



STATE OF WASHINGTON

DEPARTMENT OF HEALTH

*PO Box 47890 • Olympia, Washington 98504-7890*

*Tel: (360) 236-4030 • FAX: (360) 586-7424 • TDD Relay Service: 1-800-833-6388*

DECLARATION OF SHORTAGE OF PRESERVATIVE-FREE INFLUENZA VACCINE AND  
SUSPENSION OF RCW 70.95M.115(2) FOR CERTAIN INFLUENZA 2012 VACCINES IN  
MULTI-DOSE VIAL PRESENTATIONS

**WHEREAS** RCW 70.95M.115(2) prohibits vaccinating a person who is known to be pregnant or under three years old with influenza vaccine that contains more than 1.0 micrograms mercury per 0.5 milliliter dose. RCW 70.95M.115(3) authorizes the secretary of the department of health (department) to temporarily suspend those limits if there is an outbreak of vaccine-preventable disease or a shortage of vaccine that complies with the limits. RCW 70.95M.115(3) directs that a person who is known to be pregnant or lactating or a parent or legal guardian of a child under 18 years old be informed if the person or child is to be vaccinated with any product exceeding the limits under RCW 70.95M.115(2).

**WHEREAS** thimerosal is a mercury-containing organic compound used as a preservative to prevent contamination of influenza vaccine. The thimerosal content in certain influenza vaccines produced in multi-dose vial exceed state limits under RCW 70.95M.115(2), so pregnant women or children under three years old in Washington may not ordinarily receive those vaccines. Influenza vaccines in single-dose presentations, whether a single-dose vial, pre-filled syringe, or nasal spray, do not exceed state limits under RCW 70.95M.115(2). Pregnant women and children under three years old may receive single-dose influenza vaccine under Washington law. For example:

There is one single-dose vial influenza vaccine presentation, Fluzone® 0.5mL, by Sanofi Pasteur. It is licensed to be administered to pregnant women, but is not the correct dosage for children under three years old.

There is one product of nasal spray presentation, FluMist®, by MedImmune. It is licensed to be administered to children two years old and older, but not to pregnant women.

There are seven influenza vaccine products provided in pre-filled syringes. Only one of these products is licensed for children under three years old (Fluzone®0.25mL, by Sanofi Pasteur). It cannot be used for pregnant women. The other six products (Fluzone® 0.5mL and Fluzone® Intradermal by Sanofi Pasteur; Fluarix®, by GlaxoSmithKline, Inc; Afluria®, by CSL Biotherapies; Fluvirin® and Agriflu®, by Novartis Vaccine) are licensed to be administered to pregnant women but not children under three years old.

OFFICE OF THE CODE REVISER  
STATE OF WASHINGTON  
FILED

**DATE: January 25, 2013**

**TIME: 4:51 PM**

**WSR 13-04-018**

**WHEREAS** nationally and within Washington, influenza activity during the 2012-2013 influenza season has been elevated and widespread. Data from the Centers for Disease Control and Prevention show the nation is experiencing a moderately severe influenza season, as measured by visits to providers for influenza-like illness. In Washington, 17 lab-confirmed influenza-related deaths have been reported as of January 23, 2013. The proportion of patient visits to emergency rooms in Washington for influenza-like illnesses has been higher than the levels experienced during the previous two influenza seasons.

Vaccination is considered the most effective method to stop community outbreaks as well as reduce overall sickness and death. Elevated influenza activity has increased demand for vaccine in Washington. Local media coverage has helped to raise public awareness and further increase demand. Washington state-supplied influenza vaccine for everyone under 19 years old is being ordered and distributed at a markedly higher rate compared to previous influenza seasons.

Influenza vaccine is manufactured annually and in limited supply. Washington cannot rely on more vaccine being available for either public or private purchase for the 2012-2013 influenza season. At the current rate of influenza vaccine distribution there will not be enough thimerosal-free vaccine for all the state's pregnant women and children under three years old at all times and at every location.

**NOW, THEREFORE**, I, Mary C. Selecky, Secretary of the Department of Health, under RCW 70.95M.115 (3), and under the circumstances set forth above, declare that there is a shortage of vaccine that complies with the limits in RCW 70.95M.115(2) for influenza vaccine for pregnant women and children under three years old.

I also, under RCW 70.95M.115(3), effective immediately, temporarily suspend the limits imposed by RCW 70.95M.115 on administering the Influenza 2012 Trivalent Vaccines in multi-dose vial (5mL) presentations licensed for use in the United States and produced by the manufacturers GlaxoSmithKline, Novartis, CSL Biotherapies and Sanofi Pasteur to pregnant women and children under three years old. This suspension is in effect until June 30, 2013.

To assist health care providers to meet the requirement for notice in RCW 70.95M.115(3), the department has prepared a notice document explaining the thimerosal content of influenza vaccine in multi-dose vials that can be provided to persons known to be pregnant or lactating or the legal guardians of children under 18 years old.

At the end of this period of suspension, I will reassess the available supply of vaccine to determine if it is necessary to continue this declaration of vaccine shortage.

Signed this 25 day of January, 2013 at Olympia, Washington.



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Mary C. Selecky, Secretary  
Washington State Department of Health