



California
Department of
Health Services

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November 2, 2006

TO: California Physicians

FROM: Mark B. Horton, MD, MSPH
State Public Health Officer

SUBJECT: Use of Thimerosal-containing Influenza Vaccine In Children Younger Than 3 Years of Age From November 2, 2006 – December 14, 2006

SUMMARY

Effective July 1, 2006, California law [Health and Safety Code Section 124172 subdivision (a)] provides that vaccines containing specific levels of mercury cannot be administered to pregnant women and young children, except under certain circumstances. The Secretary of the California Health and Human Services Agency has granted an exemption to this restriction for influenza vaccine for children younger than 3 years of age that contains thimerosal in excess of the legal limit, when there is insufficient inventory of vaccine that complies with the law, from November 2, 2006 – December 14, 2006. The exception is being granted because of the dangers posed by influenza to young children, and because there is currently insufficient supply of the thimerosal-free influenza vaccine formulation licensed for use in young children.

Influenza Disease and Vaccine in Young Children

Each year, approximately 36,000 people in the United States die from influenza and its complications and at least 200,000 are hospitalized. During the 2004 flu season, more than 150 children in the U.S. died from influenza, and many more were hospitalized as a result of complications. No other vaccine-preventable disease kills more people in this country.

Otherwise healthy young children are hospitalized for influenza at rates comparable to other groups considered at high risk for influenza-related complications. In the past 2005-06 season in California, at least 112 children were hospitalized in intensive care because of influenza, and at least 16 died.

In February 2006, the federal Advisory Committee on Immunization Practices (ACIP) expanded its recommendations for influenza vaccination for the 2006-07 season from all children 6-23 months old to all children 6-59 months old, including the 6-35 month old children affected by the new mercury limits in California law.

However, because of delays in production or shipment, California is experiencing a temporary shortfall of the only formulation of influenza vaccine that meets California's new mercury standard for children under the age of 3 years (sanofi pasteur Influenza Virus Vaccine [Fluzone®], 0.25 ml single-dose syringes for pediatric use). Sufficient additional supplies of mercury-free vaccines are anticipated to be available within six weeks; however, while waiting for this supply, we could lose an irretrievable opportunity to vaccinate young children.

Because the delay in supply is creating a dangerous situation for our youngest children, the California District of the American Academy of Pediatrics, California Medical Association, California Academy of Family Physicians and Kaiser Permanente have all called for an exemption to allow use of thimerosal-containing vaccine in young children. These groups have expressed well-founded concerns that some parents do not have the option to delay vaccination because of personal barriers, like access to transportation.

Exemption to California Mercury Free Vaccine Act

California Health and Safety Code Section 124172 subdivision (c) permits the Secretary of the Health and Human Services Agency to exempt the use of a vaccine from section 124172 subdivision (a) "if the secretary finds, and the Governor concurs, that...shortage of supply of a vaccine that would prevent children under three years of age and knowingly pregnant receiving the needed vaccine," making "necessary the administration of a vaccine containing more mercury than the maximum level set forth in subdivision (a)..." (http://www.leginfo.ca.gov/pub/03-04/bill/asm/ab_2901-2950/ab_2943_bill_20040928_chaptered.html)

Because of the dangers posed by influenza to young children, and because there is currently insufficient supply of the thimerosal-free influenza vaccine formulation licensed for use in young children, an exemption has been granted from California Health and Safety Code Section 124172 subdivision (a) for influenza vaccine administered to children younger than 3 years old for the period of November 2, 2006 – December 14, 2006. Vaccine supplies will continue to be assessed during and after the period in the attempt to see that children receive maximal protection against influenza and reduced exposure to thimerosal.

During this exemption period, physicians who immunize young children against influenza should continue to seek ways to minimize thimerosal exposure to young children, including administering available single dose syringes of 0.25 ml influenza vaccine only to children 6-35 months of age.

As with all childhood vaccines, providers should continue to provide parents or guardians with the specific Vaccine Information Statement (VIS) that lists risks and benefits before immunization (<http://www.cdc.gov/Nip/publications/vis/>). Providers should also discuss their current and future availability of thimerosal-free vaccine with parents and guardians prior to immunization. During this discussion, please consider

- Children younger than 9 years old who have never received influenza vaccine are recommended to receive 2 doses of vaccine their first season
- Annual flu season usually peaks after December
- Whether or not your patient will have opportunities to return for immunization prior to the onset of influenza in your community

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For additional information about these topics, please contact the California Department of
Health Services Immunization Branch at (510) 620-3737 or www.getimmunizedca.org.

cc: DHS Immunization Branch Field Representatives
Local Health Officers
Local Health Department Immunization Coordinators