

Appendix A: Readiness Guidance for Pandemic Influenza Vaccination in Pharmacy Settings*

SUPPORTS MOU BETWEEN MDH AND PHARMACY

Introduction & Purpose

The purpose of this guidance is to utilize the existing infrastructure of pharmacies in Minnesota to assist in providing pandemic influenza vaccinations during an influenza pandemic. The planned/potential responsibilities of the pharmacy and of public health agencies are outlined below. In most instances, “Public Health” refers to the Minnesota Department of Health (MDH) however; local jurisdictions may cover some of these responsibilities. Thus, we suggest that pharmacies and pharmacists engage with public health at the local level as well.

More general all-hazard public health emergency response agreements between public sector public health programs and pharmacies may be in place, but this guidance addresses the specifics of preparing for a pandemic influenza vaccination campaign.

Influenza pandemics are not localized public health emergencies, but are rather, by definition, wide scale, multi-national outbreaks requiring a large-scale response that may last many months. 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.

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.

[CDC Pandemic Influenza Plans](http://www.cdc.gov/flu/pandemic-resources/planning-preparedness/national-strategy-planning.html) (www.cdc.gov/flu/pandemic-resources/planning-preparedness/national-strategy-planning.html)

[National Pandemic Strategy](http://www.cdc.gov/flu/pandemic-resources/national-strategy/index.html) (www.cdc.gov/flu/pandemic-resources/national-strategy/index.html)

*Readiness guidance is preliminary and may be updated at the time of a pandemic.

Preparing for a Vaccination Response

Assumptions:

- The Federal government will activate contracts with pandemic vaccine manufacturers to develop, fill and finish pandemic vaccine.
- Vaccine will be available, but there may not be enough to vaccinate everyone during the early weeks/months.
- The Federal government will purchase and procure vaccine and Minnesota will receive a pro-rate (census-based) allocation from that Federal Supply.
- In general, MDH will make allocations to individual providers and manage all individual provider orders.
- A federally contracted distributor will ship the pandemic vaccine allocation for Pharmacy and its sites to Pharmacy's designated distribution depot in Minnesota.
- In times of low supply, an allocation process would be implemented.
- To ensure accountability and consistency, health care providers that receive and administer pandemic vaccine will need to enter into a "provider agreement" with the State of Minnesota.

Planning Elements:

1. Determination of Priority Groups

When vaccine first becomes available, supply and capacity to vaccinate may be limited. Groups of people with highest risk of complications, or whose illness would cause critical problems with infrastructure (e.g. health care workers, emergency services personnel) are priority groups for vaccination. CDC and MDH define these groups, and health care providers help ensure that they are vaccinated.

Groups of people at high risk will vary on the epidemiology of the virus, but typical priority groups include pregnant women, young children, and those with immunocompromising conditions. Those at high-risk for seasonal flu are likely to be impacted, along with additional groups specific to the circulating virus (e.g. age cohorts, travelers, etc.).

The recommendation to vaccinate will progress to broader population groups as vaccine becomes available. MDH will communicate guidance and providers will need to ensure they are receiving updates and following new guidelines to help ensure consistency between vaccination sites.

MDH will also be working to communicate general guidelines to the public (e.g., children under 2 should seek vaccine now).

2. Allocation of Vaccine

When vaccine supply is limited, vaccine may be allocated to health care providers based on typical patient demographics and their capacity to administer vaccine.

To ensure equity across providers, the amount of pandemic vaccine initially allocated during the first several weeks of vaccination may be a function of:

- The health care provider's or pharmacy's capacity;
- Availability of pandemic vaccine in Minnesota;
- Need to fulfill vaccine prioritization guidelines for special populations;
- Needed geographic distribution of public access pandemic vaccination points, as determined by MDH;
- Capacity of other pandemic vaccine providers to administer pandemic vaccines; and
- Any other method of allocation as MDH in its discretion deems most appropriate to best serve public health.

Allocations may be adjusted throughout the vaccination campaign by this method or by MDH due to epidemiologic and other factors, as needed.

Vaccine allocations will be sent to the provider via email and the provider will have 1 business day to accept, reduce or decline the allocation.

3. Provider Agreements

Any health care provider who plans to order pandemic influenza vaccine will be required to sign a formal agreement with the State of Minnesota that establishes appropriate use of the vaccine. This includes the responsibilities to store, handle, and administer the influenza vaccine, per established protocols and in accordance with the directives provided by the state of Minnesota.

Health care providers that enter into a provider agreement will ensure that all vaccinating personnel are appropriately licensed or delegated to administer pandemic vaccines and pandemic constituent products.

When a provider enters into the agreement, MDH will survey the provider's capacity to administer vaccines and collect information on their patient demographics to help inform allocation. In addition, MDH will share information on underserved populations and geographic areas (as allowed by law), to work in collaboration with health care providers in making decisions about allocations to individual sites or geographic regions.

MDH will provide information about allocation strategies and communicate changes in plans to local health departments and health care providers.

4. Shipment of Vaccine

Once vaccine is allocated by MDH to a pharmacy or provider, a contracted vendor will ship the vaccine. Shipment timeframes are expected to be similar to seasonal influenza.

Action Steps:

- Know the demographics of your client population for vaccine services.

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- Consider how you interact with your customers, can you promote MDH’s messages regarding prioritization? (i.e. encouraging the recommended groups to come in, and those who aren’t yet recommended to wait)
- Some health care providers won’t receive vaccine right away, consider how you can play a role in referring your customers that are in a high-risk group to other venues to get vaccinated.
- Providers may be recruited through their licensure board or the Minnesota Immunization Information Connection (MIIC) to complete provider agreements. Ensure contact information is up-to-date.
- Consider how you would ensure that vaccinating staff met the criteria of the provider agreement (e.g. conduct “just-in-time” training).

Resources:

[Guidance on Allocating and Targeting Pandemic Influenza Vaccine](http://www.cdc.gov/flu/pandemic-resources/pdf/allocatingtargetingpandemicvaccine.pdf) (www.cdc.gov/flu/pandemic-resources/pdf/allocatingtargetingpandemicvaccine.pdf)

Vaccinating During a Pandemic

Assumptions:

- The federally contracted distributor will ship the pandemic vaccine allocation for Pharmacy and its sites to Pharmacy's designated distribution depot in Minnesota.
- Health care providers continue to follow best practices and all applicable laws and statutes.
- Storage and Handling of pandemic vaccine is similar to seasonal influenza vaccines.
- Vaccination campaigns will last several months.

Planning/Response Elements:

1. Staffing

Staff may become ill during the pandemic, at the same time as demand for vaccine is increasing. Alternative staffing plans may be necessary to carry out regular business and potential distribution of antivirals in addition to vaccination.

2. Customer Traffic

Ill persons may present to the pharmacy alongside of healthy persons seeking vaccine. Traffic may increase dramatically, impacting wait times and availability of medication. Customers/patients may be anxious. Security plans may be implemented.

3. Potential for Emergency Use Authorizations (EUA) or Additional Screening Measures

Certain groups of people may need to sign an EUA to receive vaccine if required by the Food and Drug Administration.

Depending on available vaccines, you may receive a vaccine like live attenuated inactivated vaccine (LAIV) that requires additional screening questions.

Patients will need to be screened for previous receipt of pandemic vaccine. Vaccine providers will ensure that all vaccinating staff 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 for pandemic vaccination. Preferably, this assessment is completed via MIIC at the point of administration. If documentation of the dose is not available in MIIC, then other means can be used, such as through a patient's individual shot card.

MDH will post screening guidelines and pertinent forms for health care providers to use.

4. Receiving and Storing Vaccine

Because vaccine may be shipped through different mechanisms, staff may need to be available to receive vaccine for additional hours or days of the week.

The volume of vaccine distributed to individual providers is likely to vary throughout the pandemic and may be unpredictable. Health care providers should know their storage capacity and be prepared to handle larger quantities of vaccine if capable. To the extent possible, MDH will communicate the expected doses of vaccine in a shipment in advance.

Pandemic vaccine will likely be produced by several manufacturers, but all types of vaccine are not likely to be available at the same time. Especially in the early stages of the pandemic, providers will not be able to select the type of vaccine they receive. You may receive vaccine that is manufactured by a different company and is in a different package or presentation than you use for seasonal flu (e.g. multi-dose vials instead of pre-filled syringes).

Some providers (e.g. clinic systems or chain pharmacies) may elect to have their vaccine sent to a central depot. Once the vaccine arrives at the depot from the federally contracted distributor, the central entity is responsible for final distribution of pandemic vaccine to the individual sites.

Pandemic vaccine will likely require the same storage guidelines as seasonal flu vaccine. The easiest way to be ready is to adhere to storage and handling best practices all the time.

5. Ancillary Supplies/Constituent Products

The Federal government plans to provide ancillary supplies for vaccination. These supply kits will likely include needles, syringes, gloves, sharps disposal boxes and other necessary items. You may be unfamiliar with the brand or type of items you receive. (There will be training material available to use.)

Ensure appropriate use of other vaccine constituent products like adjuvants. Vaccinators may need to prepare (mix) vaccine antigen and adjuvant at the point of vaccine administration, including matching the vaccine antigen and adjuvant type between vaccine dose one and vaccine dose two.

Action Steps:

- Consider storage capacity. Would there be a limitation to how many doses of vaccine you could accept in an allocation?
- With potential for different products and/or ancillary supplies, how might you implement a “just-in-time” training to get staff ready to handle these products?
- If vaccine required an adjuvant to be mixed at the point of administration, patient wait times could be impacted. Consider how you could handle this situation. Appointments? Traffic control? Separate vaccination area?

Resources:

[Checklist of Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations](http://www.izsummitpartners.org/off-site-vaccination-clinic-checklist)
(www.izsummitpartners.org/off-site-vaccination-clinic-checklist)

[CDC Storage and Handling Toolkit](http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html) (www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html)

[Minnesota Department of Health](http://www.mdhflu.com/) (www.mdhflu.com/)

Follow-up: Documentation and Accountability

Assumptions:

- Pandemic vaccine procured by the Federal government is a government asset and would require enhanced accountability from seasonal influenza.
- Follow-up activities will overlap with vaccination efforts.

Planning/Response Elements:

1. Use of the Immunization Information System (IIS), the Minnesota Immunization Information Connection (MIIC)

It may be necessary to review the MIIC record for all clients seeking immunization in the pharmacy setting.

It is the expectation that all vaccine doses administered be entered into MIIC within 1 week of administration and sooner when possible. Data submitted to IIS must include all core elements as required for IIS submission for seasonal influenza vaccine administration and additional data elements as designated by MDH. The timely data entry is essential to individuals who may need a second dose of vaccine and to the state for planning purposes.

Possible use of additional functions within MIIC: MIIC has functionality in vaccine ordering, inventory, and return. In a pandemic vaccination scenario, providers may be required to use these functions in addition to entering doses administered and assessing the patient's vaccine history.

2. Insurance and Billing

Health care providers are prohibited from charging patients, health insurance plans, or other third-party payers for the cost of the vaccine or ancillary supplies that were provided at no cost by the Federal government. Health care providers are also prohibited from selling the vaccine and ancillary supplies. Vaccines allocated by MDH cannot be distributed outside the state of Minnesota.

Health care providers may bill for the cost of administration. 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 Minnesota Medicaid administration fee, if one exists.

Providers are strongly encouraged to administer vaccine to all patients that present for vaccine whenever the provider is licensed and trained to vaccinate those individuals.

3. Inventory Reporting

Pharmacies will provide MDH with doses on hand/inventory at each location before placing orders or accepting an allocation of vaccine. Inventory may also be requested at additional time points to assist with planning and distribution of vaccine equitably across the state.

4. Disposal

Providers will follow MDH and Federal guidelines for all providers in retrieving and/or disposing of pandemic vaccine.

Secure any unused pandemic vaccine until a time when public health provides arrangements or directives for retrieval or disposal.

Action Steps:

- Evaluate the current use of MIIC in your pharmacy
 - When do you use MIIC to assess vaccine history?
 - Is there any lag-time in submitting data to MIIC?
- Would a patient's ability to pay an administration fee be a challenge that impacts your response participation?
 - For example: patients that are out-of-network may seek vaccination in your pharmacy more often than in a seasonal flu situation.

Resources:

MIIC and Pharmacies Webpage

(www.health.state.mn.us/divs/idepc/immunize/registry/pharmacies.html)

MIIC Helpdesk: 651-201-5207 or health.miichelp@state.mn.us.

Pharmacists can request additional training assistance via the helpdesk.

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To obtain this information in a different format, call: 651-201-5414. Printed on recycled paper.