



STATE OF WASHINGTON

DEPARTMENT OF HEALTH

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DECLARATION OF VACCINE SHORTAGE 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 of age with influenza vaccine that contains more than 1.0 micrograms thimerosal per 0.5 milliliter dose. RCW 70.95M.115(3) authorizes the secretary of the department of health to temporarily suspend those limits if there is an outbreak of vaccine-preventable disease or a shortage of vaccine that complies with the limits.

Certain influenza vaccines produced in multi-dose vial exceed state thimerosal limits. Pregnant women or children under three years of age in Washington State 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 thimerosal limits. Pregnant women and children under three may receive single-dose influenza vaccine under Washington law.

On October 07, 2010, I declared a shortage of vaccine for the 2010 influenza virus that complies with the limits of RCW70.95M.115(2). I also temporarily suspended the thimerosal limits imposed by RCW 70.95M.115(2) on use of the Influenza 2010 Trivalent Vaccines in multi-dose vial (5mL) presentations. On June 28, 2011, I extended this declaration and suspension to apply to the use of the Influenza 2011 Trivalent Vaccines in multi-dose via (5mL) for the 2011-2012 influenza season. The suspension will last until June 30, 2012. This was done to allow children under three and pregnant women access to protection against the 2011 influenza virus they would not otherwise have. It specifically applies to a subset of these two populations whom a health care provider determined to be at risk of allergic reaction to latex. The declaration also explained that I would determine if an extension of this declaration and suspension is appropriate for the 2012-2013 influenza season.

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In July 2010 the federal Food and Drug Administration notified vaccine manufacturers that the tip caps used on pre-filled syringes may contain natural rubber latex which may cause allergic reactions in latex-sensitive patients. Manufacturers issued notification to providers in the United States and changed their product label to include this information. The situation remained the same for the 2011 influenza vaccine supply. It continues for the 2012 influenza vaccine supply. Rubber stoppers to be used on pre-filled syringes of influenza vaccine for the 2012-2013 influenza season may also contain natural rubber latex. Manufacturers will include the same notices in their product inserts. Influenza vaccine is produced annually and is in limited supply.

**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 and in my original declaration signed October 07, 2010, declare that there remains a shortage of vaccine that complies with the limits in RCW 70.95M.115(2) for influenza vaccine for pregnant women and children under age three who are at risk of allergic reaction to latex.

I also, under RCW 70.95M.115(3), effective immediately, temporarily extend the suspension of thimerosal limits imposed by RCW 70.95M.115(2) on use of 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, Sanofi Pasteur, and CSL Biotherapies for administration to pregnant women and children under age three whom a health care provider determines to be at risk of allergic reaction to latex. The department has prepared a notice document that can be provided to persons known to be pregnant or lactating or the legal guardians of children under eighteen years old regarding the thimerosal content of influenza vaccine in multi-dose vials, as required by RCW 70.95M.115(3).

This suspension is in effect until June 30, 2013. 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 14<sup>th</sup> day of June, 2012 at Olympia, Washington.

  
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Mary C. Selecky, Secretary  
Washington State Department of Health