



STATE OF MARYLAND
DHMH

Maryland Department of Health and Mental Hygiene

Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – John M. Colmers, Secretary

H1N1 Influenza Vaccine Update #1

Guidance for Placing Initial H1N1 Vaccine Order

Thank you for registering to administer 2009 H1N1 pandemic influenza vaccine and receive updates on Maryland's H1N1 response. This update and other resources are available on the DHMH website: www.dhmh.state.md.us (H1N1 Flu Response / Provider Resources).

Introduction

The Maryland Department of Health and Mental Hygiene (DHMH) established a pre-registration process for vaccination providers to identify their facilities as possible vaccine administration sites for the 2009 novel H1N1 influenza vaccine. Registration with DHMH is the only way to receive H1N1 influenza vaccine.

H1N1 vaccine is being purchased by the federal government and will be made available and shipped to registered sites at no charge. Syringes, needles, sharps containers, and alcohol prep pads will also be provided at no charge. H1N1 vaccine will begin shipping in early October to selected sites that have completed the provider agreement and submitted their initial vaccine order.

This update contains guidance for completing the Maryland 2009 H1N1 Pandemic Influenza Vaccine Provider Agreement and placing initial H1N1 vaccine orders. The agreement can be completed through the online survey described below. Initial vaccine orders must be placed using this survey tool.

Provider Agreement

Completing the Provider Agreement and Order Form

- A link to the online questionnaire to complete the provider agreement and initial vaccine order was provided in the body of this email.
- The online questionnaire contains two parts: The Provider Agreement and the Vaccine Order Form. The Provider Agreement section requires acceptance of each of the terms of the agreement. Data collected through the agreement are mandated by the federal government and DHMH. If this is incomplete your initial order cannot be accepted.
- The second section, the Vaccine Order Form, allows for the placement of an initial vaccine order. All orders must be placed by the number of doses of vaccine for a 30 day period. It is possible that your initial vaccine order will arrive in several partial shipments. **However, you must have the capacity to store your entire initial order in your vaccine storage unit in the event that it arrives in a single shipment.**
- Additional information about provider reporting of doses administered will be made available in a subsequent communication.
- If you must discontinue completing the online questionnaire prior to completion, access the survey link at the same computer you began the survey on to automatically resume the questionnaire.

Placing the Initial Vaccine Order

Use of Personal Identification Number (PIN)

- Your office should be in receipt of your facility's PIN (i.e., H9999). This number is required to complete the Provider Agreement and submission of the initial and all subsequent vaccine orders.
- **VFC Providers ONLY:** Vaccines for Children (VFC) Program providers shall use their existing VFC PIN to assure linkage to the office's current shipping account.
- If you have not received a fax containing your facility's PIN, please send an email with your facility name and address including County of business to:
H1N1Info@dnhm.state.md.us.

Initial Vaccine Allocations

- The first shipment of H1N1 vaccine is expected to be received by select registered providers in early October. It is anticipated that this order will be of limited quantities of H1N1 LAIV (live, attenuated intranasal vaccine). Increasing supplies of inactivated H1N1 vaccine are expected to ship throughout the month of October.
- H1N1 vaccine shipments to vaccine providers that serve the CDC target groups will be prioritized for early shipments. Please review the CDC Questions and Answers document for additional information on the CDC target groups.
- While DHMH is unable to predict how quickly orders will be delivered once they have been placed, it is expected that this process might take from 7 – 10 days.

Notification of Vaccine Shipments and Reorders

- DHMH will place vaccine orders for registered providers as vaccine formulations are received at the vaccine distribution center, McKesson.
- Please note: McKesson does not provide advance notice of shipments to recipients.
- Vaccine reorders will be considered after you have been shipped the complete initial order. A specific “reorder” form must be used. This form will be sent to the pre-registered point of contact in your facility.
- **Reorders will not be considered for providers who fail to report weekly doses administered during the period that reporting is required by the federal government.**

Vaccine Shipments

Vaccines and ancillary supplies (with the exception of shot cards for intranasal vaccine, which are shipped in the same box as the vaccine) will be sent to providers using two separate shipments. Cold chain shipment is not required for ancillary kits and sharps containers. Our goal is for supplies to arrive at the same time as or prior to vaccine delivery, but this will not be possible for each and every shipment.

Please ensure your address and office hours are accurate and up to date with each order transmission. Providers may not specify preferred delivery dates, but office hours and days will be factored into the shipment schedule.

Ancillary Supply Kits (consisting of needles, syringes, shot cards and alcohol prep pads), and sharps containers will be shipped with each vaccine order. The type of ancillary kit shipped will be determined by DHMH based on the type and quantity of vaccine ordered. Please review page 4. for additional information. There are three types of kits:

1. Pediatric Prefilled Syringe Kit,
2. Adult Prefilled Syringe Kit, and
3. Multi-dose Vial Kit.

Additional guidance on H1N1 vaccine storage planning, vaccine handling instructions and vaccine administration billing can be found on the following pages. Questions can be emailed to H1N1Info@dnhm.state.md.us.

Contents of Ancillary Supply Kits

Product	Content	Comments
Prefilled syringe kit (pediatric)	Needles (100 ea)	All products are OSHA compliant; specific brands and products may vary; needles are 25G, 5/8"
	Isopropyl Prep pads (100 ea)	Specific products and brands may vary
	Vaccination cards (100 ea)	Dimensions: 14.5" x 12" x 3" - 1.8 lbs
Prefilled syringe kit (adult)	Needles (100 ea)	All products are OSHA compliant; specific brands and products may vary; needles are 23-25G, 1-1.5"
	Isopropyl Prep pads (100 ea)	Specific products and brands may vary
	Vaccination cards (100 ea)	Dimensions: 14.5" x 12" x 3" - 1.8 lbs
Multidose vial kit	Needle/syringe units for vaccine administration (100 ea)	All products are OSHA compliant; specific brands and products may vary; syringes range from 1-3 mL; needles are 23-25G, 1-1.5"
	Needle/syringe units for mixing vaccine and adjuvant (10 ea)*	All products are OSHA compliant; specific brands and products may vary; syringes are 5-6 mL.
	Isopropyl Prep pads (100 ea)	Specific products and brands may vary
	Vaccination cards (100 ea)	Dimensions: 17.5" x 12" x 3" - 2.68 lbs
Sharps containers	Small	specific brands and products may vary; holds 200 needles
	Medium	specific brands and products may vary; holds 525 needles
	Large	specific brands and products may vary; holds 1350 needles
	Extra large	specific brands and products may vary; holds 2850 needles
		*Dimensions for Sharps containers will be included as soon as they are available
*Adjuvant mixing needle included as a precaution. Use not anticipated.		

Ancillary Supply Kits and Sharps Containers will not be shipped with MedImmune's intranasal vaccine

H1N1 Vaccine Packaging for Storage Capacity Planning
(Data provided by the Centers for Disease Control and Prevention)

Listed below are the configuration details for all types of H1N1 vaccines to be distributed for your planning purposes.

Novartis Pre-Filled Syringe (PFS)

Notes:

- H1N1 pre-filled syringe (PFS) packs are to be based on the Fluvirin Luer Lok 10 x syringe pack
- Packs are supplied without needles
- Each pack contains 2 paper lidded plastic trays, holding 5 syringes per tray
- Catalent: 1 box contains 240 syringes (240 doses). 1 pallet contains 8,640 syringes (8,640 doses)
- Novartis – Rosia: 1 box contains 480 syringes (480 doses). 1 pallet contains 14,400 syringes (14,400 doses)

Components	Dimensions	Contents	Comments
Tray: Catalent	Not yet available	5 syringes (5 doses)	Providers receive 20 paper lidded plastic trays
Tray: Novartis - Rosia	Not yet available	5 syringes (5 doses)	Smaller than Catalent trays and syringe pockets cannot be separated

Novartis Multi-dose Vial (MDV)

Notes:

- Novartis - Liverpool: Filling is done in 10-dose vials. One vial packaged per carton (10 doses). 10 cartons per brick (100 doses). 108 bricks per case (10,800 doses). 8 cases per shipping container (86,400 doses)
- DSM: Filling is done in 10 dose vials. 25 vials per carton (250 doses). 300 vials per case (3,000 doses). 72 cases per shipping container (21,600 doses)

Components	Dimensions	Contents	Comment
Carton	Not yet available	1 vial (10 doses)	Provider receives increments of 10 cartons

Medimmune

Components	Dimensions	Contents	Comment
Carton	6 1/4"x4 3/4"x1 1/2"	10 Doses (sprayers)	Provider receives increments of 10 cartons

CSL Pre-Filled Syringe (PFS)

Components	Dimensions	Contents	Comment
Carton	94mmx61mmx125mm (3.7"x2.4"x4.92")	2 trays of 5 syringes	Provider receives increments of 10 cartons

CSL Multi-dose Vial (MDV)

Components	Dimensions	Contents	Comment
Carton	66mmx39mmx39mm (2.59"x1.53"x1.53")	1 vial (10 doses)	Provider receives increments of 10 cartons

Sanofi Pasteur Multi-dose Vial (MDV)

Components	Dimensions	Contents	Comment
Package	2.5" x 1.125" x 1.125"	10 doses	Providers receive increments of 10 packages
Master Carton	12.5"x 6.5" x 5.625"	100 packages (1,000 doses)	Provider can store as master carton or as packages

Sanofi Pasteur Single Dose Syringe (SDSN) – 10-pack

Components	Dimensions	Contents	Comment
Package	5.375" x 1.75" x 4.5"	10 doses	Providers will receive increments of 10 packages
Master Carton	23.125" x 11.875" x 9.5"	50 packages (500 doses)	Provider can store as master carton or as packages

Sanofi Pasteur Single Dose Syringe (SDSN) – 25-pack

Components	Dimensions	Contents	Comment
Package	5.375" X 4.5" X 4.5"	25 doses	Providers will receive increments of 4 packages
Master Carton	23-1/8" x 11-3/16" x 9-3/4"	20 packages (500 doses)	Provider can store as master carton or as packages

HANDLING INSTRUCTIONS FOR 2009 H1N1 VACCINE

(ISSUED BY THE CENTERS FOR DISEASE CONTROL AND PREVENTION: SEPTEMBER 16, 2009)

VACCINE RECEIPT INFORMATION:

Upon receipt of the package, the below steps should be followed:

- Inspect the package and contents for damage.
- Review the temperature monitor card in the package IMMEDIATELY.
- If package is damaged or if there are any concerns about vaccine integrity, please call McKesson Customer Service at 877-836-7123 right away.
- If the contents are in satisfactory condition, receive and process documents in accordance with the following procedures.
 - Count vials/product and place vaccine in monitored refrigerator immediately.
 - If the doses that you have received do not match the packing list, please email DHMH at H1N1Info@dhhm.state.md.us immediately.

Note: If multiple boxes are received, segregate the vaccine by box. Annotate box and temperature monitors/indicators to identify which temperature monitors belong to which box of vaccine (each box will contain a cold monitor and a warm monitor). The purpose of this is to be able to identify which vials or sprayers were affected if one of the boxes has become compromised in shipment.

VACCINE STORAGE INFORMATION:

- 2009 H1N1 vaccine must be maintained at a temperature of 2 to 8 degrees Celsius (35.6 to 46.4 degrees Fahrenheit). **The vaccine must be kept at this temperature at all times.**
- The vaccine **MUST NOT BE EXPOSED TO FREEZING TEMPERATURES!** The temperature monitoring device in your refrigerator must have a temperature reading capability to ensure the efficacy of the vaccine prior to administration.
- It is the receiving provider's responsibility to maintain proper storage temperature until vaccine administration.
- Any refrigerator used for vaccine storage must be dedicated to storage of biologics (i.e., food or beverages should not be stored in vaccine storage units). Refrigerators should have sufficient usable space to store the largest number of vaccine doses expected at one time without overloading. Vaccines stored in combination refrigerator/freezer units should **NEVER** be stored in areas directly underneath air vents, in deli-crispers/vegetable bins, or in the doors. Bottles of water can be added to these areas to create thermal mass, thus stabilizing refrigerator temperature.
- Dorm-style refrigerator units (freezer and refrigerator with shared exterior door) provide poor temperature control and often freeze vaccines, therefore should not be used to store vaccines any longer than the length of a clinic for a particular clinical day (i.e., vaccines should not be stored overnight in dorm-style refrigerators).
- The refrigerator storage unit must be electronically alarmed or manually monitored; temperatures should be recorded at a minimum of every 12 hours.
- A record of these readings should be maintained at the location of the vaccine storage unit, for example on the door. Refer to the Centers for Disease Control and Prevention's Vaccine Storage and Handling Toolkit for further guidance. This site can be accessed at the following link: <http://www2a.cdc.gov/vaccines/ed/shtoolkit/pages/resources.htm>.

H1N1 Vaccine Administration Billing Q & As

<p>Q1: Is billing of third party payors/insurers permissible in public health clinics or mass vaccination sites/clinics conducted by, or on behalf of a public health jurisdiction?</p> <p>A1: It is permissible to bill third party payors/insurers in public health clinics or mass vaccinations sites/clinics conducted by, or on behalf of a public health entity. Public health jurisdictions that do not currently have a robust billing system in place may <u>not</u> use PHER funds to develop billing systems.</p>
<p>Q2: Is it permissible to charge patients a co-pay or any out-of-pocket charge in public health clinics or mass vaccinations sites/clinics conducted on behalf of a public health entity?</p> <p>A2: It is not permissible to charge patients in public health clinics or mass vaccinations sites/clinics conducted by or on behalf of a public health entity.</p>
<p>Q3: What is the definition of a 'public health clinic'?</p> <p>A3: A 'public health clinic' is defined as a clinic that is conducted by, or on behalf of a state or local health jurisdiction and receives PHER implementation funds to administer H1N1 vaccine in any setting. For example, this may include a commercial community vaccinators (CCV) or other private provider that has a formal agreement with the public health entity.</p>
<p>Q4: Is it permissible to use PHER funds to offset the costs to private providers to vaccinate uninsured or under-insured persons?</p> <p>A4: It is permissible to use PHER funds to offset the costs to private providers to vaccinate the uninsured or under-insured population providing that the jurisdiction has systems in place to assure accountability through auditing and/or other means of accountability. Those that do not have current systems in place are encouraged not to use PHER funds to develop systems of accountability.</p>