



May 18, 2010

Dear Colleague,

The 2009 H1N1 influenza vaccination campaign reached an estimated 72-81 million individuals in the United States. The efforts of every provider who received vaccine were essential to making the program a success. As disease continues to decrease in the U.S., demand for this vaccine has steadily decreased as well. Many health care providers who received the 2009 H1N1 influenza vaccine have unused doses. The purpose of this letter is to inform you that the U.S. Government has organized a Central Vaccine Recovery Program to recover unused doses of the 2009 H1N1 influenza vaccine.

The Central Vaccine Recovery Program is a voluntary program intended to recover unused doses of 2009 H1N1 influenza vaccine (i.e. unopened vials/pre-filled syringes/nasal sprayers). The program has been developed with input from the necessary authorities to ensure compliance with state regulations. Only 2009 H1N1 influenza vaccine products are included in this program; ancillary supplies (i.e. needles, syringes, and sharps containers) supplied by the federal government should not be returned through this recovery program.

Health care providers who received 2009 H1N1 vaccine and have signed a Provider Agreement should expect to receive more detailed information from the State Immunization Program. This will include state-specific information on how to initiate return of vaccine. States vary in their regulatory requirements for return of expired vaccines; therefore, the program is tailored to the regulatory requirements of particular states. We ask that you pay particular attention to information you will receive from your own State Immunization Program.

At this time, providers should return vaccine doses that will expire by the end of June 2010 (Novartis, CSL, and MedImmune), and should continue to store and use vaccine expiring in 2011 (sanofi pasteur vaccine in multi-dose vials). The Centers for Disease Control and Prevention (CDC) recommends that health care providers continue to vaccinate people who wish to be protected. In addition, providers should retain the vaccine that will expire in 2011 as a reserve, should H1N1 disease incidence result in increased demand for vaccination before seasonal vaccine becomes available in sufficient quantity. In Fall 2010 providers will have another opportunity to return the late-dated 2009 H1N1 vaccine.

Your support during this 2009-10 has been instrumental to the success of this unprecedented national vaccination program. Thank you, and please contact your Immunization Program if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Stephen C. Redd".

Stephen C. Redd, MD
Rear Admiral, United States Public Health Service
Director, Influenza Coordination Unit

Central 2009 H1N1 Influenza Vaccine Recovery Program Quick Reference Sheet

ITEMS TO RETURN

Please Return

- Unopened and non-viable vials, pre-filled syringes, and nasal sprayers of the 2009 H1N1 influenza vaccine (see Tip # 1 below)

Please DO NOT Return

- Syringes that providers filled themselves but did not use
 - Syringes with needles attached, broken vials
 - Used or empty multi-dose vials
 - Other needles, syringes, and sharps containers
 - Other unused vaccines
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IMPORTANT PACKING TIPS

1. Render all vaccines non-viable by removing vaccine (including expired doses) from refrigeration and maintaining at room temperature for a minimum of 24 hours. Separate from other viable vaccines and label DO NOT USE.
 2. Complete the Central Vaccine Recovery Program packing slip, record the vaccine manufacturer, formulation, lot numbers, doses returned, and the date/time vaccine was removed from refrigeration
 3. Line shipping boxes with a large plastic bag to prevent any leaks during transport
 4. Maintain the original shipping configuration as much as possible (e.g. if 10 vials in 1 box, keep it in all in the box)
 5. Place vaccines and packing slip in sealable plastic bags
 6. Use packing materials (e.g. newspaper, Styrofoam, bubble wrap) to fill any excess room in shipping box
 7. Label boxes as "FRAGILE"
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APPROPRIATE USE OF UPS SHIPPING LABELS

- Pre-paid UPS label can be used for the return of up to 20 lbs of unused vaccine PER label, which is the equivalent of: 360 multi-dose vials **-OR-** 650 pre-filled syringes **-OR-** 750 nasal sprayers
 - **DO NOT USE the UPS shipping labels if you are required to hold an EPA identification number**
 - Fall 2010 (date to be determined) a third pre-paid label will be mailed to providers
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PROVIDER IDENTIFICATION NUMBERS

The Provider Identification Number (PIN) can be found on the shipping label above the provider's name and address.

Example: **USA0987654321**
John Doe, MD
Happy Hospital USA
Smalltown, USA 12345

VACCINE RETURN DATES

- | <u>Vaccine Type</u> | <u>Return Date</u> |
|---|-------------------------------|
| • CSL, Novartis, and MedImmune vaccines | By June 30, 2010 |
| • sanofi pasteur multi-dose vials | To Be Determined in Fall 2010 |
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IMPORTANT PHONE NUMBERS

- | <u>Question or Concern</u> | <u>Point of Contact</u> |
|---|--|
| • Lost/misplaced provider identification number (PIN) | State Immunization Program
(775) 684-5900 |
| • Pick-up of vaccine returns (up to 20 lbs per label) | United Parcel Service (UPS)
1-800-PICK-UPS (742-5877) |
| • Lost/misplaced pre-paid UPS shipping label | HHS Supply Service Center
1-800-642-0263 |
| • Cannot use the pre-paid UPS shipping label because: <ul style="list-style-type: none">○ Provider is required by law to hold an EPA ID number○ Provider has shipments over 20 lbs per UPS label | Monday – Friday
7:00 am to 7:00 pm EST
http://sscweb.psc.gov/h1n1 |

Central 2009 H1N1 Influenza Vaccine Recovery Program Packing Slip

INSTRUCTIONS

Please complete all the required information below. This packing slip must be kept with the 2009 H1N1 influenza vaccine that will be returned. If you do not know your H1N1 PIN or if you have questions about this form, please call the Department of Health and Human Services, Supply Services Center at 1-800-642-0263 Monday through Friday 7:00 am to 7:00 pm EST.

PROVIDER INFORMATION

H1N1 PIN:	DATE:	
FIRST NAME:	LAST NAME:	
CLINIC/ORGANIZATION:		
ADDRESS:		
CITY:	STATE:	ZIP:
PHONE NUMBER:	EMAIL ADDRESS:	

2009 H1N1 INFLUENZA VACCINE INFORMATION

MANUFACTURER (CSL, NOVARTIS, SANOFI, MEDIMMUNE)	FORMULATION (MDV, PFS, LAIV) ⁱ	LOT NUMBER	DOSES RETURNED	DATE / TIME REMOVED FROM REFRIGERATION
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				
11.				
12.				
13.				
14.				
15.				
COMMENTS				

Please use additional sheets if necessary

ⁱ MDV= Multi-dose vials (10 doses per vial); PFS = pre-filled syringes; LAIV = live attenuated influenza nasal sprayers