STATE OF WASHINGTON

DEPARTMENT OF HEALTH

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DECLARATION OF VACCINE SHORTAGE AND SUSPENSION OF RCW 70.95M.115(1) FOR CERTAIN INFLUENZA 2010 VACCINES IN MULTI-DOSE VIAL PRESENTATIONS

WHEREAS RCW 70.95M.115 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. Those vaccines may not ordinarily be administered to pregnant women or children under three years of age in Washington State.

Influenza vaccines in single-dose presentations, whether a single-dose vial, pre-filled syringe or nasal spray, do not exceed state thimerosal limits. Those single-dose vaccines may be administered to pregnant women and children under three under Washington law.

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 licensed to be administered to children under three years of age.

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 six influenza vaccine products provided in pre-filled syringes. Only one of these products is licensed for children under three years of age (Fluzone®0.25 mL, by Sanofi Pasteur). The other five products (Fluzone® 0.5mL, 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 of age.

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In July of 2010, the federal Food and Drug Administration (FDA) 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 were required to issue notification to providers in the United States and change the labeling in their product information to state this fact, which occurred in August of 2010.

Influenza vaccine is produced on an annual basis due to the seasonality of the disease. Public and private health care providers purchase influenza vaccine months before actual vaccine is delivered. The Washington State Department of Health (the department) ordered influenza vaccine for the state's Childhood Vaccine Program in March of 2010, before the FDA issued the information about potential latex content in pre-filled presentations.

The department ordered thimerosal-free influenza vaccine in the pre-filled syringes, which may contain natural rubber latex, for pregnant women and children under three years of age. Because of the manufacturer's notification regarding potential latex content in pre-filled syringes, providers may decide not to vaccinate with this product. The department also ordered Flumist®, but this presentation is not licensed for children under two years of age or for pregnant women.

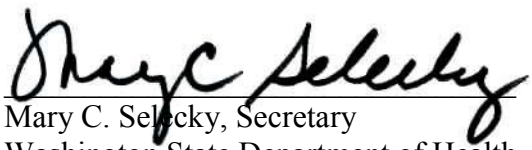
The ability for public and private health care providers, at this late date, to now obtain single-dose influenza vaccine vials, which would be thimerosal-free and not contain latex, is uncertain.

Under all these circumstances, pregnant women and children under three years of age with a latex allergy may not have access to influenza vaccine in Washington State. This is especially true for people with Spina Bifida, who are are considered at high risk for latex allergy. These groups are also at risk for serious complications if they were to get influenza disease.

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 age three who are at risk of allergic reaction to latex.

I also, under RCW 70.95M.115(3), effective immediately, temporarily suspend the thimerosal limits imposed by RCW 70.95M.115 on use of the Influenza 2010 Trivalent Vaccines in multi-dose vial (5mL) presentations licensed for use in the United States and produced by the manufacturers GlaxoSmithKline, Novartis, and Sanofi Pasteur, 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. This suspension is in effect until June 30, 2011. 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). 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 7th day of October, 2010 at Olympia, Washington.



Mary C. Selecky, Secretary
Washington State Department of Health