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Director

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



ARNOLD SCHWARZENEGGER
Governor

October 15, 2009

TO: Interested Parties

SUBJECT: H1N1 Vaccine and Thimerosal Exemption

In 2004, in order to ensure that pregnant women and children under age 3 years have access to mercury-free vaccines, Governor Schwarzenegger signed AB 2943 (Pavley, Chapter 837, Statutes of 2004). Under the terms of AB 2943 and Health and Safety Code Section 124172, since July 1, 2006 vaccines containing levels of mercury greater than specified limits cannot be administered to pregnant women and young children, except under certain circumstances.

While many commonly used vaccines administered in the United States are available in ample supplies of mercury-free formulations, there are currently limited supplies of the new vaccine to protect Californians against pandemic (H1N1) influenza [Influenza A (H1N1) 2009 Monovalent Vaccine] that have levels of mercury below the state legal limits.

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 have been at higher risk of this pandemic influenza. The incidence of hospitalization from pandemic influenza in the United States and in California has been greatest among children younger than 4 years. 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.

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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 – November 30, 2009. Vaccine supplies and distribution will continue to be assessed to determine whether an extension of the exemption will be needed to protect Californians against pandemic (H1N1) influenza.

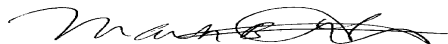
In accordance with the intent of the law, during this exemption period immunizers should prioritize supplies of thimerosal-free vaccine to young children and pregnant women as long as prioritization does not prevent the immunization of others.

Secretary Belshé and Governor Schwarzenegger have granted this exemption because of the health risk posed to California by pandemic (H1N1) influenza, and because there are inadequate supplies of vaccine to comply with the law.

Governor Schwarzenegger and Secretary Belshé remain deeply committed to implementing AB 2943 and ensuring that pregnant women and young children have access to mercury-free vaccines whenever possible.

If you have any questions about this topic, please contact the California Department of Public Health's Immunization Branch at (510) 620-3737 or www.getimmunizedca.org.

Sincerely,



Mark B. Horton, MD, MSPH
Director

Influenza A (H1N1) 2009 Monovalent Vaccines

Vaccine type	Manufacturer	Presentation	Age group	# of doses	Thimerosal	Route
Inactivated	Sanofi Pasteur	0.25 mL prefilled syringe	6--35 months	2 [†]	No	Intramuscular
		0.5 mL prefilled syringe	≥36 months	1 or 2 [†]	No	Intramuscular
		5.0 mL multi-dose vial	≥6 months	1 or 2 [†]	Yes	Intramuscular
Inactivated	Novartis Vaccines	0.5 mL pre-filled syringe	≥4 years	1 or 2 [†]	Trace < 0.1	Intramuscular
		5.0 mL multi-dose vial	≥4 years	1 or 2 [†]	Yes	Intramuscular
Inactivated	CSL Limited	0.5 mL prefilled syringe	≥18 years	1	No	Intramuscular
		5.0 mL multi-dose vial	≥18 years	1	Yes	Intramuscular
LAIV	MedImmune*	0.2 mL sprayer	2--49 years	1 or 2 ^α	No	Intranasal

[†]Two doses administered approximately 4 weeks apart (≥21 days acceptable) are recommended for children aged 6 months through 9 years.

*Not recommended for use in pregnant women or persons with chronic medical conditions.

^αTwo doses administered approximately 4 weeks apart are recommended for children aged 2--9 years.

Influenza A (H1N1) 2009 Monovalent Vaccine Dosage, by Age of Patient

Inactivated Influenza A (H1N1) Monovalent Vaccine¹ Dosage, by Age Group

Age Group	Dose	Number of Doses	Route
6 months through 35 months	0.25 mL	2²	Intramuscular³
3 years through 9 years	0.50 mL	2²	Intramuscular³
10 years and older	0.50 mL	1	Intramuscular³

Live Attenuated Intranasal Influenza A (H1N1) Monovalent Vaccine¹ Dosage

Age Group	Dose	No. of Doses	Route
2 years through 9 years^{4,6}	0.20 mL⁵	2⁶	Intranasal⁵
10 years through 49 years	0.20 mL⁵	1	Intranasal⁵

¹ Both inactivated and live-attenuated monovalent H1N1 vaccine prepared for the 2009-10 season will contain A/California/07/2009 (H1N1) strain.

² Two doses of inactivated monovalent H1N1 administered 4 weeks apart are recommended for children aged 6 months through 9 years of age.

³ For adults and older children, the recommended site of vaccination is the deltoid muscle. The preferred site for infants and young children is the vastus lateralis muscle located on the anterolateral aspect of the thigh.

⁴ Live attenuated monovalent H1N1 vaccine may be considered for healthy persons aged 2-49 years. This vaccine is not approved for use in pregnant women or persons with chronic medical conditions.

⁵ Live attenuated monovalent H1N1 is intended for intranasal administration only and should be equally divided between each nostril.

⁶ Two doses of live attenuated monovalent H1N1 vaccine administered 4 weeks apart are recommended for children aged 2-9 years of age.

The following is a guide to administering both seasonal and H1N1 vaccines:

- Providers may administer both the inactivated seasonal and the inactivated H1N1 influenza vaccines at the same visit (using separate anatomical sites) or at any time before or after each other.
- Providers may administer the inactivated seasonal and live H1N1 influenza vaccines together or at any time before or after each other.
- Providers administer the live seasonal and inactivated H1N1 influenza vaccines together or at any time before or after each other.
- Administering both the live attenuated seasonal and the live attenuated H1N1 influenza vaccines at the same visit is NOT recommended because of concerns about competition between the two vaccine viruses. If you have only live vaccines for both seasonal and H1N1 influenza available, you should separate the doses of the two live vaccines by at least 4 weeks.