

NEW YORK STATE'S COVID-19 VACCINATION PROGRAM

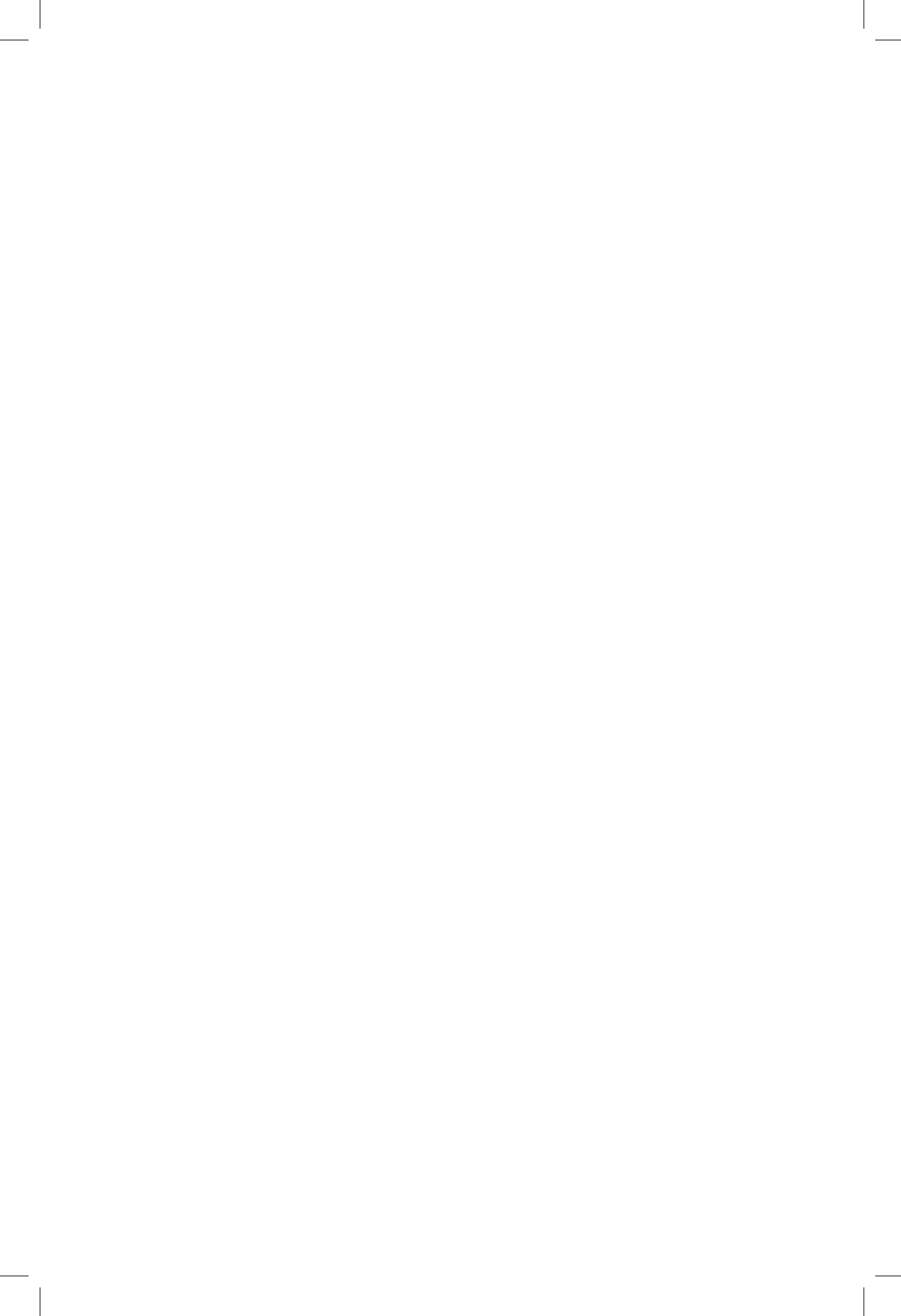


OCTOBER 2020



Department
of Health







“What do we want to accomplish in New York? We should have the best vaccination program in the United States of America. I think the way we have handled COVID has been a model for this country. I want New Yorkers to do the same thing with vaccines.”

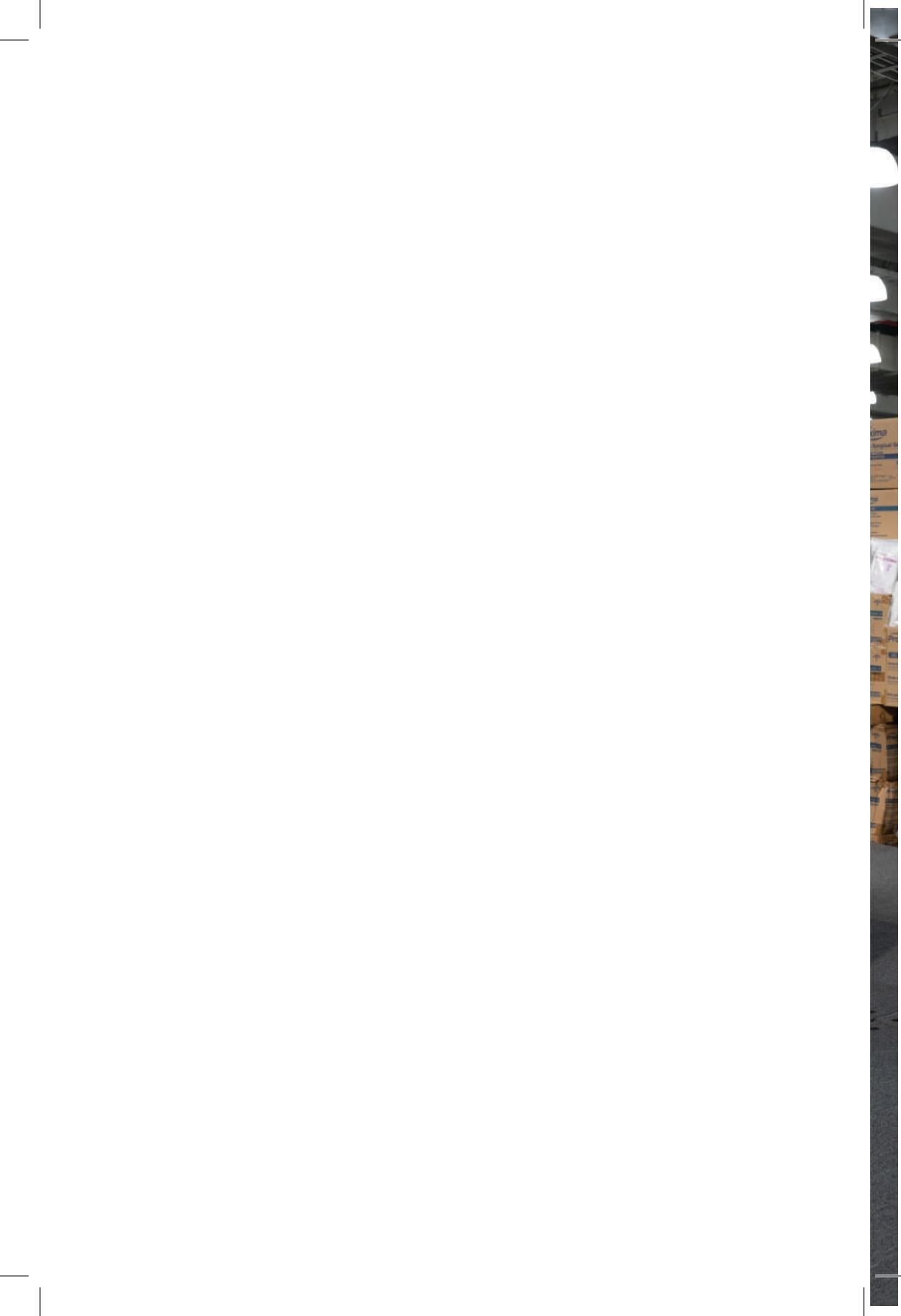
Governor Andrew M. Cuomo
September 2020

Note: While New York State has set forward the following operational plan, several details remain unknown and there are future decisions that will need to be made that are dependent on further information regarding the delineation of federal and state responsibilities; the funding needs associated with those responsibilities; and the planned supply chain management and vaccine allocation process. As a result, the approaches and methodology discussed in the New York State COVID-19 Vaccination Program plan should be considered proposed and interim, and final strategies will be established once further details and decisions are known.

TABLE OF CONTENTS

EXECUTIVE SUMMARY	5
1. GUIDING PRINCIPLES	11
2. KEY ASSUMPTIONS AND UNKNOWNS	15
CURRENT UNKNOWN VARIABLES.....	16
PUBLIC HEALTH PREPAREDNESS IMPROVEMENT PLANNING	20
3. VACCINE SAFETY AND EFFECTIVENESS	21
4. VACCINE DISTRIBUTION AND IMPLEMENTATION	25
5. VACCINE PRIORITIZATION BASED ON CLINICAL GUIDANCE	29
VACCINE PRIORITIZATION MATRIX	31
POPULATION RISK & ESSENTIAL WORKER PHASES	32
TRIBAL NATIONS	33
HEALTH EQUITY	34
6. VACCINE DISTRIBUTION & DELIVERY	37
STORAGE & INVENTORY.....	39
VACCINE DISTRIBUTION & DELIVERY - POSSIBLE REGIONAL COLD STORAGE LOCATIONS	40
7. ADMINISTRATION OF VACCINE	41
PREPARATION FOR EACH VACCINATION ADMINISTRATION SITE (VAS)	45
PHARMACIES	46
LOCAL HEALTH DEPARTMENTS	47
STATE OPERATED AND SUPPORTED VACCINATION SITES	48
REPORTING	50
8. DATA AND INFORMATION TECHNOLOGY (IT) INFRASTRUCTURE	51
NEW YORK STATE IMMUNIZATION INFORMATION SYSTEM (NYSIIS)	52
PATIENT SUPPORT & PUBLIC REPORTING	57
SECOND-DOSE REMINDERS	58

9. PUBLIC EDUCATION & COMMUNITY ENGAGEMENT REGARDING VACCINATION PROGRAM	61
10. ORGANIZATIONAL LEADERSHIP	67
REGULATORY AND LEGAL REVIEW	70
VACCINE INFORMATION STATEMENTS (VISs)	72
11. PROCUREMENT OF NECESSARY SUPPLIES AND EQUIPMENT	73
12. POST-VACCINATION MONITORING	78





EXECUTIVE SUMMARY

EXECUTIVE SUMMARY

The New York State COVID-19 Vaccination Program is drafted to ensure the distribution and administration of a safe and effective COVID-19 vaccine to all residents of the Empire State who wish to receive it. The program is designed to be flexible given many unknowns at this point in the process, including the uncertainty on vaccine availability, timeline for vaccine approval, delineation of federal and state responsibilities, funding, supply chain needs, and allocation requirements. The program is drafted on the advice and recommendation of clinical and public health experts, and its success is contingent on partnership and collaboration with local departments of health, community partners and organizations. Recent public opinion polls suggest that the percentage of Americans who would get the vaccine if it were available today has dropped to just over 50 percent in September from 72 percent in May, making the vaccine program's effectiveness also dependent on the building and maintaining of public trust in the product and the process.

This document - the New York State COVID-19 Vaccine Program - describes the steps that are being taken and protocols that are being put in place to ensure the safe and efficient distribution and administration of vaccine to New York residents. The document outlines:

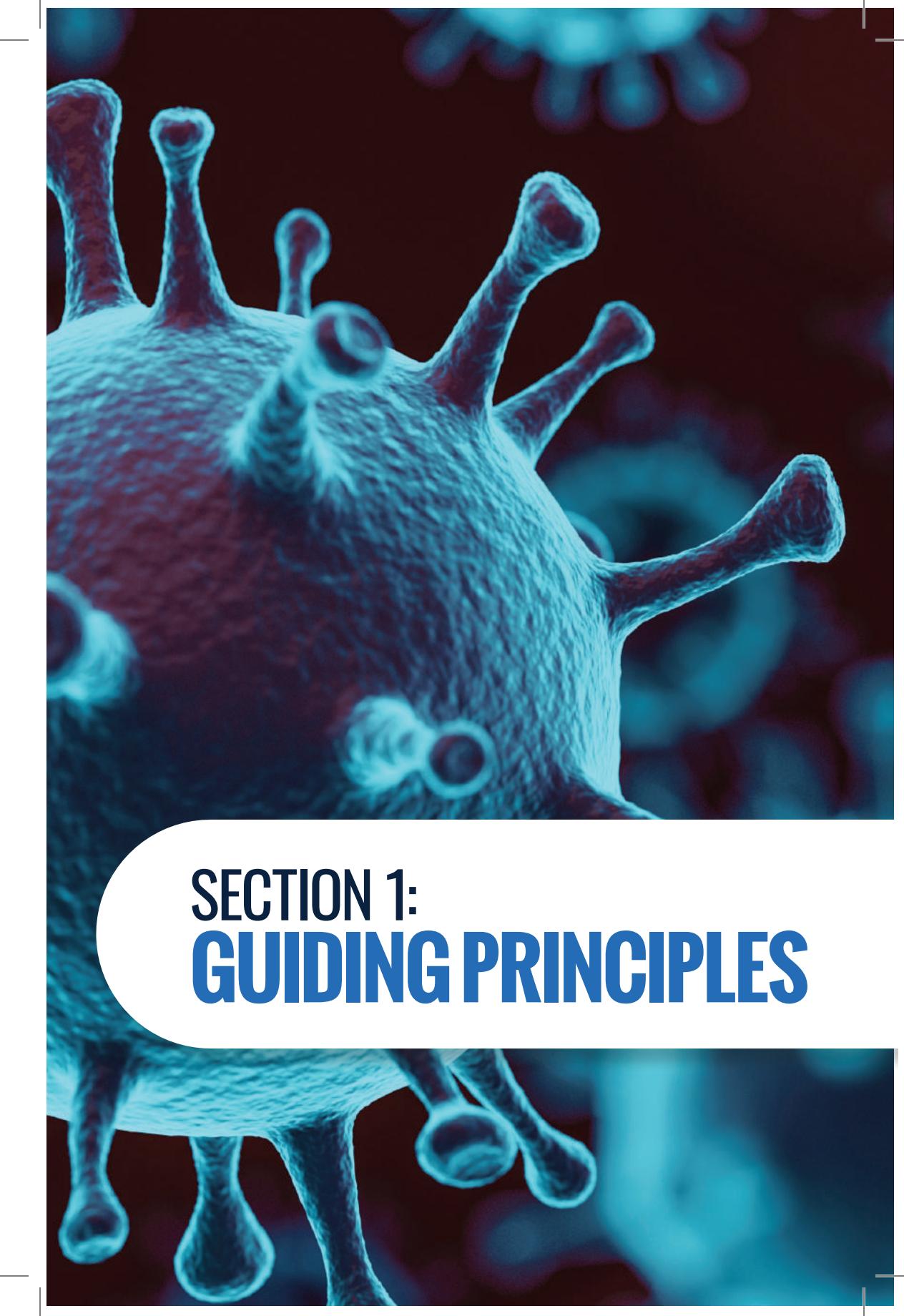
1. Guiding principles to be adhered to throughout the vaccine process

2. Key assumptions, unknowns, and variables that may impact vaccine planning
3. Measures to ensure vaccine safety and effectiveness (pre and post administration)
- 4.. Expertise to guide vaccine distribution and implementation
5. A vaccine prioritization matrix based on clinical guidance
6. A process for efficient vaccine distribution & delivery
7. Measures to train, register, deploy, and support providers to administer the vaccine
8. A data and IT infrastructure to coordinate and monitor all aspects of the vaccine program
9. A public education & community outreach campaign to build trust and inform the public
10. A Vaccine Central Command Center to manage the entire vaccine program
11. A budget and procurement process to obtain necessary supplies and equipment

It is expected that vaccine distribution and administration approaches will be informed by the federal government upon release of the vaccine to states. The “COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations,” released by the Centers for Disease Control and Prevention (CDC) on September 16, 2020, requested states to submit plans by October 16, 2020. The New York State COVID-19 Vaccination Program is responsive to this request and details the state’s preparatory efforts for a mass vaccination effort.

NEW YORK STATE'S COVID-19 VACCINATION PROGRAM





SECTION 1: GUIDING PRINCIPLES

SECTION 1. GUIDING PRINCIPLES

New York State based its COVID-19 vaccine distribution and administration process on ten guiding principles.

1. Safety: New York State will only endorse and distribute a COVID-19 vaccine if it is determined to be safe and will only be used according to the indication under which it received its authorization or license. This includes pharmacovigilance post-licensure and adverse event monitoring post administration.

2. Effectiveness: New York State will only endorse and distribute a COVID-19 vaccine if it is demonstrated to be appropriately effective in the populations intended for use.

3. Expert approved: New York State will rely on the advice and counsel of established clinical experts and scientists to review and approve the safety and efficacy of every vaccine that is authorized by the federal government for distribution.

4. Equitable & clinically driven distribution: New York State's COVID-19 vaccine distribution approach will be based solely on clinical and equitable standards that prioritize access to persons at higher risk of exposure, illness and/or poor outcome, regardless of other unrelated factors, such as wealth or social status, that might confer unwarranted preferential treatment.

5. Transparency: Throughout the COVID-19 crisis, the state's daily public presentation of facts and reliance on science and medical expertise helped build public trust and confidence in

government action. Similarly, New York State will continue to be transparent regarding all aspects of the COVID-19 vaccine distribution, administration, and monitoring process to ensure New Yorkers are fully informed.

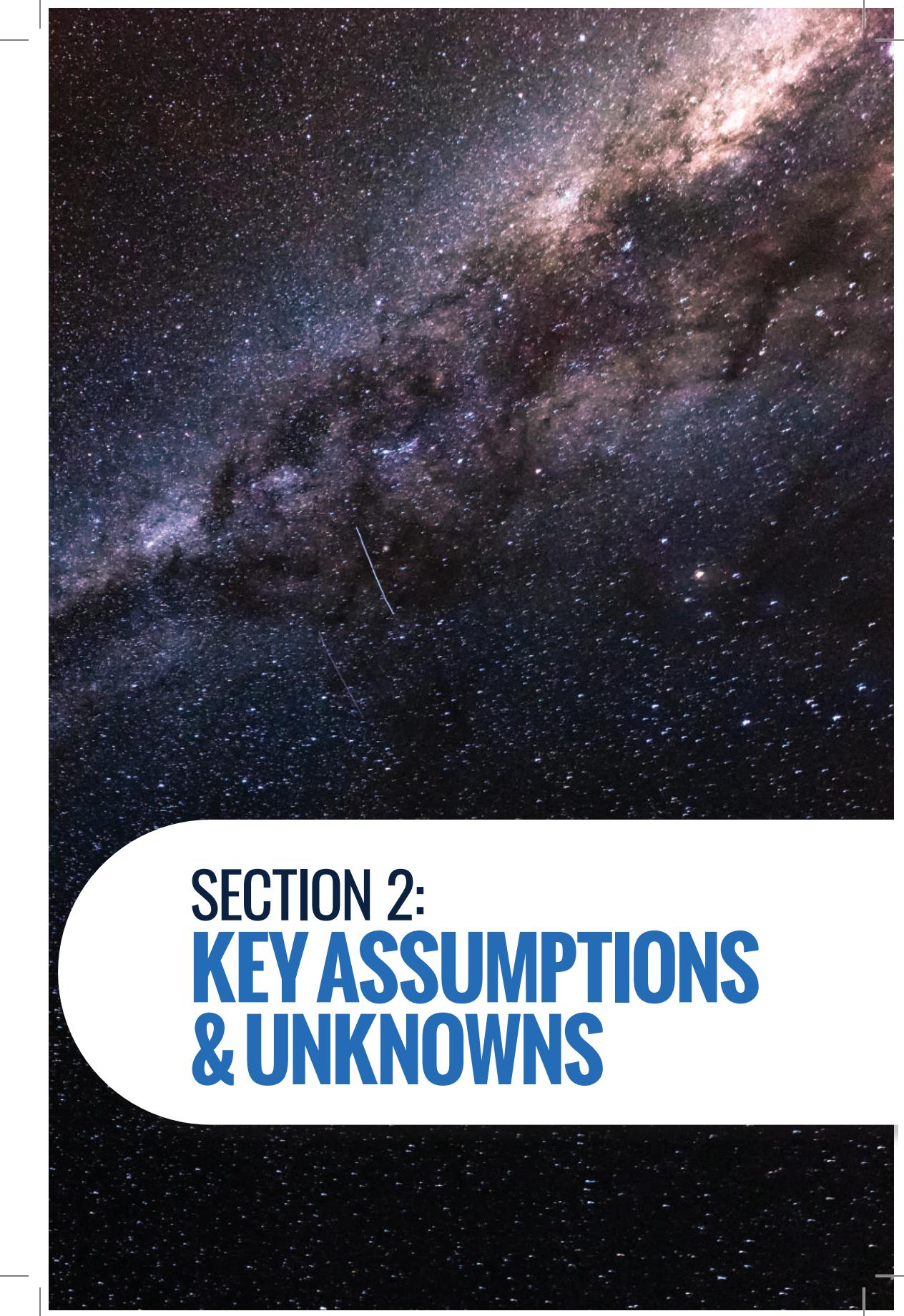
6. Use of Data: Coordination of a successful vaccination program will require robust tracking, data and analytics capabilities. New York State will use robust data and information technology platforms to guide all parts of the COVID-19 vaccine distribution and administration process to maximize safety, accuracy, and efficiency and meet all Federal reporting requirements.

7. Privacy and Patient Safety: Vaccination does not negate the importance of other public health measures that have served us well to date in the containment of COVID-19. New York State will continue to urge compliance with social distancing, mask wearing, hand washing, and other measures. In addition, New York State will ensure all vaccination processes prioritize patient safety, and all information systems guarantee patient privacy.

8. Partnership, Coordination & Public Outreach: New York State recognizes that coordination with local organizations and community providers is essential to the safe and successful distribution and administration of COVID-19 vaccines. The state's outreach efforts will especially focus on reaching underserved, hard to reach, vulnerable, less accessible and vaccine hesitant populations, as well as those at highest risk for COVID-19 infection and poor outcomes.

9. State Leadership: New York State hopes for and expects a robust federal engagement on vaccine vetting, distribution, administration, and funding. However, given the shortcomings of the federal response experienced since the outset of the COVID-19 epidemic, New York State will undertake necessary preparatory steps and require local coordination with the state's centralized approach to ensure an efficient and organized vaccine distribution.

10. NEW YORK TOUGH: Throughout this COVID-19 crisis, New Yorkers have shown that there is nothing we cannot do if we work together as one community. Our approach to the COVID-19 vaccine will be tough, strong, united, disciplined, and loving.



SECTION 2:

KEY ASSUMPTIONS & UNKNOWNS

SECTION 2. KEY ASSUMPTIONS AND UNKNOWNs

As of mid-October 2020, much is still unknown about the potential COVID-19 vaccines and the process that the federal government will undertake regarding its allocation, distribution and administration. New York State's COVID-19 Vaccination Program therefore accounts for multiple variables and scenarios, an approach that will help guide the state as situations and circumstances change. Consideration of a range of possibilities will ensure New York State is fully prepared to adapt operational and clinical decisions to achieve the best outcome as initial assumptions change or are confirmed.

CURRENT ASSUMPTIONS REGARDING COVID-19 VACCINE

- Initially, COVID-19 vaccines are expected to be approved for use by the Food and Drug Administration (FDA) under an Emergency Use Authorization (EUA). Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases when there are no adequate, approved, and available alternatives. Vaccines granted EUA will be approved for distribution while the vaccine manufacturer simultaneously seeks full licensure. The CDC's Advisory Committee on Immunization Practices (ACIP) will develop recommendations for appropriate use of each vaccine once approved.

- Although some COVID-19 vaccines may only require one dose, the current plan assumes a more challenging scenario of vaccines requiring a two dose regimen, administered 21 to 28 days apart. Doses must be from the same vaccine manufacturer and cannot be interchanged from one product to another. As a result, supply must be reserved to ensure second dose coverage before administering initial doses.
- COVID-19 vaccine supply may initially be limited in the first months after initial EUA approval, expanding rapidly within future months.
- Initial federal allocation to New York State may be pro-rata based on priority populations in the state as determined by federal data systems such as HHS Protect and state data sources.
- While there are still unknown aspects of vaccine prioritization, initial vaccine distributions may be informed by the federal government and doses may be released to states on condition they are prioritized for use by certain priority populations, likely to include front line health care workers, residents of long-term care facilities, and other persons at high risk of mortality from COVID-19. More information will need to be known on this distribution prioritization and what decisions are expected to be made by the states and which by the federal government.
- Vaccine characteristics will determine which vaccine should be used in which populations (i.e., older adults). Approval for use in pregnant women and children may not be immediate.

- Varied cold chain requirements for the vaccines from refrigerated (2°C to 8°C) to frozen (-15°C to -25°C) to ultra-cold freezers (-60°C to -80°C) may pose unique challenges to storage, handling, and distribution.
- Public opinion is mixed on the safety and efficacy of any vaccine. Misinformation will likely be actively disseminated on social media and other sources.

CURRENT UNKNOWN VARIABLES

- Federal v. State responsibilities and roles: On October 14, Governor Cuomo released a letter from the National Governors Association (NGA) asking President Trump for a meeting to discuss how a vaccination program would be conducted and what are the respective roles of the federal and state governments. The letter noted that states including New York are willing to assist the federal government's efforts to ensure a national vaccination campaign is implemented smoothly and efficiently, however, additional guidance and clarification is needed on the roles and expectations of states in a successful COVID-19 vaccine distribution and implementation plan. The hope of this meeting is to discuss what is required to ensure a strong partnership, including but not limited to: the delineation of federal and state responsibilities; the funding needs associated with those responsibilities; and the planned supply chain management and vaccine allocation process.

- Funding: A robust vaccine administration program will require robust funding. It is unknown whether and the extent to which the federal government will allocate this funding to states for this purpose. CDC Director Robert Redfield recently stated that Congress will need to allocate \$5.5 to \$6 billion to the states for this purpose. New York State to date has received \$7.8M for COVID-19 vaccination purposes.
- State vs. Local Distribution: It is unknown whether the federal government will distribute all vaccinations for New York's 19.5 million residents directly to the state government, or whether private entities or local governments will receive their own separate allotment, or a combination of any of these options. To ensure coordinated and efficient statewide distribution and administration, all localities and entities in New York State will be required to follow the state's guidance and protocols for COVID-19 vaccination.

To keep fully abreast of the changing landscape and adjust for all scenarios, New York State will track daily updates on vaccine trials, clinical data, and federal plans for distribution and administration.

PUBLIC HEALTH PREPAREDNESS IMPROVEMENT PLANNING

The NYSDOH 2009 H1N1 Influenza Pandemic After-Action Report and Improvement Plan presented an in-depth analysis of New York's health emergency response to the first influenza pandemic that had occurred in 42 years, from the spring of 2009 through early 2010. The report identified the strengths, areas for improvement, and corrective actions that resulted from this real-world event.

In addition, through the ongoing public health emergency preparedness funding, the state and local health departments (LHDs) actively engage in ongoing emergency preparedness activities that include improvement-related deliverables such as trainings, workshops, tabletop exercises and full-scale drills. These allow for continuous improvements in operationalizing a vaccination campaign.

Lessons from the H1N1 vaccination effort and emergency preparedness exercises are being incorporated into the COVID-19 vaccine planning process.



SECTION 3: **VACCINE SAFETY** **& EFFECTIVENESS**

SECTION 3. VACCINE SAFETY AND EFFECTIVENESS

It has been publicly reported that a majority of Americans are skeptical of the current federal administration's credibility on COVID-19 vaccine safety and effectiveness, with reports showing the number of Americans willing to receive the vaccine if it were available today has declined since spring. To establish and build public trust, on September 29, Governor Cuomo appointed members to New York's independent Clinical Advisory Task Force comprised of leading scientists, doctors, and health experts who will expeditiously review every COVID-19 vaccine authorized by the federal government, and will advise New York State on the vaccine's safety and effectiveness in fighting the virus.

The Clinical Advisory Task Force will help NYS determine if the vaccine safe and effective. The Task Force is comprised of Department of Health subject matter experts and recognized external experts in medicine, law, and science:

- 1. Charles M. Rice, PhD, The Rockefeller University (Chair)**

- 2. Scott H. Hammer, MD, New York-Presbyterian/Columbia University Medical Center (Chair)**

- 3. Shawneequa Callier, MA, JD, George Washington University School of Medicine and Health Sciences**
- 4. Bruce Farber, MD, Northwell**
- 5. Adolfo Garcia-Sastre, PhD, Icahn School of Medicine at Mount Sinai**
- 6. Kelvin Lee, MD, Roswell Park**
- 7. Sharon Nachman, MD, Renaissance School of Medicine at Stony Brook**

The Task Force's independent review of any federally authorized COVID-19 vaccine will help address publicly reported concerns about the scientific process and rush to market. The Task Force will rely on numerous data sources including public information and the findings of expert third party independent organizations. In addition, they will provide for the involvement and/or input of regional/local clinical and other leadership representative of all areas of the state. The Task Force will advise on the vaccine safety profile, legal authority to withhold vaccine, and clinical best practices if New York State must withhold or pause distribution of the vaccine. The group will also advise New York State as to the implications of a vaccine being released under an FDA EUA.





SECTION 4: **VACCINE DISTRIBUTION** **& IMPLEMENTATION**

SECTION 4. VACCINE DISTRIBUTION AND IMPLEMENTATION

Once New York's independent Clinical Advisory Task Force has advised that a COVID-19 vaccine is safe and effective, the vaccine will be distributed and administered throughout New York State.

To help guide this process, on September 24 the Governor established a Vaccine Distribution and Implementation Task Force to advise the set up and operation of the state's COVID-19 vaccination program. The Vaccine Distribution and Implementation Task Force is comprised of experts in public health, immunizations, government operations, data and other fields relevant to vaccine distribution and administration:

MEMBERS OF THE VACCINE DISTRIBUTION AND IMPLEMENTATION TASK FORCE:

- **Howard Zucker, MD, JD, Commissioner, NYS Dept. of Health**
- **Karim Camara, NYS Office of Faith-Based Community Development Services**
- **Mantosh Dewan, MD, Interim President, SUNY Upstate Medical Center**
- **Michael Dowling, President & CEO, Northwell Health**
- **Rose Duhan, President, Community Healthcare Association for NYS**

- Michael Duteau, President, Chain Pharmacy Association of New York State
- Deanna Ennello-Butler, Executive Director, Pharmacy Society of State of New York
- Helen Evans, President, NYS Association of Rural Health
- Bea Grause, President, Healthcare Association of New York State
- George Gresham, President, 1199SEIU United Healthcare Workers East
- Rev Diann Holt, AME Zion Church, Doula, Buffalo area
- Micky Jimenez, Regional Director, Capital District LATINOS
- Bonnie Litvack, MD, President, Medical Society of State of New York
- Jim Malatras, SUNY Chancellor
- Michael Martin, Executive Director, Native American Community Services of Erie and Niagara Counties, Inc.
- Robert Mujica, Division of Budget
- Patrick Murphy, Commissioner, Division of Homeland Security and Emergency Services
- Alicia Ouellette, JD, President, Albany Law School

- **Rajiv Rao, Chief Technology Officer, NYS**
- **Kenneth Raske, President, Greater New York Hospital Association**
- **Sarah Ravenhall, Executive Director, NYS Association of County Health Officials**
- **Rosanna Rosado, NYS Secretary of State**
- **Eli Rosenberg, Professor, SUNY University of Albany Department of Epidemiology and Biostatistics**
- **Chanie Sternberg, President & CEO, Refuah Health**
- **Ramon Tallaj, Executive Director, Somos**

Additional members will continue to be added to the NYS Vaccine Distribution and Implementation Task Force as the vaccination program is operationalized.



SECTION 5:

VACCINE PRIORITIZATION BASED ON CLINICAL GUIDANCE

SECTION 5. VACCINE PRIORITIZATION BASED ON CLINICAL GUIDANCE

Following the determination that the vaccine is safe and effective, New York State will prioritize vaccination recipients based on science, clinical expertise, and federal guidelines. Critical populations will be identified and recommended by the Advisory Committee on Immunization Practices (with input from the National Academies of Sciences, Engineering, and Medicine). Prioritization decisions will take into account evolving surveillance data and closely monitor the clinical efficacy of the vaccination program. Prioritization decisions will be made mindful of the disparate impact of COVID-19 on communities of color, and the health disparities present in underrepresented and marginalized communities, and those with historically poor health outcomes.

All prioritization planning will be sufficiently detailed and flexible in order to quickly adjust target recipient populations given changes in the supply of vaccine that is designated for distribution in New York State, the number of New Yorkers seeking vaccination, and new understandings regarding the vulnerability of certain populations to COVID-19. Further information is needed regarding the federal government's expectations regarding vaccine prioritizations before final decisions can be made.

In anticipation of limited numbers of vaccine initially available coupled with current knowledge of COVID-19

morbidity and mortality, public health concerns, and the need to maintain essential services, one of New York's prioritization strategies for vaccine distribution is designed to ensure early vaccination of the most vulnerable New Yorkers as well as essential frontline workers, with distribution potentially directed to these populations who reside or work within communities with highest prevalence of COVID-19.

Vaccine Prioritization Matrix

	High COVID-19 Prevalence in Geographic Area	Low COVID-19 Prevalence in Geographic Area
High Risk Population/ Essential Healthcare Workers	PRIORITY 1	PRIORITY 2
Lower Risk Population/ Other Essential Workers	PRIORITY 3	PRIORITY 4
General Population	PRIORITY 5	PRIORITY 6

Once the vaccine is first approved for use, New York State will use up-to-date data to determine which geographic areas of the state may derive a greater public health benefit to receiving early vaccine. This may include areas with higher historical burden of disease or areas that have the highest prevalence of COVID-19. In addition, individual factors for hospitals and nursing homes will be considered including cases per facility in prior 14 days, and vulnerability index of population served. New York will also consider whether the vaccine can be used effectively as a potential outbreak interruption strategy and if so, what the criteria will be.

Population Risk & Essential Worker Phases

Phase 1	<ul style="list-style-type: none">Healthcare workers (clinical and non-clinical) in patient care settings<ul style="list-style-type: none">ICU, ED, EMS top priorityLong-term care facility (LTCF) workers who regularly interact with residentsMost at-risk long-term care facility patients
Phase 2	<ul style="list-style-type: none">First responders (fire, police, national guard)Teachers/school staff (in-person instruction), childcare providersPublic Health workersOther essential frontline workers that regularly interact with public (pharmacists, grocery store workers, transit employees, etc.) or maintain critical infrastructureOther long-term care facility patients and those living in other congregate settingsIndividuals in general population deemed particularly high risk due to comorbidities and health conditions
Phase 3	<ul style="list-style-type: none">Individuals over 65Individuals under 65 with high-risk comorbidities and health conditions
Phase 4	<ul style="list-style-type: none">All other essential workers
Phase 5	<ul style="list-style-type: none">Healthy adults and children

Within each phase, sub-populations will be identified to allow for additional micro-level prioritization based on vaccine availability and vaccination rates. For example, healthcare workers that regularly interact with patients may be prioritized over those that do not, and ICU and emergency department healthcare workers will likely be prioritized in hospitals if supply is not enough for the entire hospital staff. All entities receiving the vaccine will be given a level of autonomy to determine the internal order of employee vaccination based on risk and within the boundaries of NYS and federal guidance. To guide prioritization, New York State will collect up-to-date numbers of all prioritization and micro-level prioritizations groups statewide including sub-populations.

The state will also use data and clinical expertise to continue to determine which populations are at most risk for COVID-19 infection as well as poor outcomes, hospitalization and death, as well as which populations are

most critical for societal and economic function. To guide prioritization and allocation decisions, New York State will maintain up-to-date estimates on the number of New Yorkers in, and geographic distribution of, each of these population groups.

Prior to the first vaccine(s) being approved for distribution and administration, New York will prepare detailed allocation scenarios based on this data and variables for vaccine allotment amounts and vaccination rates within priority populations.

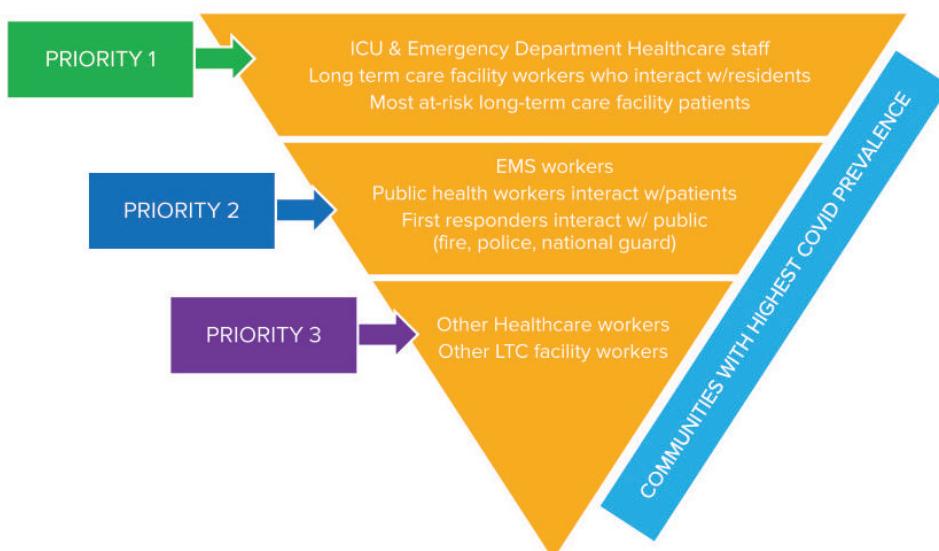
TRIBAL NATIONS

Although CDC has stated they will work directly with the Indian Health Service (IHS) at the federal level, NYSDOH will also plan to include New York State tribal organizations as part of state planning efforts, pending further federal direction. Tribal Nations, being sovereign entities, maintain government-to-government relationships at the State and Federal levels, and may choose to work directly through these relationships. However, counties that are contiguous to Tribal Nations routinely collaborate with these communities to ensure vaccination needs are met. Therefore New York State will also prepare plans to distribute COVID-19 vaccine to those tribes that are not federally recognized or that are unable to access vaccine through federal agency distributions.

HEALTH EQUITY

Heightened COVID-19 mortality among Black and Hispanic communities (relative to white non-Hispanic) is well established. In addition, compared to white non-Hispanic adults, racial/ethnic minority populations had disproportionately higher per population likelihoods of COVID-19 diagnosis and hospitalization. New York State will continue to work closely with partners across the state who can assist in addressing health equity issues and ensure that access to healthcare and vaccine are not a barrier for COVID-19 treatment strategies. Healthcare providers, community-based organizations, and religious and community leaders will continue to assist New York State to achieve these goals and will be represented across the various stakeholder groups.

Scenario: Hypothetical Allocation of 100,000 doses (two doses per person - 50,000 people):



While New York has set forward a detailed vaccine prioritization approach, it is unknown the extent to which federal allocation priorities will be pre-determined for state governments to follow at the onset of vaccine distribution. All allocation strategies discussed in the New York State COVID-19 Vaccination Program plan should be considered proposed and interim, and final allocation decisions will be established when initial vaccine doses are shipped to New York State.

NEW YORK STATE'S COVID-19 VACCINATION PROGRAM





SECTION 6: **VACCINE DISTRIBUTION & DELIVERY**

SECTION 6. VACCINE DISTRIBUTION & DELIVERY

Distributing and delivering enough vaccine to administer two doses to every New Yorker will be a complex logistical undertaking. New York will assign management of this critical task to state agencies with operational and logistical expertise including the Department of Health, Division of Homeland Security and Emergency Services, the Division of Military and Naval Affairs, New York National Guard, the Office of General Services, and the Department of Transportation, and other agencies who will coordinate all aspects of vaccine acquisition and distribution with private and community health care and partners and local governments. Distribution planning will be flexible to allow for changes in vaccine type and availability and other public health considerations based on the most up-to-date scientific literature and CDC recommendations, with the goal of maximizing public health protection. Distribution planning will provide for strict adherence to handling and storage requirements of the vaccine to maintain stability and potency. In addition, it will be essential to ensure chain of custody of all federal and state assets throughout the distribution process.

Federal vaccine distribution plans may allow for some private entities to distribute certain vaccines. For example, McKesson, the current distributor for the CDC, is expected to distribute the Moderna vaccine. While still under federal control and direction, Pfizer, because of storage and handling specifications, is expected to ship directly

to end users. New York State will seek more information on vaccine-specific distribution plans from the federal government to ensure proper delineation of what is expected of federal and state government and private entities as part of the vaccine distribution process.

STORAGE & INVENTORY

A critical component to managing vaccine distribution and delivery will be vaccine storage and inventory management. In order to address the critical time constraints in distributing this material, New York State will work with local jurisdictions to identify and operationalize appropriate regionally based storage locations, each that comply with CDC and manufacturer recommendations for storage including at temperatures as low as minus 80 degrees celsius. Additional information regarding the ultra-cold COVID-19 vaccine candidate indicates the vaccine may be shipped in a flat “pizza box-like” container with dry ice that would not need recharge until the 10-day mark. This may increase the number of sites without ultra-cold storage that could receive these doses, with the assumption they could successfully administer all doses before the 10-day expiration. Capacity to store and handle vaccines across the full cold-chain spectrum will be assessed as part of the provider enrollment process.

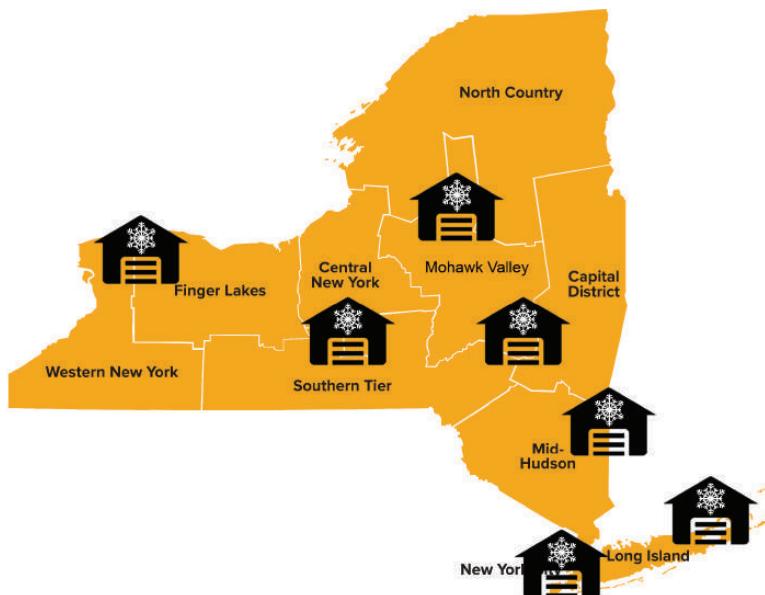
To address limited specialized storage capacity, the plan may utilize larger vaccination administration sites to also serve as the regional storage locations, following the same format as the Strategic National Stockpile of Chempack supplies.

Inventory management will be performed with state-of-the-art data technology platforms to ensure each vaccine dosage is tracked from point of delivery to point of administration, and storage sites are integrated into the delivery process to sites designated for vaccination administration.

To ensure vaccines are transported in a manner consistent with CDC and manufacturer recommendations that maximizes vaccine stability and minimizes wastage, New York State may deploy vehicles equipped to transport vaccines that meet required cold-chain requirements.

New York State will seek more information on storage requirement and inventory management needs the federal government and private vaccine manufacturers to ensure adequate supply chain processes are put in place.

VACCINE DISTRIBUTION & DELIVERY - POSSIBLE REGIONAL COLD STORAGE LOCATIONS





SECTION 7: **ADMINISTRATION OF VACCINE**

SECTION 7. ADMINISTRATION OF VACCINE

To administer the vaccine, New York State will rely on an established network of health care providers, including hospitals, LTCFs (nursing homes, adult care facilities (ACFs), assisted living), Federally Qualified Health Centers (FQHCs), Community Health Centers, Rural Health Clinics, private provider offices, local health departments, and other entities that will serve as Vaccination Administration Sites (VAS). In addition, the state will work with commercial and independent pharmacies, businesses, and other organizations to enable on-site vaccination at these sites. Other VASs include schools, colleges and universities, homeless shelters, correction facilities, and sites where target populations gather (i.e., senior centers, social service offices, food pantries, etc.)

New York State will plan for quick activation and mobilization of mass vaccination point of dispensing (POD) sites, designed to be operationalized once vaccine availability increases and outpaces provider administration capacity. In addition, New York State will designate mobile vaccination units, similar to the rapid response team testing efforts that have been deployed statewide to help control viral spread and outbreaks to increase access to hard to reach populations including smaller congregate living facilities.

Providers of all types will need to enroll with the NYSDOH Vaccine Program to be a COVID-19 vaccinator by completing and submitting a COVID-19 Vaccination

Provider Agreement and Provider Profile available through the Health Commerce System (HCS). The enrollment process can accommodate a range of providers including individual clinicians and large, multi-facility health systems. Eligible providers will then be activated in the New York State Immunization Information System (NYSIIS) with COVID-19 vaccine ordering capability. A comprehensive provider outreach, enrollment and training effort is already underway and will be supported by associations representing the various provider groups.

As the vaccine availability increases, the state will establish on its own and in partnership with private and local partners public clinics to serve targeted populations, as well as mass vaccination point of dispensing (POD) sites that can provide doses to thousands of New Yorkers each day. All VAS and health care providers that administer the vaccine will need storage capabilities, PPE, and integration into the state's data and IT infrastructure.

Providing nearly forty million vaccination doses will require the recruitment and training of additional personnel authorized to administer the vaccine. In addition to supporting efforts by existing providers to hire more personnel, the state will mobilize the existing public health workforce and train addition staff capable of assisting at mass vaccination sites and supporting provider networks.

Prior to the vaccine's approval, the state will:

- Identify all existing providers capable of providing COVID-19 vaccination and require registration of

each to develop an accurate database of VAS and help ascertain communities that may need additional vaccination administration sites.

- Work to train, enroll, and register additional providers to expand the network of authorized health providers who can administer the vaccine, including: pharmacists, dentists, veterinarians, paramedics and EMTs, physician assistants (PAs), student nurses, professionals who are currently licensed in other states and interested in supporting New York's vaccination efforts.

Once becoming eligible for a vaccine, New Yorkers will need to know where and when they should seek vaccination. The below table outlines where different populations may be directed to obtain vaccination at each phase of vaccine availability. This is strictly a planning scenario based on current assumptions that is subject to change.

TYPES OF PRIMARY VACCINATION ADMINISTRATION SITES (VAS) WILL INCLUDE:

- In Facility (hospital, long-term care facilities, etc.)
- FQHCs/Community health centers/Rural health clinics
- Primary care provider physician offices (PCP)
- Commercial/Independent Pharmacies
- Local Health Departments
- Mass vaccination point of dispensing sites (MVS/PODs)
- Mobile vaccination units (push PODs), targeted to smaller congregate living facilities

- Other VASs include businesses, schools, colleges and universities, homeless shelters, correction facilities and sites where target populations gather (i.e. senior centers, social service offices, food pantries, etc.)

PREPARATION FOR EACH VACCINATION ADMINISTRATION SITE (VAS)

Each VAS will be required to be registered with New York State. The state began enrolling providers as VASs in early September. New York State is continuing to identify additional vaccine administration locations that can be used to administer the vaccine, including hospitals, nursing homes/ACFs, clinics (FQHCs, CHCs, RHCs), private provider offices, LHDs, and other providers. Prior to vaccine issuance, New York State will issue detailed guidance regarding provider roles, patient messaging, process for scheduling patients for second dose, on-site vaccine storage and temperature monitoring, vaccine safety and efficacy, vaccine administration, vaccine ordering, vaccine reporting, best practices, and other helpful advisory topics.

The Vaccine Distribution and Implementation Task Force will be charged with working with local providers regarding distribution and administration of the COVID-19 vaccine in New York State, and will work to increase providers' trust in the new vaccine for themselves and their patients, and provide support to other physicians as they administer a new vaccine for the first time.

PHARMACIES

Pharmacies have become an increasingly important immunization partners in New York State since they first began providing vaccinations in 2008. Over the past months, pharmacies across the state have been a critical part of New York's battle against COVID-19, including providing testing access in counties across the state. To support pharmacies in their work to administer the COVID-19 vaccine, and ensure the information is available to the patient's primary care provider and/or second dose vaccination provider, New York State DOH will develop and provide trainings, webinars, and technical support, specifically focusing on facilities and providers who have not used the New York State Immunization Information System (NYSIIS) previously and promoting NYSIIS enrollment. In addition, New York State will provide pharmacies with information and support for proper handling and storage of each COVID-19 vaccine.

New York's planning efforts will become more clear once additional federal guidance has been issued. For example, per the CDC's September guidance, the "CDC is working to engage large pharmacy partners to assist with on-site vaccination in Long Term Care Facilities (LTCF). These partners have existing distribution and administration infrastructure (including cold chain) and relationships with some LTCFs to provide medication and, in some cases, vaccination services (e.g., seasonal influenza) for staff and residents in LTCFs; this may reduce burden on jurisdictional health departments. CDC will

ensure jurisdictions have visibility on this work with large pharmacy partners.” More details will be required to determine how such federal efforts will dovetail with what is expected of New York state.

LOCAL HEALTH DEPARTMENTS

Since the onset of the COVID-19 crisis, New York State has worked in close partnership with local health departments (LHDs) across the state. To support local health departments in the administration of the COVID-19 vaccine, New York State will: advise each LHD regarding storage requirements for vaccines that the LHD may be expected to store and/or administer; ensure they are prepared to fully implement their local mass vaccination plans in accordance with State and Federal guidance; advise on protocols for building public trust in the vaccine, and provide technical and logistical assistance as needed.

New York State government, as authorized by the state legislature in statute, has throughout the COVID-19 crisis made uniform and consistent decisions for the entire state regarding public health emergency response, a successful model that has helped New York flatten the curve. To ensure coordinated and efficient statewide distribution and administration, all localities, vaccine recipients and administration entities in New York State will be required to follow the state’s central planning process and guidance for COVID-19 vaccination.

STATE OPERATED AND SUPPORTED VACCINATION SITES

Beginning in March, New York State launched and operated dozens of COVID-19 testing facilities including high volume drive-through sites as well as smaller walk-in sites in collaboration with religious communities and commercial pharmacies, providing convenient locations for New Yorkers to schedule and receive a free coronavirus test. In addition, the state provided PPE, test kits, staff, and other resources to support hundreds of state-supported testing sites across New York, including temporary rapid-testing facilities to help control cluster situations.

Similarly, New York State will mobilize and operationalize a statewide network of state-operated and supported vaccination sites that have the capacity to vaccinate anywhere from a few dozen to thousands of New Yorkers per day. The state will identify strategically located facilities that can host state-operated vaccination sites and build necessary infrastructure to meet the vaccination delivery expectation of each site. In addition, the state will provide local governments, local health departments, and other impactful local organizations and community partners with necessary support to establish local vaccination sites that can increase the volume of doses delivered per day. Similar to New York's rapid pop-up testing approach, the state will be able to operationalize pop-up vaccination sites if certain geographic regions, communities, or

Expected Vaccine Availability Status to Population Group	Likely Unavailable	Mostly Unavailable	Somewhat Available	Mostly Available	Completely Available
Color Code	Red	Orange	Yellow	Green	Blue

Population Group	Phase 1 (Vaccine available for less than 1% of NYS population)	Phase 2 (Vaccine available for 1% - 5% of NYS population)	Phase 3 (Vaccine available for 5-10% of NYS population)	Phase 4 (Vaccine available for 10% - 50% of NYS population)	Phase 5 (Vaccine available 100% of NYS population)
Health Care Personnel	In facility	In facility, PCP, pharmacies	In facility, PCP, pharmacies, mobile units, public clinics, MVS	In facility, PCP, pharmacies, mobile units, public clinics, MVS	In facility, PCP, pharmacies, mobile units, public clinics, MVS
Long Term Care Facility Staff	In facility	In facility, PCP, pharmacies	In facility, PCP, pharmacies, mobile units, public clinics, MVS	In facility, PCP, pharmacies, mobile units, public clinics, MVS	In facility, PCP, pharmacies, mobile units, public clinics, MVS
Long Term Care Facility Residents	In facility	In facility	In facility	In facility	In facility, PCP, pharmacies, mobile units, public clinics, MVS
EMS/Public Health Workers	In facility, mobile units	In facility, PCP, pharmacies, mobile units	In facility, PCP, pharmacies, mobile units, public clinics, MVS	In facility, PCP, pharmacies, mobile units, public clinics, MVS	In facility, PCP, pharmacies, mobile units, public clinics, MVS
First Responders (Police, Fire, National Guard)	In facility, mobile units	In facility, PCP, pharmacies, mobile units	In facility, PCP, pharmacies, mobile units, public clinics, MVS	In facility, PCP, pharmacies, mobile units, public clinics, MVS	In facility, PCP, pharmacies, mobile units, public clinics, MVS
Other frontline workers (pharmacists, grocery store workers, transit workers, etc.)	In facility, mobile units	In facility, PCP, pharmacies, mobile units	In facility, PCP, pharmacies, mobile units, public clinics, MVS	In facility, PCP, pharmacies, mobile units, public clinics, MVS	In facility, PCP, pharmacies, mobile units, public clinics, MVS
Teachers, school staff, child care providers	In facility, mobile units	In facility, PCP, pharmacies, mobile units	In facility, PCP, pharmacies, mobile units, public clinics, MVS	In facility, PCP, pharmacies, mobile units, public clinics, MVS	In facility, PCP, pharmacies, mobile units, public clinics, MVS
Individuals over age 65	In facility, PCP, pharmacies	In facility, PCP, pharmacies, mobile units, public clinics, MVS	In facility, PCP, pharmacies, mobile units, public clinics, MVS	In facility, PCP, pharmacies, mobile units, public clinics, MVS	In facility, PCP, pharmacies, mobile units, public clinics, MVS
Individuals under age 65 with health conditions	In facility, PCP, pharmacies	In facility, PCP, pharmacies, mobile units, public clinics, MVS	In facility, PCP, pharmacies, mobile units, public clinics, MVS	In facility, PCP, pharmacies, mobile units, public clinics, MVS	In facility, PCP, pharmacies, mobile units, public clinics, MVS
Other essential workers	In facility, PCP, pharmacies	In facility, PCP, pharmacies, mobile units, public clinics, MVS	In facility, PCP, pharmacies, mobile units, public clinics, MVS	In facility, PCP, pharmacies, mobile units, public clinics, MVS	In facility, PCP, pharmacies, mobile units, public clinics, MVS
All other healthy Adults & Children	In facility, PCP, pharmacies	Primary care provider, public clinics, MVS, pharmacies	In facility, PCP, pharmacies, mobile units, public clinics, MVS	In facility, PCP, pharmacies, mobile units, public clinics, MVS	In facility, PCP, pharmacies, mobile units, public clinics, MVS

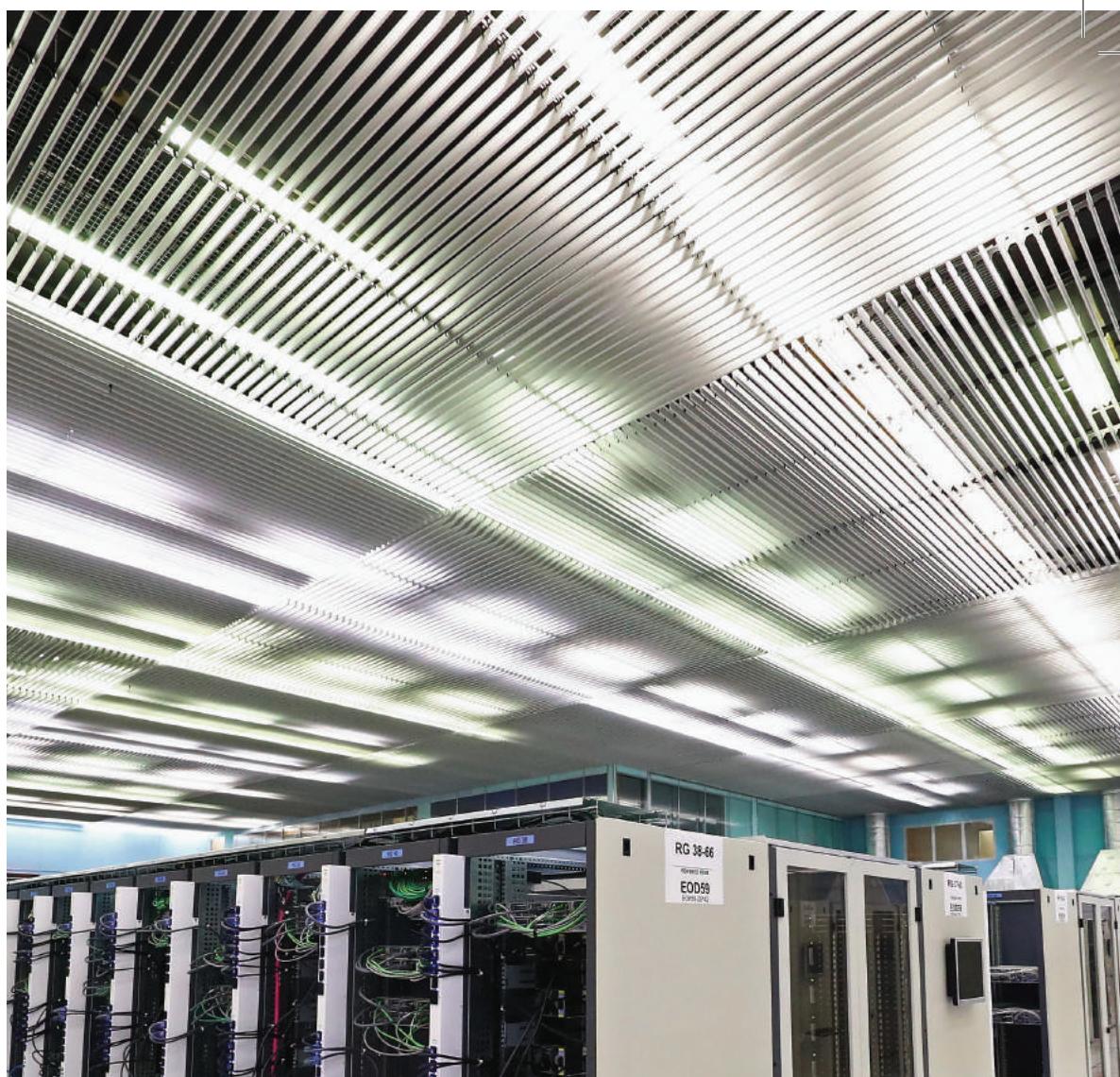
NEW YORK STATE'S COVID-19 VACCINATION PROGRAM

neighborhoods have eligible populations that lack access to vaccination. New York State could consider the use of a one-dose COVID-19 vaccine, when approved, in transient or other populations where follow-up to ensure administration of a second dose may be difficult. New York State DOH will develop and issue standard operating procedures regarding staffing qualifications, second-appointment scheduling, PPE use, reporting of doses administered, and other necessary protocols to ensure these sites operate and perform in a quality manner.

Guided by a robust data management system, New York State will operationalize and provide or direct vaccination doses to sites based on algorithmic methodology that takes into account local distribution capabilities, amount of available vaccine, and eligible population in each region. The goal of the state's approach is to ensure that whatever amount of vaccine is designated and/or delivered to New York, the required operational delivery and administration mechanisms are in place to ensure large numbers of vaccines - enough to vaccinate the entire state - can be administered as quickly as possible.

REPORTING

The complete and accurate reporting of vaccination administration information will be critical to tracking vaccination progress and keeping New Yorkers informed. Prior to the first vaccine being distributed, New York State will work to enroll all vaccination providers in NYSIIS to ensure seamless integration once the vaccine begins to be administered. NYSIIS will allow providers to order vaccine supply relative to local population that is eligible for vaccination at each phase of vaccine availability.



SECTION 8: **DATA & INFORMATION TECHNOLOGY (IT) INFRASTRUCTURE**



SECTION 8. DATA AND INFORMATION TECHNOLOGY (IT) INFRASTRUCTURE

A robust data and analytics infrastructure will be created to support all aspects of the vaccination program including inventory and distribution logistics, monitoring of vaccine administration, scheduling of patient appointments, as well as track ongoing surveillance monitoring to guide clinical and geographic prioritization decisions. The creation of this system will be overseen by computer science and data management experts within the New York State Office of Information Technology Services (OITS) in partnership with the NYSDOH Office of Health Information Management (OHIM) and third-party IT and data analytics providers. The data and IT infrastructure system will be charged with creating a user-friendly system that is accessible to patients and the general public to provide relevant information and transparency regarding ongoing vaccination efforts.

NEW YORK STATE IMMUNIZATION INFORMATION SYSTEM (NYSIIS)

The New York State Immunization Information System (NYSIIS) is a confidential, secure, web-based system that collects and maintains demographic and immunization information in one consolidated record for persons of all ages in New York State (outside of New York City). NYSIIS was formally launched in 2008 and tested immediately in its infancy in support of the 2009 H1N1

vaccination effort. NYSIIS has been greatly enhanced and expanded over the last 10+ years and is widely used and accepted by all pediatric vaccination providers, all 58 local health departments and a more limited group of adult immunization providers.

NYSIIS will be the system for pre-ordering vaccine, ongoing tracking, reporting, and collecting of priority group information. Facilities and providers, including hospitals, nursing homes, adult care facilities, clinics, pharmacies, Federally Qualified Health Centers (FQHCs), and additional public and private providers will be trained and enrolled in NYSIIS.

Currently, over 6,600 provider practices actively report to NYSIIS. Approximately 80% of data is received electronically from 100 different Electronic Health Record (EHR) vendors. Over 12,400 organizations (including pharmacies) and 36,000 individuals currently actively utilize NYSIIS to access vaccine information.

New York State's Immunization Registry Law requires health care providers to report all immunizations administered to persons less than 19 years of age, along with the person's immunization histories, to the New York State DOH using the NYSIIS. In enacting this statute and creating a centralized immunization information system, the Legislature and State aimed to establish a complete, accurate, secure, real-time immunization database that promotes public health by helping ensure as many individuals as possible, appropriate to age and risk, are immunized.

NEW YORK STATE'S COVID-19 VACCINATION PROGRAM

To meet the new challenge of providing potentially two COVID-19 vaccine doses to all New Yorkers, the State will expand and strengthen NYSIIS to serve as a secure, centralized database that will be used to order COVID-19 vaccine, record and track inventory, track vaccine administration, and monitor priority groups. NYSIIS will capture a broad range of information, including:

- Provider profile and enrollment as a vaccination site
- Documentation of micro-level statistics on priority groups in order to properly match vaccine allotment amounts with populations prioritized for vaccination
- Vaccine ordering and distribution as well as inventory management, including vaccine expiration dates, unused and expired vaccine, etc.
- Documentation of all aspects of vaccine administration including patient consent as well as sharing of information to the immunization registry
- Documentation to record and track doses administered by priority groups
- Documentation of patient demographics and dose-level vaccination information adhering to national standards
- Documentation of a second dose and related communications with patients
- Documentation of adverse reactions and events

The information provided to the database will enable the State to offer a range of digital tools, public facing dashboards, patient and provider support mechanisms,

and other features to ensure effective implementation and management of the NYS vaccine program, including:

- A web-based, searchable, and provider-friendly user interface
- A streamlined online provider enrollment and training process
- Platform to enable timely reporting
- Platform to compile information on priority groups to help facilitate vaccination of priority populations
- Internal dashboards for NYS and local partner planning and coordination, and data sharing with LHDs
- Internal dashboard to manage entire supply chain, including inventory, and transportation
- A vaccine ordering module for all providers, including healthcare facilities, and local health departments
- External public facing dashboard to keep New Yorkers informed of vaccination progress and relevant updates
- Built-in interfacing and support for data reporting to any other regulatory entity
- 24/7 support service to address any issues including reporting glitches and problems with user experience,
- Interoperability with provider electronic health records
- Support for first and second dose appointment scheduling and appointment reminders

Data to be collected for monitoring of COVID-19 vaccine coverage:

- Race and ethnicity
- Priority group
- Age
- Gender
- Geographic area
- Facility type (if applicable)
- Occupation (if applicable)
- School/college (if applicable)

Special attention may be needed to track patient residence and place of work/school to inform vaccination administration needs, especially for second dosing.

Vaccine characteristics to be stored in NYSIIS will include: manufactured date, NDC, trade name, lot number and expiration date. 2D Barcodes and Quick Response (QR) codes placed on the vaccine carton will help streamline the capturing of this data.

Facilities and providers, including hospitals, nursing homes, adult care facilities, clinics, pharmacies, FQHCs, and additional public and private providers will be trained and enrolled in NYSIIS.

Electronic health record (EHR) vendors will be integrated into the process to ensure safe, timely and accurate

transfer of information from hospital and provider systems to NYSIIS. A mass vaccination module will be offered to allow providers to quickly and efficiently enter immunization records for large groups. This is useful for those times that the clinic is being held outside of the provider offices and the EHR is not able to be used or in those instances where the provider does not regularly use an EHR to submit records to NYSIIS.

All state data collection, reporting, and public facing systems will prioritize patient privacy, cybersecurity, and will provide to the CDC and other federal agencies information as required. To ensure full realization of the benefits of NYSIIS, the state will require uniform reporting for all local health departments and vaccine providers.

PATIENT SUPPORT & PUBLIC REPORTING

An external public facing dashboard will be launched to keep New Yorkers informed of vaccination progress and relevant updates. To the extent feasible, the dashboard will be designed to track and report:

- Doses administered by day
- Doses administered by county and ZIP code
- Doses administered by age group
- Doses administered by priority group
- Doses administered by facility type (e.g. pharmacy, hospital, nursing home)

- Measures of health equity – race/ethnicity, rural/urban, under- or uninsured, etc.
- Vaccine two dose series completion statistics by date, county, age group, priority groups and facility type

An online website for New Yorkers seeking information regarding vaccine eligibility and appointment scheduling will be available that offers a vaccine eligibility screening tool and a vaccine administration site locator. Individuals will be able to enter information on the website to see if they meet vaccine eligibility

In addition to the support services offered online, a call center will be available for patients and providers to access live support to raise any issues with vaccine access and delivery. A robust data analytics program will track issues that are identified and processed through the call center and online support modules to enable quick action to troubleshoot common issues as they arise. Websites and call centers will be designed to offer support for all New Yorkers including for those with disabilities, non-English speakers, and those with limited language proficiency.

SECOND-DOSE REMINDERS

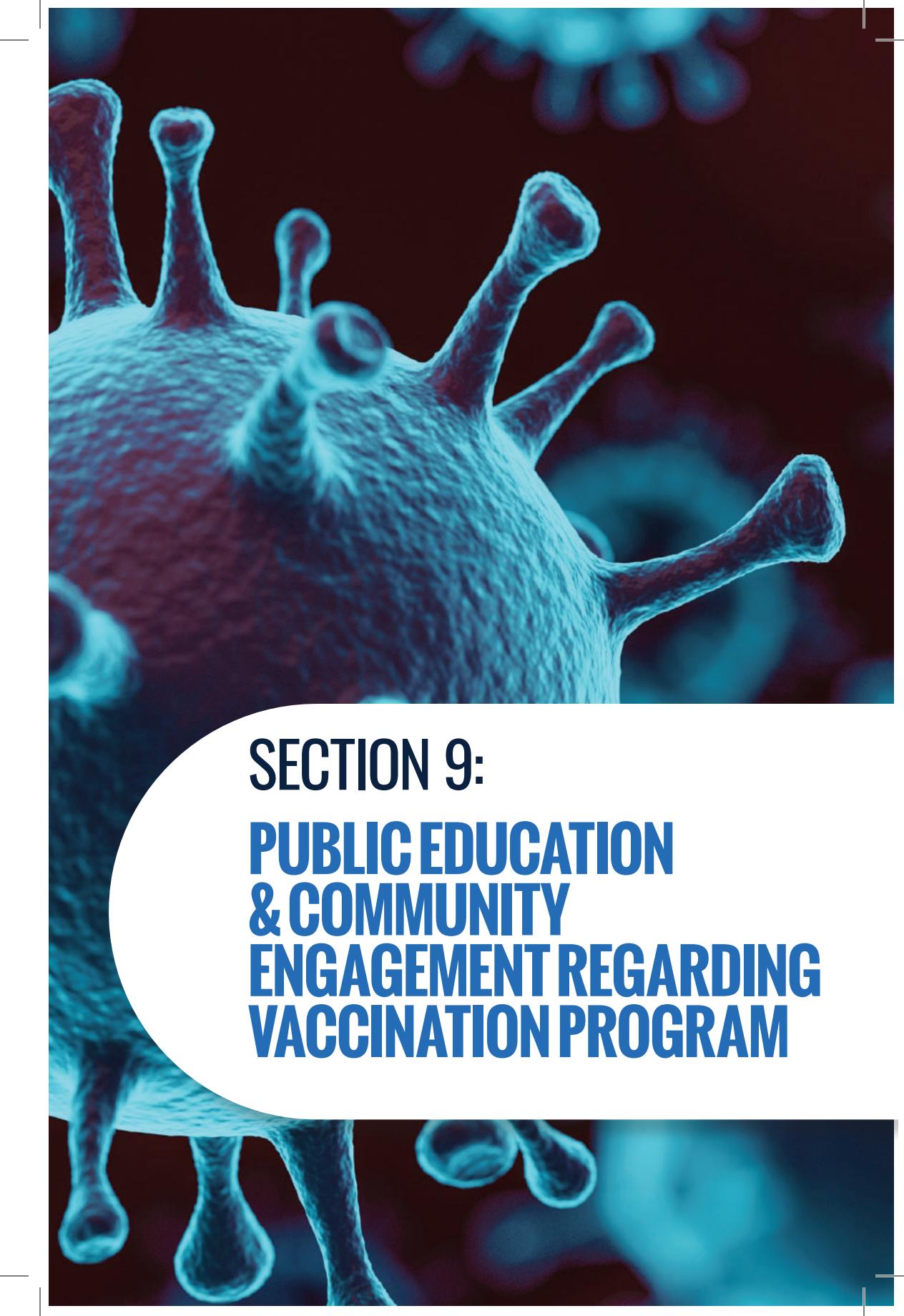
For most COVID-19 vaccine products currently in development, two doses of vaccine, separated by 21 or 28 days, will be needed. Because different COVID-19 vaccine products will not be interchangeable, a vaccine recipient's second dose must be from the same manufacturer as their first dose. Second-dose reminders for vaccine recipients

will be critical to ensure compliance with vaccine dosing intervals and achieve optimal vaccine effectiveness.

New York State COVID-19 vaccination providers can generate reminder notices within NYSIIS specific for their patient population. NYSIIS can also support centralized reminders that can be blasted out to scale via postcards, robocalls, and/or text messaging.

Per federal guidance, New York State immunizing sites will also receive COVID-19 vaccination record cards as part of vaccine ancillary kits and vaccination providers will be trained to complete these cards with accurate vaccine information (i.e., vaccine manufacturer, lot number, date of first dose administration, and second dose due date), and give them to each patient who receives vaccine.





SECTION 9:

PUBLIC EDUCATION & COMMUNITY ENGAGEMENT REGARDING VACCINATION PROGRAM

SECTION 9. PUBLIC EDUCATION & COMMUNITY ENGAGEMENT REGARDING VACCINATION PROGRAM

With more than half of Americans expressing skepticism of a COVID-19 vaccine, effective communication of health information will be a critical element of New York's vaccination program, to fully coordinate with appropriate stakeholders and build public trust regarding vaccine safety and efficacy among the general public. All public education and community engagement efforts will include dedicated efforts to connect with underserved, hard to reach, vulnerable, and vaccine hesitant populations, as well as focused outreach approaches to communities at highest risk of COVID-19. New York State will work closely with partners statewide who can assist in ensuring that all public communication is done in a way to ensure that those with health inequities are represented and ensure that access to vaccine is not a barrier for underserved communities.

Achieving high rates of vaccination will depend upon a successful and robust public education campaign and properly executed communication strategy. The state will launch an ongoing public education campaign to ensure New Yorkers have the latest, and most accurate, information related to the facts about the vaccine itself, the progress and success of the program and all critical information needed regarding access to vaccination.

The state's public education and communications approach will include:

- Outreach and engagement with communities at high-risk of COVID-19 including targeted media messaging and educational materials with information specific to vaccination safety and efficacy. Special attention and resources will be dedicated to outreach to communities at high-risk of COVID-19.
- Promotion of user-friendly tools for determining vaccine eligibility, location of vaccine provider, and appointment scheduling
- Promotion of website and call center with FAQs, relevant information, and address patient concerns and comments
- Public events and media campaigns with trusted health care experts to build public confidence
- Dedicated communications effort to quickly address misinformation that may spread on social media and in other media forms.
- Dedicated public relations team to work with print, broadcast, and web-based media
- Targeted paid media campaign across all platforms (digital, social, print, broadcast, etc.) with creative material designed to communicate positive vaccine messaging with wide audience

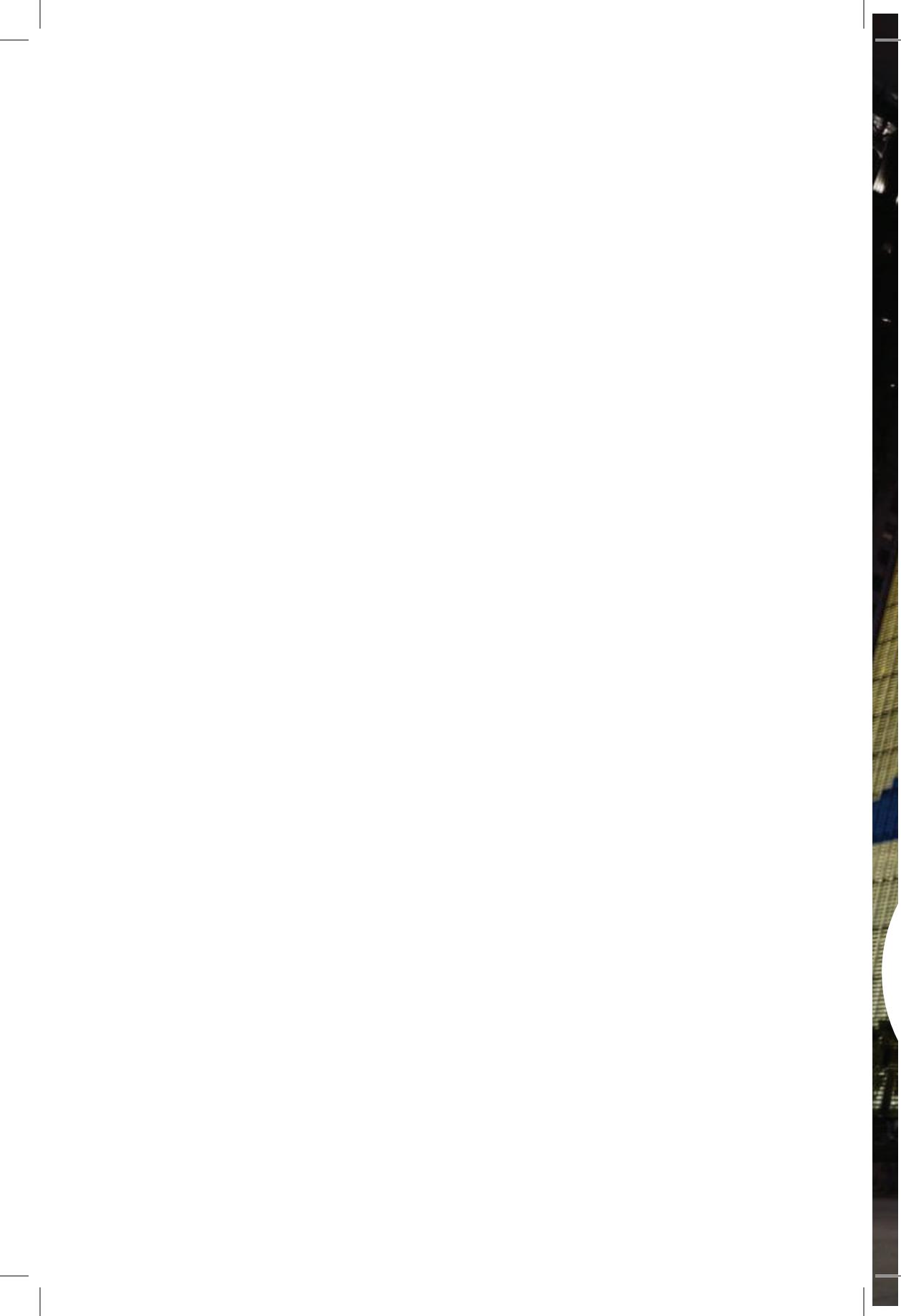
In addition, engagement with community organizations, localities, tribal nations, and healthcare providers is essential to ensure critical information is distributed reliably

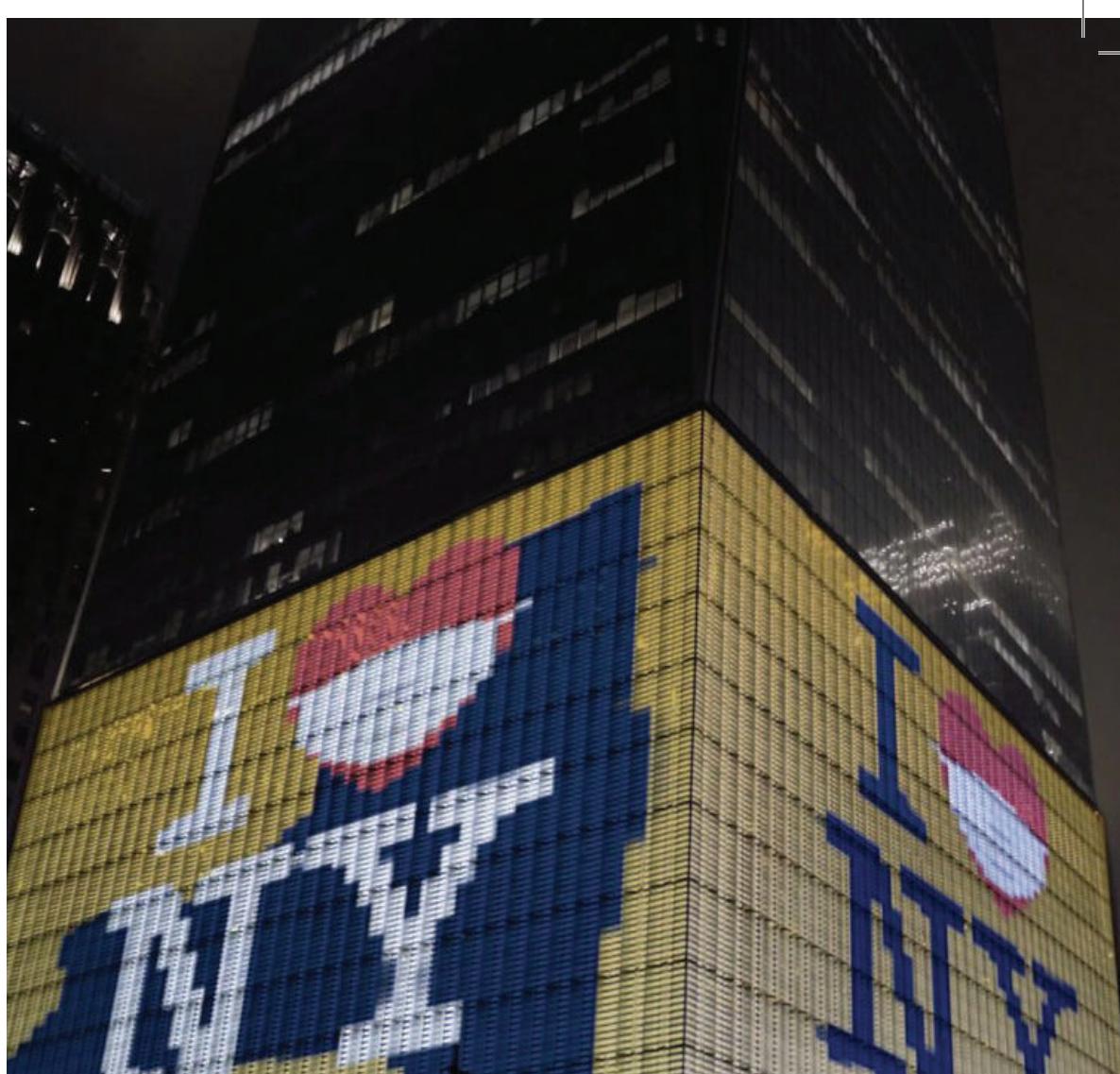
to all New Yorkers. This campaign will also continue to remind New Yorkers that we must be vigilant with the public health measures (such as hand washing, mask wearing, and social distancing) that have been critical components to our success to date mitigating the impact of this pandemic and will continue to be vitally important despite the availability of vaccine.

The state's community engagement approach will include:

- Close coordination with stakeholders, community leaders, and local organizations to disseminate information on the distribution and administration of the vaccine in NYS. This will include dedicated stakeholder engagement with community-based organizations representatives from community organizations serving underserved, hard to reach, vulnerable, and vaccine hesitant populations to advise on outreach, communication and engagement strategies. According to the CDC, people with limited access to routine vaccination services include those living in rural communities, those with disabilities, and individuals who are under- or uninsured.
- Regular communication with stakeholders, community leaders, and local organizations to allow the state to receive recommendations on how to build in each community public trust in the new vaccine

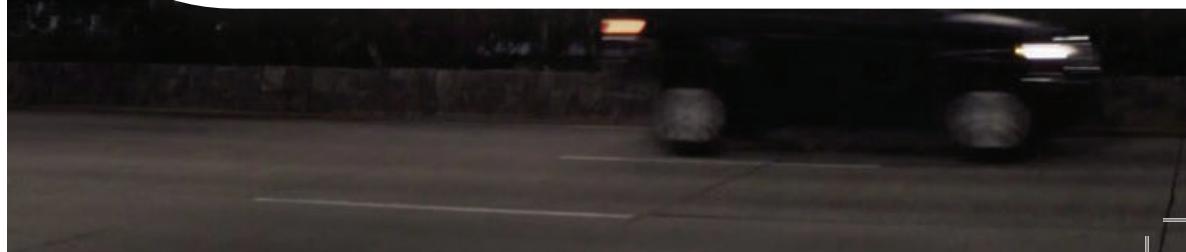
- Engagement with all health providers to implement trust building measures for themselves and their patients and provide support to other physicians as they administer a new vaccine for the first time.
- Keeping all relevant groups and organizations informed on planning status and implementation.





SECTION 10:

EXECUTIVE ORGANIZATIONAL LEADERSHIP



SECTION 10. ORGANIZATIONAL LEADERSHIP

Overall management of New York's vaccination program will require a Vaccine Central Command Center (VC3) to oversee all aspects of vaccine delivery, administration, and other operational aspects of the program. The VC3 will operate within the existing New York State Incident Command structure following sound emergency response principles, in concert with the ongoing broader pandemic response to ensure that all partners clearly understand each other's roles and responsibilities. Pandemic vaccination planning, distribution, and monitoring will require close collaboration between state and local public health, external agencies, and community partners.

The VC3 will include representatives of state agencies that will be charged with managing all aspects of the COVID-19 vaccine program in close coordination with local public health, healthcare, and community-based organizations.

NYS will establish a Vaccine Operations Center (VOC) that State agencies include:

- Department of Health (DOH)
- Department of Corrections and Community Supervision (DOCCS)
- Department of Environmental Conservation (DEC)
- Department of Financial Services (DFS)

- Department of Transportation (DOT)
- Division of the Budget (DOB)
- Division of Homeland Security and Emergency Services (DHSES)
- Division of Military and Naval Affairs (DMNA)
- New York National Guard
- New York State Police (NYSP)
- Office of Addiction Services and Supports (OASAS)
- Office of Children and Family Services (OCFS)
- Office of General Services (OGS)
- Office of Information Technology Services (OITS)
- Office of Mental Health (OMH)
- Office for New Americans (ONA)
- Office for People with Developmental Disabilities (OPWDD)
- Office of Temporary and Disability Assistance (OTDA)
- State Commission of Correction (SCOC)
- State Education Department (SED)
- State Office for the Aging (SOFA)

NEW YORK STATE'S COVID-19 VACCINATION PROGRAM

REGULATORY AND LEGAL REVIEW

The rapid implementation of such a complex and robust vaccine delivery mechanism will require careful consideration, and review, of current legal and regulatory statutes. The state will undertake a comprehensive review of all current regulatory and statutory provisions that may require expansion or revision to support the goals of the vaccination efforts. Existing regulations and processes may adequately serve their purpose under normal operations but as has been demonstrated during the COVID-19 crisis, when quick, decisive action is needed, may limit the capabilities of our delivery system. In addition, new guidance, advisory memos, regulations, or Executive Orders may be required to ensure a functional vaccine program.

Areas to be reviewed for potential expansion or revision:

- Requiring the reporting of all adult vaccine administration in the New York State to NYSIIS
- Requiring all pharmacies, hospitals, and other direct order recipients to report receipt of COVID-19 vaccine inventory (necessary if federal government distributes directly to them)
- Directing where necessary, insurance coverage of COVID-19 vaccinations
- Ensuring the proper registration, enrollment, and inspection of all providers that will administer the COVID-19 vaccine

- Requiring uniform reporting and full coordination of all local governments, ensuring all localities operate under direction and in coordination with centralized state operations center
- Ensuring adequate patient consent for vaccination, including notice regarding information sharing and disclosure and measures to provide consent on behalf of patients without capacity and without a surrogate decision maker
- Ensuring ability to build staffing capacity to administer vaccine
- Ensuring ability to construct vaccination facilities expeditiously

Initially available COVID-19 vaccine may be authorized for use under an EUA issued by the FDA as the vaccine moves through the process for full licensure. An EUA will include the criteria for issuance; scope of the EUA, including waivers of certain requirements, if any; a description of the authorized product, including its authorized uses and conditions of authorization (e.g., requirements related to distribution, reporting, and safety and monitoring); any contraindications; and accompanying materials (e.g., fact sheets for health care professionals and recipients). Information on any EUA that is issued is available on the FDA's website.

VACCINE INFORMATION STATEMENTS (VISS)

VISSs are only required for vaccines listed in the National Vaccine Childhood Injury Act (NVCIA). Pursuant to guidance issued by the CDC, optional VISSs may be produced, but only after a vaccine has been licensed (e.g., such as with zoster vaccines) and plans for a VIS for COVID-19 vaccines are not known at this time. Additionally, it should be noted that while the CDC recommends issuance of VISSs for vaccines not covered under the NVCIA such VISSs must be used when the vaccine is purchased under CDC contract. Additional information on VISSs is located at <https://www.cdc.gov/vaccines/hcp/vis/current-vis.html>



SECTION 11:

PROCUREMENT OF NECESSARY SUPPLIES AND EQUIPMENT



SECTION 11. PROCUREMENT OF NECESSARY SUPPLIES AND EQUIPMENT

Current CDC planning scenarios anticipate the federal government will make the vaccine available to all Americans at no cost. Further, the CDC has advised that each vaccine dosage will be delivered with ancillary supplies including needles, syringes, alcohol prep pads, vaccination record cards for each recipient, and a minimal supply of personal protective equipment (PPE), including surgical masks and face shields, for vaccinators.

However, there remain important supplies, equipment, operations, and other expenses that may be the responsibility of state and local governments. These include, but are not limited to:

- Building, maintaining, and enhancing data and IT systems for patient scheduling, inventory management, and supply chain management
- Staffing and operationalizing call centers and public support modules
- Hiring, training, and deploying qualified staff for vaccine administration
- Constructing and operationalizing mass vaccination POD sites
- Procuring and modifying transportation vehicles for cold-chain transit

- Procuring equipment and supplies for cold-chain storage and transit such as dry ice
- Constructing and operationalizing regional cold-chain storage sites
- Funding for public information campaigns and community engagement efforts
- Procuring and storing critical supplies such as bandages, additional PPE

To date, the state has received \$7.8 million from the federal government for vaccine planning purposes. It is anticipated the total cost to New York State will be a large expenditure, and it remains unclear what federal funding may be available to support these efforts. New York State's Division of the Budget and the Office of General Services will oversee the required budgeting and procurement for the vaccination operation.

In addition, the state will be prepared to address any billing and reimbursement issues for vaccine administration (injections) including:

- Status of whether vaccine will be made available regardless of insurance status
- Coverage by insurers/out-of-network issues
- Billing of facility fees
- New Federal billing codes

Depending on federal measures taken, it is expected that providers will not be able to bill for the cost of vaccine but should be able to bill insurance for the vaccine administration. CDC has stipulated that providers who agree to receive vaccine may not refuse service for the inability to pay administration fees. Some federal funds may become available for the reimbursement of administration costs. At present, it is unknown how long the vaccine and ancillary supplies will be free of charge, or what other costs may be not be covered.

New York State DOH will work with the Department of Financial Services (DFS) and the NYS Health Plan Association to address insurance reimbursement issues that may arise related to the vaccine cost and/or administration fees. CMS has been engaged to work out CPT codes in advance of vaccine availability.



SECTION 12: **POST-VACCINATION MONITORING**

SECTION 12. POST-VACCINATION MONITORING

Monitoring for vaccine safety, especially in an emergency where large numbers of vaccines may be given in a short period of time and safety data is limited with a novel vaccine, is an essential part of New York State's vaccination plan. While New York will establish internal and external clinical advisory groups to ensure safety, the state will also promote the Vaccine Adverse Event Reporting System (VAERS) that will be an integral component of safety monitoring. This reporting system will give all New Yorkers who receive the vaccine the opportunity to report any potential adverse effects, allowing New York State DOH and the State's Clinical Advisory Task Force to conduct robust monitoring of the vaccine's safety. New York State DOH will also work with insurance companies and Medicaid to evaluate data that may be a source for adverse events.

NEW YORK STATE'S COVID-19 VACCINATION PROGRAM

GLOSSARY OF ACRONYMS

APPENDIX A: Glossary of Acronyms

ACF: Adult Care Facility

ACIP: Advisory Committee on Immunization Practices (within CDC)

CDC: Centers for Disease Control and Prevention

CIR: Citywide Immunization Registry (NYC)

COVID-19: Novel Coronavirus Disease-2019

ED: Emergency Department

EHR: Electronic Health Record

EMS: Emergency Medical Services

EMT: Emergency Medical Technician

EUA: Emergency Use Authorization

FD&C Act: Federal Food, Drug, and Cosmetic Act

FDA: Food and Drug Administration

FQHC: Federally Qualified Health Center

HERDS: Health emergency Response Data System

ICU: Intensive Care Unit

IHS: Indian Health Service

IT: Information Technology

LHD: Local Health Department

LTCF: Long-Term Care facility

NH: Nursing Home

NVICIA: National Vaccine Childhood Injury Act

NYC DOHMH: New York City Department of Health and Mental Hygiene

NYSIIS: New York State Immunization Information System

PA: Physician Assistant

PCP: Primary Care Provider

PODs: Point of Dispensing (mass vaccination sites)

PPE: Personal Protective Equipment

QR Codes: Quick Response Codes

RHC: Rural Health Clinic

SARS-CoV-2: Severe Acute Respiratory Syndrome Coronavirus 2

VAERS: Vaccine Adverse Event Reporting System

VAS: Vaccine Administration Sites

VIS: Vaccine Information Statement

VOC: Vaccine Operations Center

New York State Agencies, Offices:

DFS: Department of Financial Services
DHSES: Division of Homeland Security and Emergency Services
DMNA: Division of Military and Naval Affairs
DOB: Division of the Budget
DOCCS: Department of Corrections and Community Supervision
DOH: Department of Health
DOT: Department of Transportation
ITS: Office of Information Technology Services
OASAS: Office of Addiction Services and Supports
OCFS: Office of Children and Family Services
OGS: Office of General Services
OHIM: Office of Health Information Management (within NYSDOH)
OMH: Office of Mental Health
ONA: Office for New Americans
OPWDD: Office for People with Developmental Disabilities
OTDA: Office of Temporary and Disability Assistance
SCOC: State Commission of Correction
SED: State Education Department
SOFA: State Office for the Aging

Partner Associations:

AAP: American Academy of Pediatrics
ACOG: American College of Obstetrics and Gynecology
CHCANYS: Community Health Care Association of New York State
CICU: Commission on Independent Colleges and Universities
GNYHA: Greater New York Hospital Association
GNYHCFA: Greater New York Health Care Facilities Association
HANYS: Healthcare Association of New York State
NYDA: New York Disability Advocates
NYHPA: New York Health Plan Association
NYSACHO: New York State Association of County Health Departments
NYSARH: New York State Rural Health Association

APPENDIX B: Partner List

A successful vaccination program will require collaboration with external entities and community partners who are familiar with their specific communities. NYS will engage a wide range of stakeholders including but not limited to:

- LHDs and their association (NYSACHO)
- Emergency preparedness, management and response agencies
- Immunization coalitions
- Healthcare provider organizations
- Health systems and hospitals (including critical access hospitals for rural areas, in-patient psychiatric facilities) and their associations (HANYS/GNYHA)
- FQHCs and Community Health Centers (CHCs) and their association (CHCANYS)
- Rural Health Clinics (RHCs) and their association
- Commercial and Independent Pharmacies
- Long-term care facilities (LTCFs; includes nursing homes, adult care facilities, assisted living, independent living (e.g., intermediate care facilities for individuals with intellectual and developmental disabilities), skilled nursing facilities)
- Businesses and occupational health organizations
- Health insurance issuers and plans
- Educational institutions
- Correctional facilities
- Religious institutions
- Tribal Nations
- Organizations serving racial and ethnic minority groups
- Organizations serving people with disabilities
 - Organizations serving people with limited English proficiency
 - Community representatives
- NYS Agencies

APPENDIX C: PRIORITY GROUP JUSTIFICATIONS

C1. Priority Groups for COVID-19 Vaccine

Essential Workers

Population	Justification
Hospital Health Care Personnel (HCP)	Hospital HCP care for critically ill patients and are at high risk of contracting COVID-19
Nursing Home HCP	Nursing Homes provide long-term care to vulnerable and high-risk patients and may become settings for COVID-19 outbreaks.
Other HCP	Outpatient HCP may diagnose and treat persons with COVID-19 and serve as surge workforce for hospitals.
Childcare Workers	Childcare will be critical to ensure other essential workers are able to do their jobs; childcare workers will be in close contact with children
Teachers/Professors/Educators	Educators provide an essential societal function; vaccination of educators may enable schools to remain open and allow other essential workers to do their jobs
Firefighters	Firefighters are critical to maintain public safety and protect property against fire
Police Officers	Police officers are critical to maintain public safety
Correction/Parole/Probation Officers	Correction/parole/probation officers are important for public safety
Security Guards and Personnel	Security guards and personnel are important for public safety
Transit Workers	Safe maintenance of public transit is critical to allow essential workers to get to their jobs
Utility Workers	Maintenance of utilities is critical to state infrastructure
Food Service Workers	A safe food supply is critical to our society
Maintenance and Janitorial/Cleaning Workers	Maintenance and cleaning will be critical for safe operation of essential workplaces
Trash and Recycling Workers	Trash and recycling collection is critical to our society
Mail and Shipping Workers	Mail and shipping is critical to our society, particularly during stay-at-home orders
Funeral Home workers	Funeral Home workers will be critical for timely interment of people who die of COVID-19

Population	Justification
Dentists, dental hygienists and dental specialists	Dental staff will be at very high risk of exposure to COVID-19; however, many closed during the peak of the spring 2020 outbreak and might do so again in future waves
Optometrists	Optometrists would be at risk of exposure to COVID-19; however, many closed during the peak of the spring 2020 outbreak and might do so again during future waves
Psychologists, psychiatrists and counselors	Mental health issues increased during the spring 2020 outbreak, particularly among essential workers and minority populations; however, many mental health professionals operated via telemedicine in the spring 2020 peak and might do so again during future waves
Social workers and support staff	Social workers play a critical work in mental health and social services; however, to some extent they may be able to work remotely
Faith-based leaders	Faith-based leaders provide mental health and social support to members of their clergy
Retail Workers at Essential Businesses	Essential retail is critical to maintain our society
Automotive Service and Repair Workers	Automotive service and repair will be necessary to enable essential workers to transport to work
Meat/Poultry/Processing	There were several documented outbreaks of COVID-19 in meat and poultry processing factories in 2020
Hotel/Motel Workers	Hotels and motels might provide temporary residence for healthcare workers and quarantined people
Animal Care Workers (e.g. Veterinarians)	Animals are important companions and family members

Medically High-Risk

Population	Justification
Nursing Home residents	Many nursing home residents are at high risk of severe COVID-19 infection, and nursing homes may become settings for COVID-19 outbreaks
People age 65 or older with 1 or more other high-risk condition	People older than 65 with 1 or more other high-risk condition are at higher risk of severe infection
People age < 65 with 2 or more high-risk conditions	People with 2 or more high-risk conditions are at higher risk of severe infection

High-Risk Conditions at increased risk of severe illness from COVID-19:

- Cancer
- Chronic Kidney Disease
- Chronic Obstructive Pulmonary Disease
- Immunocompromised State
- Obesity (BMI 30 or higher)
- Serious heart conditions
- Sickle cell disease
- Type 2 diabetes mellitus

The CDC's COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operation includes the following categories of individuals at risk for COVID-19 illness or acquiring or transmitting COVID-19:

- LTCF residents (i.e., nursing home, assisted living, independent living facility residents)
- People with underlying medical conditions that are risk factors for severe COVID-19 illness
- People 65 years of age and older
- People from racial and ethnic minority groups
- People from tribal communities
- People who are incarcerated/detained in correctional facilities
- People experiencing homelessness/living in shelters
- People attending colleges/universities
- People who work in educational settings (e.g., early learning centers, schools, and colleges/universities)
- People living and working in other congregate settings

C2: Priority Population groups for COVID-19 Vaccine Planning, estimates by Regional Economic Development Council (REDC) Area

C2: Phase 1 Priority groups for COVID-19 Vaccine Planning, estimates by Regional Economic Development Council Areas

REDC area	Hospitals	Total Hospital HCW	Nursing Homes	Total NH Residents	Total NH HCW	Adult Care Facilities	Total ACF Residents	Total ACF HCW	Total Certified EMS	Adult Health Day Cares	Total Adult Health Care HCW	Total Health Care Workers	Total NH and ACF Residents
Capital Region	9	37,089	44	5,785	7,985	49	2,436	2,105	4,514	4	297	51,990	8,221
Central New York	10	28,913	27	4,025	5,710	36	1,832	1,447	3,330	7	106	39,506	5,857
Finger Lakes	14	43,300	60	6,908	10,688	61	3,171	2,645	4,708	6	113	61,634	10,079
Long Island	23	91,320	77	11,024	18,482	94	6,393	6,344	17,800	7	333	134,378	18,317
Mid-Hudson	30	57,006	80	10,484	16,001	89	5,155	4,415	11,275	13	186	88,883	15,630
Mohawk Valley	10	18,871	32	3,717	5,401	26	1,181	879	2,214	5	88	27,456	4,898
New York City	58	302,113	169	33,689	47,475	76	7,402	5,063	23,047	13	1,523	370,251	41,001
North Country	14	14,641	18	2,003	2,974	15	582	460	2,024	2	11	20,110	2,585
Southern Tier	14	18,157	36	4,014	5,803	34	1,260	1,233	2,596	4	51	27,940	5,274
Western New York	21	42,739	61	7,503	11,007	63	4,071	3,103	6,119	4	199	63,327	11,574
Total ROS (excl. NYC)	145	352,138	444	56,363	84,131	467	26,081	22,711	54,760	52	1,384	515,124	82,444
Total All NYS	203	654,251	613	90,052	131,606	543	33,483	27,804	77,807	65	2,007	804,375	123,535

Sources:

Hospital Health Care Workers: 2020 Healthcare Personnel Influenza Vaccination Report (n=190) hospitals. 2019 Healthcare Personnel Influenza Vaccination Report was used for hospitals that did not report in 2020 (n=13).

Nursing Home and Adult Care Facility Residents: HERDS facility census data accessed 4/30/2020

Nursing Home and Adult Care Facility Health Care Workers: HERDS Weekly Nursing Home and Adult Care Facility Employee COVID Testing Survey, week 16 (9/3/2020)

Emergency Medical Services: Bureau of Emergency Medical Services, State Licensure Database (EMS Prod) 9/17/20

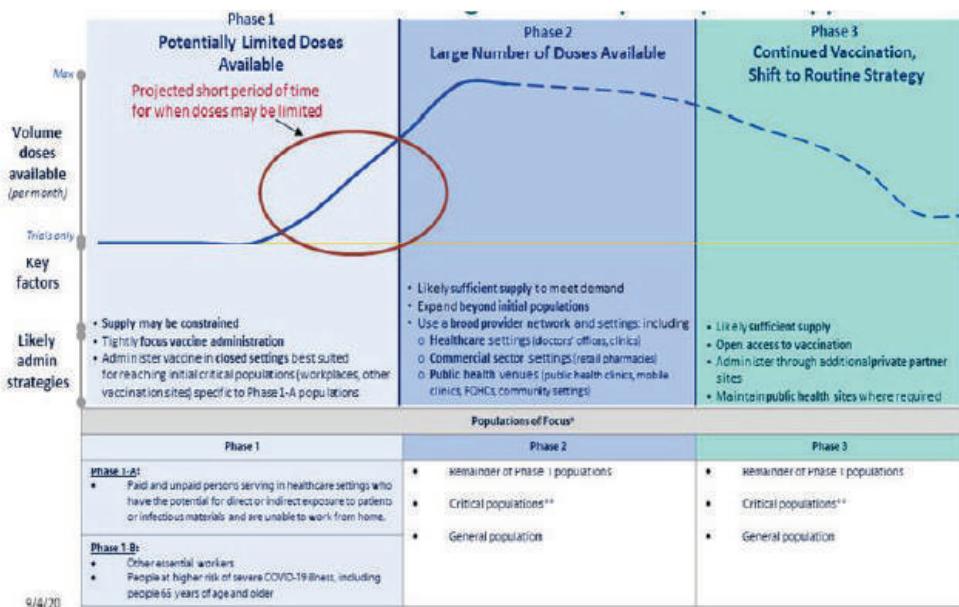
APPENDIX D: CDC COVID-19 VACCINATION PROGRAM PHASED APPROACH

As vaccine supply levels may change throughout the vaccination campaign, CDC has advised jurisdictions to plan for a phased approach to vaccine allocation and distribution, with the assumption that allocation will be quite small in early months and then increase as the federal vaccine supply increases.

Phase 1 will consist of a limited supply of COVID-19 vaccine doses available. Vaccines distribution will be tightly controlled and focused on vaccinating identified priority population(s) such as health care workers in workplace settings such as healthcare facilities.

Phase 2 will consist of a growing number of vaccine doses available. Vaccine supply will likely be sufficient to meet demands beyond the initial priority population(s) and will be administered to individuals in broader settings such as doctor's offices, retail pharmacies, public health clinics, etc.

Phase 3 will consist of a sufficient and/or excess supply of vaccine doses for the entire population. Vaccines will be administered in all appropriate settings.



*Planning should consider that there may be initial age restrictions for vaccine products.

** See Priority Group section for information on Critical Populations

CDC COVID-19 Vaccination Program Interim Playbook - September 16, 2020
https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf

NEW YORK STATE'S COVID-19 VACCINATION PROGRAM







**Department
of Health**