announced that pursuant to the CARES Act, it will reimburse providers for the cost of administering COVID-19 vaccine to people who are uninsured and Medicare Part D will reimburse for administering the vaccine to those who carry Part D. MDPH is starting to work with MassHealth, the state Medicaid program, and private insurers to secure their participation in the program.

### Equitable Access to COVID-19 Vaccine

MDPH is committed to ensuring that everyone in the Commonwealth has access to COVID-19 vaccination services and information. To optimize equitable access to the vaccine for all critical populations and achieve high vaccination coverage in these groups, as well as in the general public, MDPH, especially the Offices of Local and Regional Health (OLRH), Community Health Planning and Engagement, Office of Health Equity (OHE), and Rural Health, and external partners will work with local communities to address cultural and linguistic barriers and other impediments to vaccination. See *Section 12: Vaccination Program Communication*.

As part of enrollment in the MCVP, providers will agree to not deny vaccine to any patient because of inability to pay. In addition, during training and through other communications with providers, they will be firmly instructed to not inquire about immigration status for anyone seeking the vaccine.

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## Section 4: Critical Populations

The Massachusetts Department of Public Health (MDPH) Infectious Disease Emergency Response Plan (IDER) v2.0 February 2020, includes general estimations for Seasonal Influenza Vaccine priority groups through extrapolation of national estimates as listed in the 2018 Interim Updated Planning Guidance on Allocation and Targeting Pandemic Influenza Vaccine. Using this data along with Centers for Disease Control and Prevention (CDC) COVID-19 guidance in the Interim Playbook on the three phases of vaccine availability, MDPH will identify and prioritize critical populations within the Commonwealth consistent with National Academies of Sciences, Engineering, and Medicine (NASEM) recommendations the final prioritization of the Advisory Committee on Immunization Practices (ACIP). In addition, MDPH will refer to emerging evidence of historic and COVID-19-specific vaccine hesitancy and under-immunization risk. Particular concerns surround the African American and other Black communities who have expressed concerns about vaccine safety and efficacy, linguistic minorities who may have lesser access to current and reliable information about the vaccine, and some non-US born residents who may have concerns related to governmental engagement related to immigration status.

Once critical populations are identified, MDPH will identify parameters and data sets needed to inform the prioritization model for the distribution of the vaccine by phase (and subsets of populations within in each phase), and by priority group and location. This will be followed by completing the model, projections, and requisite mapping. This planning will be completed with a social equity lens to ensure the critical populations reflect the most vulnerable. These have included enumerating populations in need of testing. MDPH will engage the services of a vendor to provide analytical capacity and will be charged with utilizing U.S. Census (and reliable intercensal estimates of populations conducted by the University of Massachusetts Donahue Institute) to characterize communities at the city/town level—with reference to current trends in COVID-19 infections—at the subpopulation level (occupation, housing type, school enrollment, race/ethnicity, primary language, health care access, co-morbidities, socioeconomic factors), and perform analysis using the CDC's Social Vulnerability Index to assess the interaction of these forces on the likelihood members of critical populations will accept, seek, and be able to access COVID-19 vaccine.

The analysis will also include Massachusetts Immunization Information System (MIIS) data, both current influenza vaccination patterns—as a proxy for likely COVID-19 vaccine coverage to identify pockets of lower coverage to further refine critical populations, and analysis of patterns of COVID-19 vaccine update starting in Phase 1 and throughout the three Phases of vaccine administration. This analysis plan will enable responsive targeting of messaging, vaccine access, and potentially small-community-level outreach (utilizing community health worker outreach, mobile integrated health services, and community health center events to improve uptake).

MDPH will make every effort to ensure estimates are as accurate as possible to minimize potential waste of vaccine, constituent products, or ancillary supplies. As appropriate, MDPH will engage the help/support of partner agencies and organizations to provide access to key data packets as well as to verify the modeling outcomes.

MDPH will monitor the planning activities of CDC's ACIP, the National Institutes of Health (NIH), and the NASEM for updates to help inform the Commonwealth's plan.

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## Process to Define Numbers of Persons in the Critical Infrastructure Workforce

MDPH will follow the same process as outlined above and these estimates will be included in the model being planned and launched in support of the MCVP. Working in collaboration with the MDPH Office of Population Health (OPH) and its internal Office of Health Equity (OHE), the vendor will gather data and enumerate staff of the critical acute care and long-term care infrastructure in need of Phase 1 immunization (and later as these workforce complements evolve) through existing institutional survey and reporting methods and reliance on resident datasets of staff capacity maintained by hospital associations (e.g. Mass Health and Hospital Association) and professional organizations representing care for the elderly and those with underlying health conditions (e.g. Massachusetts Senior Care Association; the Disability Policy Consortium). These staffing patterns, sorted according to final ACIP recommendations, will be assembled by type of institution, level of professional training, specific role in the care of these priority populations, and by geographic distribution. Working with our collaborative Social Vulnerability Index (SVI) analytic and mapping partner, the Boston University School of Public Health, maintain superior ability to map these workforce resources at a granular level to inform planning.

## Process to Determine Additional Subset Groups of Critical Populations

MDPH will follow the same process as outlined above and these estimates will be included in the model being planned and launched in support of the MCVP. Similarly, an analytic model (utilizing with SVI and mapping support from Boston University) will enumerate and geographically locate the critical populations and subpopulations identified by NASEM, ACIP, MDPH, and the COVID-19 Vaccine Working Group. And overlay of these populations with the analysis of immunization capacity at the local level will assist with resource allocation, PPE supply readiness, data management, vaccine allocation and distribution, and workforce capacity planning efforts to ensure maximal coverage of COVID-19 immunization.

## Process to Establish Points of Contact (POCs) and Communication Methods

Once critical populations have been identified and mapped, MDPH will complete a gap analysis to identify any areas of vaccinator capacity below needed levels and if necessary, launch proactive provider recruitment to close the gap.

MDPH will leverage the mechanisms identified in *Section 12: Vaccination Program Communication* to establish points of contact (POCs) and communication methods for organizations, employers, or communities (as appropriate) within the identified critical population groups where those relationships do not currently exist. Supplementing these will be the robust MDPH direct-to-provider communications enabled by MIIS enrollment. Critical targeted midstream messaging to vaccinators ordering and being allocated vaccine through the MIIS can target providers in areas of inadequate coverage and highlight the need to engage members of critical populations where additional outreach is needed.

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## Section 5: COVID-19 Provider Recruitment and Enrollment

### Recruitment and Enrollment of COVID-19 Vaccination Providers

There are currently close to 3,000 health care provider sites registered and enrolled in the Massachusetts Department of Public Health (MDPH) Immunization Division vaccine distribution system and/or reporting data to the Massachusetts Immunization Information System (MIIS). This includes all pediatric provider sites, major hospital systems, community health centers, local health departments, and approximately 1,000 pharmacy locations.

MDPH is actively connecting with partners and stakeholders to identify provider sites that are not registered with the MIIS, but will be administering vaccine to critical populations as defined by the Centers for Disease Control and Prevention (CDC). These include but are not limited to Internal Medicine practices, obstetrician-gynecologist practices, Long Term Care Facilities (LTCF), Assisted Living Residences, and Rest Homes. Particular focus includes reaching out to providers who serve communities of color and historically marginalized groups including the African American and other Black communities, Latinx, Asian/Pacific Islander, LGBT, and non-US born communities to ensure access to the vaccine in their community.

MDPH is actively conducting outreach to identified provider sites (as listed above) informing them that they must register for the MIIS and begin the onboarding process to report their immunization data. Active recruitment of these additional health care providers is ongoing, and a streamlined enrollment, registration, and onboarding process is in process in partnership with the Virtual Gateway (MDPH's hosting agency) and MDPH's application vendor Strategic Solutions Group (SSG).

Provider sites registering with the MIIS submit their National Provider Identifier (NPI) for site validation purposes. Sites that enroll with the MDPH Immunization Division State Vaccine Program undergo a thorough enrollment process. The Vaccine Unit confirms that providers have current licenses on file and validates these through the Office of Inspector General to ensure providers do not have any exclusions on record. As a part of the COVID-19 vaccine enrollment process, which is being integrated into the existing MIIS enrollment process, providers who may administer COVID-19 vaccine in Massachusetts will provide their medical license numbers. The Vaccine Unit will check those licenses to ensure that providers are eligible to practice within the state.

Every provider that enrolls with the MCVF will need to have a Chief Medical Officer/Chief Executive Officer (CMO/CEO), or equivalent, sign CDC's COVID Vaccine Provider Agreement. In addition, sites must identify a primary and back-up COVID-19 vaccine coordinator who must ensure that staff onsite know correct procedures for maintaining vaccine cold chain. Training will be provided on these procedures for the primary and backup vaccine coordinators.

### Determination of Provider Types and Settings for First Available COVID-19 Vaccine

The first available doses of COVID-19 vaccine will be made available to providers who based on their practice profiles serve the critical populations as identified in Section 4. These include hospitals, long-term care (LTC), Community Health Centers (CHC), and adult primary care provider sites.

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## Collection and Compilation of Provider Enrollment Data

COVID-19 enrollment will be fully integrated in the MIIS. Export functionality will be built into the MIIS to allow for the Comma-separated values (CSV) export file of provider enrollment data based on the CDC template to be generated twice a week for upload into CDC Secure Access Management System (SAMS).

### Verification that Providers are Credentialed

The MIIS will track providers' NPI and their medical licenses. The Vaccine Unit will validate medical license numbers with the Board of Registration in Medicine (BORIM) as required by CDC.

### Provision and Tracking of Provider Training

The MDPH Outreach Unit and MDPH Nursing Unit along with contracted nurse educators and other personnel will provide training for providers administering COVID-19 vaccine in collaboration with training partners. MDPH will use remote learning resources, including webinars, whenever possible. After accessing and reviewing CDC-generated materials, MDPH will identify gaps and develop additional materials as needed.

For training delivery and tracking, MDPH will work with its training partners. MDPH will apply for continuing education credits for clinicians and pharmacists to encourage participation in COVID-19 vaccination training. This training will include all the training elements listed in the CDC's Interim Playbook, with an emphasis on infection control and general practices for safe delivery of vaccination services during a pandemic. The MIIS is currently used to track trainings for the Vaccine for Children (VFC) program. In the MIIS, the enrollment record can record when and how the COVID-19 primary and back-up vaccine coordinators complete training. The training record is updated by a bulk upload or direct data entry. Only providers that have completed all required trainings and submitted their MCVF enrollment will be allowed to receive COVID-19 vaccine.

Specifically, COVID-19 vaccine provider training topics will include:

- CDC's General Practices for the Safe Delivery of Vaccines During a Pandemic and Guidance for Vaccination at Satellite, Temporary or Off-Site Clinics at:  
<https://www.cdc.gov/vaccines/pandemic-guidance/index.html>
- Advisory Committee on Immunization Practices (ACIP) COVID-19 vaccine recommendations, when available
- COVID-19 vaccine storage and handling (including transport requirements)
- Countermeasures Injuries Compensation Program
- Planned redistribution from depots to individual locations and from larger to smaller locations
- Unplanned repositioning among provider locations
- Guidance on not denying COVID-19 vaccine to anyone because of inability to pay
- Guidance on not inquiring about immigration status before administering COVID-19 vaccine
- How to order and receive COVID-19 vaccine
- How to administer vaccine, including reconstitution, use of adjuvants, appropriate needle size, anatomic sites for vaccine administration, avoiding shoulder injury with vaccine administration

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- How to document and report vaccine administration via the MIIIS
- How to manage vaccine inventory, including accessing and managing product expiration dates (see *Section 7: COVID-19 Vaccine Allocation, Ordering, Distribution, and Inventory Management*)
- How to report vaccine inventory
- How to manage temperature excursions
- How to document and report vaccine wastage/spoilage
- How to report moderate and severe adverse events and vaccine administration errors to VAERS
- How to provide Emergency Use Authorization (EUA) fact sheets to vaccine recipients and guidance on responding to questions from vaccine recipients
- How to submit facility information for COVID-19 vaccination clinics to CDC's [Vaccine Finder](#) (particularly for pharmacies or other high volume vaccination providers/settings)

Depending upon the audience, COVID-19 provider training will include guidance for setting up off-site vaccination clinics. MDPH has developed guidelines for vaccination clinic operations, which provide guidance for offsite vaccination clinics. These guidelines, along with other resources or helpful links, can be found on the MDPH *Vaccine Administration and Clinical Guidance* webpage: <https://www.mass.gov/service-details/vaccine-administration-and-clinical-guidance>.

Other resources can be incorporated into provider training, as appropriate, including:

- CDC's Vaccine Administration Guidance and Materials: <https://www.cdc.gov/vaccines/hcp/admin/admin-protocols.html>
- CDC's Guidance for Vaccination at Satellite , Temporary, or Off-Site Clinics at: <https://www.cdc.gov/vaccines/pandemic-guidance/index.html>
- CDC's Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations for Mass Vaccination at: <https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html>
- CDC's Resources for Hosting a Vaccination Clinic at: <https://www.cdc.gov/flu/business/hosting-vaccination-clinic.htm> - contains guidance for safe vaccination practices at satellite or off-site clinics
- The [Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-site Locations Checklist](#) contains step-by-step guidance for activities that need to take place before, during, and after a vaccination clinic to ensure proper vaccine storage and handling, vaccine administration, and patient safety: <https://www.izsummitpartners.org/naiis-workgroups/influenza-workgroup/off-site-clinic-resources/>

Considerations for Planning Curbside/Drive-Through Vaccination Clinics: <https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/curbside-vaccination-clinics.html>

Other guidance will be incorporated as it becomes available and the training curriculum is developed.

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States are not required to provide training for federal entities and commercial partners receiving direct COVID-19 vaccine allocations from CDC. MDPH will coordinate with CDC to identify those entities receiving direct allocations from CDC and ensure they are still registered and reporting their data to MIIS.

### Approval of Planned Redistribution of COVID-19 Vaccine

MDPH will leverage a tool in the MIIS Vaccine Management module which tracks transfers. Providers may redistribute vaccine only if they have a Redistribution Provider Agreement signed and on record in the MIIS. Providers will be able to redistribute to sites that have a signed COVID-19 Provider agreement form. All transfers will be monitored by the Vaccine Unit.

### Coordination of Equitable Access to COVID-19 Vaccination Services

MDPH is reaching out to adult providers who are historically under-registered for the MIIS to provide the information and resources necessary to register for and report data to the MIIS. To further expand equitable access of COVID-19 vaccination, MDPH purchased the PrepMod System, an application that local health departments, and other entities without an Electronic Health Record (EHR) system, may use for patient management, billing, recording, and reporting of immunization events to the MIIS. MDPH continues to leverage community partnerships in order to recruit additional COVID-19 vaccination providers and expand equitable access to COVID-19 vaccination when vaccine supply increases. MDPH will map all registered providers and their patient capacities and comparing with local census numbers to ensure all areas of the Commonwealth are adequately covered. *See Section 4: Critical Populations.*

### Recruitment and Enrollment of Pharmacies not Served Directly by CDC

There are approximately 1,000 pharmacy locations registered and reporting immunization data to the MIIS, including all major commercial pharmacy chains. MDPH will outreach to independent and chain commercial pharmacies requesting that they take an inventory of all their Massachusetts locations, to ensure that all are registered with the MIIS and actively reporting data. In that communication, MDPH will provide instructions for identified pharmacies to register for the MIIS and begin the onboarding process to report their immunization data. MDPH acknowledges that some multi-jurisdictional vaccination providers will enroll directly with CDC, in order to receive COVID-19 vaccine – and CDC will notify MDPH of any entities receiving direct allocations within their areas. All enrollment for COVID-19 vaccine will be electronic and occur through the MIIS, and even large national pharmacy providers who receive vaccine directly from CDC will be required by law to report vaccine administered in Massachusetts to the MIIS.

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## Section 6: COVID-19 Vaccine Administration Capacity

In order to estimate COVID-19 vaccination capacity in Massachusetts, it is useful to start with historical provider capacity during annual influenza seasons and during the 2009 H1N1 influenza pandemic.

In Phase 1b (as identified in Section 3), health care personnel (HCP) will be the first targeted population for COVID-19 vaccination. As a condition of licensure, the Massachusetts Department of Public Health (MDPH) regulations require health care facilities, including hospitals, ambulatory surgical centers, dialysis centers, clinics, nursing homes, rest homes, and adult day health programs to:

- Document receipts of influenza vaccine administered in or outside the facility, or document the declination of immunization for HCP
- Report information to MDPH documenting compliance with the vaccination requirement, in accordance with reporting and data collection guidelines of the Commissioner (105 CMR 130.325, 105 CMR 140.150, 105 CMR 150.002(D)(8), 105 CMR 158.030(L)(8))

For the 2018-2019 influenza season, acute care hospitals reported that 94% of health care personnel (HCP) had received influenza vaccine. HCP flu vaccination rates were 72% for skilled nursing facilities and 83% for dialysis centers. Where necessary, hospitals and other health care facilities can work with commercial vaccinators to enhance their capacity to provide COVID-19 vaccine to their employees.

MDPH is reviewing its list of providers currently enrolled in the MDPH Vaccine Program, and identifying gaps in enrollment, particularly for adult providers and commercial vaccinators. MDPH will determine each provider's capacity to meet the storage and handling requirements described in the scenarios for Vaccines A and B. MDPH will assess a provider's capacity and plans to receive and administer vaccine quickly.

MDPH is engaging the additional data analytics capacity of a contractor to assess and map vaccinator capacity, drawing from public datasets, provider surveys, and professional organization data (e.g., Mass Medical Society, associations of chain and independent pharmacies), Massachusetts Immunization Information System (MIIS) enrollment data, and MDPH clinical and professional licensure data to characterize the distribution, accessibility, staff capacity, and maximum throughput of each major category of providers of immunizations. These analytics will be used to prioritize recruitment of new providers into the MIIS and the deployment of targeted response teams (Massachusetts National Guard, mobile integrated health teams, community health centers) to areas of inadequate vaccine availability or provider capacity.

MDPH will monitor provider vaccine usage data to identify areas of the state that need additional providers and will focus provider recruitment on those areas and/or direct commercial vaccinators.

MDPH will use data regarding the number and types of providers to focus provider recruitment efforts. *See Section 5: COVID-19 Vaccination Provider and Recruitment.*

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

### COVID-19 Vaccine Allocation

The Massachusetts Department of Public Health (MDPH) Vaccine Unit is responsible for vaccine allocation. Vaccine allocation will be based on priority groups, as identified by the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP), and approved by the Commissioner of Public Health, by the number, profile, and types of providers registered with the Massachusetts Immunization Information System (MIIS), and by the estimated patient volume of the provider practices.

Early dose distribution will be limited; therefore, phased allocation of early vaccine doses will likely be necessary. Populations of focus for initial COVID-19 vaccine doses are expected to include healthcare workers (including ancillary staff, vaccinators, and staff in Long-Term Care Facilities), other essential workers, and people at higher risk for severe COVID-19 illness.

The MDPH Vaccine Manager is the Designated Distribution Manager. The following guidelines will support the allocation of COVID-19 vaccine in Massachusetts:

- All providers must be registered with the MIIS in order to receive vaccine. Registration of providers is currently on-going, and a streamlined process will be implemented to rapidly register any remaining providers as needed.
- MDPH will be notified of current allocation daily through CDC's daily allocation report. The report will include number of doses and formulations available for Massachusetts.
- Based on number of doses and formulations available, MDPH will allocate doses directly to provider sites based on priority groups for vaccination and the quantities available at the time. Allocations will be made as frequently as additional supply is made available.
- Prior to being approved to receive vaccine, providers will have to attest that they have the appropriate storage units and processes available to manage the vaccine cold chain.
- Storage units for vaccine will need to be continuously monitored by Digital Data Logger (DDL) (also known as Continuous Temperature Monitoring Systems) and a report should be available to be uploaded into the MIIS to ensure that the cold chain has not been broken.

### COVID-19 Vaccine Ordering

The MDPH Vaccine Unit is responsible for managing and approving orders from enrolled providers.

During Phase 1 when vaccine is limited:

- Vaccine Unit will create the vaccine allocations using the allocation and prioritization principles outlined by both the ACIP and MDPH Leadership Group. These allocations will be made in an Excel spreadsheet or other electronic format and then uploaded into the MIIS, also known as a bulk upload. This method is used for flu vaccine during regular flu season.
- Sites that receive allocations will have a current COVID-19 Provider Agreement, appropriate storage units, and records showing that the cold chain can be maintained.

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- MIIS Unit will generate a vaccine order file that the MDPH Vaccine Unit will upload into CDC's Vaccine Tracking System (VTrckS) tool. This will then generate the vaccine order information that is transmitted to the distributor McKesson and/or the manufacturer. This is the same system currently used by MDPH for the management of close to 3.2 million doses annually.
- An email will be sent to every provider receiving an allocation informing them of the number of doses and formulations in their allocation and the necessary storage and handling requirements for that vaccine.

During Phase 2 and beyond, as vaccine supply increases:

- Providers will be able to order vaccine directly through the MIIS Vaccine Module, but all orders will continue to be reviewed and approved by the MDPH Vaccine Unit, ensuring equitably vaccine distribution.
- Vaccine Unit will approve orders based on vaccine usage and documentation of temperatures.
- Once the orders have been approved, an order file will be generated in the MIIS that will be uploaded into the CDC VTrckS tool. This will generate order information that is transmitted to the distributor McKesson and/or manufacturer.
- Assumption — Once vaccine orders have shipped from McKesson, the current centralized distribution vendor, the vaccine order confirmation information, also known as a shipment file, will be downloaded from VTrckS into the MIIS, where the shipment tracking information is made visible to the provider site. The shipment file will ensure that provider's virtual inventory is updated and maintained in the MIIS.

### COVID-19 Vaccine Distribution

COVID-19 vaccine will be distributed by McKesson for federally contracted vaccines directly to each provider site enrolled in the MIIS that is being allocated vaccine by the MDPH Immunization Division. There is a possible second vaccine that will be distributed to large providers directly from the manufacturer. At this time vaccine distributed directly from the manufacturer is to be kept at ultra-cold temperatures (-60°C to -80°C).

The Vaccine Unit will generate provider enrollment data twice a week that will be uploaded into the SAMS system using a template that has been created by CDC. This will continuously update CDC systems and McKesson distribution on the correct shipping address, provider contact information, and shipping hours.

Vaccine will be distributed in minimum quantities of 100 doses and ultra-cold formulations will be distributed in 1,000 dose quantities. Once an order is submitted to CDC, the order should be fulfilled within 48 hours. Once vaccine has shipped from McKesson, the vaccine order information should be included in a downloadable report called the Shipment File. The Vaccine Unit will upload the shipment file daily to ensure that providers maintain an accurate inventory. The shipment file should include tracking information so that providers know when to expect vaccine.

### COVID-19 Vaccine Inventory Management

COVID-19 vaccination providers will be required to report inventory of COVID-19 vaccines. The Vaccine Unit will be able to generate an inventory file for providers that can be uploaded directly in VTrckS.

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Inventory can be updated in two ways:

- Providers who are enrolled to receive COVID-19 vaccine are required to register to report data to the MIIS. As sites are reporting data, their virtual inventory should automatically decrement.
- If vaccine is not decrementing, sites will be required to submit a reconciliation via the MIIS Vaccine Management module.

## COVID-19 Vaccine Redistribution and Transfer

Redistribution may be allowed if a site is unable to use the number of doses it was allocated. Redistribution will be tracked through transfers completed in the MIIS Vaccine Management module.

Prior to planned redistribution, providers sending/transporting will do the following:

- Contact the Vaccine Unit to receive approval of the redistribution
- Sign the supplemental redistribution agreement form
- Have Standard Operating Procedures (SOPs)
- Follow CDC transport guidance: [CDC Vaccine Storage and Handling toolkit](#)

Prior to planned redistribution, receiving providers will do the following:

- Sign the COVID-19 provider agreement form
- Maintain the same storage and handling requirements as sites that receive vaccine directly from CDC distribution vendor
- Upload current temperature logs
- Accept the inventory

Prior to planned redistribution, the Vaccine Unit will do the following:

- Confirm the provider site receiving vaccine has signed the COVID-19 provider agreement form, has appropriate storage units, and has the capability to monitor temperatures
- Ensure the provider sending/transporting vaccine understands the appropriate methods to transfer vaccine while maintaining cold chain
- Transfer virtual inventory in the MIIS

## COVID-19 Vaccine Expiration and Wastage

Information about handling expiration dates will be included in training documents.

- Current information from CDC states that vaccine vials and cartons will not include a printed expiration dates. Instead, expiration dates will be updated based on stability data. Providers must go to the U.S. Department of Health and Human Services (HHS) website to determine the expiration dates for specific lots.
- CDC is developing beyond use date (BUD) tracking labels to assist with tracking expiration dates at the point of vaccine administration.

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- The inventory in the MIIS Vaccine Management module can be edited. It is possible that expiration dates can be added to the module.
- Training will be necessary to ensure that staff are aware of BUD and are not confusing the manufactured date with the expiration date.

At this time there is not guidance about how COVID-19 vaccine should be returned. Under the assumption that COVID-19 vaccine will be returned similar to the process for routine vaccines, the following will occur:

- As inventory expires or is wasted due to temperature excursions, sites can process a Storage and Handling incident in the Vaccine Management Module. This incident will track the issue and remove vaccine from the virtual inventory. The Vaccine Unit staff will have to approve each incident and will use these incidents to recommend further training. Once approved, expired and wasted vaccine for all sites will be exported into a CSV file that can be updated into VTrckS. In turn this data will be sent to McKesson to produce a return label for the provider to ship vaccine to McKesson.

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

COVID-19 vaccine products are temperature-sensitive, and must be stored and handled correctly to ensure efficacy and maximize shelf life. Proper storage and handling practices are critical to minimize vaccine loss and limit risk of administering COVID-19 vaccine with reduced effectiveness. Maintaining the vaccine cold chain will be dependent on proper staff training, reliable storage units and temperature monitoring equipment, and inventory management.

### Individual Provider Locations

The Massachusetts Department of Public Health (MDPH) will require storage and handling training for primary and back-up COVID-19 vaccine coordinators. The Chief Medical Officer/Chief Executive Officer (CMO/CEO) signatory and primary and back-up COVID-19 vaccine coordinators must ensure that staff onsite know correct procedures for maintaining vaccine cold chain. Primary and back-up COVID-19 vaccine coordinators are primarily responsible for ensuring correct COVID-19 vaccine management.

MDPH will recommend that provider sites have written Standard Operating Procedures (SOPs) and will provide template SOPs that can be adapted for each practice location. Accurate and up to date SOPs will help facilitate training other staff and ensure proper vaccine management.

MDPH is planning with the assumption that provider sites are required to use purpose-built/pharmaceutical-grade units for refrigerators.

- Provider sites receiving vaccine must have storage units that can store the vaccine being received. The type and capacity of refrigerator, freezer, and ultra-cold storage will be tracked in the enrollment record.
- Storage and handling temperature requirements for COVID-19 vaccine will vary.
  - Refrigerated: 2°C to 8°C
  - Frozen: -15°C to -25°C
  - Ultra-cold: -60°C to -80°C
  - Ongoing stability testing may impact requirements (this information is based on COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations).
- Vaccines that require ultra-cold storage can be stored in their shipping containers with dry ice. Prior to approving orders for vaccine with ultra-cold storage requirements, MDPH will ensure that there is a documented ultra-cold freezer or there is access to a dry ice vendor.

The MDPH Vaccine Unit is currently surveying providers enrolled in the Vaccine Program to evaluate ultra-cold storage capacity at pediatric provider sites, hospitals, community health centers (CHCs), and multi-specialty provider practices. The results of this survey will inform existing capacity and the need for enhancing ultra-cold storage capacity statewide. In addition, an ultra-cold storage unit is being purchased by the Vaccine Unit for maintenance of doses, if needed at MDPH. The Vaccine Unit has also reached out to a refrigeration vendor that could be contracted if needed for large capacity ultra-cold storage.

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Providers must continuously monitor COVID-19 vaccine with a Temperature Monitoring Device (TMD), also known as a Digital Data Logger (DDL). MDPH will provide DDLs to monitor temperatures, and providers are required to upload DDL reports monthly or with every order.

Accurate vaccine inventory management is critical. MDPH will send an email of the order confirmations so that provider sites can prepare to receive vaccine. The Centers for Disease Control and Prevention (CDC) centralized distributor, McKesson, will deliver vaccine directly to the provider site; for ultra-cold vaccines, the vaccines will be shipped directly from the manufacturer. Upon arrival, vaccine shipping information will be received from Vaccine Tracking System (VTrckS), and uploaded into the Massachusetts Immunization Information System (MIIS), which will automatically add those vaccine doses into the provider site's virtual inventory in the MIIS. At that point, primary and back-up vaccine coordinators are responsible for the vaccine cold chain up until the point of vaccine administration.

Vaccine vials and cartons will not contain a printed expiration date. Instead, expiration dates will be updated based on vaccine stability studies. Current expiration dates by vaccine lots for COVID-19 vaccine will be posted on a U.S. Department of Health and Human Services website. Providers will be required to check the website for expiration dates. CDC will develop label templates to track beyond use dates that will be provided to provider sites.

As of now, CDC has not provided guidance for vaccine disposal. Providers can report vaccine expired or wasted through the MIIS. Once submitted, MDPH will approve the storage and handling incident, and create an export for upload into VTrckS.

If there are any storage and handling incidents, vaccine must be marked as "Do not use" and quarantined to prevent accidental administration. The vaccine manufacturer will determine viability.

## Satellite, Temporary, or Off-site Settings

Satellite, temporary, or off-site settings can assist in providing equitable access for COVID-19 vaccination. MDPH will work with providers that are planning to host clinics to ensure that the quantity of vaccine received is based on population anticipated to be vaccinated. Provider sites that utilize satellite, temporary, or off-site settings must understand and use appropriate transport and storage protocol. Sites conducting clinics at satellite, temporary, or off-site settings must contact the Vaccine Unit to ensure the transport protocol is followed, and to receive additional DDLs if needed. Storage units for COVID-19 vaccine products must be monitored continuously. Providers will be required to upload a DDL report into MIIS after every clinic. At the end of clinic, vaccine must be moved back to a fixed storage unit with temperature monitoring.

## Planned Redistribution

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

## Unplanned repositioning

Provider sites that are eligible for redistribution will have signed the redistribution agreement, been appropriately trained, and will be required to have an SOP. If there is an unplanned move, provider sites receiving the vaccine should not administer vaccine until they have received approval from MDPH. Provider sites repositioning vaccine should contact the Vaccine Unit as soon as possible. The Vaccine Unit will confirm if vaccine can be used, and complete the transfer in MIIS.

# MASSACHUSETTS COVID-19 VACCINATION PLAN

## Section 9: COVID-19 Vaccine Administration Documentation and Reporting

### System to Collect COVID-19 Vaccine Doses Administered Data

The Massachusetts Immunization Information System (MIIS) will be used to capture COVID-19 vaccine doses administered data. The MIIS is a secure, confidential web-based system that can support both electronic data exchange and direct data entry. It contains the immunization registry, vaccine management (enrollment, vaccine ordering, inventory management), and data quality tools and support.

The ability to connect to the Immunization (IZ) Gateway to transmit and/or receive COVID-19 vaccine administration data is under programmatic and legal review. MDPH is concurrently testing its connectivity capability with the IZ Gateway.

### Process to Ensure Vaccination Providers can Report Required Data every 24 Hours

Approximately 90% of providers in the MIIS send their immunization data via Health Level Seven (HL7) electronic messaging through their Electronic Health Records (EHR) system; this data typically is sent automatically in real time or within a few hours. Additional communication by the MIIS Unit will be sent to all providers regarding the requirement to report data to the MIIS.

The MIIS Unit has increased staff capacity to ensure adequate technical support for existing providers' reporting and for onboarding new providers onto the MIIS. An additional trainer has been hired to assist with training initiatives. *See Section 5: COVID-19 Provider Recruitment and Enrollment.*

All providers who report to the MIIS meet the current federal and state reporting requirements. Additional data elements for COVID-19 are currently being assessed for implementation into the MIIS.

### Process to Ensure Real-time Reporting from Satellite, Temporary, and Off-site Clinics

MDPH BIDLS has purchased the PrepMod System, a software product for health departments and other providers to use when conducting satellite, temporary, or off-site vaccination clinics that will connect to the MIIS for real-time reporting. Rollout and training for the PrepMod System is currently underway.

We will run queries to identify and reach out to providers who do not report within the 24-hour time commitment. As previously mentioned, most sites electronically connected to the MIIS report in real time or with a few hours delay. Reporting requirements will be communicated broadly to ensure all data is entered in a timely manner.

### Process to Monitor Provider-Level Data

The MIIS Data Quality Team will run routine queries to identify and outreach to providers who are not reporting within the 24-hour time commitment. Support will be provided by the Data Quality Team when applicable to assist providers with the reporting requirements via phone or email.

### Process to Generate and Use COVID-19 Vaccination Coverage Reports

The MIIS is currently being enhanced to support COVID-19 vaccine in the existing coverage reports. Before these enhancements are in place, we will run queries against the MIIS operational data store (ODS) to assess areas of low coverage and provide outreach if warranted.

## Section 10: COVID-19 Vaccination Second-Dose Reminders

The Massachusetts Immunization Information System (MIIS) has robust Reminder Recall functionality available for all registered providers to utilize. Currently, the MIIS Unit is planning to add to text message reminders to the current Reminder Recall functionality. This functionality is expected to go live by February, 2021.

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

### Process for Documenting Vaccine Administration in Temporary or High-Volume Settings

The Massachusetts Immunization Information System (MIIS) provides functionality that supports roster entry of a large number of patients on one screen — or the user can download an excel template to use offline and upload to the MIIS at a later time. The Massachusetts Department of Public Health (MDPH) has provided a new application, the PrepMod System, to local health departments and other sites that do not have an Electronic Health Record (EHR) system, to assist with off-site vaccination clinic scheduling, billing, and IIS reporting.

### Variables MIIS will Capture for Persons who Receive COVID-19 Vaccine

MDPH collects all data elements that are required in the Health Level Seven (HL7) specifications for IIS through the MIIS, except for clinical comments. The elements collected include, but are not limited to, the following:

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

Any additional data elements unique to COVID-19 vaccine may be added to MIIS with an expected implementation timeframe of November/December, 2020.

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## Current Capacity for Data Exchange, Storage, and Reporting & Planning Improvements

As of September, 2020, there were close to 3,000 provider sites sending or entering data to the MIIS, and 996 query data from the MIIS. There are 7,987,480 unique patients and 67,559,134 vaccinations in the MIIS.

Historically, the MDPH MIIS system has seen peaks in unsolicited vaccination record update (VXU) messages at around 7,000 messages per hour and MDPH tests to about 11,000 VXU messages per hour in performance tests. For query by parameter (QBP), the historical peak is about 12,500 messages per hour, and MDPH tests to about 18,000 QBP messages per hour in performance tests. MDPH estimates that it is at about 65% of tested capacity. Outside of flu season MDPH sees approximately 2,000 VXU per hour, at which time MDPH is at 20% of its VXU capacity. QBP has not proven to be very seasonal, apart from lock-down for COVID-19. In summary, the MIIS has sufficient storage/capacity to support an increase in VXU and QBP and segment pattern response due to COVID-19 administration events.

## Rapid Enrollment and Onboarding to MIIS

MIIS team is in discussions and reviewing plans for rapid enrollment and onboarding. We have taken initial steps for enrollment that include implementing electronic signature collection for Virtual Gateway forms in lieu of paper forms/wet signatures. This is expected to be completed by the end of October, 2020. Modifications to response times for enrollment approvals and creation have also been negotiated with the Virtual Gateway. Expedition for any account requests for the MIIS will be approved and created in a 24-48-hour window, which is reduced from the normal 7-day timeframe.

Some early considerations for expediting onboarding include:

Bypassing Certification testing and sending all sites directly to production. Data Quality would be conducted in production and if issues are found, sites would be asked to fix and re-send data. This could speed up an onboarding project by weeks or months.

Sites would be set up immediately to begin entering data directly through the MIIS user interface (website). At the same time, technical onboarding could proceed through the normal process, and once complete, the technical feed could be turned on, and direct data entry would cease. Potential risk: depending on the volume of administration events this could prove to be significantly labor intensive for the organization.

## Status and Plans to Onboard to the IZ Gateway Connect and Share Components

The ability to connect and share is under programmatic and legal review. MDPH is concurrently testing its connectivity capability with the IZ Gateway.

## Backup Solutions for Offline Use

The MIIS is in discussions regarding off-line reporting. One initial consideration to support providers, if internet connectivity is lost or not possible, is to allow providers to complete a roster excel template of patient vaccination events. This template can be distributed via email prior to any foreseen outages. The template can also be accessed through the MIIS. Once internet issues have been resolved the provider may upload the template through the MIIS Roster Entry function. If internet outage is not

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resolved within the 24-hour timeframe, the template may then be faxed to the MIIS secure fax line. Helpdesk Staff will then manually enter this information through the Roster Entry functionality in the MIIS.

### Process for Monitoring Data Quality

An MDPH MIIS Unit data quality scientist monitors providers' data quality and conducts outreach to providers who require assistance to improve their data. Monitoring will continue throughout COVID-19 vaccination. We will use various reports to assist with this monitoring, such as the provider scorecard — which provides a monthly view of each providers data quality scores — broken down by completeness, timeliness, validity, and accuracy. The 7-day report monitors any sites that report outside the legal 7-day requirement, and the compliance report is used to monitor when providers stop reporting all together. Additionally, queries will be used on the Operational Data Store (ODS) to monitor any additional data quality items necessary.

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## Section 12: COVID-19 Vaccination Program Communication

To support consistency of broader communications messaging to the general public and targeted messaging to specific audiences, the Massachusetts Department of Public Health (MDPH) has identified the following goal and priorities for the Massachusetts COVID-19 Vaccination Program (MCVP):

Statewide Communications Goal:

- Provide clear, accurate, consistent, and timely information about the Massachusetts COVID-19 Vaccination Program with an emphasis on building vaccine confidence broadly among groups anticipated to receive early vaccination and to dispel vaccine misinformation to ensure vaccine uptake.

Statewide Risk Communications Priorities:

- Ensure coordination with appropriate partners to inform accurate and timely messaging around the safety of a COVID-19 vaccination to the general public as well as to various stakeholder groups.
- Ensure coordination with appropriate partners to inform accurate and timely messaging around the availability of a COVID-19 vaccine, based on the three phases of the COVID-19 Vaccination Program. See Section 3: Phased Approach to COVID-19 Vaccination.
- Ensure that information about the COVID-19 vaccine is accessible and culturally and linguistically appropriate for reaching key audiences.
- Consult with the MDPH Office of Health Equity and other established partner networks to be sure messages are effective and useful.

MCVP Communications Plan: Three Key Components

Through the Communications Group, MDPH is engaged in developing a detailed communications plan – incorporating the audiences, the messages, the channels, and the time/phases. MDPH will leverage the Centers for Disease Control and Prevention’s (CDC’s) recently developed [Vaccinate with Confidence framework](#) to support the development of MCVP messaging.

*Statewide public awareness campaign developed with an external vendor.*

- MDPH follows a data-driven process for developing messaging and creative assets for paid media/awareness campaigns and messaging to specific audiences will be based on data collected from health communications research
- For example, MDPH, with its Bureau of Infectious Disease and Laboratory Science (BIDLS), conducted a Flu Vaccination research study in July, 2020, to better understand Massachusetts residents’ attitudes toward receiving flu vaccinations. The outcomes of this study are captured in the Flu Vaccination Report and could assist MDPH in messaging for the COVID-19 vaccine

*Earned and Paid Media*

- Earned media to include outreach via press events, press releases, op-eds, and other strategies
- Paid media to include paid ads on TV, radio, digital, and social media outlets

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## *Community Engagement*

- The data demonstrate that people of color — specifically Black, Hispanic or Latinx, and American Indian and Alaska Native — have been disproportionately impacted by COVID-19 with higher rates of morbidity, mortality, and transmission and will inform MPHS’s community engagement process
- Outreach to a wide variety of community groups and partners groups, social service agencies, and other identified stakeholder organizations
- Massachusetts will leverage the CDC’s recently developed Vaccinate with Confidence framework to support the development of MCVP messaging

## *Critical Audiences for Tailored Messaging*

MDPH has identified the following critical audiences – and will identify specific community and stakeholder engagement needs as well as individualized planning requirements for each group (e.g., municipal and state elected officials will be addressed through a legislative/municipal communications and outreach plan).

- All residents of the Commonwealth of Massachusetts
- State elected officials
- Municipal officials (mayors, town managers, city and town councilors)
- Local and regional public health and healthcare officials
- Media
- Employers
- Communities disproportionately impacted by COVID
- Essential workers
- School officials
- Those in groups at risk for severe outcomes from COVID-19 infection
- Those in groups at increased risk of acquiring or transmitting COVID-19
- Those with limited access to vaccination services

MDPH is also developing engagement strategies with key partners in support of the vaccination strategy for critical populations. Key partners include, but are not limited to:

- Community-based organizations
- Community health centers
- Correctional facilities
- Councils on Aging
- Shelters serving vulnerable populations
- Local education authorities

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- 24/7 congregate care settings
- Higher education institutions
- Long term care facilities
- Acute Care Hospitals
- Meals programs
- Pharmacies
- Substance use disorder treatment programs
- Mental and Behavioral Health treatment programs
- Urgent care clinics

## Messages

As mentioned above, MDPH will implement a statewide public awareness campaign, following its recognized data-driven, research-based process for developing messaging and creative assets. For example, MDPH, with its Bureau of Infectious Disease and Laboratory Science (BIDLS), worked with a market research firm to assess residents' attitudes toward receiving flu vaccinations; formative research that may be useful to MDPH in messaging for the COVID-19 vaccine.

MDPH is dedicated to communities disproportionately impacted by COVID-19. MDPH has launched several initiatives as part of COVID-19 response operations and the strong community relationships established through these initiatives will be leveraged in the development and delivery of COVID-19 vaccination messaging:

- COVID-19 Health Equity Advisory Group (HEAG): convened to advise MDPH on the needs of communities and populations disproportionately impacted by the COVID-19 pandemic and generate recommendations informed by a health-equity lens to ensure equitable access to resources and services, and prevent inequities and disproportionate negative outcomes. These recommendations will be factored into MCVP's community outreach activities.
- COVID-19 Community Grants: The MDPH Division of Community Health Planning and Engagement put together a grant program to reduce COVID-19 infections, morbidity, and mortality among Black, Latinx, and other people of color in the state's hardest-hit cities. These grants go to community-based and faith-based organizations to help develop and deliver effective messages, and support hard-hit communities with education, training, and funding to effectively meet their communities' specific needs.
- COVID-19 Community Impact Survey: MDPH is currently conducting a statewide online survey to learn about the public's experiences directly and use answers to aid communities in the COVID-19 response. The survey is on the Mass.gov website in the top six languages spoken by the key populations (English, Spanish, Portuguese, Chinese – traditional and simplified, Haitian Creole, and Vietnamese). The link is being shared via stakeholder networks (e.g., provider organizations, MDPH listserv), virtual community events (e.g., Youth Town Hall), and through community-based organizations with connections to the key populations. Coupled with the data from this survey, community input will help inform MDPH's COVID-19 response, and ensure it is

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equitable and pertinent to the needs of those hardest hit by the crisis. This information will be leveraged in the development of MCVP messaging based on the needs of these communities.

## Communications Channels

MDPH will use a variety of communication channels to deliver accurate, coordinated, prompt, reliable, and actionable messaging to the identified audiences.

- Paid/earned media
- Owned media assets (MDPH Twitter; Mass.gov website; other Mass.gov social media, state-owned billboards, highway signage, MBTA transit stations)
- Partner and stakeholder assets (websites, newsletters, blogs, podcasts, etc.)
- Next Door Community listserv
- Massachusetts 211

In March 2020, the COVID 211 call center was established with United Way and redeployed MDPH staff collaborating to answer calls about a range of COVID-19 related topics, including transmission, prevention, symptoms, testing, school, work, travel, housing, food security, financial matters, etc. Since activation and September 27, 2020, United Way and MDPH staff have answered 121,075 such calls. Massachusetts 211 operates 7 days a week and is an easy number to advertise. It is a simple way for the general public to ask questions, discuss the details of their circumstances, and be given the most up-to-date information and referrals as needed. As MDPH prepares for and implements vaccination initiatives, Massachusetts 211 call takers will be equipped with information and resources to educate individuals and connect them with services or other resources.

The public awareness campaign messages will be used in press events, press releases, media interviews, op-ed pieces, and other earned media efforts such as:

- Daily and weekly press outlets
- Local news outlets
- Governor press conferences
- State official media avails (HHS Secretary, Public Health Commissioner)

## Time / Three Phases

Messaging will not only be tailored by audience, but will be developed for the three phases identified within the *CDC Vaccination Program Interim Playbook*. Of note, the MDPH paid media campaign messaging will not begin until vaccine is available. Messaging prior to vaccine availability will be handled via earned and owned media. Paid media messaging will be available for the three phases:

- COVID-19 vaccine is safe and effective
- Vaccine is available in limited supply for certain populations of early focus (Phase 1)
- Vaccine is increasing and available for other critical populations and the general public (Phase 2)
- Vaccine is widely available (Phase 3)

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## Expedited Procedures for Risk/Crisis/Emergency Communication

MDPH procedures for risk/crisis/emergency communication align with known Crisis and Emergency Risk Communication (CERC) principles.

- Be First
- Be Right
- Be Credible
- Express Empathy
- Show Respect

Timely public information during an emergency can calm people's fears, manage their expectations, and help persuade them to make important health-related decisions to assist in ensuring their safety.

MDPH has existing plans in place that clearly define the risk/crisis/emergency communications processes for both internal and external partners, and MDPH maintains multiple mechanisms to communicate with partners — to include the Health and Homeland Alert Network (HHAN), WebEOC, and a number of audience-specific Listservs.

If the State Emergency Operations Center (SEOC) is activated, the Massachusetts Emergency Management Agency (MEMA) may establish a Joint Information Center (JIC) to coordinate messaging across multiple state agencies, and the MDPH Public Information Officer (PIO) would participate in the JIC.

MDPH will use health literacy standards to create materials intended for the general public, including, but not limited to, consent forms, regulations brochures, fact sheets, and other health education information. MDPH is committed to reducing health disparities by setting standards for materials development that require the use of plain language, relevant visuals, and effective layout and design to ensure information is accessible to the target audience, especially those with limited language proficiency.

Depending on the scope of the emergency and populations affected, MDPH will typically produce public information materials in the five most commonly spoken languages other than English in the Commonwealth: Spanish, Portuguese, Haitian Creole, Vietnamese, and Chinese. We can also develop additional translations to meet requests or needs, such as Albanian, recently requested for one of the state's higher risk cities.

## Section 13: Regulatory Considerations for COVID-19 Vaccination

The Centers for Disease Control and Prevention (CDC) requires that all providers enrolling in the MCVF execute the CDC COVID-19 Vaccination Provider Agreement in order to receive COVID-19 vaccine. By doing so, providers agree to adhere to certain requirements, including “Before administering COVID-19 vaccine, the provider must provide an approved Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative.”

The Massachusetts Department of Public Health (MDPH) will follow all EUA protocols for record keeping, including signed consent, if necessary. MDPH will use CDC-generated product-specific EUA fact sheets for vaccine providers, which include information on the specific vaccine product and instructions for its use. MDPH will use the CDC-developed EUA fact sheets and/or vaccine information statements (VIS) for vaccine recipients. EUA protocols, forms, and information sheets will be provided to all clinics/providers and will be posted on the MDPH website. We will share information about the EUA protocols and forms with our immunization partner organizations, so they can post vaccination information on their websites and forward information to their organizational list serves.

### Vaccination Provider Training

Information about EUA procedures and forms will be included in all COVID-19 vaccine provider training - See Section 5: *COVID-19 Provider Recruitment and Enrollment*. MDPH staff will be trained to respond to questions from providers and the public about the EUA.

## Section 14: COVID-19 Vaccine Safety Monitoring

The Centers for Disease Control and Prevention (CDC) requires that all providers enrolling in the MCVF execute the CDC COVID-19 Vaccination Provider Agreement in order to receive COVID-19 vaccine. By doing so, providers agree to adhere to certain requirements, including “Organizations must report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS).” Relevant VAERS forms and guidance are posted on the MDPH Vaccine Administration and Clinical Guidance web page and will be updated as necessary. The mass.gov site link is listed below: <https://www.mass.gov/service-details/vaccine-administration-and-clinical-guidance>

As guidance for enhanced safety monitoring becomes available from CDC, it will be reviewed and incorporated.

### Vaccination Provider Training

Information about the requirement and process for reporting adverse events is included in vaccine provider training - See *Section 5: COVID-19 Provider Recruitment and Enrollment*. Massachusetts Department of Public Health (MDPH) staff is trained to respond to calls from providers and the public about COVID-19 vaccine safety and reporting of adverse events.

### Designated Massachusetts Vaccine Safety Coordinator

The MDPH Immunization Nurse Manager is the Vaccine Safety Coordinator (VSC) and serves as CDC’s contact in Massachusetts for outreach, education, communications, and exchange of information on vaccine safety issues between providers and CDC staff. The VSC responds to VAERS questions, assists providers with reporting to VAERS as needed, and promotes VAERS reporting.

The MDPH VSC has provided contact information to the CDC and monitors Epi-X for the VAERS reports. To prepare for COVID-19 VAERS data, the VSC attended the CDC call: *Planning for Your Public Health Jurisdiction’s Access to VAERS Data for COVID-19 Vaccine*, and has signed and returned the VAERS Non-Disclosure Agreement to CDC.

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## Section 15: COVID-19 Vaccination Program Monitoring

### Methods and Procedures for Monitoring Progress of MCVP Implementation

The Massachusetts Department of Public Health (MDPH) is establishing goals and developing procedures to monitor the planning and implementation of the Massachusetts COVID-19 Vaccination Program (MCVP). Monitoring will be ongoing throughout the implementation process.

#### Provider enrollment

The number of providers, along with their provider profiles, enrolled in the MDPH Vaccine Program and/or registered with the Massachusetts Immunization Information System (MIIS) is reviewed at regular meetings of the Vaccine Unit and the MIIS Unit. The Vaccine Unit and MIIS Unit are currently reviewing this information and establishing goals for provider enrollment, prioritizing the providers that will vaccinate critical populations and then expanding to other adult providers.

#### Access to COVID-19 vaccination services by population in all phases of implementation

In all phases of implementation, the Vaccine Unit will monitor the number of doses distributed by municipality to ensure that the providers in each region of the state receive vaccine commensurate to its relative proportion of the state's population. MDPH meets with local public health (LPH) officials on twice-weekly conference calls and through regular regional meetings, where LPH will report on issues in their communities regarding access to vaccination services. In addition, the MDPH Immunization Division will track calls from providers and the public and regarding issues with access to COVID-19 vaccine. Other MDPH programs, state agencies and external partners may identify access issues specific to their constituents. These will be relayed to the MDPH Immunization Division or other relevant programs for follow-up and resolution. The Immunization Division will monitor the number of doses administered, by age group and by town with additional data analysis provided by the analytical modeling as described in Section 4.

#### MIIS or other designated system performance

Monitoring of MIIS performance is ongoing. The MIIS Unit has acquired additional personnel to monitor the system and evaluate data quality, timeliness, and accuracy.

#### Data reporting to CDC

Massachusetts law limits how certain MIIS data may be shared. The MDPH COVID-19 Vaccination Leadership Team and MDPH legal counsel will review any proposals to share such MIIS data. Provider enrollment data will be submitted to CDC twice a week.

#### Provider-level data reporting

Providers receiving COVID-19 vaccine will be required to submit doses-administered data to the MIIS, and providers will not receive additional doses until previously distributed vaccine is accounted for. The Vaccine Unit and/or the MIIS Unit will follow up with providers who do not provide timely reports of vaccine usage.

The MIIS Unit uses a provider scorecard to assess the quality of the data that providers report to the MIIS. The provider scorecard provides each practice registered with the MIIS an assessment of the completeness, accuracy, validity, and timeliness of the data they have submitted to the registry. The

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scorecard indicates if the information in the application meets or does not meet expectations. These scorecards are updated monthly and found on the provider's landing page on the MIIS website.

## Vaccine ordering and distribution

MDPH will use the MIIS to monitor and process COVID-19 vaccine ordering. During Phase 1, MDPH will upload a spreadsheet of all orders into the MIIS. Once vaccine supply has increased, providers will enter orders directly into the MIIS. The Vaccine Unit will review and approve orders to ensure doses ordered are administered. The Vaccine Unit will use the temperature logs submitted by providers to ensure that storage units are maintaining the appropriate temperature range. Once approved, the MIIS will produce an export for upload into the Vaccine Tracking System (VTrckS). MDPH will require providers to contact the Vaccine Unit prior to transfer of vaccine to another site. MDPH will transfer inventory in MIIS so that virtual inventories reflect physical inventories. Prior to approving transfers, the Vaccine Unit will ensure that the site receiving vaccine has signed all required agreements and has the appropriate storage units. The Vaccine Unit will approve all COVID-19 transfer of vaccines and ensure that the site has completed all required paperwork to receive and administer vaccines.

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

Determining vaccination coverage without a wide-scale survey is a challenge because of the difficulty in determining the appropriate denominator. The U.S. Census and the American Community Survey will be used to establish denominators for age groups and geographic areas. The numerator will consist of the number of doses administered to each group, as reported by providers.

## Methods and Procedures for Monitoring Resources

MDPH will utilize the following budget, staffing, and supply tracking mechanisms to monitor resources:

- Budget: Regular monitoring includes a monthly meeting with programmatic and fiscal staff to review all budgets
- Staffing: Program managers continuously monitor staffing needs and staffing updates are provided during regular senior managers' meetings, and, on an ad hoc basis, as necessary
- Supplies: Inventory lists are used to track supplies so that re-ordering can happen when certain supply levels decrease below specified thresholds

## Methods and Procedures for Monitoring Communication

MDPH will continue to participate in CDC all-jurisdiction calls and monitor regular email communication and website updates to ensure Massachusetts' messaging is consistent with CDC national messaging.

MDPH will monitor social media to assess message delivery and reception, and to identify and dispel inaccurate information. *See Section 12: COVID-19 Vaccination Program Communications.*

## Methods and Procedures for Monitoring Local-level Situational Awareness

Frequent situational reports from local public health officials and community partners will allow MDPH and its partners to quickly identify gaps in planning and implementation at the local level and provide technical assistance as necessary. MDPH will monitor the CDC COVID-19 Vaccination Response Dashboard as data become available. *See Section 2: COVID-19 Organizational Structure and Partner Involvement.*

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### MCVP Metrics

The Massachusetts COVID-19 Daily Dashboard and Weekly Public Health Report can be found on the state's public-facing website [mass.gov](https://www.mass.gov), the state government website, under COVID-19 Updates. The MDPH COVID-19 Vaccination Leadership Team will determine what MCVP metrics will be posted and where, in conjunction with the Daily and Weekly report.

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