



Rod R. Blagojevich, Governor
Eric E. Whitaker, M.D., M.P.H., Director

525-535 West Jefferson Street • Springfield, Illinois 62761-0001 • www.idph.state.il.us

July 1, 2007

Dear Colleague:

On January 1, 2006, Public Act 94-0614, Mercury-Free Vaccine Act, became effective requiring vaccines to be mercury-free except for trace amounts. The Act provides a means for the Department to evaluate and assess the needs of Illinois citizens to have access to vaccines. The Illinois Department of Public Health has filed a statewide Declaration of Exemption on behalf of public and private health care providers for the following vaccines affected by the Act: Japanese Encephalitis, DT, Td, TT, Meningococcal Polysaccharide vaccine and the 2007-2008 Multi-dose Formula of Influenza vaccine as routinely used for individuals over three years of age. In accordance with the Act, it is the policy of the Department to preferentially distribute thimerosal free influenza vaccine to children ages 3 years and under as served through its Vaccines for Children (VFC) Program.

- **Japanese Encephalitis Vaccine**

Japanese Encephalitis Vaccine (JEV) contains thimerosal in quantities greater than trace amounts. Based upon information provided by vaccine suppliers, all currently manufactured JEV contains thimerosal in quantities greater than trace amounts and there are no plans by the manufacturer to change its formulation. JEV will be available for use in persons traveling to areas where Japanese Encephalitis is epidemic or endemic. A new formulation, in accordance with Public Act 94-0614 is currently not available from the manufacturer. Thus, the Illinois Department of Public Health has determined that JEV should be included in the Declaration of Exemption from P.A. 94-0614.

- **Combined Tetanus-Diphtheria Vaccines**

Based upon information provided by the vaccine manufacturer sanofi, Td Vaccine is available in a single-dose, pre-filled, preservative-free formulation. IDPH shall distribute only the preservative-free formulation through the VFC program. This vaccine is only administered to individuals over 7 years of age throughout adulthood. However, the Department is aware that an alternate formula is available in the marketplace that contains thimerosal in excess of 1.25 micrograms of mercury per dose. The thimerosal-free formulation is more costly for health care providers and may not be as readily available as the thimerosal-containing product. Therefore, due to the immunization requirements for booster doses in secondary and post-secondary education and the need to provide

wound care management to patients over age 7 years, the Department has determined that this vaccine shall be declared exempt from the mandates of the Mercury-Free Vaccine Act.

- **Tetanus Toxoid**

Although IDPH does not distribute tetanus toxoid through the VFC program, the Department is aware that private providers in Illinois do have the ability to purchase and administer tetanus containing vaccines, including tetanus toxoid, (referred to as TT) and Diphtheria-Tetanus vaccine, (referred to as DT vaccine), particularly in the hospital emergency department setting for wound management. These products currently contain preservatives in excess of 1.25 micrograms and must be exempted to assure protection of those requiring these products according to physician's medical judgment. It is not possible to determine availability of current usage of any preservative-free products to address private provider practice needs.

- **Meningococcal Vaccine**

Multi-dose Meningococcal vaccine (MPV) is currently produced in a single dose and multi-dose presentation. The multi-dose presentation exceeds 1.25 micrograms of preservative. IDPH does not distribute this formulation of meningococcal vaccine as part of the VFC program. However, in the event of an outbreak of meningococcal disease (i.e., in a university setting), it is critical to provide protection for at-risk individuals without delay. Delays in procuring a preservative-free formulation may result in illness and death among exposed individuals, when multi-dose MPV is readily available. Therefore, the Illinois Department of Public Health has determined that the multi-dose presentation of MPV must be included in the exemption of the Act.

- **Influenza Vaccine 2007-2008 multidose formulation**

It shall be the Department's policy that it will preferentially distribute thimerosal-free influenza vaccine to children under 3 years of age as available from the CDC for the VFC program. The Department has established that the influenza vaccine for the Vaccines for Children (VFC) program was procured from the Centers for Disease Control (CDC) through a federal contract with the manufacturer. Current manufacturing processes limit the total amount of preservative-free product that is currently available to private and public sector providers nationwide. For VFC Program needs, the Department submitted an order for 100% preservative-free product in February 2007. On February 14, 2007 the Department was notified by the CDC that Illinois' allocation of influenza vaccine would not reflect Illinois' request for 100% preservative-free product. The CDC informed the Department that because the amount of preservative-free

vaccine requested by federal grantees exceeded the amount of thimerosal preservative-free vaccine available under the federal contract, the CDC instituted an allocation formula to ensure equitable distribution to all grantees. According to the current allocation, the Illinois VFC program expects that approximately 71% of the influenza vaccine expected will be preservative-free. It is unknown what the final percentage will be until the manufacturing process and total yield is completed. As a result of the allocation, IDPH will have insufficient vaccine supply available to serve all individuals eligible through the VFC program without the use of thimerosal containing formulations. In addition, anyone over 3 years of age, including high risk adults and senior citizens would not have access to influenza vaccine without the use of thimerosal containing products administered by their primary health care provider. The manufacturer does not reserve preservative-free influenza vaccine doses for any state, and it can not target the vaccine for any one state. Therefore, the Illinois Department of Public Health has determined that insufficient amounts of preservative-free influenza vaccine are available to protect the health of all aged Illinois residents, and has issued an exemption for the influenza vaccine.

The Illinois Department of Public Health supports efforts to ensure vaccine safety. It has been committed to using preservative-free vaccines for its Vaccines for Children programs, beginning in 1999. As noted above, it shall also be the Department's policy to preferentially distribute thimerosal free influenza vaccine to children ages 3 and under as served through the VFC program. However, for the reasons cited above for specific vaccines, it is imperative that the people of Illinois continue to have access to life-saving vaccines when necessary, without potential compromise to health and safety.

If you have questions about this Declaration of Exemption, please contact Marilyn Thomas, Chief Counsel, 217-782-2043 or TTY (for hearing impaired use only) 800-547-0466. For questions about Illinois immunization requirements, please contact Karen McMahon, Immunization Program Administrator, 217-785-1455.

Sincerely,



Eric E. Whitaker, M.D., M.P.H.
Director

Attachment