

**Delaware Division of Public Health  
DECLARATION OF SHORTAGE**

NOW COMES, the Division of Public Health, by and through Karyl T. Rattay, MD, MS, FAAP, FACPM, Director, pursuant to 16 Del. C. §510(b), who has determined that a shortage of mercury-free H1N1 influenza vaccine exists for children 6 months to 8 years of age and pregnant women, and who sets forth this Declaration, and herein states as follows:

**RECITALS**

WHEREAS, pursuant to 16 Del. C. § 122(1) the Department of Health and Social Services has "supervision of all matters relating to the preservation of the life and health of the people of the State;" and

WHEREAS, 16 Del. C. § 510(a) restricts the administration of vaccines containing mercury to children under 8 years or pregnant women; and

WHEREAS, 16 Del. C. § 510(b)(3) states that the prohibition against the use of vaccines containing mercury shall not apply when "the Director determines that a shortage of vaccine exists which could threaten the health of groups of individuals within the State, including children under 8 years of age or pregnant women, or both, and additional mercury-free vaccine cannot be obtained from other medical providers, manufacturers, distributors, agencies, jurisdictions, or by any other means within the medically necessary period of time."

WHEREFORE, the Director of the Division of Public Health determines that:

- (1) There exists a shortage of supply of mercury-free H1N1 influenza vaccine that could threaten the health of children between the ages of 6 months to 8 years and pregnant women in the State of Delaware during the 2009-2010 influenza season and;
- (2) Additional mercury-free H1N1 influenza vaccine cannot be made available from other medical providers, manufacturers, distributors, agencies, jurisdictions, or by any other means; and
- (3) The use of mercury containing H1N1 influenza vaccine is necessary to ensure these groups have access to H1N1 influenza vaccine during the 2009-2010 season.

IN SUPPORT of this determination, the Director finds as follows;

- 1) The World Health Organization has declared a pandemic of H1N1 influenza. H1N1 influenza is present in Delaware.
- 2) The Centers for Disease Control and Prevention has declared pregnant women and children under 8 years of age to be priority groups for H1N1 vaccination.

- 3) Current manufacturing processes limit the total amount of mercury-free H1N1 vaccine that is available.
- 4) All H1N1 influenza vaccine available in to Delaware residents will be distributed by the Centers for Disease Control and Prevention to the Division of Public Health.
- 5) The Centers for Disease Control and Prevention plans to make this vaccine available to Delaware in weekly shipments of no more than 15,000 doses per shipment over three-months.
- 6) This schedule of vaccine shipments creates a shortage of vaccine in Delaware at any given time during the projected duration of the epidemic at a time when vaccination of pregnant women and children under 8 years of age is urgent and should not be delayed.
- 7) Approximately 170,000 doses of mercury-free H1N1 influenza vaccine will be available in Delaware during the 2009-2010 influenza season.
- 8) There will be approximately 6,000 pregnant women in Delaware during the 2009-2010 influenza season, each of whom will require one dose of vaccine. There are approximately 94,000 children in Delaware over the age of six months and under the age of eight years, each of whom will require two doses of vaccine.
- 9) The total amount of mercury-free H1N1 vaccine will be insufficient to vaccinate all pregnant women and children under 8 years of age in Delaware.
- 10) H1N1 vaccine from other states and jurisdiction is not anticipated to be available to Delaware, given that all such states and jurisdictions are experiencing H1N1 influenza.

Pursuant to 16 Del. C. §510, a provider administering a mercury containing vaccine pursuant to this determination of shortage shall inform the client, parent or legal guardian of the client that the vaccine contains mercury, that they believe the vaccine to be medically necessary, and that the Director of Public Health has made a formal determination that the vaccine may be administered due to the existence of the shortage of mercury-free vaccines.

This determination of shortage is applicable for 12 months from the date of signature, and may be re-issued or amended upon further determination by the Director. This determination will be rescinded prior to 12 months from the date of signature if the Director determines that an FDA-approved mercury-free vaccine is, or can be made, adequately available.

  
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Karyl T. Rattay, MD, MS, FAAP, FACPM  
Director, Delaware Division of Public Health

  
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Date