# Memorandum of Agreement between The Oklahoma State Department of Health And *The Pandemic Vaccine Provider* for Planning and Responding to a Pandemic

This Memorandum of Agreement (MOA) sets forth the terms of an understanding between the Oklahoma State Department of Health (OSDH) and the Pandemic Vaccine Provider (hereinafter, "the provider") for the purposes of coordinating vaccine distribution during a public health emergency.

#### Introduction & Purpose

Coordination between public health programs and private providers in pandemic planning and response is essential to expanding public access to pandemic vaccination during the next pandemic. Improved coordination ultimately saves lives by leveraging the strengths of all partners, including existing vaccine management, distribution, and administration infrastructures, resulting in earlier and more broadly available pandemic vaccination. Improved coordination prior to and during a pandemic also helps ensure consistent management and equity among pandemic vaccinators and improves relationships, not only for other public health emergencies, but also for routine public health delivery.

The purpose of this MOA is to utilize the existing infrastructure of public and private health programs to assist in rapidly providing pandemic vaccinations to the general public during a pandemic. This MOA outlines roles and responsibilities between the OSDH and the provider in planning for and responding to the next pandemic with regards to:

#### I. <u>Pandemic vaccine provider enrollment and training:</u>

#### Responsibility of the provider:

By signing this MOA, the provider and the OSDH acknowledge their understanding that the provider is responsible for storing, administering, and documenting the pandemic vaccine when notified to do so by the OSDH, per established medical protocols or algorithms, in accordance with the directives provided by the OSDH and is expected to sign a Pandemic Vaccine Provider Agreement Form, if and when available and required by the Centers for Disease Control and Prevention (CDC). The provider and other vaccinating personnel employed or contracted by the provider are required to register and enroll as individual pandemic vaccine providers with the OSDH. By signing this MOA, the provider pre-registers and enrolls with OSDH all vaccinating personnel of the provider as pandemic vaccine providers. In exchange, the provider will ensure all vaccinating personnel employed or contracted by the provider as pandemic vaccine providers.

- a) Are appropriately licensed or otherwise properly authorized to administer or dispense pandemic vaccines and pandemic vaccine constituent products;
- b) Follow guidance on vaccine prioritization and recommendations of CDC's Advisory Committee on Immunization Practices, as adopted by the CDC;
- c) Properly handle and store the vaccine as directed by the State, Food and Drug Administration (FDA)-approved regulatory requirements and any CDC guidance on storage, handling, and temperature control;
- d) Use the Oklahoma State Immunization Information System (OSIIS), where applicable or available, to document doses administered and assess timing and type of prior pandemic vaccination, if multiple doses are required;
- e) Follow all manufacturer and CDC guidance in the administration of pandemic vaccine.
- f) Exercise all other necessary skills required by the OSDH for patients to safely receive the appropriate pandemic vaccinations.

Responsibility of the OSDH:

The OSDH will provide technical assistance, material, information, and resources, as available, to assist the provider in providing the appropriate training and certifications, as required by the OSDH, for all vaccinating personnel employed or contracted by the provider in the skills listed above prior to (when feasible) and/or in the event of a pandemic.

#### II. <u>Pandemic vaccine allocation:</u>

In general, OSDH will manage all individual provider orders and make allocations to individual providers (if vaccine is consistently available). For the purposes of ordering and allocating pandemic vaccine in this MOA, the provider will be considered a single "end-user" in the OSDH overall vaccine orders to CDC. Under the assumption that during a pandemic the federal government will purchase and procure all pandemic vaccine and the OSDH will receive a pro-rata allocation of pandemic vaccine from the federal supply (if vaccine is consistently available), the general understanding is that allocation of pandemic vaccine to the provider will be based on a number of factors. To ensure equity across providers, the amount of pandemic vaccine allocated to the provider may be based on:

a) The provider shall provide the OSDH with an estimate of the number of pandemic vaccines: 1) that it is capable of storing; and 2) that staff can administer per week or day, including the minimum, maximum, and typical numbers of vaccines which can be administered.

## III. <u>Pandemic Vaccine distribution to the provider:</u>

It is assumed that during a pandemic, the federal government will directly contract with vaccine manufacturers to develop and provide all pandemic vaccine allocations to the OSDH. The OSDH is responsible for receiving, managing and distributing vaccine orders and allocation within the OSDH's jurisdictions.

Responsibility of the provider:

a) Pandemic vaccines allocated to the provider by the State of Oklahoma may not be distributed outside of Oklahoma's jurisdiction, unless authorized by the State of Oklahoma and allowable by the federal government.

## IV. <u>Tracking of vaccine administration utilizing the Oklahoma State Immunization Information</u> <u>System (OSIIS):</u>

# Responsibility of the provider:

a) Vaccine Administration:

During a pandemic, it is possible that persons of all ages will need multiple doses of pandemic vaccine separated by recommended time intervals in order to acquire an appropriate level of immune response to be protected from pandemic virus infection. Also, many patients will likely receive their first and second pandemic vaccine dose from different providers at different locations. These complexities will make the need for complete and accurate vaccine administration documentation extremely important for patient safety, so that all pandemic vaccine providers are able to access this documentation to correctly determine the need for vaccination.

b) <u>Submitting Doses Administered Data to OSIIS:</u>

The provider will submit data in a timely manner on pandemic vaccine administered by vaccinating personnel employed or contracted by the provider to OSIIS. This will allow a provider to assess a patient's prior vaccination status with the current pandemic vaccine. This will also allow the OSDH to account for use of publicly funded pandemic vaccine.

# V. Pandemic Vaccine Provider Agreement

- 1. Administer the pandemic vaccine according to the recommendations of CDC's Advisory Committee on Immunization Practices as adopted by the Centers for Disease Control and Prevention.
- 2. Store and handle the vaccine in accordance with the package insert provided with the vaccine including in compliance with cold chain requirements.
- 3. Provide a current Vaccine Information Statement (VIS) to each individual before vaccination, and answer questions about the benefits and risks of vaccination, including different indications for live versus inactivated vaccines.
- 4. Record in the patient's medical record or in an office log the date of administration, the site of administration, the vaccine type and lot number, and the name of the immunizations provider for each individual vaccinated. The record must be kept for a minimum of three years following vaccination.
- 5. Report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967, <u>http://vaers.hhs.gov/contact.htm</u>.

In addition, the provider:

- 6. Cannot charge patients, health insurance plans, or other third party payers for the vaccine, the syringes or the needles. The provider is also prohibited from selling the pandemic vaccine, syringes or needles.
- 7. May not charge a vaccine administration fee to non-Medicaid federal vaccine eligible children that exceed the administration fee cap of \$19.58 per vaccine dose. For Medicaid children, the provider will accept the reimbursement for immunization administration set by the State Medicaid agency or the contracted Medicaid health plans.
- 8. May either administer the pandemic vaccine at no charge to individuals who cannot afford the administration fee, or refer these individuals to a public health department clinic or affiliated public health provider for vaccination.
- 9. Must report the number of doses of pandemic vaccine administered to individuals as requested by the state or local public health department utilizing the Oklahoma State Immunization Information System (OSIIS).
- 10. Must report to the state health department the number of doses of vaccine that were not able to be used because the vaccine expiration date was exceeded or the vaccine was wasted for other reasons utilizing the Oklahoma State Immunization Information System (OSIIS). These doses must be adjusted out of inventory and disposed of in accordance with state regulations.
- 11. Is strongly encouraged to provide a record of vaccination to the vaccine recipient or parent/guardian, to serve as an information source if a Vaccine Adverse Event Reporting System report is needed, and to serve as a reminder of the need for a second dose of vaccine (if necessary).

# Term and Termination

This MOA shall become effective immediately upon its execution by all required signatories. This MOA shall remain in effect between the provider and the OSDH for one (1) year or until participation in this MOA is terminated by either the OSDH or the provider pursuant to written notification delivered to the other no less than thirty (30) calendar days in advance of the termination date.

# General Responsibility of the OSDH and the provider:

Signing this MOA establishes an understanding between both the OSDH and the provider. The construction, validity, performance and effect of this MOA will be governed by the laws of the State of Oklahoma. The OSDH and the provider acknowledge this MOA is only a statement of intended mutual and voluntary cooperation and is not intended to be a legally binding contractual agreement. Providers/Facilities interested in providing pandemic vaccination must also comply with all federal and state requirements, and are expected to sign a Pandemic

Vaccine Provider Agreement Form, when available and if required by Federal Centers for Disease Control and Prevention (CDC), or the Department of Health and Human Services (DHS).

Each party to this MOA shall be responsible for its own acts and omissions and those of its officers, employees and agents. No party to this MOA shall be responsible for the acts or omissions of entities not a party to this MOA. Neither party to this MOA agrees to release, hold harmless or indemnify the other party from liability that may arise from or relate to this MOA. The OSDH does not have the authority to and shall not indemnify any entity. The OSDH agrees to pay for any loss, liability or expense, which arises out of or relates to the OSDH's acts or omissions with respect to its obligations hereunder, where a final determination of liability on the part of the OSDH is established by a court of law or where settlement has been agreed to by the OSDH. This provision shall not be construed to limit the OSDH's rights, claims or defenses that arise as a matter of law or pursuant to any other provision of this MOA. No provision in this MOA shall be construed to limit the sovereign immunity of the OSDH.

Section 319F-3 of the Public Health Service Act (42 U.S.C. 247d-6d), as enacted by the Public Readiness and Emergency Preparedness Act (PREP Act) (Pub. L. No. 109-148), if enacted at the time of the pandemic, may provide additional liability protections for actions carried out under this MOA. Additional information on the PREP Act, including the declarations issued by the Secretary of HHS invoking the Act's protections, may be found at: <u>http://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx</u>.

## SIGNATURES:

My signature and receipt of the pandemic vaccine indicates agreement with the above stated understandings and conditions:

Provider Representative - Signature

Title

Provider Representative Print

Commissioner of Health Signature

Date

Date

Commissioner of Health Printed Name