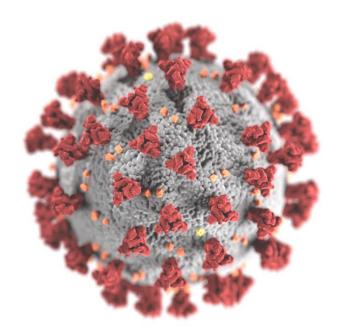
NOTICE: The COVID-19 Vaccine Plan is a living document and will change as information becomes available.



# COVID-19 Vaccination Plan

**KANSAS** 

KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT OCTOBER 16, 2020 | VERSION 1.2 | REVIEWED NOVEMBER 4, 2020

## **Table of Contents**

Record of Changes	3
Executive Summary	4
Section 1: COVID-19 Vaccination Preparedness Planning	6
Improvement Planning	6
COVID-19 Vaccination Program Planning	7
Section 2: COVID-19 Organizational Structure and Partner Involvement	8
Planning and Coordination Team (Internal)	8
State-Local Coordination	9
Tribal Nations Coordination	9
COVID-19 Vaccination Program Implementation Committee (Internal and External)	10
Section 3: Phased Approach to COVID-19 Vaccination	12
Pharmacy Partnership for Long-term Care (LTC) Program:	13
Phase 2: Large Number of Doses Available; Supply Likely to Meet Demand	15
Federal Direct Allocation to Pharmacy Partners:	15
Phase 3: Likely Sufficient Supply	16
Section 4: Critical Populations	17
Additional Data for the COVID-19 Vaccine Planning Committees	17
Section 5: COVID-19 Provider Recruitment and Enrollment	20
Section 6: Understanding a Jurisdiction's COVID-19 Vaccine Administration Capacity	22
Section 7: COVID-19 Vaccine Allocation, Ordering, Distribution, and Inventory Management	23
Vaccine Allocation Strategy	23
Vaccination Ordering Process	23
Repositioning of Vaccine	24
Vaccine Wastage Monitoring	25
Section 8: COVID-19 Vaccine Storage and Handling	26
Individual Provider Locations	26
Satellite, Temporary, or Off-Site Settings	28
Planned and Unplanned Movement of Vaccine	28
Temperature Monitoring of Vaccine	29
Section 9: COVID-19 Vaccine Administration Documentation and Reporting	32

Section 10: COVID-19 Vaccination Second-Dose Reminders	33
Section 11: COVID-19 Requirements for IIS or Other External Systems	34
Section 12: COVID-19 Vaccination Program Communications	36
COVID-19 Vaccination Communication Objectives	36
Key Audiences	36
Communication Phases	37
Communication Activities	37
Commitment to Equity Messaging	38
Crisis and Risk Communication	38
Section 13: Regulatory Considerations for COVID-19 Vaccination	39
Emergency Use Authorization Fact Sheets	39
Vaccine Information Statements	39
Section 14: COVID-19 Vaccine Safety Monitoring	40
Section 15: COVID-19 Vaccination Program Monitoring	41
Appendix A – Pharmacy Partnership for Long-Term Care Program for COVID-19 Vaccination	42
Appendix B – Pharmacy Partnership for Long-Term Care Program for COVID-19 Vaccination Frequen Asked Questions (FAQs)	•

## **Record of Changes**

Date of original version: 10/16/2020

Date	Change	Date of	Description of Change	Name of
Reviewed	Number	Change		Author
10/19/2020	1.1	10/19/2020	Addition of: Pharmacy Partnership for Long-term Care (LTC) Program, p11; Federal Direct Allocation to Pharmacy Partners, p13; Appendix A, p41; and Appendix B, p43.	CDC/AA
11/4/2020	1.2	11/4/2020	Removal of draft watermark; updated Executive Summary and Table of Contents; added Tribal Nations Coordination; Expanded the list of external planning partner recommendations; expanded list of initial recruitment focus to include federally qualified health centers/safety net clinics, and retail pharmacies; addition of "other approved COVID-19 vaccine providers" to the Phase 1 vaccinator list; addition of "continue to enroll providers throughout all phases of vaccine availability"; changed minimum dose ordering to 975.	AA

## **Executive Summary**

#### Introduction

The purpose of the Kansas COVID-19 Vaccination Plan is to outline necessary elements and activities that will guide the work of ensuring all Kansans have access to COVID-19 vaccine in a systematic, rapid, and deliberate manner. This document will provide planning assumptions, roles and responsibilities, ordering and reporting activities, and mass vaccination tools that can help local providers reduce morbidity and mortality from COVID-19.

The plan is intended to be a "living document" that will be updated as strategies and actions are refined and as new information is received from the U.S. Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention (CDC), Advisory Committee on Immunization Practices (ACIP), Food and Drug Administration (FDA), and other federal agencies involved in this aspect of the COVID-19 response.

## **Select COVID-19 Vaccination Planning Sections:**

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

The COVID-19 vaccine will initially be available in very limited doses but will scale up in production rapidly allowing for enough supply to vaccinate all. The COVID-19 vaccine planning efforts will be based on three phases of availability; potentially limited doses available, large number of doses available, and sufficient supply for all. Recommendations for each phase will take many factors into account, including each vaccine's characteristics, vaccine supply, disease epidemiology, and local community factors.

#### Section 4: Critical Populations

Critical populations and infrastructure will be identified and estimated through use of the most recent Behavioral Risk Factor Surveillance System (BRFSS) data, American Community Survey (ACS) data, and ESRI Community Analyst data. Critical populations to be gathered through these data sets include: racial and ethnic minority groups; individuals 65 years and older; individuals with disabilities; individuals that are underinsured or uninsured; individuals living in congregate settings; and individuals attending colleges or universities. Kansas has defined critical infrastructure workforce personnel to include healthcare personnel and other essential workers as included in the Cybersecurity and Infrastructure Security Agency (CISA) 4.0 guidance.

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

The CDC COVID-19 Vaccine Provider Enrollment Agreement and the Provider Profile must be completed by each organization/facility that intends to provide COVID-19 vaccinations. Provider recruitment and enrollment requirements and processes will be communicated through supporting associations, established partnerships, and new partnerships. All COVID-19 vaccine providers will need to be able to conduct vaccine clinics and/or appointments using social distancing and infection control procedures as identified by the CDC.

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

All vaccine should be maintained at the appropriate temperature to ensure vaccine viability. Vaccines remain in optimal condition when they are kept in a temperature-controlled environment, which is maintained from the manufacturing plant through distribution to the provider clinic and through vaccine administration. Appropriate temperature monitoring processes for COVID-19 vaccine will be a crucial part of being a COVID-19 vaccine provider.

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

Vaccination providers will be instructed to complete the COVID-19 vaccination record card provided in the ancillary kit with accurate vaccine information (i.e., vaccine manufacturer, lot number, date of first dose administration, and second dose due date). COVID-19 vaccine providers should use reminder/recalls available through existing electronic health record systems and/or KSWebIZ, the state immunization registry.

## Section 12: COVID-19 Vaccination Program Communication

The CDC's Vaccinate with Confidence framework along with CDC-outlined COVID-19 messaging will be used to communicate with all providers, partners, and public. Communication regarding COVID-19 vaccines is essential to the success of the COVID-19 Vaccination Program and will focus on building vaccine confidence broadly and among groups anticipated to receive early vaccination, as well as dispelling vaccine misinformation to help ensure vaccine uptake.

## Section 14: COVID-19 Vaccine Safety Monitoring

It will be imperative to monitor for any expected or unknown adverse events that occur after an individual receives the COVID-19 vaccine. This monitoring will happen using the Vaccine Adverse Event Reporting System (VAERS) and any other systems indicated by the CDC and/or FDA.

## Section 15: COVID-19 Vaccination Program Monitoring

Continuous monitoring of COVID-19 vaccination efforts will be important so that the public and providers have a good understanding of progress towards vaccinating all Kansans. The internal Kansas COVID-19 vaccine planning committee will establish processes for monitoring critical components of the program such as vaccine allocations, distribution, and uptake. Performance targets will be set and adjusted as the COVID-19 vaccination plan is implemented.

## Section 1: COVID-19 Vaccination Preparedness Planning

Pandemic vaccination response planning requires collaboration among a wide range of public - and private- sector partners, including immunization and public health emergency preparedness programs, emergency management agencies, healthcare organizations, industry groups that include critical infrastructure sectors, policy makers, and community vaccination providers (e.g., pharmacies, occupational health settings, doctors' offices). Many of these partners are engaged regularly in seasonal influenza and other outbreak vaccination campaigns, and many served as vaccination providers during the 2009 H1N1 pandemic.

### Improvement Planning

At the state level, training and drills for closed point-of-dispensing operations have been occurring for many years. Many lessons have been learned, gaps identified, and improvements made to assist in the response to public health emergencies. One of the best learning opportunities took place during the real-life response to the H1N1 pandemic in 2009.

There were lessons learned during the H1N1 pandemic that can be reviewed and considered as planning for a COVID-19 vaccine occurs. Looking back, CDC began communication of varying vaccine availability planning scenarios in the summer of 2009. Kansas realized that there was a paradigm shift from small amounts of vaccine that would be delivered primarily through a public health delivery system to large amounts of vaccine that would require a public/private partnership to accomplish vaccine delivery. KDHE worked closely with the local health departments (LHDs) to develop alternate plans for vaccine distribution and delivery.

In addition to planning for vaccine distribution, inventory management, and doses administered reporting, KDHE began planning for private provider enrollment by creating a web-based provider pre-registration system. Through extensive collaboration with local health departments, the approved provider agreements were in place by the middle of September, and additional providers were approved as vaccine availability increased.

The decision was made to do a population-based allocation of all vaccine made available to Kansas. Initially, the allocation was based on the 0-24-year-old population to accommodate the additional doses needed by those counties with secondary education facilities. The first Kansas allocation of vaccine amounted to 16,300 doses. Initial vaccine allocations were communicated to each of the counties on October 2, 2009, and vaccine orders were received and processed on that same day.

LHDs approved private provider orders based on the type and quantity of vaccine available and submitted those orders to KDHE. Vaccine amounts varied widely because state population varies widely. More than 70 percent of the State's population is in the eastern half of the state, and eight percent of the population is in the western third of the state. The small counties had to pool vaccine allocations to submit a combined order to meet the 100-dose quantity. They then sub-distributed vaccine to the counties involved. Counties had varying approaches to meeting the vaccination needs of the target groups. While this allowed for local control based on needs and resources, it also resulted in concerns voiced when there was an individual perception that one county didn't have as much as another. Differences in vaccine uptake also resulted in differences as to when the move was made from vaccinating the target groups to the general population. At that point, the Kansas Immunization Program

sought permission from counties with available inventory to redistribute doses to those counties still needing vaccine for target groups.

The 2009 H1N1 pandemic also created very significant challenges from a disease surveillance perspective. KDHE made it a priority to strengthen the statewide influenza-like illness surveillance system, known as ILINet, and used federal Public Health Emergency Response funding earmarked for H1N1 response to triple the number of ILINet sites across Kansas. A school-based surveillance system was developed based on absenteeism rates, with information reported to KDHE on a weekly basis. All information collected was collated into a weekly H1N1 surveillance report, which was made available via the KDHE website. Records of activities and reports were maintained according to record retention policies and procedures followed by the Kansas Department of Health and Environment.

The Kansas Immunization Program and the Public Health Emergency Prepared ness Program are currently taking part in seasonal influenza campaigns including vaccination of State of Kansas employees and family members. Vaccine clinic preparations have implemented a variety of COVID-19 necessary functions such as social distancing, personal protective equipment requirements, and drive-through clinic functions.

## **COVID-19 Vaccination Program Planning**

Using the lessons learned from the H1N1 pandemic and known planning assumptions for the COVID-19 vaccine, the Kansas Immunization Program and the Kansas Emergency Preparedness Program will use the seasonal influenza vaccination clinics for the State of Kansas employees and their immediate family members as a drill for closed point-of-dispensing activities. These activities will require the programs to plan for identification of vaccination locations, staffing and supply needs, vaccination throughput, infection control measures, distribution and cold chain requirements of vaccine, training of participants receiving and giving vaccinations, etc. This work will be important in identifying gaps and implementing corrective actions as the COVID-19 vaccine plan is prepared.

In addition, it is understood that the COVID-19 vaccination planning efforts will involve additional complexities than the typical vaccination program planning. Understanding the population of the state, including those working in areas critical to the pandemic response, those at greatest risk of exposure and severe illness, those with limited resources such as insurance and/or income, and those living in congregate settings, etc. will need to be considered in planning efforts.

There will also be a significant amount of education that will need to be provided to the public, partners, and healthcare workers. Each vaccine that becomes available will have its own set of indications, dosing schedule, preparation, storage and handling guidelines, and contraindications. This information will need to be available and communicated in clear and effective manner to many different individuals.

As a decentralized state, Kansas local health department programs exercise their points of dispensing once per year, on average. The agency provides the local health departments with planning templates and implementation recommendations including the Mass Dispensing standard operating guide. With COVID-19 vaccine planning, additional items will need to be included in the exercises such as vaccine reporting requirements, high volume throughput clinics, infection control measures, etc.

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

The COVID-19 vaccination planning is a combined state and local responsibility that requires close collaboration between public health, external agencies, and community partners. To successfully implement a pandemic vaccination program there must be a clear understanding of the roles and responsibilities of all involved in the response.

## Planning and Coordination Team (Internal)

The Kansas Department of Health and Environment (KDHE) has an internal COVID-19 Vaccine Planning Committee that consists of multiple stakeholders from within and outside the Agency. The planning leadership of the internal committee consists of the Immunization/Tuberculosis Clinical Section Chief and the Public Health Emergency Preparedness Program Specialist. Other members of the committee include the Immunization Information System (IIS) Manager, Immunization Clinical Field Services Manager, Vaccine Coordinator, and Immunization Outreach Coordinator. Other members outside of the Kansas Immunization Program include the Emergency Management Director, Deputy Director of Public Affairs, and GIS Database Administrators. Additional committee members that are being recruited for include an Adult Vaccine Coordinator, Correctional Liaison, and two Project Leads to assist with planning and execution of the COVID-19 Vaccine Plan. External partners include local health departments representing different sized populations, Kansas Hospital Association, and Community Care Network of Kansas.

The internal COVID-19 Vaccine Planning Committee has a wide array of experience relevant to the work that will be accomplished. This group can expand and contract in membership based on identified needs.

Team members will be assigned responsibilities based on their individual expertise to best enhance plan development and activities coordination before and during the response. Broad responsibilities include:

- Immunization/Tuberculosis Clinical Section Chief Broad oversight of the COVID-19
   Vaccine Plan development and implementation; monitor guidance, regulatory changes, staff and stakeholder activities; communicate with all levels of stakeholders; report to the Incident Command Structure (ICS) Team and others; monitor and adjust plan as needed.
- Public Health Emergency Preparedness Program Specialist Broad oversight of the COVID-19 Vaccine Plan development and implementation; ensure PHEP principles and resources are used; communicate to all levels of stakeholders; report to the ICS Team; monitor and adjust plan as needed.
- Immunization Information System (IIS) Manager Oversight of IIS needs for COVID-19
   Vaccine Plan; monitor guidance and regulatory changes; work with vendor and IIS
   community to understand and operationalize needed changes; oversee enrollment and
   onboarding of vaccine providers; maintain quality and timely data.
- Immunization Clinical Field Services Manager Develop and provide training for vaccine providers and staff; monitor guidance and regulatory changes; monitor staff needs and field activities; plan vaccine clinics if needed.
- Vaccine Coordinator Monitor guidance and regulatory changes; develop guidance for

providers and program staff on vaccine ordering and approval processes; communicate with internal and external stakeholders; ensure timely review and processing of vaccine orders.

- Immunization Outreach Coordinator Work closely with Communications Department on outreach efforts specific to COVID-19 Vaccine Plan; provide routine and special communications through established routes; identify and distribute social media tools for internal and external stakeholders; provide outreach and outreach tools as available.
- Emergency Management Director Liaison between internal planning committee and stakeholders; assist with obtaining needed assets; provide guidance on operational activities needed by planning committee.
- Deputy Director of Public Affairs Development of communication plan specific to the COVID-19 Vaccine Plan; work with media partners and other stakeholders to understand and communicate plan; emergency and risk communications
- GIS Database Administrators Assist with the identification and acquisition of data sets
  that can be used to identify specific populations, subpopulations, community assets;
  developments of maps to identify specific areas of need
- Adult Vaccine Coordinator Develop and provide training for vaccine providers and staff; monitor guidance and regulatory guidance; monitor staff needs and field activities; plan vaccine clinics if needed
- Correctional Liaison Liaison between department of corrections and public health; communicate on vaccine planning needs and resources; monitor guidance and regulatory changes; provide resources to correctional staff as available
- Project Leads Assist with all aspects of development and implementation of COVID-19 Vaccine Plan.
- Local Health Department Representatives Assist with development of the COVID-19
   Vaccine Plan assuring that the needs of the local health departments are represented.
- Kansas Hospital Association Assist with development of the COVID-19 Vaccine Plan assuring that the needs of the hospital systems are represented.
- Community Care Network of Kansas Assist with development of the COVID-19 Vaccine Plan assuring that the needs of the safety net clinics are represented.

### **State-Local Coordination**

Public health governance structures vary from state to state and play an important role in the development of COVID-19 vaccine plans. In Kansas, the public health system is decentralized and KDHE serves all 105 counties of the state. The local health departments report to their local Board of Health, which is typically the local Board of County Commissions. There must be collaboration, cooperation, and coordination of both KDHE and the local health departments in the development and implementation of the COVID-19 Vaccine Plan for Kansas. As such, local health departments are represented on the internal COVID-19 vaccine planning committee.

## **Tribal Nations Coordination**

The Kansas Department of Health and Environment will work with Tribal governments in the state, to ensure that citizens living on Tribal lands and/or receiving healthcare through Tribal healthcare centers will receive COVID-19 vaccine.

Each Tribal Nation has the sovereign authority to provide for the welfare of its people and, therefore, has the authority to (1) choose among various options to dispense vaccine (2) determine the population it chooses to serve; (3) choose how vaccines are distributed to its community; and (4) establish priority groups when there is a limited supply of COVID-19 vaccine or other accompanying resources.

Working in cooperation with the Tribal governments and Indian Health Services; capabilities, roles, and responsibilities will be discussed to determine the best approach for COVID-19 vaccine distribution among Tribal communities.

## COVID-19 Vaccination Program Implementation Committee (Internal and External)

To ensure successful implementation of the COVID-19 Vaccine Plan the creation of a COVID-19 Vaccination Program Implementation Committee will be essential. The role of this committee will be to advocate for and develop strategies that will ensure equitable access to COVID-19 vaccination services. The committee will inform decision related to the distribution of COVID-19 vaccine based upon the guidance of the Advisory Committee on Immunization Practices (ACIP), the Centers for Disease Control and Prevention (CDC), and the KDHE ICS Team. Another primary role of this group will be to develop communications that support the distribution and delivery of COVID-19 vaccine in a timely manner.

This committee will be comprised of groups that can bring knowledge, expertise, and access to a variety of populations. Recommendations from the internal COVID-19 Vaccine Plan Committee include:

- Alliance for Kansans with Developmental Disabilities
- Children's Cabinet and Trust Fund
- Community Care Network of Kansas
- InterHab
- Kansas African American Affairs Commission
- Kansas Area Agency on Aging
- Kansas Association of Local Health Departments
- Kansas Commission for the Deaf and Hard of Hearing
- Kansas Commission on Disability Concerns
- Kansas Department of Education
- Kansas Department on Aging and Disabilities
- Kansas Emergency Management
- Kansas Governor's Office
- Kansas Highway Patrol
- Kansas Hispanic & Latino American Affairs Commission
- Kansas Hospital Association
- Kansas Medical Society
- Kansas Pharmacy Association
- Kansas State Nurses Association
- Mid America Regional Council
- Native American Affairs Commission
- United Methodists Health Ministry Fun

## Related Guidance and Reference Materials

CDC's <u>public health preparedness resources</u> can assist jurisdictions and tribal organizations with strategic planning to strengthen their public health capabilities.

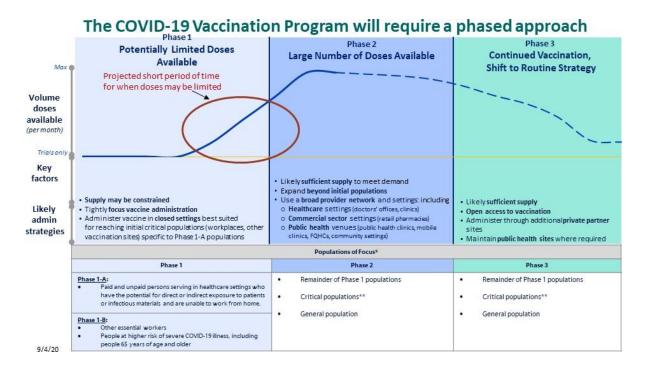
<u>Pandemic influenza-specific resources</u> on vaccine and other medical countermeasures may be helpful in strategizing for other COVID-19-related situations.

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

It is anticipated that the COVID-19 vaccine will initially be available in very limited doses but will scale up in production rapidly allowing for enough supply to vaccinate all. The amount of time before vaccines are available to all is unknown, therefore, the COVID-19 Vaccine Plan will be based on three phases of availability; potentially limited doses available, large number of doses available, and sufficient supply for all. Recommendations for the various phases, particularly when limited doses are available, will take many factors into account and could change after the vaccine is available, depending on each vaccine's characteristics, vaccine supply, disease epidemiology, and local community factors. See graph below for phased approached showing targeted populations.

Final decisions about the use of the initial vaccine will be partially informed by the Phase 3 clinical trials that are currently taking place and recommendations from the CDC and ACIP. The Kansas COVID-19 Vaccination Program Implementation Committee will develop recommendations and strategies for consideration by the KDHE ICS Team, which will ultimately make the final decisions regarding the distribution of the initial and subsequent doses of COVID-19 vaccine. The current recommendations for initial vaccine doses include individuals in the healthcare setting that have the potential for direct or indirect exposure to patients or infectious materials and are unable to work from home.

The focus of the Kansas COVID-19 Vaccination Program Implementation Committee will be on ensuring equitable access to vaccine across the entire population. Both the Kansas COVID-19 Vaccination Program Implementation Committee and the internal COVID-19 Vaccine Planning Committee will work on development and distribution of vaccine safety messaging to assist with vaccine acceptance and willingness to receive the vaccine, which will ultimately provide protection to the residents of Kansas and decrease wastage of the vaccine.



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

Phase 1 of the phased approach for the Kansas COVID-19 Vaccine Plan will include Phase 1A and Phase 1B. While there are many unknown variables about the recommendations for use of initial vaccine in Phase 1, it is likely that vaccine will be available as follows:

#### Phase 1A:

• Healthcare personnel paid and unpaid, who are likely to be exposed to or treat people with COVID-19 or infectious materials and are unable to work from home.

#### Phase 1B:

- People at increased risk for severe illness from COVID-19, including those with underlying medical conditions such as cancer, chronic kidney disease, chronic obstructive pulmonary disease, heart conditions, obesity, sickle cell disease, smokers or those with a history of smoking, and type 2 diabetes
- People 65 years of age and older
- Other essential workers
- Long-term care residents

Initial COVID-19 vaccine provider recruitment and enrollment will be targeted at hospitals, local health departments, federally qualified health centers/safety net clinics, and retail pharmacies across the state, including those that are in rural areas, that are willing and able to provide vaccine to those identified as targets for early vaccine receipt. Hospitals, local health departments, and other approved COVID-19 vaccine providers will need to be able to maintain and monitor vaccine inventory according to the guidelines provided from the manufacturer and the CDC Storage and Handling Toolkit from receipt through administration of vaccine. The hospitals should also be able to administer vaccine following the social distancing and infection control through closed point of dispensing settings that allow for the maximum number of people to be served.

If it is determined that there are areas of the state that have limited access to a hospitals , local health departments, or other approved COVID-19 providers but have populations defined as targets during Phase 1A or Phase 1B, the Kansas Immunization Program will prepare for mobile clinics using the influenza playbook that was developed for the State of Kansas employee flu clinics, lessons learned, and COVID-19 planning assumptions.

Vaccine cards provided in ancillary kits should be provided to vaccine recipients so that they have a record of what type of vaccine was received and date of administration. These cards will also provide information on when the vaccine recipients need to return for a second dose, if applicable.

Hospitals, local health departments, and the Kansas Immunization Program will be required to report vaccine administration information via the KSWebIZ system within 24 hours so that the vaccine inventory and uptake can be measured and monitored closely throughout the COVID-19 vaccine program.

## Pharmacy Partnership for Long-term Care (LTC) Program:

Kansas plans to participate in the Pharmacy Partnership for Long-term Care Program coordinated by the CDC. Participating providers in CDC's Pharmacy Partnership for LTC Program for COVID-19 Vaccine will

provide on-site vaccine clinics for residents of long-term care facilities (LTCFs) and any remaining LTCF staff who were not vaccinated in Phase 1-A. The Pharmacy Partnership for Long-term Care Program provides end-to-end management of the COVID-19 vaccination process, including close coordination with jurisdictions, cold chain management, on-site vaccinations, and fulfillment of reporting requirements. The program will facilitate safe and effective vaccination of this prioritized patient population, while reducing burden on facilities and jurisdictional health departments.

This program is free of charge to facilities. The pharmacy will:

- Schedule and coordinate on-site clinic date(s) directly with each facility. Three visits over approximately two months are likely to be needed to administer both doses of vaccine and vaccinate any new residents and staff.
- Order vaccines and associated supplies (e.g., syringes, needles, personal protective equipment).
- Ensure cold chain management for vaccine.
- Provide on-site administration of vaccine.
- Report required vaccination data (approximately 20 data fields) to the local, state/territorial, and federal jurisdictions within 24 hours of administering each dose.
- Adhere to all applicable Centers for Medicare & Medicaid Services (CMS) requirements for COVID-19 testing for LTCF staff.

If interested in participating, each facility should sign up and indicate their preferred partner from the available pharmacies.

Skilled nursing facilities (SNFs) and assisted living facilities (ALFs) will indicate which pharmacy partner (one of two large retail pharmacies or existing LTC pharmacy) their facility prefers to have on-site (or opt out of the services) between October 19–October 30.

- SNFs will make their selection through National Healthcare Safety Network (NHSN) beginning October 19.
  - An "alert" will be incorporated into the NHSN LTCF COVID-19 module to guide users to the form.
- ALFs will make their selection via online REDCap (Research Electronic Data Capture) sign-up form.
- The online sign-up information will be distributed through ALF and SNF partner communication channels (email, social media, web).
- After November 1, 2020, no changes can be made via the online forms, and the facility will have to coordinate directly with the selected pharmacy provider to make any changes in requested vaccination supply and services.
- Indicating interest in participating is non-binding and facilities may change their selection (optout), if needed.
- CDC will communicate preferences to the pharmacy partners and will attempt to honor facility
  preferences but may reassign facilities depending on vaccine availability and distribution
  considerations, and to minimize vaccine wastage.

CDC expects the Pharmacy Partnership for Long-term Care Program services to continue on-site at participating facilities for approximately two months.

After the initial phase of vaccinations, the facility can choose to continue working with the pharmacy that provided its initial on-site clinics or can choose to work with a pharmacy provider of its choice.

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

During Phase 2 there will be rapidly increasing vaccine supply available, which will allow for vaccination to populations that were not completely vaccinated in Phase 1 as well as additional critical populations and the general population.

During Phase 2 there will be a need to increase vaccination capacity through vigorous recruitment and enrollment efforts. Enrollment of traditional and non-traditional partners will be important during this phase. Continued enrollment of safety net providers (i.e., Federally Qualified Health Centers, Rural Health Clinics, etc.), pharmacies, long term facilities, and other local healthcare providers will continue to be targeted for participation in the COVID-19 vaccine program.

Due to increased availability of the vaccine, there will likely be an increase in the demand for the vaccine so provider enrollment for Phase 2 activities should occur as early as possible in Phase 1 so that providers are ready and able to vaccinate as the vaccine availability increases.

The Kansas Immunization Program will need to monitor the supply and demand of the vaccine so that vaccine distribution can be targeted to the appropriate areas ensuring access to appropriate populations.

## Federal Direct Allocation to Pharmacy Partners:

Kansas plans to participate in the federal direct allocation to pharmacy partner strategy coordinated by the CDC.

Vaccine will be allocated and distributed directly to select pharmacy partners from the federal government.

- Direct allocation opportunities will be provided to retail chain pharmacies and networks of independent and community pharmacies<sup>1</sup> (those with a minimum of 200 stores). All partners must sign a pharmacy provider agreement with the federal government.
- Once the list of federal partners has been finalized, the CDC will share the list with jurisdictions.
- On a daily basis, pharmacy partners must report to the CDC, the number of doses of COVID-19 vaccine a) ordered by store location; b) supply on hand in each store reported through VaccineFinder, and c) number of doses of vaccine administered to individuals in each state, locality, and territory.

Pharmacy providers will be required to report the CDC-defined data elements related to vaccine administration daily (i.e., every 24 hours). The CDC will provide information on these data elements and methods to report if stores are not able to directly provide data to KSWebIZ.

All states and other jurisdictions participating in this program will have visibility on number of doses distributed to and administered by each partner store.

<sup>&</sup>lt;sup>1</sup>Pharmacy services administrative organizations, or PSAOs

The Kansas Immunization Program and other jurisdictions will be given contact information for each partner participating in this program if they have any questions or concerns related to distribution of vaccine to stores in their jurisdiction.

## Phase 3: Likely Sufficient Supply

During Phase 3 COVID-19 vaccine will be widely available for all populations. The Kansas Immunization Program will continue to enroll COVID-19 providers throughout all phases of vaccine availability and will closely monitor the distribution and administration of vaccine. Continued focus will be on ensuring critical populations have been vaccinated and identification of areas with low vaccine coverage. As low coverage areas are identified, the internal COVID-19 Vaccine Planning Committee will develop and monitor strategies designed to increase vaccine uptake and decrease vaccine wastage.

#### Related Guidance and Reference Materials

CDC's Roadmap to Implementing Pandemic Influenza Vaccination of Critical Workforce provides additional information and tools for state and local planners on how to operationalize and implement specific plans for targeting critical workforce groups during an influenza pandemic response. The document also includes tools and resources for tracking progress on critical workforce vaccination planning and activities within a jurisdiction. Though currently specific to an influenza pandemic, it may help to inform the approach for COVID-19 vaccination planning for critical workforce.

## Section 4: Critical Populations

The state of Kansas will identify and estimate critical populations and infrastructure through use of the most recent Behavioral Risk Factor Surveillance System (BRFSS) data, American Community Survey (ACS) data, and ESRI Community Analyst data. Critical populations to be gathered through these data sets include: racial and ethnic minority groups; individuals 65 years and older; individuals with disabilities; individuals that are underinsured or uninsured; individuals living in congregate settings; and individuals attending colleges or universities.

Kansas has defined critical infrastructure workforce personnel to include healt hcare personnel and other essential workers as included in the Cybersecurity and Infrastructure Security Agency (CISA) 4.0 guidance. Examples of additional critical infrastructure includes law enforcement, public safety, and other first responders. Kansas will utilize the Geographic Information System (GIS) to map these critical populations. The critical infrastructure workforce of healthcare personnel will be identified utilizing licensing agencies and an estimation of licensed personnel. For subset groups of critical populations that do not have data readily accessible, estimates will be made by working with supporting associations or other partners that work closely with subset groups.

Additional critical infrastructure from CISA 4.0 guidance will be reviewed and mapped as requested by the COVID-19 Vaccine Planning Committee, COVID-19 Vaccination Program Implementation Committee, and KDHE ICS Team.

Points of contact for organizations and employers will be determined by working with state and local partners. Points of contact for critical population groups will be determined by utilizing community partners such as community health centers, rural health clinics, critical access hospitals, local health departments, and other community organizations that work closely with populations.

Rapid and timely communication will be essential to successful implementation of the COVID-19 vaccine plan in Kansas. Routine communication methods such as newsletters, special alerts, social media, media releases, website updates, etc. will continue to be used. Additional communication methods for rapidly disseminating information among partner organizations, employers, and community groups will be expanded to include email distribution lists, webinars, virtual meetings, and other methods as requested by partners.

### Additional Data for the COVID-19 Vaccine Planning Committees

The state of Kansas is 82,277 square miles and is home to 2,908,776 people according to the U.S. Census Bureau's 2018 American Community Survey. There are 105 counties in the state with various population sizes, with a high population of 597,555 people in Johnson county to a low population of 1,227 in Greely county. Six counties are classified as urban (150 persons per square mile), 10 counties are semi-urban (40-149.9 persons per square mile), 19 counties are densely-settled rural (20-39.9 persons per square mile), 34 counties are rural (6-19.9 persons per square mile), and 36 counties are frontier (less than 6 persons per square mile).

According to Kansas Information for Communities, in 2018 the population of Kansas was 87.9% white; 7.1 % black; 1.5% Native American; 3.5%; 3.5% Asian/Pacific Islander. Hispanics represent 12% of the total population. Twenty-seven percent of the population is between 0-19 years; 38% is 20-49 years; 19% is between 50-64 years; and 16% is 65 years and older.

It is well known in Kansas that approximately 130,000 individuals are uninsured, many due to income levels that are too low to afford insurance. One in ten Kansans use Community Health Centers (CHCs), also known as the safety net system, which consists of Federally Qualified Health Centers, Primary Care Clinics, Free Clinics, and Safety Net Dental Clinics. These CHCs provide access to primary and preventive care for many Kansans who otherwise would not seek care. There are 85 CHCs spread across the state of Kansas that provide primary care services for individuals regardless of their ability to pay for services.

In 2017, the Kansas Department of Health and Environment (KDHE) reported that 34.8% of adults in Kansas are overweight and 32.3% are obese. 10.5% of adults are diagnosed with diabetes, 37.4% have high cholesterol, and 32.8% have hypertension. From the 2018 Kansas Behavioral Risk Factors Surveillance System (BRFSS) data, 6.7% of adults in Kansas are diagnosed with Chronic Obstructive Pulmonary Disease (COPD), emphysema, or chronic bronchitis. 4.4% of adults have had a heart attack, 4.1% have had angina or coronary heart diseases, and 3.3% have had a stroke. This data represents a small sample of chronic health conditions that affect the health of Kansans.

As other countries and states face the COVID-19 pandemic, Kansas has also been dealing with this novel virus and the effects on the health of its population. As of October 14, 2020, the KDHE has reported 69,155 cases of COVID-19 including 838 deaths, spread among 105 counties. 15,543 of the 69,155 cases were associated with one of the 806 reported clusters in the state. These outbreaks also resulted in 470 of the 838 deaths. Clusters of COVID-19 have occurred in many settings such as, religious and other social gatherings, long term care and health care facilities, private businesses, meat packing plants, and correctional facilities.

The typical COVID-19 case characteristics in Kansas includes an average age of 39. The case ages range from 0 years of age to 107 years of age, with the median age being 36 years. Of the cases counted there were:

- 46,625 cases among White persons; case rate of 1,832.22 per 100,000
- 4,604 cases among Black/African American persons; case rate of 2,111.92 per 100,000
- 531 cases among American Indian or Alaska Natives; case rate of 819.43 per 100,000
- 1,604 cases among Asians; case rate of 1,494.64 per 100,000
- 4,065 cases among Other Race; case rate of 4,414.37 per 100,000
- 11,727 cases among an unidentified race

See below for information related to Kansas COVID-19 deaths.

## Kansas COVID-19: Death Summary

Statewide Deaths	Median Age	Youngest Age	Oldest Age
838	79	18	107

Death counts and data are preliminary and subject to verification.

A COVID-19 death is defined as a person with COVID-19 and a death certificate that lists COVID-19 or SARS-CoV-2 as a cause of death or a significant condition contributing to death.

## Deaths by Age Group

Age Group	Number of Deaths	Percent of Deaths
18-24 years	3	0.4%
25-34 years	8	1.0%
35-44 years	13	1.6%
45-54 years	35	4.2%
55-64 years	90	10.7%
65-74 years	176	21.0%
75-84 years	225	26.8%
85+ years	288	34.4%
Total	838	100.0%

## Deaths by Sex

Sex	Deaths	Percentage
Female	352	42.0%
Male	481	57.4%
Not Reported/Unkno	5	0.6%
Total	838	100.0%

## Race Death Rates per 100,000

Race	Number of Deaths	Rater per 100,000
White	604	23.74
Black or African American	93	42.66
American Indian or Alaska Na	10	15.43
Asian	17	15.84
Other Race	60	65.17
Not Reported/Missing	54	

## Ethnicity Death Rates per 100,000

Ethnicity	Number of Deaths	Rate per 100,000
Hispanic or Latino	107	30.7
Not Hispanic or Latino	646	25.2
Not Reported/Missing	85	

Note: Additional data and maps will be added to the plan after review by the internal COVID-19 vaccination planning committee.

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

During Phase 1, COVID-19 vaccine provider recruitment and enrollment efforts will be targeted at hospitals, local health departments, federally qualified health centers/safety net clinics, and retail pharmacies across the state, including those that are in rural areas. Enrollment of COVID-19 vaccine providers will be prioritized based on those that can provide a significant number of vaccinations to the target populations that have been identified.

During Phase 2, continued enrollment of groups identified above plus traditional and non-traditional partners will be the focus. Ongoing recruitment and enrollment of safety net providers (i.e., Federally Qualified Health Centers, Rural Health Clinics, etc.), pharmacies, long term facilities, and other local healthcare providers will continue to be targeted for participation in the COVID-19 vaccine program. Enrollment of these providers will be prioritized based on those that can provide a significant number of vaccinations to the target populations identified for this phase as defined by the Kansas COVID-19 Vaccination Program Implementation Committee. The goal is equitable and rapid vaccination of all populations.

During Phase 3, all other healthcare providers that would like to enroll and can meet the requirements will be added as requested. Enrollment of these providers will occur on a first come first served basis.

All COVID-19 vaccine providers will need to be able to conduct vaccine clinics and/or appointments using social distancing and infection control procedures as identified by the CDC. See <a href="CDC guidance on vaccination during a pandemic">CDC guidance on vaccination during a pandemic</a> for further details. Providers of COVID-19 vaccine will also need to meet the reporting requirements outlined in Section 9: COVID-19 Vaccine Administration Documentation and Reporting and Section 11: COVID-19 Requirements for Immunization Information Systems or Other External Systems.

Communication regarding recruitment and enrollment will be through supporting associations, established partnerships, and new partnerships. Anticipated targeted communication with the hospitals will be through the Kansas Hospital Association; local health departments through the Kansas Association of Local Health Departments and established internal listserv; safety net clinics through the Community Care Network of Kansas; pharmacies through the Kansas Board of Pharmacies and Kansas Association of Pharmacies; long term care facilities through the Kansas Department of Aging and Disabilities; etc. These lines of communication will be further defined and identified by the internal COVID-19 vaccine planning committee.

If it is determined that there are areas of the state that have limited access to COVID-19 vaccine providers, the Kansas Immunization Program will prepare for mobile clinics using the influenza playbook that was developed for the State of Kansas employee flu clinics, lessons learned, and COVID-19 vaccine planning assumptions.

Those that are willing and able to provide vaccine to those identified as targets for initial vaccine receipt. Hospitals and local health departments will need to be able to maintain and monitor vaccine inventory according to the guidelines provided from the manufacturer and the CDC Vaccine Storage and Handling Toolkit from receipt through administration of vaccine. The hospitals should also be able to administer vaccine following the social distancing and infection control through closed point of dispensing settings that allow for the maximum number of people to be served.

COVID-19 vaccine providers will be tracked in KSWebIZ. Each provider will receive a unique PIN that will be used for vaccine inventory control, vaccine administration information, plus storage and handling details in KSWebIZ. This same PIN will be used for vaccine ordering via VTrckS.

There will also be a dedicated shared file with restricted access for staff that will assist with enrolling and onboarding COVID-19 providers and maintaining signed provider enrollment agreements, provider profiles, and redistribution agreements. Provider training is part of the onboarding process and outlined in Section 11: COVID-19 Requirements for IIS or Other External Systems.

When the training step of the onboarding process is reached, providers are contacted to schedule trainings. Trainings are conducted as online webinars using the Go-To-Webinar system. Kansas provides trainings options for vaccine administration users, vaccine ordering users, and reports. New users are required to register for training and do not receive access to their KSWebIZ account until training is complete. Vaccine administration user training includes KSWebIZ system navigation, and data entry of patient and immunization information. Vaccine order user training includes information provided in the administration user training and all processes related to vaccine inventory, temperature monitoring, and ordering. Reports training includes available reports with an emphasis on reminder/recall.

CDC will have many educational resources available for use and Kansas will develop instructional materials in conjunction with CDC materials. Kansas will include communication on expectations of 24-hour data submissions with required elements provided during training and as downloadable documents in the reports module. Information will also be available for vaccination providers to report and maintain their COVID-19 vaccination information on CDC's Vaccine Finder. Vaccine administration and storage and handling guidance will also be provided. COVID-19 vaccination provider education will be documented and tracked in an internal electronic folder on the Kansas Immunization Program shared drive.

Organizations ordering COVID-19 vaccine for additional sites will be identified by the answers provided on Section B. of the CDC COVID-19 Vaccination Program Provider Agreement. If validated cold-chain procedures are in place, in accordance with the manufacturer's instructions and CDC's guidance on COVID-19 vaccine storage and handling, the organization will be required to complete the CDC Supplemental COVID-19 Vaccine Redistribution Agreement.

For large organizations whose vaccine is shipped to a central depot and requires redistribution to additional clinic locations, comments are required when placing the vaccine order notating vaccine quantities ordered for additional locations. Small organizations with orders smaller than the minimum order size will be reviewed by the jurisdiction to determine coverage and available resources. All organizations placing orders for vaccine that will be redistributed will be monitored closely for vaccine ordering, uptake, and wastage patterns to ensure appropriate distribution and handling.

## Section 6: Understanding a Jurisdiction's COVID-19 Vaccine Administration Capacity

Vaccine administration capacity is defined as the maximum achievable vaccination throughput regardless of public demand for vaccination. Kansas will be working with the internal COVID-19 vaccine planning committee, using the <a href="Pandemic Vaccination Campaign Planning Tool">Pandemic Vaccination Campaign Planning Tool</a> developed by the Health Economics and Modeling Unit and Immunization Services Division Centers for Disease Control and Prevention to estimate the number of weeks it may take to vaccinate the population of Kansas, or specific populations, based on a variety of planning inputs.

The planning tool was designed to assist jurisdictions in determining their ability to vaccinate at least 80% of their population with 2 doses of pandemic influenza vaccine (or COVID-19 vaccine in this scenario) separated by 21 days within 12 weeks of pandemic vaccine availability. Factors such as population size, number and type of vaccine providers, vaccine doses available, etc. will be assessed routinely to understand and monitor the distribution and administration of COVID-19 vaccine across the state.

The internal COVID-19 vaccine planning committee will use and update the tool based on the phases of COVID-19 availability, recommendations for priority groups as defined by the CDC and the Kansas COVID-19 Vaccination Program Implementation Committee along with the number and types of COVID-19 vaccine providers available. These variables are expected to change rapidly so the tool will be updated frequently and used to monitor for efficient delivery and administration of the COVID-19 vaccine.

Additional factors that may affect a provider's vaccine administration capacity and should be considered by those providing COVID-19 vaccine include storage capacity; storage equipment; temperature monitoring devices required; infection control measures required to prevent transmission of COVID-19; other vaccinations that are being offered simultaneously with COVID-19, and clinic hours; and clinic participant age.

The planning tool will not help in decisions on how to allocate limited number of vaccines, therefore, the work of the Kansas COVID-19 Vaccination Program Implementation Committee will be imperative to ensure equitable access among all populations in Kansas. The work of this committee will be informed by the internal COVID-19 vaccine planning committee's work using the planning tool and by the priority groups identified by CDC and the KDHE ICS Team.

The Kansas Hospital Association has surveyed all 121 hospitals in the state to determine ability, willingness, and capacity of hospitals to provide COVID-19 vaccine to paid and unpaid healthcare workers in their communities that are exposed to or likely to be exposed to COVID-19 patients. The results from this survey are currently under review and will be used to determine vaccine administration capacity, gaps in availability, and other attributes of vaccination ability. This work will continue as priority groups are identified, COVID-19 vaccine providers are enrolled, and vaccine availability increases.

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

## **Vaccine Allocation Strategy**

Vaccine allocation in Kansas will depend on numerous factors such as vaccine doses available, vaccine indications, vaccine storage requirements, minimum vaccine ordering allowed, vaccine provider availability, etc. One of the most important factors in vaccine allocation, in addition to logistical matters, include the recommendations from the CDC, ACIP, COVID-19 Vaccination Program Implementation Committee, and KDHE ICS Team. This will be especially true during the initial phases of vaccine availability. The work of scrutinizing vaccine allocation will continue throughout the vaccination campaign and/or until COVID-19 vaccine is widely available. Disease epidemiology in local communities, vaccine allocation received by CDC, state distribution, and vaccine uptake will be monitored closely to ensure efficient use of the COVID-19 vaccine.

See Section 3: Phased Approach to COVID-19 Vaccination for details on anticipated COVID-19 vaccine availability and likely priority groups.

## **Vaccination Ordering Process**

COVID-19 vaccine orders will be reviewed against the allocation process described above ensuring prioritization for critical populations specified for each phase of vaccine allocation from CDC. The Kansas Immunization Program's Vaccine Coordinator will approve COVID-19 vaccine orders through the KSWebIZ system. These vaccine orders will then be uploaded into VTrckS so that they can be processed by the central vaccine distributor and shipped directly to the COVID-19 provider. This is an established system that is currently in place and used by the Vaccines for Children (VFC) providers and mirrors the process that is used for distribution of influenza vaccine to VFC providers throughout the state annually.

The KSWebIZ maintains clinic points of contact for vaccine storage and handling matters, physical address for delivery of vaccines, clinic hours of operation and when vaccine deliveries can be received, clinic vaccine inventory, storage unit information, and digital data logger uploads to ensure storage units are maintaining appropriate temperatures for vaccines.

COVID-19 vaccines will be shipped directly to approved providers. COVID-19 vaccine(s) approved for use through EUA or FDA licensure will likely be available in minimal quantities such as 975 doses per order and will have differing storage and handling requirements (refrigerated, frozen, or ultra-cold). The specifics of each vaccine are yet to be determined but will be shared as more details become available. We do know that in addition to vaccine, the CDC will supply ancillary and administration supply kits for each vaccine type. These kits will be sent automatically in amounts that match the vaccine order that was placed.

### Ancillary supply kits will include:

- 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
- 4 surgical masks and 2 face shields for vaccinators, per kit
- COVID-19 vaccination record cards for vaccine recipients, 100 per kit

Note: Ancillary kits will not include gloves, sharps containers, or band aids.

Administration kits for COVID-19 vaccines that require reconstitution with diluent or mixing with adjuvant at the point of administration, will contain mixing kits with syringes, needles, and other needed supplies will also be included.

COVID-19 vaccine, ancillary supply kits, and administration supply kits will be shipped to enrolled providers within 48 hours of order approval. Because of cold chain requirements, ancillary supply kits (and diluent, if applicable) will ship separately from vaccine but should arrive before or on the same day as vaccine.

## Repositioning of Vaccine

COVID-19 vaccine providers may find they have more vaccine stock than they can distribute, or they may have multiple facilities participating in vaccination efforts. If practical and the cold chain can be maintained, *refrigerated COVID-19 vaccine only*, can be transferred to another approved facility if a CDC COVID-19 Vaccine Redistribution Agreement has been approved and is on file with the Kansas Immunization Program.

In some instances, the Kansas Immunization Program may determine it is necessary to transfer the vaccine to another approved COVID-19 vaccine provider. If this is needed, the Regional Immunization Consultants will transfer refrigerated COVID-19 vaccine between facilities and/or providers.

While transfers of vaccine should not routinely occur, the Regional Immunization Consultant assigned to the area must be notified prior to transportation of vaccine if the transport time is one hour or more. The Regional Immunization Consultant will handle all COVID-19 vaccine transports greater than one hour.

If the following conditions are met, providers that have a CDC COVID-19 Vaccine Redistribution Agreement on file, can transfer refrigerated vaccine.

- Approval is received, and the transfer will take place under guidance of the Kansas Immunization Program
- A process is in place to ensure vaccine viability during the transfer, following the guidance outlined in the <u>CDC Vaccine Storage and Handling Toolkit</u>
- Vaccine will be transferred in a qualified container with a certified calibrated thermometer
- Vaccine temperatures are monitored and documented throughout the transfer using the approved Vaccine Transfer Form (to be developed).

COVID-19 vaccine providers that will be conducting off-site and/or mass vaccination clinics, must follow all storage and handling requirements as outlined by the CDC and the Kansas Immunization Program. Consultation with the area's Regional Immunization Consultant prior to the clinic will ensure that requirements for such clinics are understood and followed.

Vaccines must be transported according to the guidelines outlined above. The Regional Immunization Consultant should be notified prior to any transfer of vaccine, appropriate equipment should be available and used, and temperatures should be monitored and logged on the Vaccine Transfer Form hourly while in transit.

- Vaccines must be stored correctly throughout the clinic to maintain appropriate temperatures.
- Temperatures should be monitored and documented hourly on the Vaccine Transfer form or on the paper temperature logs provided by the Kansas Immunization Program.

After completion of the clinic, the temperatures of the vaccine during transit and the clinic must be evaluated to ensure vaccine temperatures were maintained within acceptable temperature ranges. If temperatures were maintained appropriately, vaccine may be returned to regular storage units. If there were any instances of temperatures falling out of range, the vaccines should be labeled, "DO NOT USE," and the Regional Immunization Consultant should be contacted for next steps.

## **Vaccine Wastage Monitoring**

The Kansas Immunization Program will work to ensure that COVID-19 vaccine providers are following sound vaccine management practices that do not result in excessive wastage or unaccounted for vaccine. The management of the COVID-19 vaccine is one of the most important responsibilities for enrolled providers during the pandemic response. Vaccine management practices must include proper ordering and inventory management to prevent vaccine waste and ensure appropriate stock is available for the two doses series.

The Kansas Immunization Program will require providers to enter their vaccine into KSWebIZ. Vaccine inventory tracking will follow the established inventory management and tracking process. Any COVID-19 wastage must be reported in KSWebIZ within 72 hours. Vaccine wastage will be reviewed by the internal COVID-19 vaccine planning committee routinely so that corrective actions can be implemented as necessary.

Additional details on the COVID-19 vaccine recovery process are being finalized and will be communicated when available.

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

Information in this section is based on current guidelines of the Kansas Immunization Program and will be updated as additional information about COVID-19 vaccine becomes available.

#### **Individual Provider Locations**

The vaccine cold chain is a temperature-controlled environment used to maintain and distribute vaccine in optimal conditions. The cold chain begins with the cold storage unit at the manufacturing plant, extends through transport of vaccines to the distributor, delivery to and storage at the provider facility, and ends with administration of vaccine to the patient. Appropriate storage and handling conditions must be maintained at every link in the cold chain. Too much exposure to heat, cold, or light at any step in the cold chain can damage vaccines, resulting in loss of vaccine potency. Once lost, potency cannot be restored. Each time vaccines are exposed to improper conditions, potency is reduced further. Eventually, if the cold chain is not properly maintained, potency will be lost completely, and vaccines will be useless. All COVID-19 vaccine storage and handling requirements and recommendations must be in place to ensure the cold chain is maintained.

Providers must be available and onsite with appropriate staff to receive vaccine shipments. The clinic should ensure the Kansas Immunization Program has a correct physical address to receive vaccines, correct hours of operation for each facility to receive vaccines, a primary point of contact for vaccine questions, appropriate and adequate storage units to house vaccines and administration supply kits in the quantities ordered, and temperature monitoring devices that meet the Kansas Immunization Program requirements for vaccine storage units.

Vaccines are delivered in accordance with reported clinic hours of operation in KSWebIZ. Clinic hours must be reported and updated in KSWebIZ immediately.

All staff members who might receive vaccine deliveries must be aware of the importance of maintaining the cold chain. Receiving staff should be trained to immediately notify the COVID-19 vaccine primary or back-up coordinator when deliveries arrive so that vaccines are checked in and stored quickly. Upon receipt of a vaccine shipment, providers must immediately unpack vaccines, diluents, and adjuvants as store as directed. Receipt of vaccines should be documented appropriately according to the Kansas Immunization Program guidance.

#### COVID-19 vaccine providers should:

- Examine the shipping container and vaccine vials for signs of physical damage
- Compare the contents of the container to the packing list to ensure accurate shipment
- Verify correct type and quantity of diluents and/or adjuvants
- Check vaccine and diluent use by dates and/or expiration dates to ensure vaccine viability and ability to distribute timely
- Check the cold chain monitor for any indication of temperature excursion during transit; cold chain
  monitors are stored in a separate compartment of the shipping container and may not be included
  when vaccines are shipped directly from the manufacturer; cold chain monitors should be thrown
  away after being checked

• Determine the amount of time vaccines were in transit and compare it against the packing list in the container, which shows acceptable transit time (frozen vaccines only)

Note: These guidelines are based on the <u>CDC Storage and Handling Toolkit</u>, which is anticipated to be updated based on COVID-19 vaccine(s) storage and handling requirements. Updates should be expected.

Contact the Kansas Immunization Program Vaccine Coordinator immediately at 785-296-1948, if the following issues are identified with the vaccine delivery:

- Vaccine were compromised or there was a problem with the temperature monitors
- Vaccines were received that were not ordered
- Vaccines were ordered but not received

All vaccine should be maintained at the appropriate temperature to ensure vaccine viability. Vaccines remain in optimal condition when they are kept in a temperature-controlled environment, which is maintained from the manufacturing plant through distribution to the provider clinic and through vaccine administration. Too much exposure to heat, cold, or light at any step could result in loss of vaccine potency. Each time vaccines are exposed to improper conditions, potency is reduced further. If the cold chain is not properly maintained, potency will be lost completely, and vaccines will be useless.

- Correct refrigerator temperature range is 2 degrees Celsius through 8 degrees Celsius
- Correct freezer temperature range is -15 degrees Celsius through -25 degrees Celsius
- Correct ultra-cold temperature range is -60 degrees Celsius through -80 degrees Celsius

Following best practices; vaccines, diluents, and adjuvants received should be:

- Stored in original manufacturer packaging with lids closed until ready for administration; never store loose vials or manufacturer-filled syringes outside of their packaging
- Placed in a central location in the unit, 2-3 inches away from walls, ceiling, floor, and door
- Placed in units that have water bottles (labeled "DO NOT DRINK") stored against the walls, in the back, on the floor, and in the door racks throughout refrigerator and freezer units; this does not apply if the manufacturer indicates that the water bottles negatively impact the functionality of the unit
- Arranged in rows, allowing space between rows to promote air circulation and consistent temperature
- Labeled and placed on different shelves if there is similar packaging or names; adult and pediatric formulations should also be placed on different shelves to minimize the risk of administration errors
- Placed with the earliest best use by or expiration dates in front of those with later dates; check and rotate every week and when a new shipment arrives
- Removed if expired. Bag and label all expired vaccine: "DO NOT USE." *Instructions for vaccine return to be determined.*

#### Vaccine should **not** be:

- Placed in the storage unit too tightly; this can restrict air circulation and impact vaccine viability
- Stored in the door, deli/fruit/vegetable bins, on the floor of a unit, or under/near a cooling vent
- Placed in units with food and/or drinks

## Satellite, Temporary, or Off-Site Settings

COVID-19 vaccine providers that will be conducting satellite, temporary, or off-site vaccination clinics, must follow all storage and handling requirements as outlined by the CDC and the Kansas Immunization Program. Consultation with the area's Regional Immunization Consultant prior to the clinic will ensure that requirements for such clinics are understood and followed.

Vaccines must be transported according to the guidelines outlined above. The Regional Immunization Consultant should be notified prior to any transfer of vaccine, appropriate equipment should be available and used, and temperatures should be monitored and logged on the Vaccine Transfer Form hourly while in transit.

- Vaccines must be stored correctly throughout the clinic to maintain appropriate temperatures.
- Temperatures should be monitored and documented hourly on the Vaccine Transfer form or on the paper temperature logs provided by the Kansas Immunization Program.
- Vaccine should be transported in quantities sufficient for expected participants

After completion of the clinic, the temperatures of the vaccine during transit and the clinic must be evaluated to ensure vaccine temperatures were maintained within acceptable temperature ranges. If temperatures were maintained appropriately, vaccine may be returned to regular storage units. If there were any instances of temperatures falling out of range, the vaccines should be labeled, "DO NOT USE," and the Regional Immunization Consultant should be contacted for next steps.

## Planned and Unplanned Movement of Vaccine

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

COVID-19 vaccine providers may find they have more vaccine stock than they can distribute, or they may have multiple facilities participating in vaccination efforts. If practical and the cold chain can be maintained, *refrigerated COVID-19 vaccine only*, can be transferred to another approved facility if a CDC COVID-19 Vaccine Redistribution Agreement has been approved and is on file with the Kansas Immunization Program.

In some instances, the Kansas Immunization Program may determine it is necessary to transfer the vaccine to another approved COVID-19 vaccine provider. If this is needed, the Regional Immunization Consultants will transfer refrigerated COVID-19 vaccine between facilities and/or providers.

While transfers of vaccine should not routinely occur, the Regional Immunization Consultant assigned to the area must be notified prior to transportation of vaccine if the transport time is one hour or more. The Regional Immunization Consultant will handle all COVID-19 vaccine transports greater than one hour.

If the following conditions are met, providers that have a CDC COVID-19 Vaccine Redistribution Agreement on file, can transfer refrigerated vaccine.

- Approval is received, and the transfer will take place under guidance of the Kansas Immunization Program
- A process is in place to ensure vaccine viability during the transfer, following the guidance outlined in the CDC Vaccine Storage and Handling Toolkit
- Vaccine will be transferred in a qualified container with a certified calibrated thermometer

• Vaccine temperatures are monitored and documented throughout the transfer using the approved Vaccine Transfer Form (to be developed).

COVID-19 vaccine providers that will be conducting off-site and/or mass vaccination clinics, must follow all storage and handling requirements as outlined by the CDC and the Kansas Immunization Program. Consultation with the area's Regional Immunization Consultant prior to the clinic will ensure that requirements for such clinics are understood and followed.

Vaccines must be transported according to the guidelines outlined above. The Regional Immunization Consultant should be notified prior to any transfer of vaccine, appropriate equipment should be available and used, and temperatures should be monitored and logged on the Vaccine Transfer Form hourly while in transit.

- Vaccines must be stored correctly throughout the clinic to maintain appropriate temperatures.
- Temperatures should be monitored and documented hourly on the Vaccine Transfer form or on the paper temperature logs provided by the Kansas Immunization Program.

After completion of the clinic, the temperatures of the vaccine during transit and the clinic must be evaluated to ensure vaccine temperatures were maintained within acceptable temperature ranges. If temperatures were maintained appropriately, vaccine may be returned to regular storage units. If there were any instances of temperatures falling out of range, the vaccines should be labeled, "DO NOT USE," and the Regional Immunization Consultant should be contacted for next steps.

Additional resources to assist COVID-19 vaccine providers in planning efforts include <u>Guidance</u> <u>for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations</u> and <u>Vaccination Guidance During a Pandemic</u>. These resources provide information on additional considerations that are necessary during the COVID-19 pandemic, including social distancing, PPE use, and enhanced sanitation efforts.

## **Temperature Monitoring of Vaccine**

Digital data loggers (DDLs) must monitor the temperature of COVID-19 vaccine during routine storage, time in transport, and off-site storage. All COVID-19 vaccine providers must use the DDLs supplied by the Kansas Immunization Program as the primary thermometer for each storage unit that holds COVID-19 vaccines. DDLs must be placed in the center of the unit with vaccines surrounding it. DDLs should not be placed in unit doors, near or against walls, or close to the floor, ceiling, or vents.

To meet Kansas Immunization Program requirements, the DDLs must have:

- Buffered temperature probes
- An active temperature display that can be easily read from the outside of the storage unit
- The ability to continuously monitor and record temperatures
- The ability to download temperature readings

The supplied DDLs also meet the additional CDC recommended features for DDLs that are used to monitor public vaccine:

- Alarm for out-of-range temperatures
- Current, minimum, and maximum temperature display
- Low battery indicator

- Accuracy of +/-1°F (0.5°C)
- User programmable logging interval (or reading rate) recommended at a maximum time interval
- of every 30 minutes

All Kansas Immunization Program-supplied DDLs have a current and valid certificate of calibration, which is the only acceptable method of monitoring temperatures in accordance with program requirements.

The Certificates of Calibration testing must include:

- Model/device name or number
- Serial number
- Date of calibration (report or issue date)
- Confirmation that the instrument passed testing (or instrument in tolerance)

## Optional testing element:

• Uncertainty of +/- 0.5°C (+/-1° F) or less as recommended by CDC

If it is unclear as to whether the Certificate of Calibration Testing or Report of Calibration is issued by an appropriate entity, look for one or more of the following items documented regarding the calibration testing:

- Conforms to International Organization for Standardization (ISO)/International Electrotechnical
- Commission (IEC) 17025 international standards for calibration testing and traceability
- Performed by an International Laboratory Accreditation Cooperation (ILAC) Mutual
- Recognition Arrangement (MRA) signatory body. ILAC/MRA signatories may be found at:
- http://ilac.org/ilac-mra-and-signatories/
- Traceable to the standards maintained by the National Institute of Standards and Technology
- (NIST)
- Meets specifications and testing requirements for the American Society for Testing and Materials
- (ASTM) Standard E2877 tolerance Class F (≤ 0.5 °C) or better
- Includes reference to another acceptable accuracy validation method, such as comparison to other traceable reference standards or tests at thermometric fixed points
- A Certificate of Calibration Test (Report of Calibration) form can be found in the FORMS AND RESOURCES section of this manual.

BACKUP THERMOMETER: COVID-19 vaccine providers must also have a backup digital thermometer that is readily available and has a certificate of calibration testing meeting the requirements listed above. It is recommended that the calibration dates for the backup thermometer are different than the primary thermometer to stagger the need for replacement on the same date. The backup thermometer is needed in the event the DDL malfunctions or is no longer working. COVID-19 vaccine providers should contact their Regional Immunization Consultant or the Consultant On-Call immediately if the supplied DDL malfunctions or stops working. A replacement unit will be shipped immediately upon notification.

TEMPERATURE DOCUMENTATION: COVID-19 vaccine providers must have established protocols for reviewing and recording temperature readings. All providers are required to maintain paper temperature logs and electronic files from the supplied DDLs. Paper temperature logs and electronic files from the DDL downloads must be kept on file for a minimum of 3 years and be available upon request.

TEMPERATURE LOGS: Temperatures must be manually checked and recorded on the Kansas Immunization Program supplied temperature log. Minimum and maximum temperatures must be recorded at the start of each clinic day and the current temperature should be recorded twice daily; when the clinic opens and one hour prior to the clinic closing. It is also recommended that the current temperature is checked prior to accessing and administering vaccines. Documentation should include actual temperature readings, time and date of readings, the name (or initials) of the person who checked and recorded the readings, and any actions taken if a temperature excursion occurred.

In the event a facility is closed, no more than 3 days may pass without manually checking and recording the temperature.

It is not necessary to submit paper temperature logs monthly unless specifically requested by the Kansas Immunization Program.

DIGITAL DATA LOGGERS: The supplied DDLs continuously monitor temperatures of vaccine storage units and alert clinic providers when the storage unit temperatures are out of range. The DDL takes temperature readings every minute and records them every five minutes. The DDL will hold 56 days of readings.

COVID-19 providers should download DDL files (.pdf and .txt) monthly and maintain an electronic copy per the Kansas Immunization Program guidelines in addition to the monthly upload into KSWebIZ.

Data from the DDLs should be uploaded to KSWebIZ no later than the 7th day of the month (i.e., Data from January would be uploaded to KSWebIZ by February 7th).

Additional details on the supplied DDLs functions and operation, can be found on the Kansas Immunization Program website at: <a href="http://www.kdheks.gov/immunize/datalogger\_information.htm">http://www.kdheks.gov/immunize/datalogger\_information.htm</a>

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

Submission of COVID-19 vaccine administration data to the Immunization (IZ) Gateway is in the development phase. Kansas is working with the KSWebIZ vendor to create data extracts of a tab delimited file to submit for each 24-hour period. Reporting data may be transmitted daily from KSWebIZ to the CDC via the IZ Gateway "Connect" component. Additional information on the reporting process and specifications will be shared as soon as they have been finalized. Once the KSWebIZ vendor receives the specifications they will create the extract and provide assistance with how to obtain it for upload.

As COVID-19 organizations complete the CDC COVID-19 Vaccination Program Provider Agreement the Medical Director and the Chief Executive Officer agree to report the administration of a COVID-19 vaccine and adjuvant, if applicable, in the vaccine recipient's record and to the relevant state health authority within 24-hours. Kansas will reiterate this expectation and provide the required data elements during the onboarding training process. The 24-hour reporting requirement and required data elements will also be provided in the documents section of the reports module. In addition, Kansas will also test new and existing connections and verify current data status by reviewing the data quality statistics report and ensuring required field submissions are at 100%. Any provider data found under 100% will be required to make corrections before vaccine administration can begin.

KSWebIZ is an online application, which ensures real-time documentation and reporting of COVID-19 vaccine administration data in clinic settings and mobile settings such as satellite, temporary, or off-site clinic locations. KSWebIZ can easily be accessed by many types of electronic devices which allows for flexibility in vaccine clinic planning efforts. Kansas will also provide a flat file upload option if a provider is unable to access the site.

Monitoring of provider-level data for doses of COVID-19 vaccine administered and reported, will be reviewed for data completeness and quality by the Kansas Immunization Program staff before uploading data to the CDC.

With this review, the Kansas Immunization Program staff will be able to identify discrepancies with the date the vaccine was administered compared to the date the vaccine record was created, vaccine administration omissions, etc. Incomplete or late submission will be discussed with the COVID-19 vaccine provider so that corrective actions can take place. Providers that continue to be noncompliant with the documentation and reporting requirements will be placed "on hold" and unable to order additional COVID-19 vaccine until an approved correction plan is developed.

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

Vaccination providers will be instructed to complete the COVID-19 vaccination record card provided in the ancillary kit with accurate vaccine information (i.e., vaccine manufacturer, lot number, date of first dose administration, and second dose due date). The card will be given to each patient with instruction to save the vaccination card and have it available for the second dose in case the IIS or other system is not available when they return. If vaccine recipients have a smartphone, vaccine providers may also encourage them to consider documenting their vaccine administration with a photo of their vaccination record and entering the date the next vaccine dose is due on their electronic calendar. Providers can emphasize the importance of these steps by explaining that there are multiple COVID-19 vaccines available and they are not interchangeable. A vaccine recipient's second dose must be from the same manufacturer as their first dose.

COVID-19 vaccination providers should make every attempt to schedule a patient's second-dose appointment when they get their first dose to ensure compliance with vaccine dosing intervals and achieve optimal vaccine effectiveness. If available, vaccination providers should use existing systems for patient notifications and reminders such as automated patient phone calls, emails, and/or SMS text message-based systems to aid.

Vaccination providers can access the KSWebIZ Patient Reminder/Recall report to identify vaccine recipients. This report also contains templates for reminder and recall post cards and labels.

Vaccine recipients can receive an additional copy of their record with this information by contacting our program and completing a release or information or by requesting a user account to the online portal. The online portal allows the patient to login and view their immunization record at any time.

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

The primary method for documenting COVID-19 vaccine administration data will be through KSWebIZ, the state immunization registry. KSWebIZ fully supports bidirectional HL7 data exchange and transitioned to the Microsoft Azure Cloud in February 2019. All hardware and software are up-to-date. Kansas will soon be able to provide a flat file upload option to ensure the data is still available if there are technical issues with HL7 connections and data exchange.

Vaccine providers can enter data directly into KSWebIZ or via HL7 data exchange from electronic health records (EHR). As of July 1, 2020, all vaccines administered in Kansas are required to be entered in KSWebIZ. See KSA 65-2886a <a href="https://www.ksrevisor.org/statutes/chapters/ch65/065-028-0086a.html">https://www.ksrevisor.org/statutes/chapters/ch65/065-028-0086a.html</a> for complete statute. With this mandate in effect for reporting vaccines administered, most providers in Kansas are already connected to KSWebIZ and familiar with the system. The Kansas Immunization Program continually onboards new facilities and providers onto KSWebIZ as requested.

### Planned improvements to KSWebIZ include:

- Flat file upload will be added during next upgrade to the system. The upgrade will be provided to our production environment on November 10, 2020.
- Reminder/Recall Report updates to include COVID-19 vaccine. Timeline will be established and updated once finalized vaccine information is released.
- CDSI logic for vaccine forecasting and recommendations. Timeline will be established and updated once finalized vaccine information is released.

Additional improvements will be identified and added when available.

Rapid onboarding onto KSWebIZ for COVID-19 vaccination providers and facilities will be targeted to those that are likely to vaccinate in Phase 1A, 1B, and 2. Select COVID-19 vaccine providers, as outlined in *Section 3: Phased Approach to COVID-19 Vaccination*, will be sent a link to the online CDC COVID-19 Vaccination Program Provider Agreement and Provider Profile.

The provider will be directed to complete all fields on the provider agreement and provider profile, obtain signature from the Medical Officer and Chief Executive Officer, then submitted the completed forms to the Kansas Immunization Program via the link provided. The completed documents will be reviewed by staff and a unique PINs will be assigned and added to the provider agreement. Data will then be extracted and parsed into the required csv format. Cumulative data will be submitted to CDC twice a week on Monday and Thursday by 9:00pm EST using the Immunization Data Lake (IZDL) Partner Portal.

Providers requesting redistribution approval from Section B. of the provider enrollment agreement will be sent to the organization's identified primary COVID-19 vaccine coordinator so that the form can be completed and sent back to the Kansas Immunization Program. Provider facilities information will be verified and if approved, the information will be entered into KSWebIZ and submitted to CDC.

All KSWebIZ users will be required to attend training on the system and requirements of the COVID-19 vaccination program. Once training is completed, user accounts will be created and access to KSWebIZ will be granted. Provider facilities will be required to test connections and ensure quality of data is

appropriate so that reporting requirements can be met. Any issues identified will need to be corrected before COVID-19 vaccine can be ordered and vaccines provided.

Kansas has connected to the IZ Gateway Connect and Share. The KSWebIZ vendor provided test credentials and tested the connection in the test environment. The agreement was completed, and production credentials have been established. Kansas is prepared for IZ Gateway Connect and Share.

Kansas has a fully executed Data Use Agreement (DUA) with the Association of Public Health Laboratories (APHL) to participate in the IZ Gateway. The DUA was finalized on 9/18/2020.

Kansas will execute a DUA with CDC allowing access to aggregate KSWebIZ data for national coverage data analysis. This DUA has not been made available at this time.

Kansas currently has Memorandums of Understanding (MOU), allowing for bidirectional sharing of data via the IZ Gateway Share component with Arkansas and Missouri. Kansas and Missouri fully executed an MOU for IZ Gateway Share on 9/11/2020. Kansas and Arkansas fully executed an MOU for IZ Gateway Share on 11/15/2018. Oklahoma and Colorado have expressed interest with connecting with Kansas and will be completing an MOU, also.

Monitoring of provider-level data for doses of COVID-19 vaccine administered and reported, will be reviewed for data completeness and quality by the Kansas Immunization Program staff before uploading data to the CDC.

With this review, the Kansas Immunization Program staff will be able to identify discrepancies with the date the vaccine was administered compared to the date the vaccine record was created, vaccine administration omissions, etc. Incomplete or late submission will be discussed with the COVID-19 vaccine provider so that corrective actions can take place. Providers that continue to be noncompliant with the documentation and reporting requirements will be placed "on hold" and unable to order additional COVID-19 vaccine until an approved correction plan is developed.

## Section 12: COVID-19 Vaccination Program Communications

Communication regarding COVID-19 vaccines is essential to the success of the COVID-19 Vaccination Program for the Kansas Department of Health and Environment (KDHE). Our program's goal is to build vaccine confidence broadly and among groups anticipated to receive early vaccination, as well as dispel vaccine misinformation to help ensure vaccine uptake.

KDHE will utilize the risk communication principles from the CDC's <u>Vaccinate with Confidence</u> framework along with CDC-outlined COVID-19 messaging to implement a timely, evolving communications strategy for COVID-19 vaccination in Kansas.

This plan will include multiple phases, targeted to several audiences across a diversified delivery platform and in accessible formats.

## **COVID-19 Vaccination Communication Objectives**

KDHE will meet the following communication objectives:

- Educate the public about the development, authorization, distribution and execution of COVID-19 vaccines and that situations are continually evolving.
- Implement messaging that creates public confidence in the approval or authorization process, safety and efficacy of COVID-19 vaccines.
- Help the public to understand key differences in <u>FDA emergency use authorization</u> and <u>FDA approval</u>.
- 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**

The following audiences are key for communication efforts as part of this plan:

- Healthcare personnel two focuses to include administration of vaccine and receipt of vaccine as essential workers.
- Health insurance issuers and plans coverage for vaccine
- 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

#### **Communication Phases**

KDHE will initiate four phases of communications efforts. The time frames of these phases will be dependent upon vaccine availability and distribution at the federal level.

- Pre-Vaccine: Before vaccine is available, education will be shared on vaccine safety and helping
  the public understand key differences in <u>FDA emergency use authorization</u> and <u>FDA approval</u>.
  Messaging from CDC and FDA will be used to address this through various platforms.
- Phase 1: Vaccine is available in limited supply for certain populations of early focus. This phase
  will focus on delivering information to the targeted populations regarding vaccine availability
  safety and other messaging as outlined by CDC and FDA.
- Phase 2: Vaccine is increasing and available for other critical populations and the general public. This phase will expand on information in Phase 1 to be all-encompassing of the audiences. Safety and other messaging as outlined by CDC and FDA will be utilized.
- **Phase 3:** Vaccine is widely available. This phase will focus efforts on the importance of the vaccine for the general population. It will continue to include safety and other messaging as outlined by CDC and FDA.

#### **Communication Activities**

The following activities will be executed as part of the plan for Kansas across the planning phases:

- KDHE will communicate early and regularly about the safety of vaccines in general and have
  easily accessible, government information to address myths, questions and concerns. This will
  be accomplished through partner education, press conferences, website, social media and other
  methods as determined throughout the process.
- KDHE will keep the public, public health partners, and healthcare providers well-informed about COVID-19 vaccine(s) development, recommendations and public health's efforts through a cadre of methods. This will include diversified methods depending upon audience and specific needs, but will include press conferences, web updates, social media, newsletters, meetings, list servs and phone calls, among others.
- KDHE will engage with and use a wide range of partners and collaborations to achieve communication goals. KDHE works with a wide variety of partners, including 100 local health departments, all of whom will be vital to the success of this initiative. Partner groups include:
- State and local government; Employers; healthcare providers (including federally funded safety net and in-home care providers); health insurance issuers and plans; Educators; Unions and professional organizations; Organizations serving minority populations and people with disabilities; and community and faith-based groups
- KDHE will work with a vendor to develop a marketing campaign to inform and educate all audiences regarding the COVID-19 vaccine. This campaign will use CDC-based information and messaging and will amplify messaging from the national level as well as include nuances specific to Kansas' demographics and composition. Particulars will include a mainstream media approach: TV, radio and print as well as digital and social media. Additionally, it will incorporate outdoor marketing, such as billboards and bus wraps. Each target audience in each phase is unique and KDHE and its vendors will work in conjunction with our partners to identify the best communications methods for each audience.
- As part of the marketing campaign, KDHE and its vendor will develop a Vaccine Toolkit which will include marketing material that can be downloaded by all partners. It will include material

that complements CDC messaging regarding vaccine safety and information. Types of material included in the kit will be video PSA or message, messages to employees/specific audiences, social media infographics/message ideas, press release templates, poster templates, flyer templates, newsletter template, OpEd template, digital ads and other material as identified. This is something that will be adapted and fluid as the phases of implementation change.

- KDHE and any of its vendor partners will ensure that all communications meet the requirements
  of the Americans with Disabilities Act, the Rehabilitation Act, the Patient Protection and
  Affordable Care Act, the Plain Language Act, and other applicable disability rights laws for
  accessibility. This includes accessible print material, close captioning and interpretation on
  videos.
- KDHE will work closely with partner agencies, representatives of local communities with critical populations, to provide regular updates and seek input.
- KDHE will communicate transparently about COVID-19 vaccine risks and recommendations, immunization recommendations, public health recommendations and prevention measures.
   This will be in line with CDC recommendations and messaging.

## Commitment to Equity Messaging

Public health messages and products will be tailored for each audience and developed with consideration for health equity. We will use plain language that is easily understood and present information in culturally responsive language. KDHE will work with partner organizations to ensure that all people are addressed inclusively, with respect, using non-stigmatizing, bias-free language and that the materials are not misleading or confusing.

#### Crisis and Risk Communication

Crisis and emergency risk communication (CERC) is the application of evidence-based principles to effectively communicate during emergencies and is interwoven into KDHE's communications plan. These principles are used by public health professionals and public information officers to provide information that helps people, stakeholders and entire communities make the best possible decisions for themselves and their loved ones.

CERC principles include:

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

KDHE recognizes that communication messaging must exist before, during, and after COVID-19 vaccine is available to help communities understand the importance of vaccination as well as the benefits and risks. Communicating what is currently known, regularly updating this information, and continuing dialogue with media and other partners throughout the vaccine distribution and administration process is essential to establish and maintain trust and credibility.

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

As COVID-19 vaccine becomes available, it is unknown whether the vaccine(s) will be authorized for use under an Emergency Use Authorization (EUA) or if they will be approved as licensed vaccine(s) by the Food and Drug Administration (FDA). This will require effective and reliable communication by the Kansas Immunization Program so that COVID-19 vaccine providers understand responsibilities related to communication with vaccine recipients, documentation requirements, adverse events, etc.

The Kansas Immunization Program will include the most current information about the vaccine(s) approval process to COVID-19 vaccine providers through established communication methods such as: Special Alerts, newsletters, website updates, updates to KSWebIZ, listservs of COVID-19 providers, webinars, conference calls, etc.

## **Emergency Use Authorization Fact Sheets**

If COVID-19 vaccine(s) are granted an EUA by the FDA, COVID-19 vaccine providers will be directed to the appropriate website for EUA product-specific fact sheets for providers and fact sheets for vaccine recipients. The EUA will provide vaccine specific information on use or "conditions of authorization" such as distribution, reporting, safety, and monitoring requirements. The EUA will also indicate the specific time period for which the EUA is in effect. Additional general information on EUAs can be found on the FDA website.

### **Vaccine Information Statements**

Vaccine Information Statements (VIS) are required to be distributed to vaccine recipients prior to every dose of specific vaccines, only if the vaccine is added to the Vaccine Injury Table. Plans for developing a VIS for COVID-19 vaccine(s) are not known at this time but will be communicated as additional information becomes available. Additional information on the VIS can be found on the <u>CDC website</u>.

## Section 14: COVID-19 Vaccine Safety Monitoring

As with other vaccines, it will be imperative to monitor for any expected or unknown adverse events that occur after an individual receives the COVID-19 vaccine. This monitoring will happen using the Vaccine Adverse Event Reporting System (VAERS) and any other systems indicated by the CDC and/or FDA.

The VAERS system was developed to:

- Detect new, unusual, or rare vaccine adverse events;
- Monitor increases in known adverse events;
- Identify potential patient risk factors for particular types of adverse events;
- Assess the safety of newly licensed vaccines;
- Determine and address possible reporting clusters (e.g., suspected localized [temporally or geographically] or product-/batch-/lot-specific adverse event reporting);
- Recognize persistent safe-use problems and administration errors;
- Provide a national safety monitoring system that extends to the entire general population for response to public health emergencies, such as a large-scale pandemic influenza vaccination program.

As COVID-19 organizations complete the CDC COVID-19 Vaccination Program Provider Agreement the Medical Director and the Chief Executive Officer agree to report any adverse events following vaccination to the VAERS at 1-800-822-7967 or via the online reporting form at <a href="http://vaers.hhs.gov/contact.html/">http://vaers.hhs.gov/contact.html/</a>

Additionally, as COVID-19 providers are approved by the Kansas Immunization Program, part of the onboarding training will include instructions on reporting any adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine or any other adverse event or serious health problem following vaccination to the VAERS. Information on reporting avenues listed above will be shared, as well as the connection to VAERS reporting that is available on KSWebIZ.

As reportable adverse events are identified, or new reporting systems are required, updates will be conveyed to providers through established communication methods.

## Section 15: COVID-19 Vaccination Program Monitoring

Continuous monitoring of COVID-19 vaccination efforts will be important so that the public and providers have a good understanding of progress towards vaccinating all Kansans. The internal Kansas COVID-19 vaccine planning committee will establish processes for monitoring critical components of the program such as vaccine allocations, distribution, and uptake. Performance targets will be set and adjusted as the COVID-19 vaccination plan is implemented.

## Appendix A – Pharmacy Partnership for Long-Term Care Program for COVID-19 Vaccination

CDC is partnering with CVS and Walgreens to offer on-site COVID-19 vaccination services for residents of nursing homes and assisted living facilities once vaccination is recommended for them.

The Pharmacy Partnership for Long-term Care (LTC) Program provides end-to-end management of the COVID-19 vaccination process, including cold chain management, on-site vaccinations, and fulfillment of reporting requirements, to facilitate safe vaccination of this patient population, while reducing burden on LTC facilities and jurisdictional health departments. The services will be available in rural areas that may not have easily accessible pharmacies. LTCF staff who have not received COVID-19 vaccine can also be vaccinated as part of the program.

As part of this program, which is free of charge to facilities, the pharmacy will:

- Schedule and coordinate on-site clinic date(s) directly with each facility. Three visits over approximately two months will likely be needed to administer both doses of vaccine and vaccinate any new residents and staff.
- Order vaccines and associated supplies (e.g., syringes, needles, personal protective equipment).
- Ensure cold chain management for vaccine.
- Provide on-site administration of vaccine.
- Report required vaccination data (approximately 20 data fields) to the local, state/territorial, and federal jurisdictions within 72 hours of administering each dose.
- Adhere to all applicable Centers for Medicare & Medicaid (CMS) COVID-19 testing requirements for LTCF staff.

If interested in participating, LTCFs should sign up (or opt out) starting October 19. Sign up will remain open for two weeks.

- Skilled nursing facilities (SNFs) will make their selection through the <u>National Healthcare</u> <u>Safety Network</u> (NHSN). An "alert" will be incorporated into the NHSN LTCF COVID-19 module to guide users to the form.
- Assisted living facilities (ALFs) will make their selection via an online <u>REDcap</u> (https://redcap.link/ltcf)sign-up form.
- Facilities will indicate which pharmacy partner (one of two large retail pharmacies or existing LTC pharmacy) they prefer to have on site.
- Online sign-up information will be distributed through ALF and SNF partner communication channels (email, social media, web).
- Indicating interest in participating is non-binding and facilities may change their selection or opt in or out via email after the online survey closes.

Once the sign-up period has closed, no changes can be made via the online form, and the facility must coordinate directly with the selected pharmacy provider to change any requested vaccination supplies and services.

CDC will communicate preferences to CVS and Walgreens and will try to honor facility preferences but may reassign facilities depending on vaccine availability and distribution considerations and to minimize vaccine wastage.

CDC expects the program services to continue on site at participating facilities for approximately two months. After the initial phase of vaccinations, each facility can choose to continue working with CVS or Walgreens or can work with a pharmacy provider of its choice.

For questions about the Pharmacy Partnership for Long-term Care Program, please contact eocevent494@cdc.gov.

## Appendix B – Pharmacy Partnership for Long-Term Care Program for COVID-19 Vaccination Frequently Asked Questions (FAQs)

## Frequently Asked Questions (FAQs)

## 1. Can our facility obtain COVID-19 vaccine through our usual pharmacy and administer it ourselves like we do for influenza vaccine?

Yes, however, most of the COVID-19 vaccines currently in late-stage testing have stricter cold chain requirements than seasonal influenza vaccine, including requirements for some vaccines to be frozen. Additionally, each vaccine has different mixing requirements for administration and minimal interval requirements for a second dose, if indicated. Reporting requirements for COVID-19 vaccines will also be stricter than those for seasonal influenza vaccine. Anyone who administers COVID-19 vaccine is required to enroll as a vaccination provider and report individual-level administration data to the appropriate state, territorial, local, or federal jurisdiction once the vaccine has been administered. For facilities opting into the pharmacy partnership program, the pharmacy partner would be responsible for procuring vaccine, cold chain management, administration to residents (and staff who have not yet been vaccinated), and fulfillment of all reporting requirements to public health authorities on behalf of the facility.

## 2. How do I sign up for the Pharmacy Partnership for Long-Term Care Program for COVID-19 Vaccination?

Nursing homes can sign up via the National Healthcare Safety Network (NHSN; <a href="https://www.cdc.gov/nhsn/index.html">https://www.cdc.gov/nhsn/index.html</a>) and assisted living facilities can sign up via an online survey (https://redcap.link/LTCF) starting October 19 and remaining open for two weeks.

## 3. Why are facilities being asked to consider the LTC pharmacy partnership program for vaccination of LTCF residents?

CDC is partnering with pharmacies to offer on-site COVID-19 vaccination services for nursing homes and assisted living facilities. The Pharmacy Partnership for Long-term Care (LTC) Program provides end-to-end management of the COVID-19 vaccination process, including cold chain management, on-site vaccinations, and fulfillment of reporting requirements, to facilitate safe vaccination of this patient population, while reducing burden on facilities and jurisdictional health departments.

### 4. Can staff at my facility get vaccinated via this program?

It is possible that staff will be eligible to receive COVID-19 vaccine earlier than LTCF residents as part of a recommendation for vaccination for healthcare personnel, including those in LTCFs. Any staff member who was not already vaccinated could be vaccinated through these on-site clinics; however, we strongly encourage staff to be vaccinated as soon as they are eligible, which may occur through mobile clinics and clinics run by health departments for healthcare personnel.

## 5. Our facility has their own pharmacy, are we required to participate in the LTC pharmacy partnership program for vaccine distribution?

No, you are not required to participate in this program. A facility can opt to have vaccine supply and management services coordinated by a pharmacy provider of their choice or opt in at a later time by emailing <a href="mailto:eocevent494@cdc.gov">eocevent494@cdc.gov</a> to sign up if after the online form has closed. If an LTCF opts out of the pharmacy partnership program, the LTCF and the pharmacy provider of their choice are responsible for coordination of and adherence to <a href="mailto:all">all</a> vaccine supply chain, storage, handling, administration, and reporting requirements, including strict cold chain and public health reporting requirements.

 Can a combination of options be selected? For example, can we have some vaccination services be provided by our own pharmacy provider and some by the pharmacy partnership program.

Initially, a combination of options will not be possible. We are asking facilities to select a single option to facilitate efficient distribution of vaccine. We expect the pharmacy partnership services to continue on-site at the facility for approximately 2 months.

#### 7. How would new LTCF residents be vaccinated?

After the initial phase of vaccinations, the facility can choose to continue to work with the pharmacy that provided their initial on-site clinics for additional doses or can choose to work with a pharmacy provider of their choice. Depending on vaccine supply, facilities may want to work with local hospitals to ensure residents have received their first dose before being discharged.

Similarly, facilities may ask new admissions from the community to get vaccinated before admission.

## 8. What costs are we responsible for if we choose to participate in the pharmacy partnership program?

There will be no costs to the LTCF for participation in the pharmacy partnership program. It is anticipated that participating pharmacies will bill public and private insurance for the vaccine administration fees.

9. If the facility chooses its own pharmacy provider, will that pharmacy provider receive a payment for administering the vaccine?

Yes, it is anticipated that pharmacy providers will bill public and private insurance for the vaccine administration fees.

## 10. If the facility chooses its own pharmacy provider, what data will the facility or pharmacy have to report?

To administer COVID-19 vaccine, providers will need to sign a provider agreement, which requires reporting of specific data elements once vaccine has been administered. Required elements are: Administered at location: facility name/ID; administered at location: type;

administration address (including county); administration date; CVX (Product); dose number; recipient ID\*; vaccination event ID; lot Number: Unit of Use and/or Unit of Sale; MVX (Manufacturer); recipient address\*; recipient date of birth\*; recipient name\*; recipient sex; sending organization; vaccine administering provider suffix; vaccine administering site (on the body); vaccine expiration date; vaccine route of administration; vaccination series complete.

### 11. When is the deadline for choosing to participate in the LTC pharmacy partnership program?

It is anticipated that the survey will open on October 19, 2020 and remain open for two weeks. During that time, the facility can make a change to their choice of pharmacy provider (e.g., select to participate in the pharmacy partnership program, but later opt out).

However, after the form closes, no changes can be made via the National Healthcare Safety Network (NHSN) or the online from and the facility will have to coordinate directly with the pharmacy provider selected to make any changes regarding vaccination supply and services.

## 12. Our facility is not enrolled in NHSN. Do we have to enroll in NHSN to indicate our options for vaccine supply?

A nursing home or skilled nursing facility must be enrolled in the NHSN LTCF COVID-19 module to be able to make a selection of COVID-19 vaccine pharmacy providers. Please follow the enrollment steps here: <a href="https://www.cdc.gov/nhsn/ltc/covid19/enroll.html">https://www.cdc.gov/nhsn/ltc/covid19/enroll.html</a>. Assisted living facilities wishing to participate should visit <a href="https://redcap.link/LTCF">https://redcap.link/LTCF</a>.

### 13. Who do we contact if we have problems with our vaccine supply?

For facilities that opt to participate in the pharmacy partnership program, please contact CVS or Walgreens directly if you encounter any issues. For facilities that opt out of the pharmacy partnership program, please contact the pharmacy provider of your choice or your jurisdiction's health department.

## 14. Is Centers for Medicare and Medicaid Services (CMS) mandating residents to be vaccinated with COVID-19 vaccine?

Not at this time. Please refer to CMS directly for requirements around COVID-19 vaccine in LTCFs.

#### 15. Who should I reach out to if I have additional guestions?

For questions specific to the pharmacy partnership program for LTCFs, please contact <a href="mailto:eocevent494@cdc.gov">eocevent494@cdc.gov</a>.