

ILLINOIS DEPARTMENT OF PUBLIC HEALTH

**MERCURY-FREE VACCINE ACT
EXEMPTION DECLARATION**

NOW COMES, the Department of Public Health (hereinafter, the "Department"), by and through Sameer Vohra, Director, pursuant to the Mercury-Free Vaccine Act, 410 ILCS 51/1 et seq. sets forth this Exemption Declaration, and herein, states as follows:

RECITALS

WHEREAS, pursuant to the Department of Public Health Act, 20 ILCS 2305/2, the Department "has general supervision of the interests of the health and lives of the people of the State" of Illinois; and

WHEREAS, pursuant to the Communicable Disease Prevention Act, 410 ILCS 315/2, the Department has been charged with upholding "the public policy of this State that all children shall be protected, as soon after birth as medically indicated, by the appropriate vaccines and immunizing procedures to prevent communicable diseases which are or which may in the future become preventable by immunization"; and

WHEREAS, the State of Illinois has recognized and acknowledged through the Communicable Disease Prevention Act, 410 ILCS 315/1, that the general usage of "effective, safe and widely used vaccines and immunization procedures have been developed and are available to prevent ...diseases and to limit their spread"; and

WHEREAS, historically in Illinois, local health departments and private providers have provided immunization services to adults, children and other high-risk individuals since the mid-1970's. The vaccines are purchased by the individual providers or local health departments with local funds; and

WHEREAS, the Mercury-Free Vaccine Act, 410 ILCS 51/5, has set forth that any mercury-containing vaccines that contain more than 1.25 micrograms of mercury per dose are to be banned commencing on January 1, 2006; and

WHEREAS, the Mercury-Free Vaccine Act, 410 ILCS 51/5, has set forth that no person shall be vaccinated with a vaccine or injected with any product that contains, or prior to dilution, had contained as an additive, any mercury-based product, whether as a preservative or trace amount levels.

WHEREAS, the Mercury-Free Vaccine Act at 410 ILCS 51/10 also provides that the Department "may exempt the use of a vaccine from this Act if the Department finds that... (an) actual ... shortage of supply of a vaccine at a reasonable cost that would

prevent a person from receiving the needed vaccine..." makes necessary the exemption;

WHEREFORE, after conducting a review of vaccines containing thimerosal (ethyl mercury), the Department Hereby Declares an EXEMPTION to the Mercury-Free Vaccine Act for use of each of the following vaccines: Tetanus and Diphtheria Toxoid and multi-dose formulations of Influenza vaccines for the 2023-2024 influenza season.

IN SUPPORT of this Exemption to the vaccines, the Department states as follows:

In evaluating the basis for the Exemption for each of the vaccines, the Department established that the vaccine was procured either directly from the manufacturer, or via a distributor/reseller. Current manufacturing processes limit the total amount of thimerosal-free product that is currently available to private and public sector providers.

The Department's review of Tetanus and Diphtheria Toxoid Vaccine (hereinafter referred to as "Td"):

The Department preferentially distributes thimerosal-free Td vaccines through its VFC and Section 317 programs serving Illinois providers outside of the City of Chicago, when available. However, earlier this year, Td vaccines were available in VFC and Section 317 programs on an allocation basis. While no Td vaccines containing thimerosal were ordered by its publicly funded vaccine program providers as a sufficient quality of thimerosal-free Td vaccines were allocated, the Department might have been required to make this option available. Additionally, thimerosal-free Td vaccines were not available on CDC vaccine contract for the Adult Section 317 vaccine program for a period of time, so there may be unexpired Td vaccine containing traces of thimerosal remaining in the field. Further, the Department is aware that private providers in Illinois have the ability to purchase and administer tetanus-containing vaccines; Td vaccine are used particularly in the hospital emergency department setting for wound management and in public health emergencies. It is not possible to determine availability or current usage of any thimerosal-free products for private provider practice needs. Some of these products currently contain thimerosal and must be exempted to assure protection of those requiring these products according to physician's medical judgment. Therefore, the Department finds that there exists an actual or potential shortage of supply of thimerosal-free Td at a reasonable cost to meet the needs of the people of the State of Illinois, such that an exemption for use of the vaccine is necessary.

The Department's review of Influenza Vaccines 2023-2024 in multi-dose formulations (hereinafter referred to as "Influenza Vaccine")

The Department preferentially distributes thimerosal-free influenza vaccine through its VFC and Adult 317 programs serving Illinois providers outside of the City of Chicago.

To date, no thimerosal-containing vaccines were pre-ordered or procured this season for these programs. The Department procures influenza vaccine for the VFC and Section 317 programs from the CDC through a federal contract with the manufacturer. However, current manufacturing processes may limit the total amount of thimerosal-free product that is currently available to private and public sector providers nationwide.

The Department cannot predict if the vaccine supply will be sufficient to serve all individuals eligible in the public or private sectors without the use of some thimerosal-containing formulations. The influenza vaccine manufacturers do not reserve preservative-free influenza vaccine doses for any state. Therefore, the Department finds that there exists an actual or potential shortage of supply of thimerosal-free influenza vaccine at a reasonable cost to meet the needs of the people of the State of Illinois such that an exemption for the use of the vaccine is necessary.

The Department recognizes that vaccines are safe and effective. The Department supports efforts to ensure vaccine safety and it has been committed to using thimerosal-free vaccines in its Vaccines for Children programs since 1999. According to the Centers for Disease Control and Prevention, thimerosal is a mercury-containing compound that prevents the growth of dangerous bacteria and fungus. It is used as a preservative for vaccines in multi-dose vials, to keep the vaccine free from contamination. It may also be present in trace amounts from the manufacturing process. Two types of mercury to which people can be exposed - methylmercury and ethylmercury - are very different. Methylmercury is the type of mercury found in certain kinds of fish - not in vaccines. Ethylmercury is found in Thimerosal and clears the human body more quickly than methylmercury and is therefore less likely to cause harm.

The vaccine dosage and thimerosal concentration are as follows:

Vaccine	Trade Name	Manufacturer	Thimerosal Concentration ¹	Mercury
Td	TDVAX	MassBiologics	≤ 0.00012%	≤ 0.3 mcg/0.5 mL dose (single dose)
Seasonal Quadrivalent Influenza	Afluria Quadrivalent (multi-dose)	Seqirus	0.01%	12.25 mcg/0.25 mL dose, 24.5 mcg/0.5 mL dose (multi-dose) ²
	Flucelvax Quadrivalent (multi-dose)	Seqirus	0.01%	25 mcg/0.5 mL dose (multi-dose) ³
	Fluzone Quadrivalent (multi-dose)	Sanofi Pasteur Inc.	0.01%	12.5 mcg/0.25 mL dose, 25 mcg/0.5 mL dose (multi-dose) ⁴

¹ Thimerosal is approximately 50% mercury (Hg) by weight. A 0.01% solution (1 part per

10,000) of thimerosal contains 50 µg (micrograms) of Hg per 1 mL dose or 25 µg of Hg per 0.5 mL dose.

² Children 6 months of age to less than 3 years of age receive a 0.25 mL dose volume; individuals 3 year of age and older receive a 0.5 mL dose volume.

³ Individuals 6 months of age or older receive a 0.5 mL dose.

⁴ Children 6 months of age to less than 3 years of age may receive either a 0.25 mL or a 0.5 mL dose volume; individuals 3 years of age and older receive a 0.5 mL dose volume.

The Department finds that an exemption for use of the above listed vaccines is necessary due to evidence that insufficient supplies of these vaccines are available at a reasonable cost. Without the exemption, this actual or potential shortage of supply would prevent persons in the State of Illinois from receiving the needed vaccines and reasonably constitutes an actual or potential public health emergency under the Mercury-Free Vaccine Act, 410 ILCS 51/10.

Accordingly, the Department, by and through its Director, pursuant to Section 10 of the Mercury-Free Vaccine Act, hereby exempts the use of the following vaccines from the requirements of the Mercury-Free Vaccine Act:

**Tetanus and Diphtheria Toxoids (Td); and
Influenza Vaccine - 2023-2024 in multi-dose formulations.**

This Exemption is applicable for 12 months from the date of signature and may be reissued or amended upon further determination by the Department.

Sameer Vohra

**Sameer Vohra, MD
Director, Illinois Department of Public Health**

12/29/2023

Date