Memorandum of Agreement
between
The Pennsylvania Department of Health
and
(INSERT PHARMACY NAME)
for the
Coordination of A Pandemic Influenza Vaccination Campaign in Planning for and Responding to An Influenza Pandemic

This Memorandum of Agreement (MOA) sets forth the terms of an understanding between The Pennsylvania Department of Health (Department) and (INSERT PHARMACY NAME) (Pharmacy) for the purposes of coordinating influenza vaccine distribution during a public health emergency.

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 pandemic influenza 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 MOA 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

MOA outlines roles and responsibilities between the Department and Pharmacy in planning for and responding to the next influenza pandemic with regards to:

a. Pandemic vaccine provider enrollment and training
b. Pandemic vaccine allocation
c. Pandemic vaccine distribution
d. Tracking of vaccine distribution and administration including use of immunization information systems (IIS)
e. Communications

II. General Responsibility of the Department and Pharmacy:

Signing this MOA establishes the understanding that both the Department and Pharmacy agree that the planning for pandemic influenza 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 MOA will be governed by the laws of Pennsylvania. The Department and Pharmacy acknowledge this MOA 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 federal Centers for Disease Control and Prevention of the Department of Health and Human Services (CDC).

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 Department does not have the authority to and shall not indemnify any entity. The Department agrees to pay for any loss, liability or expense, which arises out of or relates to the Department's acts or omissions with respect to its obligations hereunder, where a final determination of liability on the part of the Department is established by a court of law or where settlement has been agreed to by the Department. This provision shall not be construed to limit the Department'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 Department.

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

III. Definitions

a. Authorized representative: Person or persons authorized by the Department 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.

b. Influenza pandemic: Sustained human to human transmission of a novel A virus and infection across multiple countries and continents.
c. 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.
d. 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 MOA, 'vaccine' shall refer to both vaccine antigen and vaccine adjuvant, if needed, and includes adjuvant and pandemic vaccine constituent products, excluding sharps containers.
e. Pandemic vaccine constituent products: Vaccine syringe, needle, vials, shot cards, and all other ancillary supplies utilized for vaccine administration of pandemic vaccine.
f. Pandemic vaccine provider "end-user": Any pandemic vaccine provider site designated by CDC or state and local immunization programs or both through CDC to receive pandemic vaccine and constituent products from the CDC contracted distributor during the pandemic response.

IV. Assumptions for this MOA

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

a. Federal government will directly contract with vaccine manufacturers to develop, fill, and finish all pandemic vaccine and with other entities for ancillary products.
b. The Department 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).
c. 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".
d. 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.
e. 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."
f. 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.
g. 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.
h. 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 Department in planning for, distributing, and administering pandemic vaccines to the general public during an influenza pandemic. The Department and Pharmacy agree that any and all actions taken pursuant to this MOA shall be voluntary and at each participant's sole discretion.

VI. How to Invoke Assistance

The Department'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 MOA 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 MOA, the Pharmacy and the Department acknowledge their understanding that Pharmacy is responsible for dispensing, delivering, and administering the influenza vaccine, when notified to do so by the Department, per established medical protocols or algorithms, in accordance with the directives provided by the Department 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 vaccine providers with Department. By signing this MOA, Pharmacy pre-registers and enrolls with Department 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:

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 Centers for Disease Control and Prevention;
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 Pennsylvania Statewide Immunization Information System (PA SIIS), where applicable or available, to document doses administered and assess timing and type of prior pandemic vaccination, if multiple doses are required;
e. 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
f. Exercise all other necessary skills required by the Department for patients to safely receive the proper and effective pandemic influenza vaccinations.

Responsibility of the Department: The Department will provide technical assistance, material, information, and resources, as available, to assist Pharmacy in providing the appropriate training and certifications, as required by the Department, 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, the Department 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 MOA, Pharmacy company will be considered a single "end-user" in the Department's overall vaccine orders to CDC.

a. Weekly Allocation to Pharmacy by the Department

Under the assumption that during an influenza pandemic the Federal government will purchase and procure all pandemic vaccine and the Department 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:

1. Epidemiology of the influenza pandemic;
2. Pharmacy capacity, as reported by Pharmacy;
    i. Pharmacy shall provide the Department 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
3. Availability of pandemic vaccine, as allocated to the Department;
4. Location of Pharmacy sites and need for geographic distribution of public access pandemic vaccination points, as determined by the Department;
5. Capacity of other pandemic vaccine providers and entities to administer pandemic vaccines;
6. Potential need to vary pandemic vaccine provider allocations based on vaccine prioritization guidelines for special populations; and
7. Any other method of allocation as the Department in its discretion deems most appropriate to best serve public health, in accordance with any Federal guidelines.

(*Note: The Department and Pharmacy should try to negotiate initial allocation amounts in advance, as much as possible. Additional factors which may be considered include existing seasonal 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

<u>Responsibility of Pharmacy:</u>

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

<u>Responsibility of the Department</u>:

By signing this MOA, the Department 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 Commonwealth. How much and what

information is shared is solely within the discretion of the Department, and may only be released to Pharmacy to ensure the prevention and control of disease.

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 the Department through electronic spreadsheet via email to the Department's authorized representative at least weekly or as determined by state law/policies for the duration of time requested by the Department.

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 Department 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 vaccine administration as designated by the Department 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, unless a more frequent schedule is warranted by the course of the Pandemic. Pharmacy will be notified of changes in the submission schedule by the Department prior to the expected time and date of submission. Consistency in requirements across jurisdictions within the state shall be facilitated by the Department.

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 MOA.

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

A Pharmacy participating in this program may not refuse to administer pandemic vaccine to anyone unable to pay through private pay or insurance.

XII. Communications and Additional Activities

Responsibility of the Department:

a. 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.
b. Provide statewide consistent medical screening forms to Pharmacy as guidance in implementing pandemic vaccine administration.
c. Provide Pharmacy with releasable information regarding the pandemic influenza emergency and response.
d. Provide timely updates to Pharmacy regarding vaccine allocations and changes in guidance on pandemic vaccine prioritization.
e. Manage public information activities with regard to the overall health and medical response across Commonwealth and publicly acknowledge Pharmacy as a source for pandemic vaccination.
f. 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.
g. 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.
h. Coordinate with Pharmacy to retrieve and/or dispose of any unused pandemic vaccine from Pharmacy facilities according to State/Federal guidelines.
i. 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:

a. In the absence of an Emergency Use Authorization issued by FDA, Emergency Use Instructions issued by CDC, other Federal action, or a Pennsylvania declaration of a state of emergency 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 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.
b. 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.
c. Coordinate with the Department to ensure statewide consistency with implementation of screening forms, educational material, billing, training, and other Pharmacy activities and requirements.
d. Document vaccinations administered in State IIS or as required by the Department (as above).
e. Conduct medical screening of persons receiving pandemic vaccination, based on guidance provided by the Department, to assure consistency with Federal government guidance.
f. Coordinate with state Pharmacy Association, so that a Pharmacy representative participates on in state Pharmacy Association meetings, if applicable.
g. Provide education materials (e.g. VIS, EUA, or EUI, if applicable) to all persons receiving pandemic vaccination.
h. Report any pandemic vaccine adverse events following vaccination to the Vaccine Adverse Event Reporting System (1-800-822-7967), http://vaers.hhs.gov/contact.html
i. Secure any unused pandemic vaccine until a time when the Department can provide arrangements or directives for retrieval or disposal.
j. Participate in all planning discussions and exercises with the Department, as requested.

XIII. Term and Termination

This MOA shall become effective immediately upon its execution by all required signatories. This MOA shall remain in effect between Pharmacy and the Department for five (5) years or until participation in this MOA is terminated by either the Department 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 MOA and its implementation will be formally reviewed following its use during a pandemic and recommendations from an after action report will be incorporated to update and improve any operational plan.

XV. Amendment

Either party to this MOA may request an amendment by sending a letter to the other party. The other party can agree to the amendment by countersigning the letter and returning it to the requesting party.

XVI. Assignability

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

XVII. Sole Agreement

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

XVIII. Severability

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

XIX. Authority to Sign

By signing this MOA, each party represents that it has the legal authority to enter into this MOA. This MOA is not intended to be a legally binding contractual agreement.

SIGNATURES

My signature indicates agreement with the above stated understandings and conditions:

_____ _____

Provider Representative Name - Signature Date

_____

Title

_____ _____

Provider Representative Name - Signature Date

_____

Title

_____ _____

Secretary of Health Date
(or designee) - Signature

(Not Required)

Office of General Counsel | Date

(Not Required)

Office of the Attorney General | Date