



MARK B HORTON, MD, MSPH
Director

State of California—Health and Human Services Agency
California Department of Public Health



ARNOLD SCHWARZENEGGER
Governor

June 3, 2010

RE: Central 2009 H1N1 Influenza Vaccine Recovery Program

Dear Health Care Provider,

Thank you for your continued efforts to vaccinate against the 2009 H1N1 influenza virus. As demand for the vaccine decreases there are some health care providers who received the 2009 H1N1 influenza vaccine that have unused doses. The purpose of this letter is to inform you that the US Federal Government has organized a Central Vaccine Recovery Program to recover unused doses of the 2009 H1N1 influenza vaccine. The program has been developed with input from the necessary authorities to ensure compliance with state regulations.

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). Only 2009 H1N1 influenza vaccine products are included; 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 two (2) pre-paid shipping labels from UPS in coming weeks. Providers can use the pre-paid labels to ship up to 20 lbs of unused H1N1 vaccine per label through UPS. Providers should check each shipping label for their unique provider identification number (PIN). The PIN cannot be shared and should be kept in a safe location. It will be used for by the Department of Health and Human Services (HHS) Supply Service Center (SSC) for validation purposes.

If your facility qualifies as a conditionally exempt small quantity generator (CESQG) under the federal Resource Conservation and Recovery Act (RCRA), then please make use of the federal H1N1 Recovery Program's UPS labels for CESQGs. To determine if your facility is a CESQG under RCRA, you must calculate the total quantity of RCRA hazardous waste your facility (for the entire site location) generates monthly counting all hazardous wastes generated as prescribed in 40 CFR 261.5. In general, if a provider generates no more than 100 kilograms of RCRA hazardous waste in that month, the provider may qualify as a CESQG. For a full listing of the requirements see:

<http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=f68967909055465c44a3865fd0632779&rgn=div5&view=text&node=40:25.0.1.1.2&idno=40>

Providers who wish to return more than 20 lbs of unused H1N1 vaccine per label and those providers who do not qualify as a CESQG **cannot** use the pre-paid shipping labels to return vaccine. **These providers will have two weeks after receiving the UPS labels to contact the HHS SSC at 1-800-642-0263 between 7:00 am to 7:00 pm EST, Monday through Friday to make separate arrangements.** Providers will be responsible for packing their unused 2009 H1N1 vaccines appropriately. Attached for your reference are additional return instructions and phone numbers.

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 receive a third UPS pre-paid label and have the opportunity to return the late-dated 2009 H1N1 vaccine.

If you have additional questions or concerns, please contact the H1N1 Call Center at 1-888-867-6319.

Sincerely,

A handwritten signature in cursive script that reads "John Talarico, D.O.".

John Talarico, D.O., M.P.H.
Chief, Immunization Branch
California Department of Public Health