

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

NOW COMES, the Division of Public Health, by and through Karyl T. Rattay, MD, MS Director, pursuant to 16 *Del.C.* §510(b), who has determined that a shortage of mercury-free influenza vaccine exists for children less than 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 of age and 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 of the Division of Public Health or their designee determines that a shortage of the mercury-free vaccine exists which could threaten the health of groups of individuals within the State including children under eight (8) years of age or pregnant women, and additional mercury-free vaccine cannot be made available from other medical providers, manufacturers, distributors, agencies, jurisdictions or by any other means."

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

- (1) There exists a flu epidemic and a shortage of mercury-free influenza vaccine that could threaten the health of children under 8 years of age and pregnant women in the State of Delaware during the 2012-2013 influenza season; and
- (2) Additional mercury-free 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 influenza vaccine is necessary to ensure these groups have access to influenza vaccine during the 2012-2013 season.

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

Current manufacturing processes limit the total amount of mercury-free product that is available to private and public sector providers to vaccinate children under 8 years of age and pregnant women.

Pursuant to 16 *Del. C.* §510, a provider administering a mercury-containing vaccine pursuant to this determination of a 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 until September 30, 2013 and may be re-issued or amended upon further determination by the Director. This determination may be rescinded at an earlier date if the Director determines that an FDA-approved mercury-free vaccine is, or can be made, adequately available.



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

01/22/2013

Date