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TO: California Physicians

FROM: Mark B. Horton, MD, MSPH
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SUBJECT: H1N1 Vaccine and Thimerosal Exemption

SUMMARY

Due to the emergence of the H1N1 influenza pandemic, it was necessary to begin unprecedented production of a second influenza vaccine specific to the pandemic H1N1 virus this year. Unfortunately, supplies of the new vaccine, including thimerosal-free doses, have been delayed. Because of the dangers posed by pandemic (H1N1) influenza, in particular for young children and pregnant women, an exemption was granted in mid-October pursuant to Health and Safety Code Section 124172 subdivision (a) to ensure that patients and parents had access to the vaccine as soon as possible.

The exemption applied only to the influenza A (H1N1) 2009 monovalent influenza vaccine and not to the seasonal influenza vaccine; moreover, it was time limited for the period of October 12, 2009 – November 30, 2009. The continued delay in production of this vaccine, limited quantities of thimerosal-free product and high public demand for the vaccine compel us to extend the exemption through September 30, 2010. Next year, we expect the seasonal influenza vaccine to incorporate the pandemic strain, resulting in the need for only one influenza vaccine with sufficient supplies of thimerosal-free product.

Pandemic Influenza (H1N1) Disease and Vaccine in Young Children

In April 2009 a novel pandemic influenza A (H1N1) virus was determined to be the cause of influenza illness in Southern California and the cause of outbreaks of respiratory illness in Mexico. On June 11, 2009, the World Health Organization (WHO) declared a worldwide pandemic, indicating uncontained community-level transmission of the pandemic influenza A (H1N1) virus in multiple areas of the world. Worldwide transmission of the pandemic influenza A (H1N1) virus has continued since June in both the Northern and Southern Hemispheres and is expected to increase in California during the autumn or winter.

Young children and pregnant women are amongst the groups that have been at higher risk of pandemic (H1N1) influenza. The incidence of hospitalization from pandemic influenza in the United States and in California has been highest among children younger than 4 years. Medical risk factors for severe infection, including pregnancy, are similar to those identified for seasonal influenza. At least four pregnant women in California have died from pandemic influenza A (H1N1) to date, and the incidence of hospitalization associated with pandemic

influenza in pregnant women has been at least four times higher than that of the general population.

Influenza vaccination can prevent influenza and influenza-related complications. The federal Advisory Committee on Immunization Practices (ACIP) has recently recommended that certain groups at highest risk for infection or influenza-related complications, including children and pregnant women, should be the initial targets for pandemic influenza A (H1N1) vaccination programs. Therefore, the national and California immunization campaigns are attempting to immunize pregnant women and young children promptly to protect them against pandemic (H1N1) influenza disease.

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)..."

Because of the dangers posed by influenza posed by pandemic (H1N1) influenza, and because there are currently insufficient supplies of influenza A (H1N1) 2009 monovalent influenza vaccine that have levels of mercury below the state legal limits, an exemption has been granted from California Health and Safety Code Section 124172 subdivision (a) for influenza A (H1N1) 2009 monovalent influenza vaccine administered to children younger than 3 years old and pregnant women for the period of October 12, 2009 - September 30, 2010.

In accordance with the intent of the law, during this exemption period physicians should prioritize supplies of thimerosal-free vaccine to young children and pregnant women as long as prioritization does not prevent the immunization of others.

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. Providers should also discuss the availability of thimerosal-free influenza A (H1N1) 2009 monovalent influenza vaccine with patients, parents and guardians prior to immunization. During this discussion, please consider

- Children younger than 3 years old are among those recommended to receive 2 doses of vaccine for full protection
- Pandemic (H1N1) influenza virus is currently circulating in California
- Whether your patients of any age will have additional opportunities to return for immunization in time to be protected against infection

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.

cc: CDPH Immunization Branch Field Representatives
Local Health Officers
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