



COMMONWEALTH of VIRGINIA

Department of Health

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KAREN REMLEY, MD, MBA, FAAP
STATE HEALTH COMMISSIONER

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December 15, 2009

Dear Colleague:

Today the Centers for Disease Control and Prevention (CDC) announced a non-safety related voluntary recall of certain lots of H1N1 vaccine. Some of the recalled vaccine has been distributed in Virginia. I am writing to provide you with information as you may receive inquiries from some of your patients. The CDC has Frequently Asked Questions (FAQs) concerning this at http://www.cdc.gov/h1n1flu/vaccination/syringes_qa.htm (please copy and paste this link into your browser in order to view the FAQs).

The identified lots are all pediatric H1N1 vaccine for 6- to 35-month olds contained in 0.25 mL pre-filled syringes manufactured by Sanofi Pasteur. Providers are being asked to return any vaccine to the manufacturer in the following lots that remains unused:

- 0.25 mL pre-filled syringes, 10-packs (NDC # 49281-650-25, sometimes coded as 49281-0650-25):
UT023DA
UT028DA
UT028CB
- 0.25 mL pre-filled syringes, 25-packs (NDC # 49281-650-70, sometimes coded as 49281-0650-70):
UT030CA

Sanofi Pasteur will send directions for returning unused vaccine from these lots directly to providers.

This recall is based on the finding in routine ongoing testing that the potency of some lots of pediatric H1N1 vaccine dropped over time below a pre-specified limit and so no longer met the manufacturers' specifications for potency. The vaccine potency was only slightly below the specified range. **There are no safety concerns with these lots of vaccine and all passed pre-release testing for purity, potency and safety.**

Children and infants who received vaccine from these lots do not need to be revaccinated. The vaccine is expected to be effective in stimulating a protective response. You should follow the current recommendation which is that all children 6 months of age through 9 years of age should receive a second dose of H1N1 vaccine spaced at least 28 days apart.

The Virginia Department of Health's (VDH) Division of Immunization will be contacting H1N1 vaccinators to assist them in responding to this recall.

The VDH Inquiry Center is available at 1-ASK-VDH3 weekdays from 8:30am to 4:30pm to help your patients with their questions about this and other H1N1-related matters. Thank you.

Sincerely,

A handwritten signature in cursive script, appearing to read "Karen Remley".

Karen Remley, MD, MBA, FAAP