Kentucky's COVID-19 Vaccination Plan

Approved:

SECTION 1: PREPAREDNESS PLANNING

Introduction

Since the 1970s, responding to infectious disease pandemics — predominantly those caused by the influenza virus — has been a recurring activity in the United States. As part of these efforts, both states and the federal government have planned for mass distribution of vaccines and other pharmaceuticals long before the advent of COVID-19. On an annual basis, a unique seasonal influenza (flu) vaccine is manufactured and distributed for public consumption. As recently as 2009-2010, the H1N1 influenza virus resulted in a global pandemic necessitating the development and distribution of unique vaccines at a national scale. These prior experiences along with others for unrelated threats such as anthrax requiring medical countermeasure distribution plans provide substantial knowledge and experience to inform the Kentucky Department for Public Health's (KDPH) COVID-19 vaccine strategy.

On May 15, 2020, the Trump administration announced Operation Warp Speed (OWS) which aims to "deliver 300 million doses of a safe, effective vaccine for COVID-19 by January 2021." OWS includes major federal support for the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics. Once a vaccine is developed, the federal government is likely to procure all available product and centralize distribution to states. The algorithms for allocation are unknown at this time, but current recommendations for vaccination apportionment suggests that it be done in proportion to state populations, as occurred during the 2009 influenza pandemic.

OWS has shared that COVID-19 vaccine deployment will be a multi-agency effort. The U.S. Department of Health and Human Services (HHS) will remain the lead agency for the federal COVID-19 response. Playing substantial support roles, the U.S. Department of Defense (DOD) will assist with distribution and administration of the vaccine, while the Defense Logistics Agency (DLA) will provide contract, logistics, and administrative support to the distribution process. The exact nature of how other DOD elements may be used and how processes will be adapted is still being defined as of October 2020.

On July 30th, the CDC held a meeting with immunization stakeholders and outlined a general framework for distribution. The announcement alludes to a distribution model similar to that used for H1N1 vaccine: industry will deliver vaccine to a central distributor from which supply states and territories will receive weekly allocations. Vaccine administration sites – including private providers, clinics, government-run points of dispensing (POD), and others – will submit requests to the states who will prioritize and approve those requests against their daily allotment. Once a request has been approved by the state, the distribution will be made directly from the central distributor to the receiving site via contracts arranged by the DLA. Additional direct allocations will be made to select private partners (including major retail pharmacies, names TBA) to expand access.

Many candidate vaccines for the SARS-CoV-2 virus are in development. There is hope that one or more of these candidates will soon be shown to be sufficiently safe and effective to achieve either approval or emergency use authorization from the U.S. Food and Drug Administration. When a vaccine is authorized for use, its supply is usually limited due to finite manufacturing capacity, the slower speed of some technologies, and the logistical challenges of distribution and administration of the vaccine. Distribution and logistics issues also have implications for other vaccines that may contribute to improved health status. Therefore, the entire vaccine distribution system should be considered.

KDPH will consider the short, medium and long-term actions that are necessary to lay the foundation for a smooth and orderly COVID-19 vaccination campaign. Concurrently, electronic health record vendors and immunization information systems (IIS) must update and prepare these data reporting systems accordingly with consideration given to expected target populations and phases of vaccine distribution across the health care system, critical population groups, and the general public.

Purpose

Kentucky's Vaccination Plan outlines the actions, roles, and responsibilities of state agencies and collaborating organizations that are necessary for a smooth and orderly COVID-19 vaccination distribution and administration process. This plan primarily covers those "critical" activities that have been identified for a successful COVID-19 vaccination campaign. Adjunct objectives and tasks may be added during operations to cover situations that arise or that are not addressed in this plan.

Scope

Kentucky's Vaccination Plan is applicable to Kentucky's COVID-19 vaccination campaign and will be used in conjunction with the Kentucky Emergency Operations Plan (EOP), the Emergency Support Function (ESF) #8 – Public Health and Medical Services Annex, the Kentucky Medical Countermeasures (MCM) Plan, the Kentucky Disease Outbreak Support Plan (DOSP), and other relevant plans as listed in the Authorities and References section.

Objectives

- Ensure timely and equitable distribution of vaccine;
- Track vaccine use across the state;
- Monitor vaccine safety; and
- Ensure access to accurate and timely information on vaccine use and availability.

Planning Assumptions

Planning assumptions are events, or circumstances that are expected to occur during an incident and affect the operational environment of the response. The following assumptions have been made in the development of this plan:

a. The efficacy of vaccines that may be approved/authorized is uncertain at present and will not be known with certainty for some time.

b. Vaccine will be free of cost, but administration fees may not be reimbursable while a vaccine product is administered under an Emergency Use Authorization (EUA).

c. More than one vaccine may be available at the same time. These vaccines may have different safety and efficacy profiles across different population groups and may have different logistical requirements.

d. Limited COVID-19 vaccine doses may be available in late 2020, but COVID-19 vaccine supply will increase substantially in 2021.

e. Initially available COVID-19 vaccines will either be approved as licensed vaccines or authorized for use under an Emergency Use Authorization (EUA) issued by the U.S. Food and Drug Administration (FDA).

f. Cold chain storage and handling requirements for each COVID-19 vaccine product will vary from refrigerated (2° to 8°C) to frozen (-20°C) to ultra-cold (-60° to -80° C) temperatures, and ongoing stability testing may impact these requirements. Note: Updated information will be provided as it becomes available.

g. As with other new medical treatments, post-marketing surveillance will be necessary to more fully define the long-term safety profile of approved vaccines.

h. KDPH will receive a vaccine allocation based on Kentucky's proportion of the U.S. population.

i. Some of the candidate vaccines will require two doses to produce protective immunity.

j. The number of healthcare personnel qualified to dispense or administer the vaccines and the number of volunteers available to perform support functions will limit the rate at which the vaccines can be dispensed.

k. It may take many months before most U.S. residents have access to vaccination; bottlenecks at various stages of the vaccine manufacturing process (e.g., supply of vials or syringes, fill and finish process) could cause further delays in vaccine availability.

l. Specialized vaccine distribution systems and outreach efforts to provide access to some of the highest-risk populations may be needed.

m. Access to sufficient personal protective equipment (PPE) may be a limitation once wide scale vaccination operations take place.

n. The vaccine will be distributed and administered via multiple pathways such as hospitals, medical offices, clinics, local health departments, pharmacies, and other locations.

o. A portion of the U.S. population may hesitate to receive a COVID-19 vaccine.

p. CDC will provide ancillary vaccination supplies such as needles, syringes, alcohol swabs, etc.

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SECTION 2: COVID-19 ORGANIZATIONAL STRUCTURE

Planning and Coordination Team

Kentucky's vaccination planning is a combined state and local responsibility that requires close collaboration between KDPH, Local Health Departments (LHDs) external agencies, and community partners. Kentucky public health has a "shared governance" health structure within which both KDPH and LHDs will play a key roles ensuring a successful COVID-19 vaccination campaign.

In May of 2020, KDPH stood up a COVID-19 Vaccination Planning Team. The current COVID-19 Vaccination Planning Team structure follows the structure set forth in the Incident Command System (ICS) and is a "Branch" under KDPH's COVID-19 ICS structure. The COVID-19 Vaccination Planning Team has a wide array of expertise and representation. Some team members represent partners (e.g. Fire, EMS, and Law Enforcement) and will serve as conduits for communication and planning assistance. Many of the team members involved in planning will also be involved in the execution and implementation of the vaccination plan.

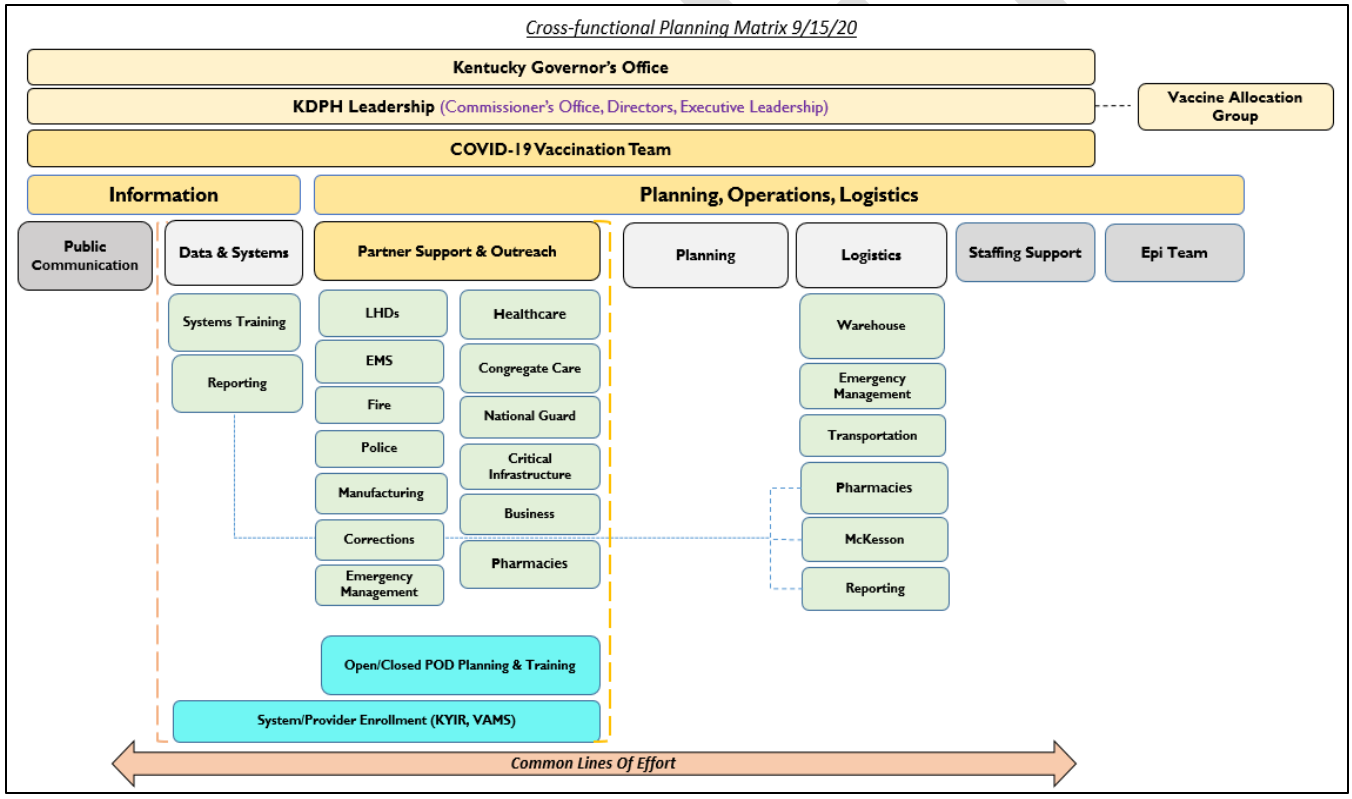

Figure 1 Cross-functional Planning Matrix

Vaccine Allocation Committee

Reaching intended vaccine recipients is essential to achieving desired levels of COVID-19 vaccination coverage. To ensure equitable access to vaccinations, information about populations within a jurisdiction and the logistical requirements for providing them access to COVID-19 vaccination services will require

collaboration with external entities and community partners. KDPH will establish a COVID-19 Vaccination Allocation Committee (VAC). KDPH is planning to utilize the Kentucky Health and Medical Preparedness Committee (HMPAC), as well as leadership from KDPH's COVID-19 planning and coordination team and representatives for critical population groups identified by CDC. In 2011 the CDC Public Health Emergency Preparedness (PHEP) Cooperative Agreement required funding recipients to establish and maintain an advisory committee(s) comprised of senior officials from governmental and nongovernmental partners to integrate preparedness efforts across jurisdictions. It is advantageous for KDPH to use the HMPAC because membership includes senior representatives from multiple disciplines and partner organizations as well as community-based partners representing at-risk populations (individuals with disabilities and others with access and functional needs). The VAC will ultimately consist of applicable HMPAC members and KDPH leadership. The VAC will review and discuss the "CDC's suggested COVID-19 vaccine targeting guidance" in which they will advise whether the vaccine targeting guidance should be used or if it should be modified and how, based upon Kentucky's unique circumstances. The VAC's recommendations will then be reviewed by the Governor and the Public Health Commissioner for final endorsement or adjustment. Further details are explained in "Section 4: Critical Populations."

Operational Coordination Structure

KDPH will utilize the Kentucky Emergency Operations Plan (EOP), the ESF #8 – Public Health and Medical Services Annex, the State Health Operations Center (SHOC) Support Plan and the Kentucky Medical Countermeasures Distribution Plan to guide and coordinate vaccine distribution. The aforementioned plans contain detailed information on how incidents will be managed and coordinated. KDPH will use these plans to coordinate, support, and/or manage vaccine operations.

The SHOC will serve as the base of direction, control, and coordination for Kentucky's COVID-19 vaccination campaign. The SHOC will work in coordination with the State Emergency Operations Center (SEOC). The agencies and organizations identified within this plan will ensure the necessary personnel and resources are available to achieve the operational objectives. It is expected that personnel from supporting agencies will operate in accordance with the rules, regulations, and capabilities of their respective agency or organization and that local governments are responsible under all applicable laws, executive orders, proclamations, rules, regulations, and ordinances for vaccination operations and response within their respective jurisdiction(s).

KDPH will utilize the following systems to share information and manage the COVID-19 vaccination campaign (where applicable):

- Kentucky Immunization Registry (KYIR)
- Vaccine Adverse Events Reporting System (VAERS)
- Vaccine Tracking System (VTrckS)
- Tiberius
- ReadyOp
- WebEOC
- Email

SECTION 3: VACCINATION PLANNING PHASES

Due to changing vaccine supply levels at various points during the COVID-19 Vaccination Program, planning should be flexible but as specific as possible to accommodate a variety of scenarios. We anticipate vaccine supply will be limited at the beginning, so the allocation of doses must consider vaccination providers and settings for vaccination of limited critical populations. The vaccine supply is projected to increase quickly, however, allowing vaccination efforts to be expanded to include additional critical populations and the general public. Additionally, recommendations on the various population groups targeted for initial doses of vaccine could change after vaccine is available, depending on each vaccine's characteristics, vaccine supply, disease epidemiology, and local community factors.

Since final decisions are being made about use of initially available supplies of COVID-19 vaccines, decisions will be partially informed by the demonstrated efficacy of the vaccines coming out of Phase 3 trials. Populations of focus for initial COVID-19 vaccination are:

- Healthcare personnel and First Responders likely to be exposed to or treat people with COVID-19;
- Essential workers and Workers in high public contact jobs (e.g. social service support workers, grocery workers, transportation workers); and
- People at increased risk for severe illness from COVID-19, including those with underlying medical conditions and people 65 years of age and older.

The CDC outlines the following phases for jurisdictions to consider in planning:

Phase 1: Potentially limited supply of COVID-19 vaccine doses available
Focus initial efforts on reaching the critical populations listed above. Ensure vaccination locations selected can reach populations, manage cold chain requirements, and meet reporting requirements for vaccine supply and uptake.

We anticipate in Phase 1 that initial doses of vaccine will be distributed in a limited manner with the goals of maximizing vaccine acceptance and public health protection while minimizing waste and inefficiency. The key considerations in planning for this phase are:

- COVID-19 vaccine supply will be limited;
- COVID-19 vaccine administration efforts must concentrate on targeted populations to achieve vaccination coverage in those groups; and
- Inventory, distribution, and any repositioning of vaccine will be closely monitored through reporting to ensure end-to-end visibility of vaccine doses.

Enrollment activities will be prioritized for vaccination providers and settings who will administer COVID-19 vaccine to Phase 1 targeted populations.

Phase 2: Large number of vaccine doses available
Focus on ensuring access to vaccine for members of Phase 1 critical populations not yet vaccinated, extend efforts to reach the general population, and expand the vaccine provider network. Phase 2 will likely include the need for additional vaccinators to staff PODs (i.e., points of distribution), contract for vaccination services, and expand professional scopes of practice (if necessary). As the supply of available vaccine increases, distribution will expand to increase access to vaccination services to a larger population. When larger quantities of vaccine become available, we plan to conduct two simultaneous objectives:

- Provide equitable access to COVID-19 vaccination for target groups; and
- Provide equitable access to COVID-19 vaccination for critical populations.

As the supply of available vaccine increases, access to vaccination services will expand for a larger population. Key considerations in Phase 2 will be:

- COVID-19 vaccine supply will likely be sufficient to meet demand for critical populations as well as the general public;
- Additional COVID-19 vaccine doses available will permit an increase in vaccination providers and locations;
- A surge in COVID-19 vaccine demand is possible, so a broad vaccine administration network for surge capacity will be necessary; and
- Low COVID-19 vaccine demand is also a possibility, so jurisdictions should monitor supply and adjust strategies to minimize vaccine wastage.

Phase 3: Sufficient supply of vaccine doses for entire population (surplus of doses)
Focus on ensuring equitable vaccination access across the entire population. Monitor vaccine uptake and coverage, and reassess strategies to increase uptake in populations or communities with low coverage.

Phase 3 will begin as COVID-19 vaccine becomes widely available and integrated into routine vaccination programs. In Phase 3, it is likely COVID-19 vaccine supply will exceed demand and vaccine administration networks will increase access. KDPH will:

- Continue to focus on equitable vaccination access to vaccination services;
- Monitor COVID-19 vaccine uptake and coverage in critical populations and enhancing strategies to reach populations with low vaccination uptake or coverage;
- Partner with commercial and private entities to ensure COVID-19 vaccine and vaccination services are widely available; and
- Monitor supply and reposition vaccine products to minimize vaccine wastage.

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SECTION 4: CRITICAL POPULATIONS

Identification of Target Groups

It is important to acknowledge that a critical difference between the current pandemic (COVID-19) and the context envisioned in the CDC's "2018 guidance for pandemic influenza vaccine allocation" is not only the epidemiological differences between COVID-19 and influenza, such as the higher rates of asymptomatic transmission and fatality risk, but also that we are currently in the midst of a social justice movement across the country.

Minimizing COVID-19 illness and deaths is a primary goal of vaccination, but this is not the only dimension of wellbeing and common good that should be considered. Health, economic stability, and social connection are all central to wellbeing, for both individuals and communities. Thus, promoting wellbeing and the common good involves not only promoting public health but also promoting economic and social wellbeing. This is reflected in a statement in the CDC's 2018 pandemic influenza vaccine allocation document: "*The overarching objectives guiding vaccine allocation and use during a pandemic are to reduce the impact of the pandemic on health and minimize disruption to society and the economy.*"

The CDC's Advisory Committee on Immunization Practices (ACIP), the National Institutes of Health (NIH), and the National Academies of Sciences, Engineering, and Medicine (NASEM) are working to determine populations of focus for COVID-19 vaccination and ensure equity in access to COVID-19 vaccination availability across the United States. CDC has established an ACIP work group to review evidence on COVID-19 epidemiology and burden as well as COVID-19 vaccine safety, vaccine efficacy, evidence quality, and implementation issues to inform recommendations for COVID-19 vaccination policy.

KDPH will establish a Vaccination Allocation Committee (VAC) in which they will review the CDC's recommended target populations and adjust as necessary. The tasks for the committee include reviewing allocation priorities, and the populations that will be added successively as vaccine supplies increase. Among the factors that the committee is expecting to consider are: health disparities and other health access issues; individuals at higher risk (e.g., elderly and those with underlying health conditions); occupations at higher risk (e.g., health care workers and essential industries); populations at higher risk (e.g., racial and ethnic groups, incarcerated individuals, and residents of nursing homes); and geographic distribution of active virus spread. It is likely that KDPH's recommendations for vaccine prioritization will reflect the recommendations set forth by the CDC's advisory committee with minimal changes. KDPH recognizes, though, the potential for alterations of these recommendations based on the evolving epidemiology of COVID-19 and will monitor national recommendations for changes that may occur.

In a fact sheet posted on June 16, Operation Warp Speed (OWS) — the U.S. government's program to develop a vaccine for the COVID-19 pandemic — stated its intention to use a modified version of the 2018 pandemic influenza guidance as the foundation for SARS-CoV-2 vaccine guidance over the coming weeks and months. Furthermore, on October 2, the National Academies of Sciences, Engineering, and Medicine's Committee on Equitable Allocation of Vaccine for the Novel Coronavirus released the *"The National Academies' Framework for Equitable Allocation of COVID-19 Vaccine" (2020)* in which it outlines a preliminary framework for equitable allocation of COVID-19 vaccine. By looking at the various guidance documents, KDPH can speculate about who the targeted/target groups may be for the COVID-19 vaccine.

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The COVID-19 vaccination campaign is expected to occur in "four phases" targeting different workforces and populations. *The distribution plan is subject to change as we learn about the safety and effectiveness of the vaccine.*

- Target Groups – People targeted for vaccination defined by a common occupation, type of service, age group, or risk level.

- Phases – Vaccine will be allocated and administered according to "phases" where all groups designated for vaccination within a "phase" have equal priority for vaccination.

  At present, we will follow the National Academies of Sciences, Engineering, and Medicine allocation framework.

- *The targeted groups and phases are subject to revision as we receive feedback and additional information.*

Please see:
Attachment 3 NASEM Allocation Criteria to Specific Population Groups
Attachment 4: Projected Vaccination Target Groups

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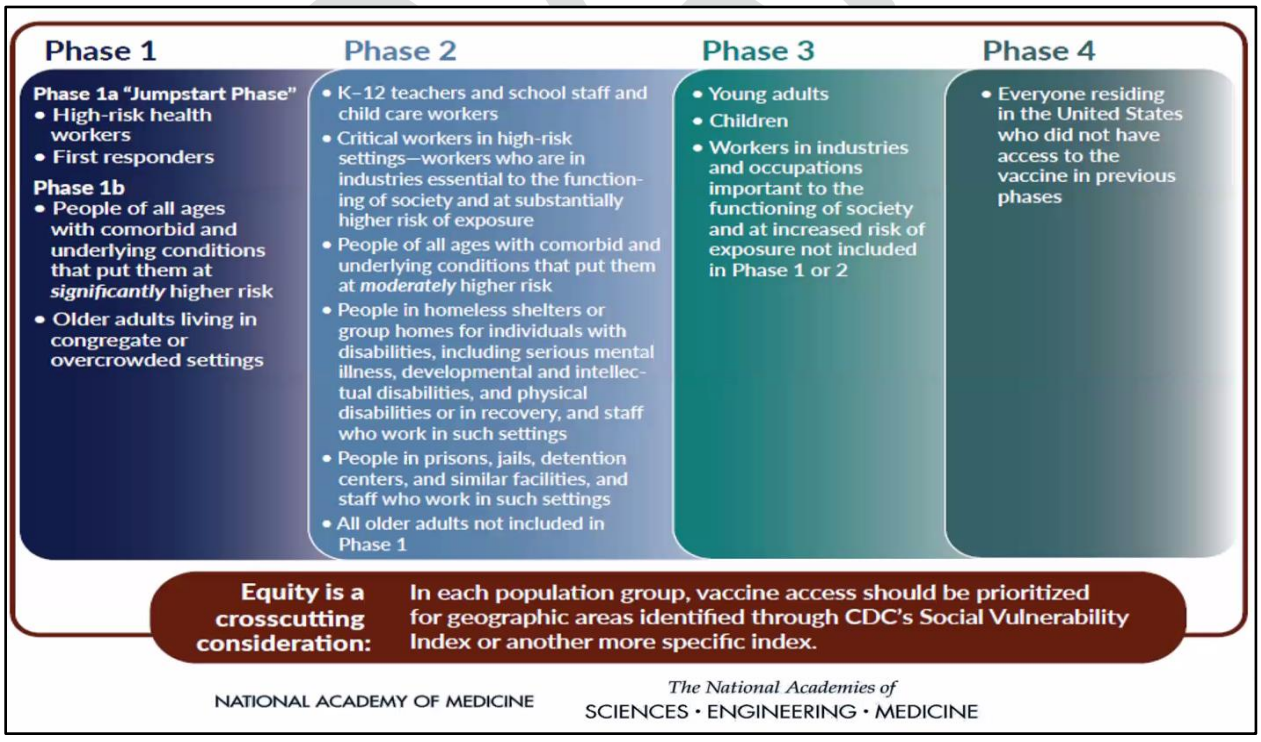
After the target groups have been vaccinated and additional vaccine stocks become available, KDPH will ensure that communities suffering disproportionately from COVID-19, including communities of color, older adults, people with disabilities, and people with comorbidities are prioritized appropriately for vaccination. KPDH will work with local community partners and providers to strategically target underserved populations for vaccinations. KDPH currently anticipates that independent and community pharmacies will be a major partner in providing vaccine to those targeted underserved areas.

KDPH will phase-in vaccination for the remainder of the population, based on age or other criteria to ensure fair, equitable, and orderly distribution. The CDC has indicated that COVID-19 vaccine prioritization will "be adjusted based on experience during the first wave of the COVID-19 response, data on the virus and its impact on populations and the performance of each vaccine, and the needs of the essential workforce."

Ultimately, KDPH and the Vaccine Allocation Committee will use new guidance in conjunction with previously published guidance to determine target populations and groups. Commonly referenced documents are:

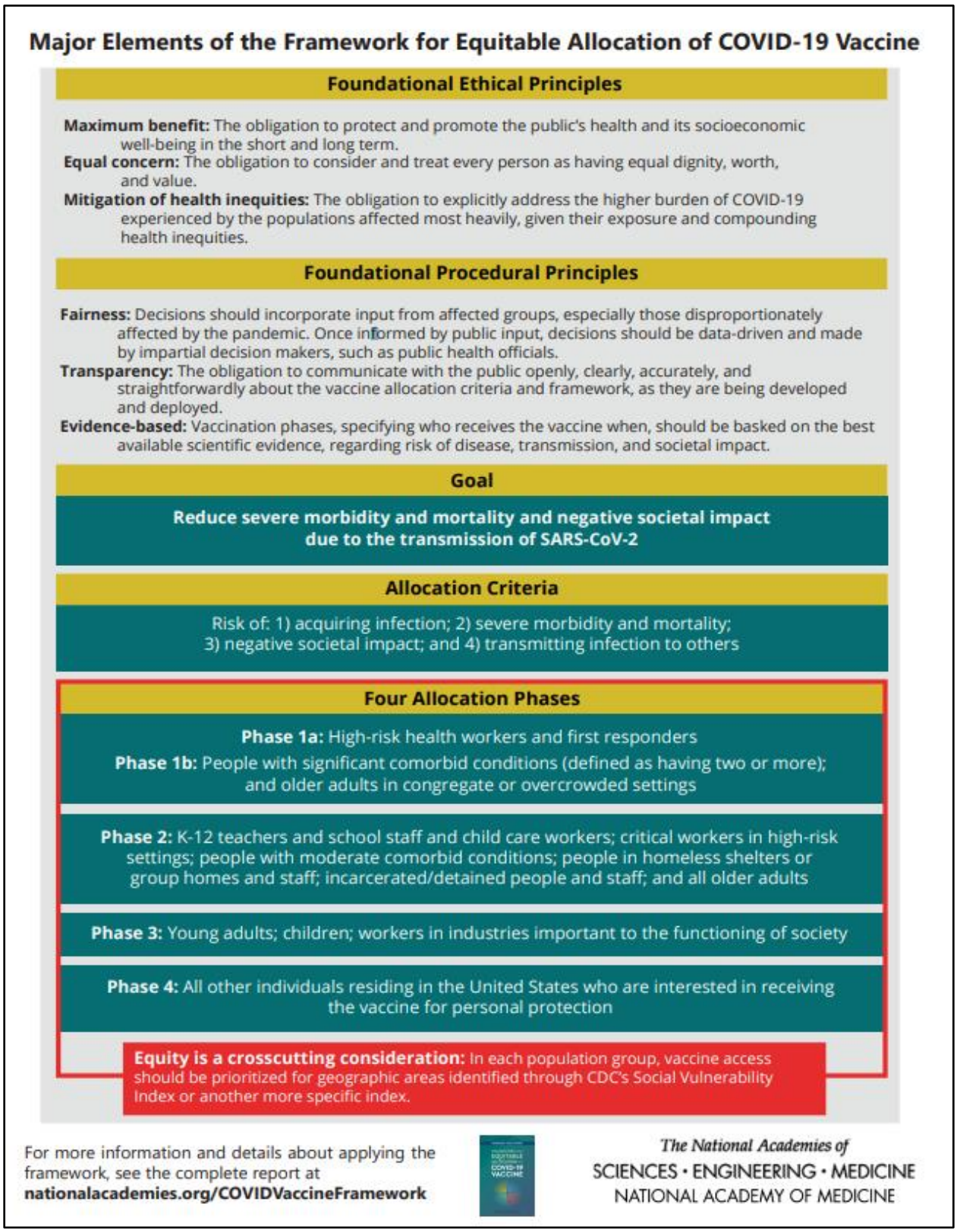
- The National Academies' Framework for Equitable Allocation of COVID-19 Vaccine
- Johns Hopkins- Interim Framework for COVID-19 Vaccine Allocation and Distribution
- 2018 Pan Flu Allocation Guidance
- 2020 CISA Essential Worker Guidance
- Critical Workforce Roadmap

The National Academies Framework for Equitable Allocation of COVID-19 Vaccine (10-2-20)



nationalacademies.org/COVIDVaccineFramework

The National Academies Framework for Equitable Allocation of COVID-19 Vaccine (10-2-20)



SECTION 5: VACCINATION PROVIDER RECRUITMENT AND ENROLLMENT

An adequate network of trained, technically competent COVID-19 vaccination providers in accessible settings is critical to COVID-19 Vaccination Program success. For this reason, KDPH began recruiting and enrolling COVID-19 vaccination providers in the early spring of 2020. KDPH concentrated early planning efforts engaging those vaccination providers that can rapidly vaccinate initial populations of focus. Once enrollment of critical phase one providers is completed, geographic information system (GIS) mapping will be used to identify gaps in coverage and targeted recruitment efforts will be implemented to fill those gaps.

To receive and administer the COVID-19 vaccine, providers must enroll in the COVID-19 Vaccination Program coordinated through the KPDH Immunizations Branch. Providers must sign and agree to conditions outlined in the COVID-19 Vaccination Program Provider Agreement. The CDC has made this agreement available to Kentucky for use in conducting outreach and enrolling vaccination providers. KDPH is required to collect and submit data to the CDC on each enrolled vaccination provider/site including provider type and setting, patient population (i.e., number and type of patients served), refrigerated/frozen/ultra-cold temperature storage capacity, and logistical information for receiving COVID-19 vaccine shipments.

Provider Recruitment and Enrollment

Healthcare and Congregate Settings

KDPH is recruiting and enrolling COVID-19 vaccination providers with the assistance of the Kentucky Hospital Association (KHA), the Kentucky Health Department Association (KHDA), Kentucky Primary Care Association (KYPCA), Kentucky Medical Association (KMA), Kentucky Department of Justice (KDOJ), the Kentucky Pharmacists Association (KPhA), the Kentucky Emergency Preparedness for Aging & Long Term Care Program, and the Kentucky Board of Pharmacy (KBP). These providers will vary in types and settings to address each of the previously described phases of vaccine availability. KDPH will provide technical assistance to hospital/healthcare systems to develop their own Phase 1 vaccine administration plan to vaccinate frontline healthcare staff. As the vaccination campaign evolves, this plan will expand to include their smaller clinics.

Community and Independent Pharmacies

The KDPH Immunizations Branch, the Kentucky Immunization Registry Coordinator, and the Emergency Preparedness Pharmacist from the Kentucky Pharmacists Association (KPhA) have been instrumental in enrolling and “on-boarding” new providers in preparation for flu season and for COVID-19 vaccination via the “outreach program.” The team primarily focused on “community and independent pharmacies.” Recruiting materials focused on the enrollment of community and independent pharmacies not currently in the program. In many rural Kentucky counties, the community pharmacist is the healthcare provider seen most frequently. This outreach program is vital to ensuring that as many pharmacies as possible participate in the COVID-19 Vaccination Program and that citizens, specifically in rural areas, have convenient access to the vaccine.

All providers wishing to participate in the COVID-19 Vaccination Program will be validated through the applicable board of licensure by the KDPH Vaccine Accountability section (VAS) staff to ensure they are eligible to participate in the program. KDPH will use an electronic database to enter the newly enrolled providers that will be updated daily. The data will be converted to excel and submitted to the CDC through VTrckS twice weekly. KDPH will provide education and training to providers upon enrollment.

Vaccination providers will sign a "provider agreement" with KDPH in which they agree to enter all vaccines administered into the Kentucky Immunization Registry (KYIR). This will enable KDPH to actively monitor vaccine ordering, usage, inventory, and waste as well as give the provider the ability to generate patient reminders to ensure a second dose of vaccine is given and recorded. Both written guidance and recorded trainings will be part of KYIR use. Completion of those trainings will be recorded and tracked in an Access database. For more information on training see: "Section 8: Vaccine Storage and Handling."

KDPH will require that all providers complete the CDC "You Call the Shots" storage and handling training module. The provider will then send or fax a copy of the completion certificate to the KYIR Help Desk. The provider can attend a storage and handling training or choose to have an in-person site visit. The Immunizations branch will assure that the provider has the proper equipment and training before vaccine is distributed. Once COVID-19 vaccine materials are available from the CDC, FDA, and vaccine manufacturer, KDPH will provide mandatory training prior to vaccination locations receiving vaccine supplies. This training will be specific to the COVID-19 vaccines that have been approved. These trainings will be documented in the Access database. For more information on training see "Section 8: Vaccine Storage and Handling."

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SECTION 6: VACCINE ADMINISTRATION CAPACITY

Community pharmacies play an essential role in expanding vaccine access. High-risk Medicaid patients visit their pharmacies about 35 times a year and approximately 93% of Americans live within five miles of a pharmacy. Millions of patients receive the influenza and other recommended vaccines from pharmacists annually. Specifically, in the 2018-2019 flu season, one in three adult influenza vaccines were provided at a community pharmacy.

Modeling

In 2016, the CDC partnered with Battelle to analyze every state's pandemic flu vaccination capacity for adults. Battelle worked closely with state immunization programs and pharmacy partners to construct a simulation model to assist states in pandemic planning by estimating pandemic influenza vaccine administration capacity and comparing pandemic vaccine administration scenarios with and without retail pharmacies. *(This report contains sensitive material and is not publicly available via reference site).*

Given a number of assumptions the model suggested that it may take approximately 11 weeks for non-pharmacy providers and pharmacies to administer vaccines to 80% of the adult population in Kentucky during a pandemic, assuming an unprecedented number of adult providers would enroll as pandemic vaccine providers. Even though the results do not show less time to cover 80% of the adult population with the help of pharmacies, we still believe it is important to utilize retail pharmacy vaccinators during a pandemic. The model furthermore suggested that vaccine administration capacity among pharmacists was limited by order limits, such that if more vaccine were allocated to pharmacies it would likely take less times to reach 80% adult pandemic vaccination coverage. Pharmacists are not only highly accessible (93% of Americans live within five miles of a community retail pharmacy), but they are also commonly available for longer hours and more days than non-pharmacy providers. Further, targeted enrollment and coordination with pharmacy chains and retail stores with pharmacies as pandemic vaccine providers can identify a large number of vaccine providers to substantially augment medical and public health vaccine providers. The model did not include the potential impact of mass vaccination clinic Points of Dispensing (PODs). It is suspected that the impact of PODs will be most felt during the initial stages of a vaccination campaign and can potentially help improve vaccination administration capacity, though it is unlikely that POD staffing can be sustained at maximum capacity throughout a >26 week response and public health programs will have to rely heavily on non-pharmacy and pharmacy vaccinators for the majority of vaccinations.

This model should not be viewed as a static final assessment of the likely vaccination administration capacity in Kentucky. This is an optimistic estimate of the potential capacity of Kentucky's vaccinators during a severe pandemic. It should be viewed as tool to help public health preparedness and immunization programs in planning for the numbers and types of providers and resources they still need to enlist in addition to their existing workforce and assets.

Vaccination Workforce

KDPH is recruiting and enrolling COVID-19 vaccination providers with the assistance of numerous state agencies and professional organizations. These providers will vary in types and settings to address each of the previously described phases of vaccine availability. KDPH will provide technical assistance to hospital/healthcare systems to develop their own Phase 1 vaccine administration plan to vaccinate frontline healthcare staff. Furthermore, pharmacists and pharmacy technicians contribute significantly to

vaccine awareness and immunization rates through clinical efforts such as patient screening and education, vaccine administration, and accurate reporting of adverse events. KDPH is working with major "chain pharmacies" and is recruiting "community and independent pharmacies" to assist in administering the vaccine. In many rural Kentucky counties, the community pharmacist is the healthcare provider seen most frequently. KDPH will continue to enroll and onboard these providers in order to ensure an expanded COVID-19 administration capacity.

KDPH plans to utilize "mobile vaccination teams" to support and provide mass vaccination clinics to defined targeted groups and populations (i.e. meat processing plants, worksites). Another objective of the mobile vaccination teams will be to deploy to areas impacted by health inequity, often referred to as "at-risk" or "vulnerable populations." This initiative builds upon the knowledge and experience gained during the 2018 Hepatitis A Outbreak where KDPH deployed mobile vaccination teams throughout the Commonwealth. KDPH will work to integrate the mobile vaccination teams through partnerships among LHDs, health care partners, housing agencies, and Continuum of Care partners.

Modified Scope of Practice

Each state determines the permitted scope of practice for the professions it regulates, including limiting the activities or procedures a person in that profession may undertake. Scopes of practice, which are defined by state practice acts, set forth the range of services that licensed practitioners are authorized to perform. Modifying scope of practice is one strategy that states have used in responding to public health emergencies. The 2009 H1N1 influenza pandemic saw broader use of modified scope of practice by states than in prior public health emergencies. States primarily modified scope of practice to increase the numbers of vaccinators available to meet real or anticipated demand. This was primarily accomplished by expanding the types of healthcare practitioners authorized to administer seasonal and H1N1 influenza vaccinations and by increasing the age range of patients that specified healthcare practitioners could vaccinate (e.g., adding children over a certain age). Pharmacists and EMT/EMS personnel were the two groups most frequently affected by scope of practice changes during H1N1. Other strategies some states used included allowing physicians to issue standing orders permitting vaccination without issuing prescriptions to individual patients. KDPH is currently working with the appropriate state agencies to ensure that the necessary processes and procedures are in place to ensure that any modified scope of practice is safely carried out and implemented.

Reference:
ASTHO Modified Scope of Practice Toolkit 1
ASTHO Modified Scope of Practice Toolkit 2

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SECTION 7: VACCINE ALLOCATION, ORDERING, DISTRIBUTION, AND INVENTORY MANAGEMENT

Allocation and Ordering

The federal government will determine the amount of COVID-19 vaccine designated for each jurisdiction. Using this allotment, KDPH will then be responsible for managing and approving orders from enrolled providers The amount allotted will change over time and may be based on critical populations recommended for vaccination), COVID-19 vaccine production and availability, and overall population of the jurisdiction. For further information on allocation strategies see "Section 4: Critical Populations" for more information.

Federal agencies and additional commercial partners will also receive allocations directly from CDC once larger volumes of vaccine are available. The CDC is currently developing procedures to ensure that jurisdictions have full visibility of COVID-19 vaccine supply and vaccination activities among these entities located within their boundaries.

Kentucky will follow the vaccine request procedures as presented by CDC at the time of availability and need. All states will need vaccine and it will be shipped as it becomes available to the states based on the percentage of the total U.S. population that resides within that state. During Phase 1 and 2, it is expected that vaccine will be shipped from the manufacturer or distributor directly to the vaccine providers Vaccine will be distributed through McKesson to public and private providers, similar to how the Vaccines for Children Program (VFC) vaccines are currently distributed. It is anticipated that vaccine will be shipped using climate controlled containers and directly shipped to vaccination providers. The CDC currently states that Phase 3 and 4 vaccine distribution will be done similarly to the Vaccines for Children Program.

Distribution

KDPH, in collaboration with Kentucky Emergency Management (KYEM), will ensure the regional and local distribution of vaccines to pre-determined sites. Local emergency management, public health, and public safety authorities, in conjunction with the state authorities, will play key roles in ensuring the safe and proper storage and handling of the vaccine. Portions of the Kentucky Medical Countermeasures Plan will be used to support vaccine distribution operations.

Although plans may change, the CDC currently assumes vaccine distribution will be managed centrally, although vaccines may be handled through more than one distributor. Distribution may be expanded to include additional healthcare organizations and vaccination providers who can provide pandemic vaccinations to targeted groups. Vaccine will be sent directly to vaccination providers (e.g. physician's office) or designated depots for secondary distribution to administration sites (e.g. chain drug stores central distribution).

Providers willing to administer the vaccine continue to be enrolled in the Kentucky Immunization Registry (KYIR) and agree to requirements for receiving, storing, administering, and tracking vaccine administration. See "Section 5: Vaccination Provider Recruitment and Enrollment" for more detailed information on provider enrollment. Enrolled providers will place orders for the vaccine with the state immunizations program. The CDC is expected to provide each state an allocation of vaccine based on population, and states can prioritize and fill orders against those allotments. Orders are then sent to the CDC and vaccines will be shipped directly to the provider through a centralized vaccine distributor. For

some critical workforce groups, KPDH and Local Health Departments may have to coordinate separate vaccine clinics with employers. For example, hospitals or health systems may vaccinate their own workforce.

In some situations, KDPH may occasionally allow local transport of vaccines from one location to another if adherence to cold chain and tracking requirements are maintained. Each provider must store and handle all vaccines within proper temperature ranges. Each storage unit that would be approved to store COVID-19 vaccine must have monitored temperatures at all times using a digital data logging thermometer and all storage practices as outlined in the CDC's Vaccine Storage and Handling Toolkit. A COVID-19 Provider will only be approved for shipment of vaccines once their storage unit (refrigerator/freezer) exhibits stable temperatures within the specified range. The CDC does not pay for or reimburse jurisdictions, COVID-19 vaccination provider organizations, facilities, or other entities for any redistribution beyond the initial designated primary CDC ship-to location, or for any vaccine-specific portable refrigerators and/or qualified containers and pack-outs. See "Section 8: COVID-19 Vaccine Storage and Handling" for more information.

Vaccine Distribution to Target Groups

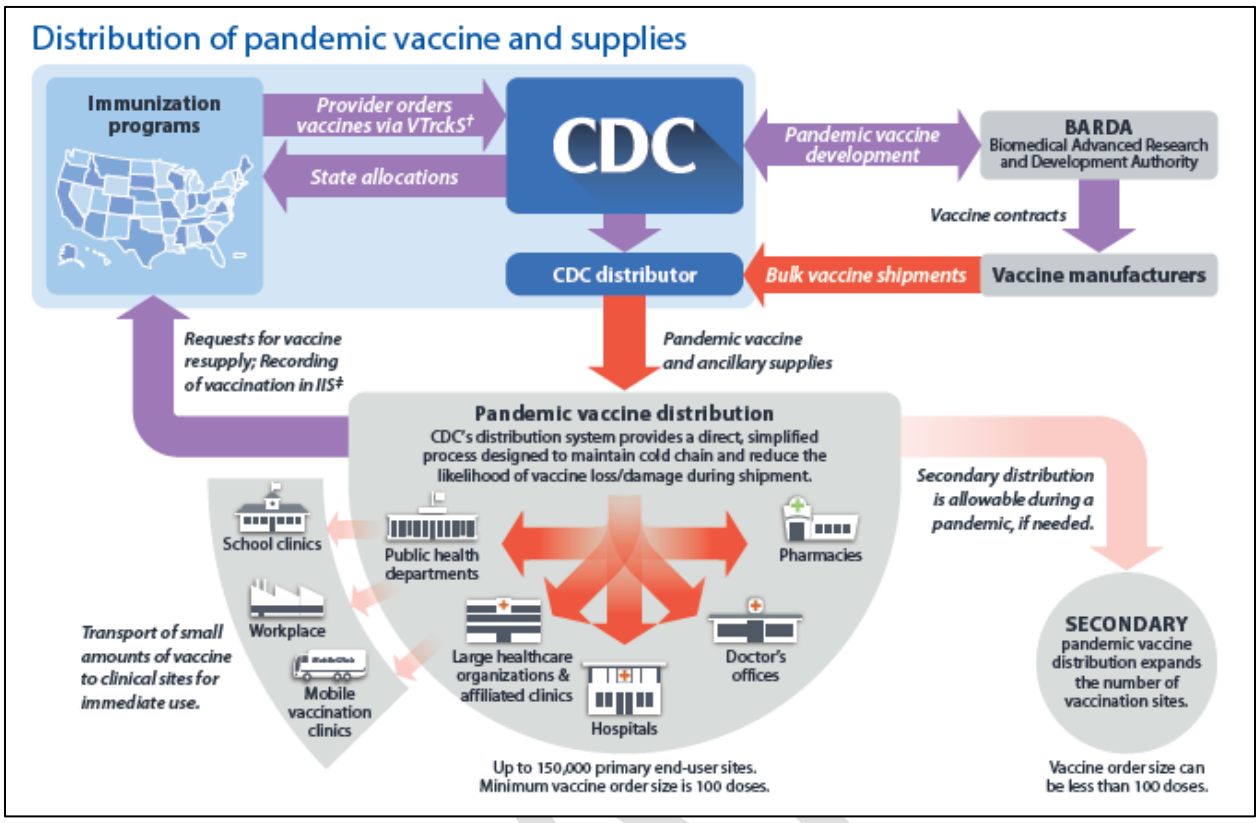
When the vaccine for Phase 1 target groups is available, KDPH will order from weekly allocations of the vaccine to be shipped by the centralized distributor to the designated site(s). It is expected that vaccine will be shipped from the manufacturer or distributor, directly to the Phase 1 target group such as a hospital or Long-Term Care Facility, and in rare cases, the KDPH warehouse. For some critical workforce groups, KDPH and Local Health Departments may have to coordinate separate vaccine clinics with employers. For example, hospitals or health systems may vaccinate their own workforce. Phase 2 and 3 target groups could include direct shipment to LHDs that could then further distribute the vaccine to other private providers or administer the vaccine. In some local jurisdictions, the LHD may choose to also have private providers designated as ship-to sites to expedite the distribution process. KDPH will allocate vaccine to target groups and local jurisdictions according to the number of persons in target groups, general population, and the disease burden. Timing of shipping will follow the target scheme for allocation according to the target groups identified.

Vaccine will be administered per the phased target structure through those methods deemed most appropriate by state and local authorities. Initially, when vaccine is extremely limited, it will be direct shipped to sites where the identified target groups are located. KDPH will work in coordination with the receiving organization to ensure proper vaccine distribution and administration. These methods may include clinics at the site of the prioritized recipients, through mass clinics, and through other distribution and administration structures as best fits the needs and resources of each local community.

KDPH may also choose to administer all or some of the vaccine through state and local-run vaccination sites. If so, they may use emergency mass dispensing as a model for distribution, for which extensive plans have been developed for other threats such as anthrax.

When it is time to vaccinate the Phase 2 target groups, KDPH anticipates that LHDs may need to complete distribution on a very small scale to area providers who do not meet the minimum ship to order for McKesson. In those cases, KDPH and the LHD will work with the provider to ensure that cold chain is maintained throughout the transfer.

Interim pandemic distribution plan, 04/20/20



Inventory Management

KDPH will maintain, on a real-time basis, a database inventory of each dose of vaccine that is shipped from the manufacturer or distributor and received at each ship-to site. Ship-to sites will maintain, on a real-time basis, an inventory of vaccine in stock, the manufacturer, lot numbers, expiration dates for each lot, and a record of each dose of vaccine transferred to any clinics designated to conduct the vaccination clinics. COVID-19 vaccination providers will be required to report inventory of COVID-19 vaccines. All such data will be transmitted to KDPH electronically via the KYIR, and KDPH will transmit it to CDC. The COVID-19 vaccinating provider may also choose to utilize the CDC Vaccine Administration Management System (VAMS) tool, which will allow data to be electronically sent to KYIR via the Immunization Gateway. Inventory management is explained in further detail in "Section 9: Vaccine Administration Documentation and Reporting."

It is anticipated COVID-19 vaccines will initially be authorized under an EUA. Vaccines authorized under the EUA will contain slight variations from approved Food and Drug Administration (FDA) products, including:

- **Expiration Date**: The vaccine vials and cartons will not contain a printed expiration date. Expiration dates may be updated based on vaccine stability studies occurring simultaneously with COVID-19 vaccine distribution and administration. Current expiration dates by vaccine lots for all authorized COVID-19 vaccines will be posted on a U.S. Department of Health and Human Services (HHS) website accessible to all COVID-19 vaccination providers. To ensure that information systems continue to work as expected, CDC has worked with FDA and the manufacturers to include a two-dimensional (2D) barcode on the vaccine vial (if possible) and carton (required) labels that includes a National Drug Code (NDC), lot number, and a placeholder expiration date of

12/31/9999 to be read by a scanner. The placeholder 12/31/9999 expiration date is not visible on the vaccine packaging nor found anywhere else; it is only to facilitate information system compatibility. CDC is developing "beyond use date" (BUD) tracker labels to assist clinicians with tracking expiration dates at the point of vaccine administration. The label templates will be available on the CDC website.

- **Manufactured Date**: A manufactured date will be on the packaging and should not be used as the expiration date when documenting vaccine administration. This date is provided to help with managing stock rotations; however, expiration dates should also be considered (see above) as using manufactured date alone could have some limitations.
- **2D Barcode**: The 2D barcode available on the vaccine carton (also on the vials for some vaccines) will include NDC, lot number, and a placeholder expiration date of 12/31/9999.
- **QR Code**: Each vaccine manufacturer will include a Quick Response (QR) code on the vaccine carton for accessing FDA-authorized, vaccine product-specific EUA fact sheets for COVID-19 vaccination providers and COVID-19 vaccine recipients.

Ancillary Supplies

COVID-19 vaccine and ancillary supplies, commonly referred as "COVID-19 Vaccination Kits" will be procured and distributed by the federal government at no cost to enrolled COVID-19 vaccination providers. COVID-19 Vaccination Kits will be sent in concert with the vaccine. Sharps containers, gloves, bandages, and other supplies will not be included.

Ancillary supplies will be packaged in kits and will be automatically ordered in amounts to match vaccine orders in VTrckS . Each kit will contain supplies to administer 100 doses of vaccine, including:

- Needles, 105 per kit (various sizes for the population served by the ordering vaccination provider);
- Syringes, 105 per kit;
- Alcohol prep pads, 210 per kit;
- Four surgical masks and two face shields for vaccinators, per kit; and
- COVID-19 vaccination record cards for vaccine recipients, 100 per kit.

For COVID-19 vaccines that require reconstitution with diluent or mixing with adjuvant at the point of administration, mixing kits with syringes, needles, and other needed supplies will also be included. Ancillary supply kits will not include sharps containers, gloves, and bandages. Additional personal protective equipment (PPE) may be needed depending on vaccination provider site needs.

Facilities ordering outside of Kentucky's allocation (i.e., commercial and federal entities with federal MOUs in place) will order directly from the CDC and the CDC will be responsible for approval of those orders.

Vaccine Security

Security at the "state level" will be the responsibility of KDPH who will work in coordination with the Kentucky State Police (KSP). "Local level" security operations will be the responsibility of the LHD and local law enforcement agencies. Should a LHD require security, arrangements should be made with the local

law enforcement agencies. If necessary, local security operations may be supplemented by KSP. If the county believes extra security is warranted then they should work through their local emergency manager and their local law enforcement agencies and if necessary submit a resource request through KYEM.

Local law enforcement agencies will be responsible for securing fixed facilities involved in the vaccine distribution process. This includes any regional storage "nodes" and dispensing sites such as mass vaccination clinics. Local law enforcement officials should engage with LHDs and county officials in the planning process necessary to provide this security function.

When applicable, KDPH, KYEM, KSP, and the Kentucky Transportation Cabinet (KYTC) will coordinate transportation security through the SHOC and provide escorts for transport vehicles to sites and/or health care facilities. KYEM and KDPH will provide resource support such as credentials, vehicle markers, and communication devices to each driver of state-operated vehicles.

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SECTION 8: VACCINE STORAGE & 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. Jurisdictions should work with staff at each COVID-19 vaccination provider site to ensure appropriate vaccine storage and handling procedures are established and followed.

It is expected that cold chain storage and handling requirements for COVID-19 vaccine products will vary in temperature from refrigerated (2°C to 8°C) to frozen (-15° to -25°C) to ultra-cold (-60°C to -80°C in the freezer or within the dry ice shipping container in which product was received). Ongoing stability testing may impact these requirements. Note: These temperatures are based on information available as of September 2020. Updated information will be provided as it becomes available.

The cold chain begins at the COVID-19 vaccine manufacturing plant, includes delivery to and storage at the COVID-19 vaccination provider site, and ends with administration of COVID-19 vaccine to a person. Jurisdictions and vaccination providers are responsible for maintaining vaccine quality from the time a shipment arrives at a vaccination provider site until the dose is administered. KDPH will minimize opportunities for breaks in the cold chain. Most COVID-19 vaccine will be delivered from CDC's centralized distributor directly to the location where the vaccine will be stored and administered, although some vaccine may be delivered to secondary depots for redistribution. Certain COVID-19 vaccine products, such as those with ultra-cold temperature requirements, will be shipped directly from the manufacturer to the vaccination provider site. KDPH does have a means to store vaccine if an "unplanned repositioning" of vaccine is required. KDPH has procured resources to assist in adhering to all cold chain requirements and has developed a partnership with a private entity should KDPH have to expand its ultra-low cold storage capacity.

The KYIR implementation team has established multiple training outlets for vaccine storage and handling. Existing quick guides and YouTube training videos on basic KYIR functionality are already embedded directly in the KYIR system. The KYIR team also plans to hold a series of live-webinars for COVID-19 providers on inventory management, mass vaccination usage, and reminder/recall functionality. Inventory management trainings have also been created in the TRAIN system that will allow those who need training on KYIR inventory management to self-register for the course and to complete the training on their own time. Offering a variety of venues for training will allow the end-user to decide which platform works best with their schedule. Internet usage and accessibility to KYIR will be determined in the early planning phases via a survey to ensure each identified partner has the necessary resources to report doses administered. Utilizing supplemental funds, the Immunization Branch will also hire a VAMS implementation team to roll-out the mass vaccination tool to necessary providers. The VAMS implementation team will be the point of contact for training and technical support to COVID-19 providers. Other trainings include the CDC webinars called "You Call the Shots – VFC" and "You Call the Shots – Storage and Handling." All clinic staff involved with the vaccine delivery process should be required to complete the above-mentioned trainings and have a clear understanding of all storage and handling policies.

The CDC is currently developing an addendum to the Vaccine Storage and Handling Toolkit that specifically addresses COVID-19 vaccines. However, there are numerous resources that KDPH and other vaccine providers will use to ensure proper vaccine storage and handling, such as:

- CDC's Vaccine Storage and Handling Toolkit
- CDC's You Call the Shots Trainings

Satellite, Temporary and Off-Site Clinics

Satellite, temporary, and off-site vaccination clinics play an important role in improving vaccination coverage rates and vaccinating hard-to-reach populations. Vaccination clinics held in these settings have unique challenges and providers must follow specific guidelines for managing publicly supplied vaccine in these non-traditional settings. KDPH has limited "mobile" ultra-low cold storage capacity and is currently planning for the possibility of having regional storage nodes where vaccine can be properly stored and shipped. Regional distribution nodes will allow the vaccine to arrive at locations faster and may be used during Phase 3 and 4 when the vaccine is targeted at the general population. KDPH may establish Regional Response Command Centers (RRCCs) to help facilitate distribution at the regional distribution nodes. However, the CDC has been consistent in its messaging saying that states do not need to acquire ultra-low cold storage equipment. Furthermore, KDPH is working with KYEM on contingency plans in case there is a breakdown or an unplanned event that impacts the cold-chain storage ability of the CDC and its central distributor. It is anticipated that Kentucky will form a partnership or agreement with one of the three major shipping hubs that are located within the state.

KDPH and LHDs are very familiar with operating vaccination clinics, but are inexperienced dealing with a vaccine that requires ultra-low cold storage. There are numerous best practices and reference materials for off-site vaccination clinics (see Attachment 1: Vaccination Resources and Checklists . KDPH will work with LHDs on vaccine storage and utilize the guidelines set forth in the Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations when conducting vaccination clinics. However, these situations require additional oversight and enhanced storage and handling practices, including:

- The quantity of COVID-19 vaccine transported to a satellite, temporary, or off-site COVID-19 vaccination clinic will be based on the anticipated number of COVID-19 vaccine recipients and the ability of the vaccination provider to store, handle, and possibly transport the vaccine appropriately. This is essential to minimizing the potential for vaccine wastage and spoilage.
- COVID-19 vaccines may be transported — not shipped — to a satellite, temporary, or off-site COVID-19 vaccination clinic setting using vaccine transportation procedures outlined in the upcoming COVID-19 addendum to CDC's Vaccine Storage and Handling Toolkit *(still in development)*. The procedures will include transporting vaccines to and from the provider site at appropriate temperatures, using appropriate equipment, as well as monitoring and documenting temperatures.
- Upon arrival at the COVID-19 vaccination clinic site, vaccines must be stored correctly to maintain appropriate temperature throughout the clinic day.
- Temperature data must be reviewed and documented according to guidance in the upcoming COVID-19 addendum to CDC's Vaccine Storage and Handling Toolkit *(still in development)*.
- At the end of the clinic day, temperature data must be assessed prior to returning vaccine to fixed storage units to prevent administration of vaccines that may have been compromised.
- As with all vaccines, if COVID-19 vaccines are exposed to temperature excursions at any time, the temperature excursion should be documented, reported, and acted upon according to the immunization program's procedures.

SECTION 9: VACCINE ADMINISTRATION, DOCUMENTATION AND REPORTING

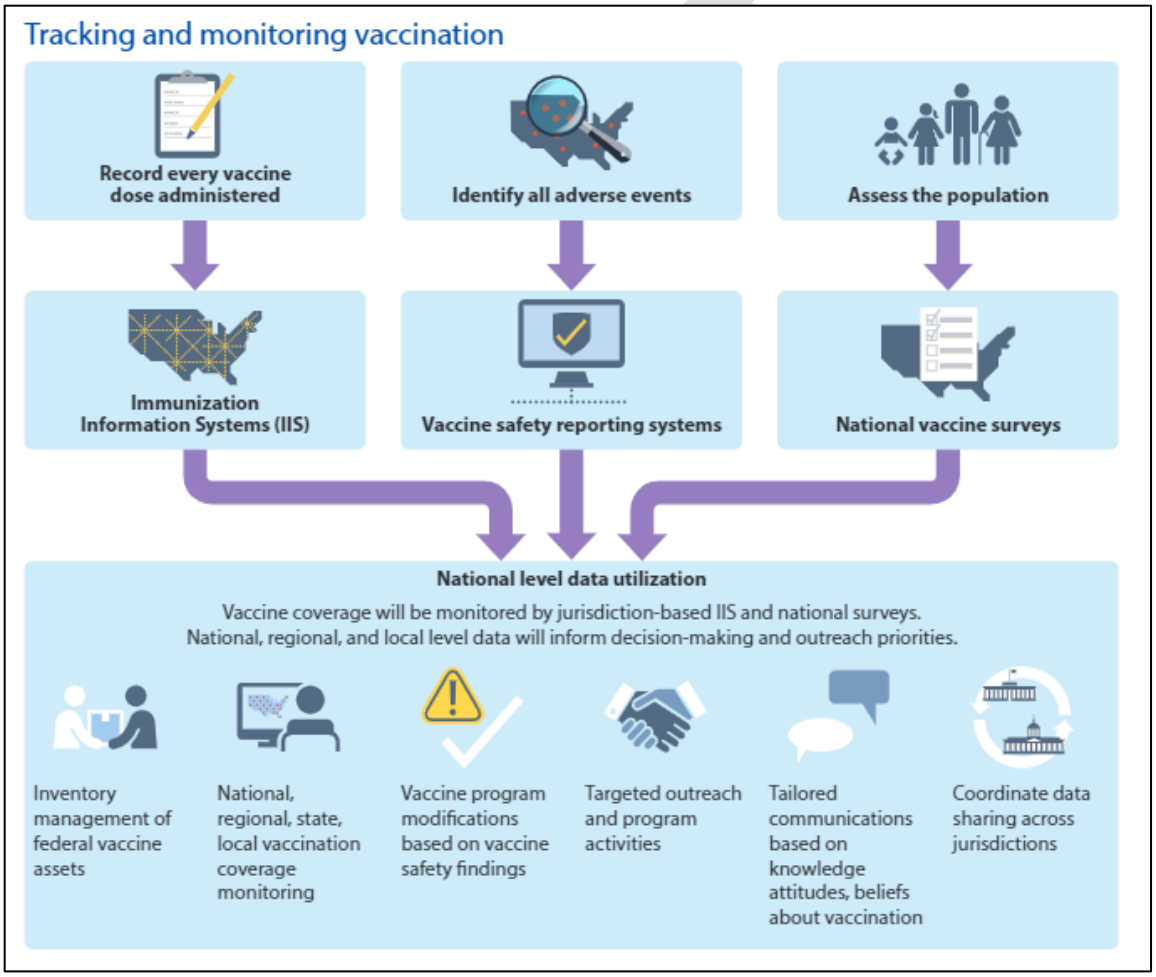
COVID-19 Vaccine Providers will be required to submit data to the Kentucky Immunization Registry (KYIR). If the facility has an existing electronic HL7 connection through the Kentucky Health Information Exchange (KHIE) then this will be the preferred method of receiving data. If a facility is not yet on-boarded with KHIE for electronic data submission of immunization data, or does not have the resources to onboard with KHIE, then manual data entry to the KYIR will be required. The COVID-19 vaccinating provider may also choose to utilize the CDC Vaccine Administration Management System (VAMS) tool that will allow data to be electronically sent to KYIR via the Immunization Gateway. If any provider is utilizing VAMS for mass vaccination clinics, then documentation of the administered vaccine will NOT need to be entered manually in KYIR as data should be submitted to KYIR via the IZ Gateway. If providers already have an established HL7 connection with KYIR, then they should not utilize VAMS as this will cause duplicate data entry. COVID-19 providers manually entering administered vaccines in KYIR will be encouraged to use the Mass Vaccination module in order to reduce the steps involved in documentation. Non-traditional vaccinators and larger federal sites, such as the Department of Defense, are expected to onboard directly to the IZ Gateway. It is still to be determined if data will be submitted to CDC through the IZ Gateway or through an electronic file upload. The KYIR team is working closely with its IIS (e.g., immunization information system) vendor to determine the most efficient way of providing necessary data through a file method to CDC, if needed. Final decisions will be based on further information provided by the CDC.

KDPH must be able to ensure that each COVID-19 vaccination provider is ready and able to report the appropriate data elements. Multiple training outlets have been established by the KYIR implementation team. Existing quick guides and YouTube training videos on basic KYIR functionality are already embedded directly in the KYIR system. The KYIR team also plans to hold a series of live-webinars for COVID-19 providers on inventory management, mass vaccination usage, and reminder/recall functionality. Inventory management trainings have also been created in the TRAIN system, which will allow those who need training on KYIR inventory management to self-register for the course and complete the training on their own time. Offering a variety of venues for training will allow the end-user to decide which platform works best with their schedule. Internet usage and accessibility to KYIR will be determined in the early planning phases via a survey to ensure each identified partner has the necessary resources to report doses administered. Utilizing supplemental funds, the Immunization Branch will also hire a VAMS implementation team to roll-out the mass vaccination tool to necessary providers. The VAMS implementation team will be the point of contact for training and technical support to COVID-19 providers.

Satellite, temporary, and off-site vaccination clinics play an important role in improving vaccination coverage rates and vaccinating hard-to-reach populations. Vaccination clinics held in these settings have unique challenges and providers must follow specific guidelines for managing publicly supplied vaccine in these non-traditional settings. KDPH must ensure that providers have the ability to ensure real-time documentation and reporting of COVID-19 vaccine administration data from satellite, temporary, or off-site clinic settings. Access to internet during off site clinics will be provided by a combination of services, including Wi-Fi “hotspots” and cellular cradle point devices. However, if data cannot be entered into KYIR during off site or satellite clinics, then the clinic will have to document doses administered once back in the office. Documentation must be entered within 24 hours of the conclusion of the clinic to meet CDC reporting requirements.

KDPH will monitor provider-level data to ensure each dose of COVID-19 vaccine administered is fully documented and reported every 24 hours. KYIR Data Quality Analyst and KYIR on-boarders will utilize internal reports from KYIR to monitor data quality and timeliness of data submission for COVID-19 providers. If data is not submitted in a timely manner, notice will be sent via email or phone call to instruct the vaccine provider on the requirements of reporting data to KYIR. The Vaccine Accountability Section (VAS) team will also assist in monitoring providers' HL7 electronic feed while checking reconciliations prior to approving COVID-19 vaccine orders in KYIR. If issues with a clinic's data feed arise, the VAS representative will notify the KYIR Data Quality Analyst who will then troubleshoot connection concerns with the KYIR on-boarders. KDPH coverage reports will be generated directly out of KYIR. The Immunization Branch will utilize coverage reports to identify pockets of need and monitor vaccine uptake.

Tracking and Monitoring Vaccination, CDC Webinar September 2020



SECTION 10: VACCINE SECOND DOSE REMINDERS

Some vaccines for COVID-19 will require two doses, administered approximately two to three weeks apart, to produce an adequate immune response. Recommendations on the number of required doses and the timing of the second dose will be issued once immunogenicity trials have been completed.

If two doses are required, it will be necessary to ensure that vaccinated persons return for the second dose. KDPH, along with local health departments/districts, will arrange for information about the need for a second dose to be provided to recipients at the time of initial vaccination.

The Kentucky Immunizations Branch will use the KYIR Mass Event Model for the majority of second dose reminders. One of the many capabilities of the KYIR is to transmit patient reminders/recalls via email and text.

COVID-19 Providers will be encouraged to schedule the patient's second-dose appointment when delivering their first dose. The CDC says that vaccination "verifications and reminder cards" will be included in the vaccine shipments and that providers will be required to provide vaccination cards to those receiving their COVID-19 vaccination.

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SECTION 11: IMMUNIZATION INFORMATION SYSTEMS

Immunization registries, also known as immunization information systems (IIS), are defined by the CDC as confidential, population-based, computerized databases that record all immunization doses administered by participating providers to persons residing within a given geopolitical area. Immunization registries offer a consolidation of patient immunization records. Compiling all immunizations in one database allows easy access for healthcare providers. Certificates for proof of immunization are also easier to obtain for the purposes of school and childcare centers. The registry also offers timely reminders for vaccines coming due for patients. The Kentucky Immunization Registry (KYIR) is KDPH's IIS. The KYIR has many functionalities, but during the COVID-19 Vaccination Program it will be primarily used to:

- Preregister or enroll in the COVID-19 Vaccination Program;
- Place orders for COVID-19 vaccine;
- Document vaccine administration;
- Manage and report vaccine inventory;
- Report vaccine spoilage/wastage; and
- Provide reminders to COVID-19 vaccine recipients indicating when the next dose of a multi-dose vaccine is due.

The KYIR is able to capture standard data elements submitted via an HL7 message, including patient demographic information such as name, DOB, race, ethnicity, address, sex, etc. KYIR is also able to capture and store detailed vaccine administration information such as CVX, lot number, vaccine expiration date, precautions and contraindications, and additional data requirements set by the CDC. KDPH plans to capture two optional fields – race and ethnicity – during the COVID-19 vaccination campaign.

Data Exchange

The Kentucky Health Information Exchange (KHIE) automates the reporting of immunizations directly to the KYIR in support of eligible hospitals (EHs), critical access hospitals (CAHs) and eligible providers (EPs) for all stages of Meaningful Use of electronic health record technology. For the purpose of sending and receiving immunization data, the Kentucky Immunization Registry has implemented an interface that strictly adheres to the CDC and Health Level Seven (HL7) Standards as well as specific constraints recommended in the "WebIZ Immunization Registry Local Implementation Guide for HL7 2.5.1." WebIZ is Kentucky's immunization registry system implemented at the state level, known as KYIR. All HL7 connections are facilitated through KHIE. All onboarding capacities to establish electronic connections will be determined by the resources offered by KHIE. KYIR is cloud- hosted and has ample capacity for data storing. The KYIR team is working closely with its vendor to improve data extraction methodologies. Kentucky has already signed the data use agreements (DUA) needed for the "Connect" piece and the "Share" piece of the IZ Gateway. KDPH was fully on-boarded with the Gateway by the end of September, putting us ahead of schedule. The DUA with the Association of Public Health Laboratories (APHL) to participate in the IZ Gateway is completed, but the DUA with the CDC for national coverage analyses is not yet available. Further IIS and HL7 technical information.

Onboarding

KDPH is aggressively recruiting and enrolling COVID-19 vaccination providers with the assistance of multiple partner organizations. See "Section 5: Provider Recruitment and Enrollment" for more detailed information. The Immunizations Branch has hired additional individuals to assist with the increase of KYIR enrollments. KHIE will work with KYIR onboarding staff to increase onboarding efforts as well.

The KYIR on-boarders will utilize the on-boarding module in KYIR to streamline the process. The onboarding module allows the EHR technical contacts to troubleshoot issues with message formatting and data independently, reducing some of the labor intensive review conducted by KYIR on-boarders directly. KYIR staff are currently reviewing existing connections with emphasis on providers (e.g., hospital systems) who will be responsible for COVID-19 vaccination response in the early phases to confirm that data is being submitted consistently.

Data Quality

The KYIR on-boarding team has put a significant emphasis on ensuring the required data fields listed by the CDC are accurately captured during the onboarding process. The KYIR staff will utilize the reporting system in KYIR to frequently monitor data submission and quality. To ensure data is available, complete, timely, valid, accurate, consistent, and unique, KDPH will:

Completeness

- Review the Data Quality – Statistics report for whatever timeframe is required to analyze the necessary quantity of data (preferably at least 40 patients worth of data).
- Confirm that patient and vaccination data completeness listed on the Data Quality – Statistics report reaches program standards as spelled out in the Recommendations for KYIR Completeness Measure Thresholds document.
- Review the HL7 message log to ensure that there are no issues or anomalies that affect completeness.

Accuracy

- Review the HL7 message log in QA and confirm that commonly confused CVX codes are being entered correctly.
- Review the HL7 message log in QA and confirm that accuracy of lot numbers (i.e. not placeholders).
- Review at least 40 random patient charts with clinic staff to confirm accuracy. If data is inaccurate, work with clinic to address any issues.
- Review HL7 message log for eligibility and funding source compatibility.
- Review the HL7 message log to ensure that data being received is logical.

Validity

- Review the HL7 message log and individual messages for syntax quality.
- Review the HL7 message log for fields that contain contradictory values.
- Review the HL7 message log for VFC facility ID associations. Confirm their validity by ensuring that data is available in reports for the VFC clinic.

Consistency

- Review the HL7 message log for both quantity and contents of messages to confirm that they accurately reflect the source.
- Confirm that we are receiving both new and historical immunizations, in accordance with what would be considered normal for the sending provider.

Timeliness

- Review the Data Quality – Statistics report for a timeframe appropriate for the quality and quantity ascertained when reviewing the HL7 message log. Confirm that vaccination event recording reaches program standards of timeliness. 95-100% of vaccinations should be entered into KYIR less than 24 hours of the vaccine being administered.

Documentation

- KYIR on-boarders will document the process in SharePoint and document the go-live.
- Data Quality Analyst will document the data quality review process.

Immediately Post-Go Live (one to two weeks, performed by assigned KYIR on-boarder and data quality analyst)

- Continue review for message quality and quantity consistency in the HL7 message log and through the Data Quality – Statistics report.

References:

- CDC About Immunization Information Systems
- Health Level 7 (HL7)
- CDC Meaningful Use
- Vaccines For Children

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SECTION 12: VACCINATION COMMUNICATION

Vaccine hesitancy was declared a top 10 global health threat by the World Health Organization in 2019. In the United States, public reluctance to be vaccinated is expanding: Recent measles outbreaks reflect parental concerns about vaccines, and each year, many adults refuse the seasonal influenza vaccine or get it late. It is very likely that public health officials and politicians will compete against an anti-vaccination movement that floods social media with misinformation, conspiracy theories and propaganda aimed at convincing people to not receive the COVID-19 vaccine. Therefore, it is of the upmost importance to have coordinated public education and communication about the COVID-19 vaccine. It should be noted that KDPH is committed to providing the public a transparent and evidence based communication strategy.

The Kentucky Strategic National Stockpile (SNS) Crisis Communication Guide was created to assist state and regional public health personnel in their response to a public emergency. The Kentucky SNS Crisis Communication Guide will serve as a resource for public communication during the COVID-19 vaccination campaign. KDPH, in cooperation with the Cabinet for Health and Family Services (CHFS), will provide public information for the media and the citizens of Kentucky. The CDC has stated that it will develop COVID-19 communication resources for jurisdictions to use with key audiences and that these resources will be available on a public-facing website currently under development, however, KDPH will likely need to tailor messaging and resources specific to special populations in Kentucky communities. KDPH will incorporate the CDC's communication resources into its public communication efforts when applicable. Information may be disseminated via social media, web site postings, interviews, newspaper editorials, flyers, billboards, television and radio broadcasts.

KDPH is in the process of structuring a vaccine communication strategy for the Commonwealth. A number of pathways are being explored and will likely result in a "multi-front" communication strategy utilizing the KDPH Commissioner's Office, the CHFS Office of Public Affairs, the Governor's Office, and external partner agencies to ensure effective messaging across all populations. Furthermore, social, behavioral, and compliance practices and trends will be assessed in an effort to ensure accurate, proactive, time-sensitive, real-time messaging.

In order to understand Kentuckians attitude about the potential COVID-19 vaccine KDPH is working with external partners to develop a statewide assessment of public and provider attitudes and beliefs surrounding the COVID-19 vaccine. A survey will be used to collect actionable information from the public that can be used to maximize COVID-19 vaccination uptake in Kentucky, including but not limited to information specific to subpopulations including rural, urban, African-American, and Hispanic Kentuckians. Information and data obtained via the survey will be used to assist KDPH and our partners with the development of appropriate messaging and delivery mechanisms for the public and for healthcare providers.

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KDPH COVID-19 Vaccination Communication Objectives

- Educate the public about the development, authorization, distribution, and execution of COVID-19 vaccines and that situations are continually evolving.
- Ensure public confidence in the approval or authorization process, safety, and efficacy of COVID-19 vaccines.

- Help the public to understand key differences in FDA emergency use authorization and FDA approval (i.e., licensure).
- Engage in dialogue with internal and external partners to understand their key considerations and needs related to COVID-19 vaccine program implementation.
- Ensure active, timely, accessible, and effective public health and safety messaging along with outreach to key state/local partners and the public about COVID-19 vaccines.
- Provide guidance to local health departments, clinicians, and other hosts of COVID-19 vaccination provider locations.
- Track and monitor public receptiveness to COVID-19 vaccination messaging.

Key Audiences

KDPH will tailor messaging for each audience to ensure communication is effective. Key audiences include:

- Healthcare personnel (i.e., organizations and clinicians who will receive information about receiving and administering vaccine)
- Health insurance issuers and plans (coverage for vaccine, in-network providers)
- Employers
- Government and community partners and stakeholders
- Public/consumers
- Essential workers
    - 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

Call Center

KDPH has a full partnership plan for the implementation and operation of an assistance hotline with Norton Healthcare. This assistance hotline has served as the Kentucky COVID-19 assistance hotline throughout the current response. KDPH will also make use of this hotline for general information dissemination about the COVID-19 vaccine and to answer various questions from the public that are relevant to the COVID-19 vaccine.

Additionally, KDPH is considering a separate “call center” to answer and direct questions from vaccination providers. At the beginning of the COVID-19 response KDPH opened a clinician hotline to field questions about COVID-19 testing and isolation guidance. Based upon the feedback we received from clinicians, the internal KDPH “call center” was well received and will likely be used again once a vaccine is available.

SECTION 13: REGULATORY CONSIDERATIONS

Initially available COVID-19 vaccines may be authorized for use under an Emergency Use Authorization (EUA) issued by FDA or approved as licensed vaccines.

Emergency Use Authorization Fact Sheets

The EUA authority allows FDA to authorize either (a) the use of an unapproved medical product (e.g., drug, vaccine, or diagnostic device) or (b) the unapproved use of an approved medical product during an emergency based on certain criteria. The EUA will outline how the COVID-19 vaccine should be used and any conditions that must be met to use the vaccine. FDA will coordinate with CDC to confirm these "conditions of authorization." Vaccine conditions of authorization are expected to include distribution requirements, reporting requirements, and safety and monitoring requirements. The EUA will be authorized for a specific time period to meet response needs (i.e., for the duration of the COVID-19 pandemic). Additional information on EUAs, including guidance and frequently asked questions, is located on the FDA website.

Product-specific EUA fact sheet for COVID-19 vaccination providers will be made available that will include information on the specific vaccine product and instructions for its use. The FDA will develop EUA fact sheets for vaccine recipients. The EUA facts sheets will likely be made available on the FDA website and through the CDC website. KDPH will use multiple communication mediums to reach COVID-19 vaccine providers such as email distribution lists, webpages, and ReadyOp alerts to contact enrolled providers and make them aware of the appropriate EUA fact sheets. Furthermore, KDPH will host conference calls and provide training webinars on the EUA fact sheets and the VISs to ensure that providers understand the information, and are clear on the requirement to provide the recipient fact sheet to each client/patient prior to administering vaccine.

Vaccine Information Statements (VIS)

VISs are required only if a vaccine is added to the Vaccine Injury Table. Optional VISs may be produced, but only after a vaccine has been licensed (e.g., such as with zoster vaccines). Plans for developing a VIS for COVID-19 vaccine are not known at this time but will be communicated as additional information becomes available. KDPH will disseminate VISs similarly to how the EUA facts will be disseminated.

Modified Scope of Practice

KDPH leadership is currently looking at the potential expansion of existing scopes of practice for vaccine administration. Scopes of practice set forth the range of services that licensed health care practitioners are authorized to perform. A health care professional can only provide services they are deemed eligible to perform by the terms of his/her professional license. Authority to dispense vaccines turns, at least in part, on state law, and is accomplished through several different mechanisms. While legal considerations may vary according to dispensing modality and the type of professional authorized to administer a vaccine, KDPH can adjust vaccine dispensing through legislation, regulatory changes (e.g., health professional boards), standing orders, and emergency orders.

Administration Fees

While partner agencies or organizations that provide the COVID-19 vaccine cannot charge clients for the vaccine that they receive from federal and state caches, private partners, such as commercial pharmacies or hospitals, will likely charge an administration fee. This fee offers a financial incentive to provide the vaccine, and covers costs associated with storage and the health care providers' time, however, it also imposes another barrier to vaccination. Though the administration fees are likely to be capped by federal officials, any fee will frustrate uninsured Kentuckians and reduce vaccination rates among some of the same people most likely to be exposed to infection. KDPH is currently considering a limit on administration fees and will work with providers to ensure the COVID-19 vaccine is accessible and affordable.

To reach uninsured individuals, federal support and funding should be provided for mass vaccination clinics and for reimbursement for providers serving uninsured individuals directly. In all cases, a billing code of some kind will be needed to monitor uptake. KDPH will work to keep barriers to provider participation in administration of the vaccine as low as possible, especially for those providers who are in communities that are disproportionately impacted by COVID-19 by assuring vaccines are available at no cost and that administration of the vaccine is adequately reimbursed even if there is no cost sharing for the patient.

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SECTION 14: VACCINE SAFETY AND MONITORING

The reporting of adverse events provides the government and the manufacturers with reliable and critical information that is used to evaluate the actual safety and efficacy of the vaccines used in the field. Reporting allows the government and manufacturers to monitor for emerging trends in events and then investigate whether or not the events can be attributed to the vaccine or product. Health care providers and clients benefit from communicated updates of such clinically relevant information. These reports allow the ability to take appropriate actions such as a vaccine recall or a product label change.

In response to vaccine safety, the KDPH Immunizations Branch will use the Vaccine Adverse Event Reporting System (VAERS) to report and investigate adverse events following immunization with the COVID-19 vaccine. VAERS reports should go directly to the VAERS site. KDPH will provide technical assistance and communicate with the CDC on all aspects of vaccine adverse event reporting. Vaccine safety and education will be provided by the CDC and the KDPH Immunizations Branch to providers statewide. It should be emphasized that reports of adverse events from manufacturers or health care practitioners are for the most part only suspected associations.

- Vaccine recipients will be passively monitored for adverse reactions to the vaccine. They will receive instruction on identifying and seeking care for adverse reactions.
- Vaccinators will be responsible for the examination and care of persons with adverse events that occur immediately after vaccination (such as anaphylactic reactions).
- KDPH will provide guidance and recommendations established by the CDC Advisory Committee on Immunization Practices (ACIP) regarding vaccine administration that will include the appropriate immunization schedule, dosage and contraindications. See “Section 4: Critical Populations” for further information.
- KDPH will identify information that must be captured to provide appropriate follow-up of primary vaccines, including adverse reactions. KDPH will educate medical care providers and LHDs regarding adverse reactions and reporting requirements. LHDs will educate patients about reporting adverse events. Adverse events that occur at the vaccinating clinics will be treated and reported at the time of vaccination.
- Medical care providers and Pharmacies will report to VAERS vaccine adverse reactions. LHDs will provide follow up in consultation with KDPH and with support from KDPH as needed. KDPH will report adverse reactions and investigation findings to CDC.

References:

- Vaccine Adverse Event Reporting System (VAERS): http://vaers.hhs.gov/
- VAERS Frequently Asked Questions: https://vaers.hhs.gov/faq.html
- Medical Management of Vaccine Reactions: http://www.immunize.org/catg.d/p3082a.pdf

SECTION 15: VACCINATION PROGRAM MONITORING

Continuous monitoring for situational awareness throughout the COVID-19 Vaccination Program is crucial for a successful outcome. KDPH has established procedures for monitoring various critical program planning and implementation elements, including performance targets, resources, staffing, and activities.

COVID-19 Vaccination Program Monitoring

The majority of the aforementioned elements are regularly monitored through normal day-to-day operations and under the current COVID-19 State Health Operations Center (SHOC) Incident Command System (ICS). KDPH has hired additional personnel throughout the COVID-19 response and has hired and trained additional personnel in order to handle the expected expansion of services when a vaccine becomes available. Additional staffing and resource needs will be handled utilizing the SHOC ICS reporting structure. The SHOC will work in coordination with the Immunizations Branch to monitor and assess the various information requirements, such as inventory of vaccine, PPE usage, etc. This is discussed further in "Section 2 COVID-19 Organizational Structure and Partner Involvement."

Dashboards

The KDPH Vaccination Planning Team will continue to assess the need for having various information systems and dashboards to monitor and display COVID-19 Vaccination Program information. However, to provide situational awareness for jurisdictions and the general public throughout the COVID-19 vaccination response, the CDC will have two dashboards available.

The **Weekly Flu Vaccination Dashboard** will include weekly estimates of influenza vaccination for adults, children, and pregnant women (when approved for these groups) using existing (National Immunization Survey [NIS]-Flu) and new (IQVIA) data sources. Data and estimates from additional sources will be added, as available.

The **COVID-19 Vaccination Response Dashboard** will include:

- Data for planning (e.g., estimates of critical population categories, number and attributes of healthcare providers and facilities)
- Implementation data (e.g., number of enrolled COVID-19 vaccination providers, COVID-19 vaccine supply and distribution, COVID-19 vaccine administration locations)
- COVID-19 vaccine administration data

An additional OWS information systems is the Tiberius Platform. Tiberius provides a COVID-19 vaccine distribution planning, tracking, modeling, and analysis ecosystem to support the OWS mission. Leveraging the same technologies as the HHS Protect Platform. Tiberius integrates data sources from Federal agencies, State and Local partners, private sector partners, and open data providers to create a comprehensive Common Operating Picture ("COP") for the COVID-19 vaccine planning, distribution, and administration effort. Tiberius provides flexible and real time data-backed applications that enable users of all types to make data-driven decisions. KDPH will review the Tiberius Platform and integrate into vaccination operations if it is beneficial and applicable to KDPH information systems.

The COVID-19 Vaccination Response Dashboard will be implemented in stages based on data availability and shareability. Both dashboards will include a "secure" view tailored for jurisdictions (via SAMs Account), and a view for the general public on the CDC's website.

ORGANIZATION AND ASSIGNMENT OF RESPONSIBILITIES

The following Primary Agencies will coordinate operations with supporting agencies prior to, during, and after the COVID-19 vaccination campaign. KDPH will serve as the Primary Coordinating Agency during the COVID-19 vaccination campaign. Adjunct responsibilities and tasks may be added during planning and operations to cover situations that arise or that are not addressed in this plan and/or listed below.

Primary Agency – Kentucky Department for Public Health (KDPH)

1. KDPH-Division of Public Health Safety and Protection- Preparedness Branch
    a. Serves as the lead agency for ESF #8 – Public Health and Medical Services and will activate the SHOC to support public health and medical-related operations.
    b. Maintains vehicles, trailers, Personal Protective Equipment(PPE), equipment, and supplies needed for the distribution of vaccine and vaccine supplies;
    c. Coordinates with response partners, bordering states, and the federal government throughout the event;
    d. Provides regular updates and new information as available to all stakeholders, including the community;
    e. Activate and direct the management of a call center focused on providing health information Coordinates with the Office of Communications to use media relations and outreach plan disseminate risk communication messages;
    f. Provides operational support for vaccine response activities determined to be appropriate by the Division of Epidemiology and Health Planning.

2. KDPH-Division of Epidemiology and Health Planning- Infectious Disease Branch
    a. Reviews surveillance data to aid prioritization decisions for vaccines and antivirals;
    b. Provides epidemiological support to LHDs, hospitals, and other healthcare agencies
    c. Recommends use of control measures including non-pharmaceutical interventions, vaccine, and antivirals in accordance with CDC guidelines;

3. KDPH-Division of Epidemiology and Health Planning- Immunizations Branch
    a. Oversees the procurement of the vaccine (if necessary) as it is made available by the manufacturers over several months, for distribution through multiple phases as the situation unfolds.
    b. Coordinates the distribution of the vaccine through established systems for the venders to transport to the appropriate community services providers (i.e., hospitals, health care providers, or local health departments) in accordance with the CDC guidance to facilitate access for the specified Target groups.
    c. Assembles fact sheets for health care professionals about the novel virus, diagnosis and treatment;

d. Develops and/or provides guidance on delivery protocols and procedures;

e. Coordinates with partner organizations to implement systems to identify target populations, and estimate amount of antiviral medications and vaccine they will need;

f. Ascertains from CDC and manufacturers the availability of vaccine and antivirals;

g. Implements plans for delivery, storage, and administration of vaccine as it becomes available (update plans as necessary in coordination with the Public Health Preparedness Branch);

h. Monitors vaccine, antiviral, and other supplies using the Mass Event module of the Kentucky Immunization Registry or other system as needed;

i. Ensures that all identified vaccinators are authorized, identified, and have access to the Kentucky Immunization Registry;

j. Leads the state response to vaccine shortage related issues;

k. Packages and distributes educational materials for the public, health professionals, and the media for reporting adverse events for antiviral medications using MedWatch and for vaccine using the Vaccine Adverse Event Reporting System (VAERS);

l. Reviews data from MedWatch and VAERS reports;

m. Notifies LHDs, Infection Control Professionals, physicians, hospitals, and health systems, the media, and all other relevant health care professionals and associations including those responsible for special populations of the vaccine campaign and associated operations.

Support Agencies

The following Support Agencies have a major role during the COVID-19 vaccination campaign as outlined within this plan. Other local, state, or federal agencies may provide logistical and technical support per the Kentucky EOP and supporting ESF Annexes. Adjunct responsibilities and tasks may be added during planning and operations to cover situations that arise or that are not addressed in this plan and/or listed below.

1. Cabinet for Health and Family Services (CHFS) - Office of Communications

   a. Coordinates the communications response and media relations for ESF #8 through coordination with CHFS, KDPH, and ESF #8 agencies;

   b. Serves in the Public Information role for ESF #8 from a virtual setting or at the state's JIC, KDPH's SHOC, or in field settings;

   c. Provides support to local and state agencies in the development and release of public information.

2. Kentucky Emergency Management (KYEM)

   a. Supports ESF #8 in coordinating public health and medical preparedness, response and recovery activities with other ESFs and local, state, and federal agencies;

   b. Provides support to local and state agencies for developing and releasing emergency public information and warnings through ESF #15 – Public Information and/or activation of a Joint Information Center (JIC);

c. Provides administrative support to recovery efforts by assisting in the processing of documents authorizing payments to local governments, and state agencies.

3. Kentucky Pharmacists Association (KPhA)

   a. Supports public health and medical response efforts as a liaison between ESF #8 – Public Health and Medical Services and pharmaceutical partners;

   b. Work with healthcare partners and other stakeholders to distribute, deliver, and administer pandemic vaccines to priority groups;

   c. Disseminates information to statewide pharmaceutical providers;

   d. Collaborates with public health agencies to distribute vaccine;

   e. Keeps KDPH updated on the available inventory and shortages of pharmaceuticals;

   f. Identifies volunteer pharmacists to assist with administration of vaccine;

   g. Considers development of vendor agreements to streamline acquisition and distribution of vaccine.

4. Kentucky Hospital Association (KHA)

   a. Supports public health and medical response efforts as a liaison between ESF #8 – Public Health and Medical Services, hospitals, HCCs, and other community healthcare partners;

   b. Disseminates information to statewide healthcare providers;

   c. Assists in the distribution of practitioner-level information related to medical countermeasures through appropriate distribution channels;

   d. Assesses supply chain, staffing, and other impacts on medical care facilities and ascertains whether medical resources are sufficient;

   e. Assists with the collection and interpretation of hospital reporting data;

   f. Assists with the deployment of prepositioned medical response assets including but not limited to pharmaceuticals, antiviral medications.

5. Kentucky National Guard (KYNG)

   a. Provides available personnel and equipment to support the receipt and distribution of state and federal assets;

   b. Coordinates the activation and deployment of appropriate response personnel and other assets to provide immediate response capabilities including command and control, logistical support and transportation;

6. Kentucky State Police (KSP)

   a. When necessary, provides support to KDPH and local law enforcement agencies when vaccine is being transported, distributed or dispensed;

   b. Assists local law enforcement with any requested tasks such as law and order, and crowd control;

c. Coordinates with the local law enforcement agencies for security and traffic control during operations involving the movement and dispensing of resources such as vaccines.

7. Kentucky Board of Emergency Medical Services (KBEMS):
   a. Works with KDPH to organize and vaccinate emergency medical services (EMS) agencies;
   b. If necessary, works with KDPH to modify scope of practice for EMTs and Paramedics to carry out vaccinations

8. Kentucky Transportation Cabinet (KYTC)
   a. Serve as the lead agency for ESF #1 - Transportation;
   b. Coordinate the state's transportation resources for the routing and logistical movement of personnel, equipment, and supplies;
   c. Supports the storage, transportation and distribution of the vaccine through established systems to transport to the appropriate community services providers (i.e., hospitals, health care providers, or local health departments).

Local Agencies

Generalized coordination responsibilities and actions for elements of local government are outlined below. Other local, state, or federal agencies will provide support as applicable.

1. Local Health Department/District
   a. In coordination with KDPH, coordinate the planning for and the implementation of COVID-19 vaccination operations;
   b. Maintain specific strategies, plans, and protocols for administering vaccine pursuant to the State's guidelines;
   c. Work with healthcare partners and other stakeholders to distribute, deliver, and administer pandemic vaccines to priority groups;
   d. Work with large business and schools regarding plans for vaccination;
   e. Identify vaccination clinic sites (number, locations, points of contact, alternative sites, accessibility)
   f. Conduct training for public health staff and partners involved in distributing and administering vaccines;
   g. Monitor vaccine supplies, distribution, and use;
   h. Monitor and report adverse events;
   i. Coordinate the operation of Points of Dispensing (PODs) for mass vaccination;
   j. Provide effective communications to staff, community partners, news media, and the public;
   k. Coordinate with healthcare coalition and support the information and resource needs of healthcare facilities

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2. Community Hospitals

   a. Work with LHD and other stakeholders to administer vaccine to priority groups;

   b. Allocate, secure, and monitor the use of the vaccine distributed to the hospital, as vaccine is made available;

   c. Maintain specific strategies, plans, and protocols for administering vaccine pursuant to the State's guidelines;

   d. Administer vaccine to priority groups among staff pursuant to the State's guidelines

   e. Monitor vaccine supplies, distribution, and use;

   f. Monitor and report adverse events;

   g. Coordinate with the LHD and support the information and resource needs of the LHD.

3. County Emergency Management Agencies

   a. Supports the LHD in coordinating COVID-19 vaccination preparedness and response activities;

   b. Coordinates the activation and deployment of appropriate response personnel and other assets to support vaccination operations;

   c. Coordinate with LHD to receive and act on requests for assistance;

   d. Maintain communications with local government officials and KYEM.

4. Local EMS Agencies

   a. If applicable, coordinate with the LHD, healthcare facilities and other applicable agencies to support vaccination operations.

5. Local Law Enforcement Agencies

   a. When necessary, provides support to the LHD when vaccine is being transported, distributed or dispensed;

   b. Assists with any requested tasks such as law and order, and crowd control;

   c. Coordinate security and traffic control during operations involving the movement and dispensing of resources such as vaccines.

   d. Coordinate and assist KSP.

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AUTHORITIES AND REFERENCES

Legal Authorities

Federal

- Robert T. Stafford Act Disaster Relief and Emergency Assistance Act Section 319 of the Public Health Service Act – Declaration of a Public Health Emergency;

State

- Kentucky Revised Statutes (KRS), Title XVIII-Public Health;
- KRS 39B.045 - Mutual aid agreements between Kentucky or its agencies or political subdivisions and units of government from another state;
- KRS 311A.170 – Paramedics – Permitted activities – Employment by hospitals – Reasonable control by employers;
- KRS 311A.175 – Exceeding scope of practice – Discipline prohibited for refusal to exceed scope of practice;
- KRS 315.500 - Emergency authority for pharmacists during state of emergency;
- KRS 411.148 - Non-liability of licensees and certified technicians for emergency care;
- 106 KAR 5:040 - Initiation of a crisis or disaster response;
- 202 KAR 7:701 - Scope of Practice Matters- Exemptions;
- 902 KAR 2:055. Immunization data reporting and exchange
- 214.015 Reporting of authorized or required immunization

References

Federal

- National Incident Management System, U.S. Department of Homeland Security, December 2018.
- National Response Framework, U.S. Department of Homeland Security,2018;
- CISA Guidance on Essential Critical Infrastructure Workers Version 4.0 (2020)
- CDC's established General Principles and Interim Guidance on Pandemic Vaccination (2018)

State

- Modeling Pandemic Influenza Vaccination Capacity for Adults-Kentucky Report (2016)
- Kentucky Immunization Providers Manual (2020)
- Cabinet for Health and Family Services' Emergency Communication Plan;
- Kentucky Department for Public Health's Disease Outbreak Support Plan;
- Kentucky Department for Public Health's State Health Operations Center Support Plan;
- Kentucky Emergency Operations Plan;
- Kentucky Medical Countermeasures Plan;

Other

- National Academies of Sciences, Engineering, and Medicine-Framework for Equitable Allocation of COVID-19 Vaccine (2020)
- Johns Hopkins University's Center for Health Security- Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States

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ATTACHMENT 1: VACCINATION RESOURCES AND CHECKLISTS

In an effort to standardize the process of holding clinics in non-traditional settings, the National Adult and Influenza Immunization Summit developed tools your organization can use when organizing satellite, temporary, or off-site vaccination clinics. You can access these resources at izsummitpartners.org under Tools to Assist Satellite, Temporary, and Off-Site Vaccination Clinics or use the direct links to the vaccination clinic resources below:

Best Practices Checklist

This checklist is a step-by-step guide to help clinic coordinators/supervisors overseeing vaccination clinics held at satellite, temporary, or off-site locations follow Centers for Disease Control and Prevention (CDC) guidelines and best practices for vaccine shipment, transport, storage, handling, preparation, administration, and documentation. This checklist outlines CDC guidelines and best practices that are essential for patient safety and vaccine effectiveness.

- Checklist of Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-site Locations

Vaccination Clinics Organization Pledge

This annual pledge is for organizations that conduct satellite, temporary, or off-site vaccination clinics to affirm that they will adhere to best practices, including using the Checklist of Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations. Organizations that sign the pledge will be recognized on the Summit website for their commitment to provide safe and effective vaccine clinics. Companies seeking to hire an organization to conduct a vaccination clinic can check to see if that organization has signed the pledge and is recognized on the Summit website.

- Pledge for Organizations Implementing Vaccination Clinics Held at Satellite, Temporary, or Off-site Locations

Ten Principles for Holding a Safe Vaccination Clinic

This resource, which supplements the checklist, serves as a quick reference guide highlighting the main points of the checklist that can be used by all staff (not just the clinic coordinators/supervisors who are completing the checklist). This document can be posted on the wall of the clinic or given out to all the staff who are vaccinating at the clinic.

- Ten Principles for Holding Safe Vaccination Clinics at Satellite, Temporary, or Off-site Locations

Frequently Asked Questions about the Best Practices for Vaccination Clinics

This list of Frequently Asked Questions provides answers to some of the most common questions about the purpose of the checklist and pledge, the intended users of the checklist, how to use the checklist, and technical questions.

- Frequently Asked Questions about the Checklist of Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-site Locations and Pledge for Implementing the Checklist

Other Resources:

Checklist of Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations
https://www.izsummitpartners.org/content/uploads/2018/08/off-site-vaccination-clinic-checklist-v4.pdf

Skills Checklist for Vaccine Administration
http://www.immunize.org/catg.d/p7010.pdf

Checklist for Safe Vaccine Storage and Handling
http://www.immunize.org/catg.d/p3035.pdf

CDC Vaccine Storage and Handling (link to CDC's Vaccine Storage and Handling Toolkit may be found from this site)
https://www.cdc.gov/vaccines/hcp/admin/storage-handling.html

CDC Vaccine Admin
https://www.cdc.gov/vaccines/hcp/admin/admin-protocols.html

Provider's Role: Importance of Vaccine Administration and Vaccine Storage & Handling
https://www.cdc.gov/vaccines/hcp/admin/storage/providers-role-vacc-admin-storage.html

IAC Vaccine Storage and Handling
http://www.immunize.org/handouts/vaccine-storage-handling.asp

IAC Vaccine Admin
http://www.immunize.org/handouts/administering-vaccines.asp

Vaccine Storage and Handling Video (50 mins with CE credit available)
https://www2.cdc.gov/vaccines/ed/shvideo/shvideo.asp

You Call the Shots (CDC web-based training course on many vaccines with CE credit available)
https://www.cdc.gov/vaccines/ed/youcalltheshots.html

Critical Infrastructure Employees:
https://www.cisa.gov/sites/default/files/publications/Version_4.0_CISA_Guidance_on_Essential_Critical_Infrastructure_Workers_FINAL%20AUG%2018v2_0.pdf

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ATTACHMENT 2: OVERVIEW OF ALLOCATION FRAMEWORKS

Overview of Allocation Frameworks Developed for Vaccine Allocation during the COVID-19 Pandemic

Effort	Leaders	Goals	Guiding Principles	Prioritized Groups

Interim Framework for COVID-19
Vaccine Allocation in the United States: Assisting Policy Maker, Stakeholder, and Public Deliberation
	Johns Hopkins Center for Health Security	• Provide an interim framework for COVID-19 vaccine allocation and distribution in the United States.	• Promote the common good
			  ○ Promote public health
			  ○ Promote economic and social well-being
			• Treat people fairly and equally
			  ○ Address background and emerging inequities between groups
			  ○ Give priority to worst-off individuals
			  ○ Reciprocity
			• Promote legitimacy, trust, and a sense of ownership in a pluralistic society
			  ○ Respect the diversity of views in a pluralistic society
			  ○ Engage community members to improve vaccine program design and effectiveness
				Tier 1:
				• Those most essential in sustaining the ongoing COVID-19 response
				• Those at greatest risk of severe illness and death, and their caregivers
				• Those most essential to maintaining core societal functions
				
				Tier 2:
				• Those involved in broader health provision
				• Those who face greater barriers to access care if they become seriously ill
				• Those contributing to maintenance of core societal functions
				• Those whose living or working conditions give them an elevated risk of infection, even if they have lesser or unknown risk of severe illness and death

ACIP COVID-19 Vaccine Workgroup	ACIP	• Develop a plan for allocation of vaccine in the United States.	• Maximize benefits and minimize harms • Equity • Justice • Fairness • Transparency	In progress at the time of this writing

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ATTACHMENT 3: FRAMEWORK FOR EQUITABLE ALLOCATION OF COVID-19 VACCINE

Applying the National Academies of Sciences, Engineering, and Medicine allocation criteria to specific population groups as discussed in the: *National Academy of Sciences: "Framework for Equitable Allocation of COVID- 19 Vaccine," page 3-16, table 3-2 (2020)*

Applying the Allocation Criteria to Specific Population Groups (Sub-prioritization)

Phases	Population Group	Criterion 1: Risk of Acquiring Infection	Criterion 2: Risk of Severe Morbidity and Mortality	Criterion 3: Risk of Negative Societal Impact	Criterion 4: Risk of Transmitting Infection to Others	Mitigating Factors for Consideration
1a	High-risk health workers	H	M	H	H	Adequate access to personal protective equipment. Workplace management of exposure.
1a	First responders	H	M	H	H	Adequate access to personal protective equipment. Workplace management of exposure.
1b	People with significant comorbid conditions (defined as having two or more)	M	H	M	M	Ability to maintain social distance and isolate.
1b	Older adults in congregate or overcrowded settings	H	H	L	M	Effective institutional management of exposure.
2	K–12 teachers and school staff and child care workers	H	M	H	H	Online schooling, especially for lower grades, recognizing educational and social impacts.
2	Critical workers in high-risk settings	H	M	H	M	Adequate access to personal protective equipment. Workplace management of exposure.
2	People with moderate comorbid conditions	M	M	M	M	Ability to maintain social distance and isolate.

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2	People in homeless shelters or group homes and staff	H	H	L	H	Adequate access to personal protective equipment. Effective institutional/ workplace management of exposure.
2	Incarcerated/detained people and staff	H	M	L	H	Adequate access to personal protective equipment. Effective institutional/workplace management of exposure.
2	All older adults	M	H	L	L	Ability to maintain social distance and isolate.
3	Young adults	H	L	M	H	Ability to maintain social distance and isolate. Closure of congregate settings (e.g., bars).
3	Children	M	L	M	H	Ability to participate in online schooling.
3	Workers in industries important to the functioning of society	M	M	M	M	Adequate access to personal protective equipment. Effective institutional/ workplace management of exposure.

National Academy of Sciences: "Framework for Equitable Allocation of COVID- 19 Vaccine," page 3-16, table 3-2 (2020)

NOTES: Cell entries are for a typical member of each group. H = high risk; L = low risk; M = medium risk. All groups are heterogeneous, and ratings indicate the median risk. All cell entries are relative to risks in the overall population, not measures of absolute risk, and are based on the committee's expert judgment of the evidence and the unknowns at the time of the report's writing. There is no weighting of these different criteria and no aggregation. Within each phase, the population groups are of similar priority, and authorities have the flexibility to adapt the priority population groups to their specific conditions. Lastly, the committee has elected not to use the designation "essential worker." Instead, the committee refer to these workers as critical workers in high-risk settings as they are both working in industries vital to the functioning of society and in occupations where they cannot avoid exposure risk by, for example, teleworking. This is described in additional detail later in this chapter.

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ATTACHMENT 4: PROJECTED VACCINATION TARGET GROUPS

On October 2, the National Academies of Sciences, Engineering, and Medicine's Committee on Equitable Allocation of Vaccine for the Novel Coronavirus released the *"The National Academies' Framework for Equitable Allocation of COVID-19 Vaccine" (2020)* in which it outlines a preliminary framework for equitable allocation of COVID-19 vaccine. By looking at the various guidance documents, KDPH can speculate about who the phased targeted/target groups may be for the COVID-19 vaccine. Possible COVID-19 phased target groups are reflected in the table below. It is important to emphasize that we are not providing a set of definitive recommendations about who should be prioritized for vaccination. Rather, we have identified candidate groups that will be given serious consideration as priority groups. Ultimately, KDPH and the Vaccine Allocation Committee will use new guidance in conjunction with previous published guidance to ultimately determine who the target populations and target groups are.

Category	Targeted Group/Priority Group	Rationale	Est Pop
Phase 1A			
Health Care	Front-line inpatient and hospital-based health care workers *(persons essential for maintaining function in emergency departments, intensive care units, and other front-line medical and nursing staff)*	Critical role in providing care for the sickest persons; highest risk of exposure and occupational infection	In Progress
Health Care	Long Term Care and Assisted Living Facilities workers	Critical role in providing care for the highest risk population; close contact with people at very high risk of poor outcomes	In Progress
**Medically Vulnerable Population*	Vulnerable congregate care setting residents	People at greatest risk of becoming infected and seriously ill	In Progress
Critical Infrastructure	Front-line Emergency Medical Service personnel *(those providing patient assessment, triage, and transport).*	Provide critical medical care including procedures such as intubation that increase risk of aerosol exposure and occupational infection	In Progress
Critical Infrastructure	Front-line Fire and Law Enforcement personnel	Essential to public order and safety;	In Progress
Critical Infrastructure	Pharmacists and Pharmacy Technicians	Critical role in provision of health services; working conditions give them elevated risk of infection	In Progress
Critical Infrastructure	Manufacturers of Pandemic Vaccines & Antivirals	Critical role in provision of health services; working conditions give them elevated risk of infection	In Progress
Phase 1B			
Health Care	Outpatient health services focused on serving high risk groups *(oncology clinics, dialysis clinics)*	Critical role in providing care for the highest risk population; close contact with people at very high risk of poor outcomes	In Progress

Health Care	Front-line outpatient health care providers	Effective outpatient care is critical to decrease the burden on hospitals; high risk of exposure and occupational infection	In Progress
Critical Infrastructure	High risk National Guard personnel	Essential to public order and safety	In Progress
Critical Infrastructure	Frontline medical device repair and maintenance workers	Critical role in provision of health services; working conditions give them elevated risk of infection	In Progress
Critical Infrastructure	Corrections Facilities workers	Essential to public order and safety; Working conditions give them elevated risk of infection; close contact with people at very high risk of poor outcomes	In Progress
**Vulnerable Population*	Correctional Facility Residents	People who would prevent the risk of spread if vaccinated	In Progress
Community Support Services	Frontline Social Services workers	Workers carrying out critical, frontline interventions in the community; working conditions give them elevated risk of infection	In Progress
Health Care	Critical outpatient health services *(mental health providers, etc.)*	Critical role in provision of health services;	In Progress
Community Support Services	High Risk Congregate setting workers (*community food and housing)*	Critical role in provision of health services; working conditions give them elevated risk of infection	In Progress
Phase 2			
Critical Infrastructure	Pre K-12 Education personnel	School workers are essential to educating children and enabling many parents to return to work; Working in high-density or high-contact jobs where distancing may not be feasible.	In Progress
Critical Infrastructure	Utility and Telecommunications personnel *(water and sewer, gas and electric, communication infrastructure)*	Protect workers needed to maintain critical infrastructure; Essential to public order and safety;	In Progress
Critical Infrastructure	Public Transportation workers	Working in high-density or high-contact jobs where distancing may not be feasible; Worker groups with a high rate of lower-income workers	In Progress

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Critical Infrastructure	"Targeted" food manufacturing and processing facility workers	Working in high-density or high-contact jobs where distancing may not be feasible; Worker groups with a high rate of lower-income workers	In Progress
Critical Infrastructure	Retail Food and Grocers, Food Service workers	Working in high-density or high-contact jobs where distancing may not be feasible; Worker groups with a high rate of lower-income workers	In Progress
Critical Infrastructure	Higher Education personnel	Working in high-density or high-contact jobs where the risk of spread is elevated	In Progress
Critical Infrastructure	Critical Government personnel	Essential to public order and safety;	In Progress
Critical Infrastructure	Transportation delivery drivers and warehouse workers	Protect workers needed to maintain critical infrastructure; Working in high-density or high-contact jobs where distancing may not be feasible; Worker groups with a high rate of lower-income workers	In Progress
**Vulnerable Population*	Disadvantaged and vulnerable populations (possibly addressed in Phase 3)	Mitigate the impact of social inequities on COVID-19 outcomes in disadvantaged communities at risk of disproportionate burdens	In Progress
Phase 3			
**Vulnerable Population*	Vulnerable general population (age 60+, co-morbid conditions)	People at greatest risk of becoming infected and seriously ill	In Progress
**Vulnerable Population*	High-risk Children, High-risk nonelderly adults, Pregnant women (subject to change)	People at greatest risk of becoming infected and seriously ill	In Progress
Critical Infrastructure	Workers in industries and occupations at an increased risk of exposure not included in previous phases	Protect workers needed to maintain critical infrastructure; Working in high-density or high-contact jobs where distancing may not be feasible;	In Progress
Phase 4			
"General Population"			

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