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State of California—Health and Human Services Agency
California Department of Public Health



EDMUND G. BROWN JR.
Governor

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TO: Interested Parties

SUBJECT: TEMPORARY EXEMPTION TO HEALTH AND SAFETY CODE SECTION 124172 (MERCURY-CONTAINING VACCINES) FOR SEASONAL INFLUENZA A VACCINE FROM OCTOBER 9, 2015 – DECEMBER 31, 2015.

Since 2006, California law [Health and Safety Code Section 124172 subdivision (a)] has stated 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 a temporary exemption to this restriction for 2015-16 Seasonal Influenza Vaccine (TIV) for children younger than three years of age from October 9, 2015 through December 31, 2015. This exemption was requested by the California District of the American Academy of Pediatrics, the California Academy of Family Physicians, the California Medical Association and the California Immunization Coalition.

The temporary exemption is being granted because of the danger posed in the next months by widespread influenza activity in California, and because there are limited supplies of thimerosal-free influenza vaccine for young children. The need for an extension of the temporary exemption will be assessed over this period, and the California Department of Public Health (CDPH) will be in regular contact with the vaccine manufacturer to assess product availability and to continue to monitor the vaccine supply.

Seasonal Influenza Disease and Vaccine

As in past years influenza activity is expected to become widespread nationwide between now and the Spring of 2016. Influenza vaccination can prevent influenza and influenza-related complications. The federal Advisory Committee on Immunization Practices (ACIP) and CDPH recommend influenza vaccine for everyone 6 months of age and older, especially those who are most vulnerable to severe influenza, including young children, pregnant women, people with chronic conditions, and the elderly.

While thimerosal-free formulations of influenza vaccine administered to adults in the United States appear to be ample, there are currently limited supplies of thimerosal-free influenza vaccine to protect California's young children, many of whom will need two doses of vaccine for maximal protection.

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 ... an epidemic or shortage of supply of a vaccine that would prevent children under three years of age and knowingly pregnant women receiving the needed vaccine," making "necessary the administration of a vaccine containing more mercury than the maximum level set forth in subdivision (a)..."

Because of the dangers posed by the seasonal influenza epidemic, and because there are currently insufficient supplies of thimerosal-free influenza vaccine that have levels of mercury below the state legal limits, a temporary exemption has been granted from California Health and Safety Code Section 124172 subdivision (a) for 2015-16 seasonal influenza vaccine administered to children younger than three years old for the period of October 9, 2015 through December 31, 2015, to be used as needed based on vaccine availability.

This temporary exemption will help protect young children at high-risk for severe influenza complications and is similar to exemptions issued in 2006, 2009 and 2013. Similar exemptions for influenza vaccine are currently in place in other states that have restrictions on mercury content, including Illinois and Iowa.

In accordance with the intent of the law, during this exemption period physicians should prioritize any remaining supplies of thimerosal-free influenza vaccine to young children when feasible. As with other routine vaccines, providers should continue to provide patients and parents or guardians with the specific Vaccine Information Statement (VIS) that lists risks and benefits before immunization.

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



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