

Memorandum of Understanding
between
[INSERT GOVERNMENT AGENCY NAME] (“STATE”)
and
[INSERT PHARMACY NAME] (“PHARMACY”)
for the
Coordination of A Pandemic Influenza Vaccination Campaign in Planning for
and Responding to An Influenza Pandemic

This Memorandum of Understanding ("MOU") sets forth the terms of an understanding between [INSERT STATE GOVERNMENT NAME] ("STATE") and [INSERT PHARMACY NAME] ("Pharmacy") for the purposes of coordinating influenza vaccine distribution during a pandemic.

I. Introduction & Purpose

Coordination between public sector public health programs and private sector pharmacies in pandemic influenza planning and response is essential to expanding public access to influenza pandemic vaccination during the next influenza 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.

More general all-hazard public health emergency response agreements between public sector public health programs and pharmacies may be in place, but preparing for a pandemic influenza vaccination campaign may be different from other public health emergency responses. For example, influenza pandemics are not localized public health emergencies, but are rather, by definition, wide scale, multi-national outbreaks requiring a large scale response. Influenza pandemics affect all groups and ages; thus, the public health response must be broad and often must be sustained for many months to be effective. Since influenza epidemics occur annually during the winter months in the U.S., there are existing systems used for routine delivery of seasonal influenza vaccines, which can be leveraged during an influenza pandemic response. Furthermore, unlike other countermeasures, during an influenza pandemic, it is possible that multiple vaccine doses may be recommended, multiple vaccine products may be available, and adjuvant may need to be matched and mixed with vaccine antigen products at the point of administration to patients. These differences point to the need for more specific agreements regarding the logistics of pandemic influenza vaccine campaign planning and response among public health programs and pharmacies in each state.

The purpose of this MOU is to utilize the existing infrastructure of Pharmacy to assist in rapidly providing pandemic influenza vaccinations to the general public during an influenza pandemic. This MOU outlines roles and responsibilities between STATE and Pharmacy in planning for and responding to the next influenza pandemic with regards to:

- Pandemic vaccine provider enrollment and training
- Pandemic vaccine allocation
- Pandemic vaccine distribution
- Tracking of vaccine distribution and administration including use of immunization information systems (IIS)
- Communications

II. **General Responsibility of STATE and Pharmacy:**

Signing this MOU establishes the understanding that both STATE and Pharmacy agree that the planning for pandemic vaccination through Pharmacy will be done jointly and will occur before a pandemic is declared and immediate assistance in pandemic vaccination is requested. The construction, validity, performance and effect of this MOU will be governed by the laws of [INSERT STATE]. The STATE and Pharmacy acknowledge this MOU is only a statement of intended mutual and voluntary cooperation and is not intended to be a legally binding contractual agreement. Pharmacies 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 CDC.

Each party to this MOU shall be responsible for its own acts and omissions and those of its officers, employees and agents. No party to this MOU shall be responsible for the acts or omissions of entities not a party to this MOU. Neither party to this MOU agrees to release, hold harmless or indemnify the other party from liability that may arise from or relate to this MOU.

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 influenza pandemic, may provide additional liability protections for actions carried out under this MOU. Additional information on the PREP Act, including the declarations issued by the Secretary of HHS invoking the Act's protections, may be found at:

<http://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx>.

III. **Definitions**

- Authorized representative: Person or persons authorized by STATE to request or Pharmacy to agree to provide assistance in distributing and administering pandemic vaccine and to serve as chief point of contact for other communications, unless otherwise agreed upon.
- Influenza pandemic: Sustained human to human transmission of a novel influenza A virus and infection across multiple countries and continents.

- Immunization information systems (IIS): Confidential, population-based, computerized databases that record all immunization doses administered by participating providers to persons residing within a given geopolitical area.
- Pandemic vaccine: Vaccine product, as defined by United States Government, used to provide either immune priming for or direct protection from infection from a novel and/or pandemic influenza virus, as prophylaxis. For the purposes of this MOU, 'vaccine' shall refer to both vaccine antigen and vaccine adjuvant, if needed, and includes adjuvant and pandemic vaccine constituent products, excluding sharps containers.
- Pandemic vaccine constituent products: Vaccine syringe, needle, vials, shot cards, and all other ancillary supplies utilized for vaccine administration of pandemic vaccine.
- Pandemic vaccine provider "end-user": Any pandemic vaccine provider site designated by CDC and/or state and local immunization programs through CDC to receive pandemic vaccine and constituent products from the CDC contracted distributor during the pandemic response.

IV. Assumptions for this MOU

The following conditions for the general purposes of pandemic influenza vaccine management are assumed in this MOU. If these assumptions regarding pandemic vaccine management are different during an influenza pandemic, this MOU may need to be amended to reflect these changes.

- Federal government will directly contract with vaccine manufacturers to develop, fill, and finish all pandemic vaccine and with other entities for ancillary products.
- STATE will manage all individual vaccine provider "end-user" orders and make allocations to individual "end-user" providers on a weekly basis at a minimum (if vaccine is consistently available).
- Pandemic Vaccine Provider Agreement Form will be developed and required to be signed by healthcare providers who wish to receive and administer pandemic vaccine products as "end-user".
- CDC's Advisory Committee on Immunization Practices, as adopted by the Centers for Disease Control and Prevention, will developed recommendation on use of pandemic influenza vaccine products.
- CDC may use an option in the Vaccines For Children (VFC) program's vaccine distribution contract to distribute pandemic influenza vaccine products to "end-users."
- Persons of all ages may need multiple doses of pandemic vaccine separated by recommended time intervals in order to mount an appropriate level of immune response to be protected from pandemic virus infection.
- Use of vaccine adjuvant may be required in each pandemic vaccine dose, with the need to be mixed at the point of administration to patient.
- Furthermore, it may be possible that only certain types or brands of adjuvant will be approved for use with certain types or brands of pandemic vaccine antigen.

V. Participation

The Pharmacy has a desire to assist the STATE in planning for, distributing, and administering pandemic vaccines to the general public during an influenza pandemic. The STATE and Pharmacy

agree that any and all actions taken pursuant to this MOU shall be voluntary and at each participant's sole discretion.

VI. How to Invoke Assistance

The STATE's authorized representative may request assistance of Pharmacy in distributing and administering pandemic vaccine by contacting the authorized representative of Pharmacy. The provisions of this MOU only apply to requests for assistance made by and to such designee(s). Requests may be oral or written. If oral, the request shall be confirmed in writing as soon as possible.

VII. Pharmacist Provider Enrollment & Training

Responsibility of Pharmacy: By signing this MOU, the Pharmacy and the STATE acknowledge their understanding that Pharmacy is responsible for dispensing, delivering, and administering the influenza vaccine, when notified to do so by the STATE, per established medical protocols or algorithms, in accordance with the directives provided by the State and is expected to sign a Pandemic Vaccine Provider Agreement Form, if and when available and required by CDC. Pharmacists and other vaccinating personnel employed or contracted by Pharmacy are not required to register and enroll as individual pandemic influenza vaccine providers with STATE. By signing this MOU, Pharmacy pre-registers and enrolls with STATE all pharmacists and other vaccinating personnel of Pharmacy as pandemic vaccine providers. In exchange, Pharmacy will ensure all pharmacists and other vaccinating personnel employed or contracted by Pharmacy:

- Are appropriately licensed (INSERT STATE code) or otherwise properly authorized to administer or dispense pandemic vaccines and pandemic vaccine constituent products;
- Follow guidance on vaccine prioritization and recommendations of CDC's Advisory Committee on Immunization Practices, as adopted by the Centers for Disease Control and Prevention;
- Properly handle and store the influenza vaccine as directed by the state, Food and Drug Administration (FDA)-approved regulatory requirements and any CDC guidance on storage, handling, and temperature control;
- Use STATE'S immunization information system (IIS), where applicable or available, to document doses administered and assess timing and type of prior pandemic vaccination, if multiple doses are required;
- Mix vaccine antigen and adjuvant at the point of vaccine administration (if needed), and match the vaccine antigen and adjuvant type between vaccine dose one and vaccine dose two (if required); and
- Exercise all other necessary skills required by STATE for patients to safely receive the proper and effective pandemic influenza vaccinations.

Responsibility of State: STATE will provide technical assistance, material, information, and resources, as available, to assist Pharmacy in providing the appropriate training and certifications, as required by STATE, for all pharmacists and other vaccinating personnel employed or contracted by Pharmacy in the skills listed above prior to (when feasible) and/or in the event of an influenza pandemic.

VIII. Pandemic Vaccine Product Allocation

In general, STATE will manage all individual provider orders and make allocations to individual providers on a weekly basis at a minimum (if vaccine is consistently available). For the purposes of ordering and allocating pandemic vaccine in this MOU, Pharmacy company will be considered a single “end-user” in STATE’s overall vaccine orders to CDC.

a. Weekly Allocation to Pharmacy by the State

Under the assumption that during an influenza pandemic the Federal government will purchase and procure all pandemic vaccine and STATE will receive a weekly 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 Pharmacy and its individual sites will be based on a number of factors. To ensure equity across providers, the amount of pandemic vaccine allocated to Pharmacy during the first few weeks of vaccination may be based on:

- Epidemiology of the influenza pandemic;
- Pharmacy capacity, as reported by Pharmacy;
 - Pharmacy shall provide STATE with an estimate of the number of pandemic vaccines: 1) that it stores; and 2) that staff can administer per week or day, including the minimum, maximum, and typical numbers of vaccines which can be administered
- Availability of pandemic vaccine, as allocated to STATE;
- Location of Pharmacy sites and need for geographic distribution of public access pandemic vaccination points, as determined by the STATE;
- Capacity of other pandemic vaccine providers and entities to administer pandemic vaccines;
- Potential need to vary pandemic vaccine provider allocations based on vaccine prioritization guidelines for special populations; and
- Any other method of allocation as the STATE in its discretion deems most appropriate to best serve public health, in accordance with any Federal guidelines.

(Note: STATE and Pharmacy should try to negotiate initial allocation amounts in advance, as much as possible. Additional factors which may be considered include existing seasonal influenza vaccine market share and patient population served in jurisdiction, demonstrated pandemic vaccine administration surge capacity, level of seasonal vaccination which occurs in pharmacy during recent influenza seasons based on the Behavioral Risk Factors Surveillance System (BRFSS) or other sources, etc.)

b. Allocations to Pharmacy Stores/ Sites

Responsibility of Pharmacy:

Pharmacy, their contracted vaccine distributor, or designee will be responsible for allocating pandemic vaccine to individual stores/ sites within STATE’s jurisdiction from Pharmacy’s weekly allocation of STATE’s supply of pandemic vaccine. Pharmacy’s authorized representative will work in collaboration with STATE in planning for vaccine allocation to stores based on factors listed above in section VIII.a.

Responsibility of STATE:

By signing this MOU, STATE acknowledges that it intends to share information with Pharmacy authorized representative as needed and authorized under state and federal law, which may include relevant epidemiologic information and information on underserved populations and geographic areas, in order to work in collaboration with the Pharmacy in making decisions about allocations to individual stores/ sites or regions of the STATE.

IX. Pandemic Vaccine Product Secondary Distribution to Pharmacy Sites or Stores

a. Responsibility of Pharmacy:

Once the VFC distributor distributes the pandemic vaccine to the Pharmacy's or its distributor's depot, the Pharmacy and its designees, which may include the Pharmacy's existing distributor and/or vaccine wholesalers, are responsible for final distribution of pandemic vaccine to Pharmacy's individual sites and/or stores. Pandemic vaccines allocated to Pharmacy by STATE may not be distributed outside of STATE's jurisdiction, unless authorized by STATE and allowable by federal government. Pharmacy shall disclose to STATE the location of its designated distribution depot(s) for STATE's jurisdiction. The Pharmacy warrants that its distribution network information is proprietary to the Pharmacy and not made publicly available.

X. Tracking of Pandemic Vaccine Distribution and Administration

a. Vaccine Distribution Data

Under the assumptions that during an influenza pandemic the Federal government directly contracts with vaccine manufacturers to develop, fill, and finish all pandemic vaccine and that the STATE is responsible for receiving and managing vaccine orders and allocation within the STATE, the Pharmacy, through its authorized representative, will share data with STATE on pandemic vaccine distributed, including type of antigen and adjuvant distributed and on hand in inventory by each Pharmacy store address (street, city, state, zip code). The Pharmacy's data on pandemic vaccine distributed will be shared with STATE through electronic spreadsheet via email to STATE's authorized representative at least weekly or as determined by STATE law/policies for the duration of time requested by STATE.

b. Vaccine Administration:

During an influenza pandemic, it is possible that persons of all ages will need multiple doses of pandemic vaccine separated by recommended time intervals in order to mount an appropriate level of immune response to be protected from pandemic virus infection. It may also be possible that adjuvant would be required in each pandemic vaccine dose, with the need to be mixed at the point of administration to patient. Furthermore, it may be possible that only certain types or brands of adjuvant will be approved for use with certain types or brands of pandemic vaccine antigen. 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 assess and therefore correctly match pandemic vaccines and adjuvants between doses in each patient.

- i. **Assessing Pandemic Vaccination Dose Status at the Point of Vaccine Administration:**
Responsibility of Pharmacy: Pharmacy will ensure that all pharmacists, other vaccinating personnel, and designated personnel employed or contracted by Pharmacy have the resources, training, and equipment to assess the timing and type of prior pandemic vaccine and adjuvant, administered (if multiple vaccine doses are required) for each person presenting to a Pharmacy site or stores for pandemic vaccination. Assessment of prior pandemic vaccination by Pharmacy personnel should preferentially be made through the STATE or jurisdiction's IIS at the point of administration and then by other means, such as through a patient's individual shot card.
- ii. **Submitting Doses Administered Data to STATE IIS:**
Responsibility of Pharmacy: Pharmacy will submit data on pandemic vaccine administered by pharmacists and other vaccinating personnel employed or contracted by Pharmacy to jurisdiction's IIS, where available. This will allow a provider to assess a patient's prior vaccination status with the current pandemic vaccine. This will also allow the STATE to account for use of publicly funded pandemic vaccine.

For both the vaccine antigen and the adjuvant (if required), Pharmacy must ensure administration data is recorded in the patient's STATE's IIS or in a permanent office log, if IIS submission is not feasible. The record needs to include the patient's name, the date of administration, the site of administration, the vaccine and adjuvant manufacturer, the type and lot number of the vaccine and adjuvant dose, and the name and address of the immunization provider for each individual vaccinated. The record must be kept for a minimum of three years following vaccination (or longer if specified by state law). Medical records must be made available as requested by the state or local health department to the extent authorized by law. Further, data submitted to IIS must additionally include all core elements as required for IIS submission for seasonal influenza vaccine administration as designated by STATE and/or the Association of Immunization Registries of America's (AIRA) core elements (<http://www.cdc.gov/vaccines/programs/iis/core-data-elements.html>). All data submission will comply with the Health Insurance Portability and Accountability Act (HIPAA), as applicable, and any applicable STATE law.

It is expected that Pharmacy will submit all data on pandemic vaccine administered during the prior week by Pharmacy to STATE's IIS by 8:00 AM each Monday. Consistency in requirements across jurisdictions within the STATE shall be facilitated by the STATE.

XI. Vaccine Cost and Payment

Under the assumptions that during an influenza pandemic the Federal government directly contracts with vaccine manufacturers to develop, fill, and finish all pandemic vaccine and with other entities for ancillary products, Pharmacy is prohibited from charging patients, health insurance

plans, or other third-party payers for the cost of the vaccine or ancillary supplies provided at no cost to the Pharmacy by the Federal government. Pharmacy is also prohibited from selling the vaccine and ancillary supplies to other third parties.

Responsibility of Pharmacy: Pharmacy will be expected to follow STATE/Federal guidelines for all providers in retrieving, administering and/or disposing of pandemic vaccine. Pharmacy may charge a fee for the administration of the vaccine to the patient, their health insurance plan, or other third-party payer. The administration fee cannot exceed the regional Medicare vaccination administration fee. If the administration fee is billed to Medicaid, the amount billed cannot exceed the STATE Medicaid administration fee, if one exists.

Responsibility of Pharmacy: Pharmacy is strongly encouraged to administer pandemic vaccines to all customers seeking vaccine in their stores. If the [Emergency Prescription Assistance Program \(EPAP\)](#) is enacted by the Federal government for use during an influenza pandemic, and pandemic influenza vaccine administration is included in that enactment, Pharmacy may utilize the EPAP mechanism, if allowable under Federal law, to obtain vaccine administration fees for vaccine administered to these persons (see reference for EPAP). Pharmacy acknowledges that it has enrolled with EPAP prior to signing this MOU.

Neither the STATE nor Pharmacy will charge the other any fee, or be reimbursed for any costs, associated with or related to the performance under this MOU, except as specifically set forth in this MOU.

XII. Communications and Additional Activities

Responsibility of STATE:

- Provide planning and technical assistance to Pharmacy, including but not limited to, use of IIS, fact sheets, electronic newsletters and alerts, CDC guidance, and other requirements, especially if multiple pandemic vaccines doses and adjuvants are required.
- Provide statewide consistent medical screening forms to Pharmacy as guidance in implementing pandemic vaccine administration.
- Provide Pharmacy with releasable information regarding the pandemic influenza emergency and response.
- Provide timely updates to Pharmacy regarding vaccine allocations and changes in guidance on pandemic vaccine prioritization.
- Manage public information activities with regard to the overall health and medical response across STATE and publicly acknowledge Pharmacy as a source for pandemic vaccination.
- Provide educational materials, if appropriate, to Pharmacy for the purposes of distributing to all persons during the influenza pandemic, including but not limited to Vaccine Information Statement (VIS), if available, or Emergency Use Authorization (EUA) patient documents, if applicable.
- Coordinate with STATE Pharmacy Association and/or Board of Pharmacy in advance of a pandemic to include a representative in the STATE's Incident Command Structure and

Emergency Operation Team or other such designated team for the influenza pandemic response.

- Coordinate with Pharmacy to retrieve and/or dispose of any unused pandemic vaccine from Pharmacy facilities according to STATE/Federal guidelines.
- If available and possible, coordinate with Pharmacy on security personnel to protect pandemic vaccine supply and assist in vaccination process in Pharmacy sites.

Responsibilities of Pharmacy:

- In the absence of an Emergency Use Authorization issued by FDA, Emergency Use Instructions issued by CDC, other Federal action, or *[INSERT: STATE emergency dispensing/ vaccination policy/ statute/declaration]* waiving or altering vaccination use, age restriction, or other requirements for pharmacists, Pharmacy will ensure that all of its pharmacists administer pandemic vaccines under existing influenza vaccination regulations and authority (protocol, prescription) with/from a licensed health care prescriber or lawful order issued by local or STATE health officer, as applicable in STATE. In addition, Pharmacy will ensure that all pharmacists adhere to any state and CDC-specific guidance or agreements on pandemic vaccine use and administration, which may be issued at the time of an influenza pandemic declaration.
- Pharmacy will ensure that all of its personnel licensed to vaccinate during the influenza pandemic adhere to any applicable Emergency Use Authorization or Emergency Use Instructions as well as STATE and CDC recommendations on which populations can receive pandemic vaccinations, including pregnant women.
- Coordinate with STATE to ensure statewide consistency with implementation of screening forms, educational material, billing, training, and other Pharmacy activities and requirements.
- Document vaccinations administered in State IIS or as required by the STATE (as above).
- Conduct medical screening of persons receiving pandemic vaccination, based on guidance provided by STATE, to assure consistency with Federal government guidance.
- Coordinate with STATE Pharmacy Association, so that a Pharmacy representative participates on in STATE Pharmacy Association meetings, if applicable.
- Provide education materials (e.g. VIS, EUA, or EUI, if applicable) to all persons receiving pandemic vaccination.
- Report any pandemic vaccine adverse events following vaccination to the Vaccine Adverse Event Reporting System (1-800-822-7967, <http://vaers.hhs.gov/contact.htm>)
- Secure any unused pandemic vaccine until a time when STATE can provide arrangements or directives for retrieval or disposal.
- Participate in all planning discussions and exercises with STATE, as requested.

XIII. Term and Termination

This MOU shall become effective immediately upon its execution by Pharmacy and STATE. This MOU shall remain in effect between Pharmacy and STATE until participation in this MOU is

terminated by either STATE or pharmacy pursuant to written notification delivered to the other no less than thirty (30) calendar days in advance of the termination date.

XIV. Operational Plan Review

This MOU will be reviewed at least once annually by an advisory group made up of STATE and Pharmacy representatives, as convened by STATE.

This MOU and its implementation will be formally reviewed following its use during an influenza pandemic and recommendations from an after action report will be incorporated to update and improve any operational plan.

XIV. Amendment

This MOU may be amended by written and signed mutual agreement of the STATE and Pharmacy at any time.

XV. Assignability

Neither party may assign this MOU, or any interest in this MOU, without the prior written consent of the other party.

XVI. Sole Agreement

This document specifies the entire agreement between the parties concerning the subject matter of this MOU.

XVII. Severability

If any provision of this MOU is held to be invalid, the remaining provisions of this MOU are not to be affected and will continue in effect.

XIII. Authority to Sign

By signing this MOU, each party represents that it has the legal authority to enter into this MOU.

Signatures

Authorized Representative – Contact Information