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



EDMUND G. BROWN JR.
Governor

December 5, 2011

**NOTICE OF PUBLIC AVAILABILITY
OF MODIFIED SUPPORTING DOCUMENTS
AND CLARIFICATION FOR EMERGENCY REGULATIONS REGARDING
School Immunization Requirements: Grades 7 through 12 (DPH-10-004E)
Title 17**

Pursuant to Government Code Section 11346.8(d), notice is hereby given that the Department has modified the material listed below to the record of the rulemaking proceeding for emergency regulations regarding School Immunization Requirements: Grades 7 through 12, DPH-10-004E; and is hereby available for a 15-Day Comment Period.

This notice is intended to clarify that as provided for in Section 120335(d) and (f), the 7th grade pertussis booster requirement will continue to be effective past June 30, 2012.

Clarification is also provided regarding costs associated with DPH-10-004E. All costs originate from statute, Assembly Bill 354 (Arambula, Chapter 434, Statutes of 2010), and no cost is specifically due to the regulations. This information is now reflected in the STD 399 and Cost Estimating Methodology (CEM). Additional revisions to the new STD 399 and CEM are based on updated student enrollment and mandated cost reimbursement data. In addition, the Reference Note was updated to include Health and Safety Code section 120365.

Three reference documents were used in the preparation of the revised STD 399, CEM and related fiscal analysis. Added to the rulemaking file are:

- “Office of State Controller, State Mandated Costs Claiming Instructions No. 2003-18, Immunization Records: Hepatitis B, October 6, 2003, Revised July 1, 2011”
- “State of California, Department of Finance, *California Public K-12 Graded Enrollment and High School Graduate Projections by County, 2010 Series*, California, February 2011”
- “California Private Schools Kindergarten through Grade Twelve Enrollment and Staff Report 2008-09”

An obsolete form, Immunization Assessment of Seventh Grade Students, DHS 8259 (8/98) is repealed.

A new form is adopted, Pertussis Booster Immunization Assessment of Seventh Grade Students, CDPH 8259 (9/11), and is incorporated by reference. This is an annual report in which schools will report the pertussis booster status of their enrolled 7th grade pupils beginning in the 2012-2013 school year.

Section 6075 "Reporting" of the regulation text has been amended to delete a reference to an obsolete form, DHS 8259 (8/98) and to reflect the inclusion of the new form, Pertussis Booster Immunization Assessment of Seventh Grade Students, CDPH 8259 (9/11).

The fiscal and economic impacts in the STD 399 and Cost Estimating Methodology have been recalculated to include the costs of the ongoing requirement as well as the initial 2011-2012 requirement. Thus, the Fiscal Impact Estimate statements have been updated to reflect the revised STD 399 and Cost Estimating Methodology. Accordingly:

FISCAL IMPACT ESTIMATE:

A. Fiscal Effect on Local Government: There are no costs that result solely from this regulation. Costs resulting from the statute are as follows: Local health department costs are estimated to be up to \$765,000 for the one year, 7th through 12th grade requirement, Fiscal Year (FY) 2011-2012. The costs are estimated to be up to \$127,500 per year for the ongoing 7th grade only requirement for FY 2012-2013 and 2013-2014.

B. Fiscal Effect on State Government: There are no costs that result solely from this regulation. It is anticipated that additional costs to State Agencies resulting from the statute will be absorbed within their existing budgets. These estimated costs are:

Medi-Cal and Child Health and Disability Prevention program fee-for-service providers – The State portion of vaccine administration cost reimbursements are estimated to be \$480,000 in FY 2011-12, and \$80,000 for FY 2012-2013 and FY 2013-2014.

State Controller's Office (SCO) – Reimbursement by the SCO for the mandated cost of checking pertussis immunization records could reach \$4,350,000 in FY 2011-2012, if all eligible schools invoice for reimbursable costs. The cost could reach \$705,000 per year in FY 2012-2013 and FY 2013-2014. The savings to the State budget in mandated costs for discontinuing the hepatitis B immunization records check is estimated to be up to \$2,140,000, for FY 2011-2012, FY 2012-2013, and FY 2013-2014.

California Department of Education (CDE) – The annual cost is estimated to be approximately \$27,200 per year in FY 2011-2012, FY 2012-2013, and FY 2013-2014. These costs will be absorbed by CDE.

Managed Risk Medical Insurance Board (MRMIB) – Tdap immunizations have been a covered benefit under the Healthy Families Program since 2005, therefore, no new State costs will be incurred.

C. Fiscal Effect on Federal Funding of State Programs: There are no costs which result solely from this regulation. Cost resulting from the statute will include: the federal Medi-Cal program may bear up to \$480,000 for reimbursement of vaccine administration for the one year 7th through 12th grade requirement in FY 2011-12. The Medi-Cal program may bear up to \$80,000 for reimbursement of vaccine administration in FY 2012-2013 and FY 2013-2014.

D. All cost impacts, known to the Department at the time the notice of proposed action was submitted to the Office of Administrative Law, that a representative private person or business would necessarily incur in reasonable compliance with the proposed action:

Private Persons: Health insurance plans in California cover the cost of the pertussis booster vaccine and office visit except for any co-payments or deductibles. In 2014, the federal Affordable Care Act will eliminate co-payments or deductibles for immunizations for most health plans. The current average out-of-pocket cost for a pertussis booster immunization given to an insured adolescent is unknown. Families may also need to pay for immunizations given to insured adolescents at public health clinics. California statute provides exemptions to school entry immunization requirements based on parent/guardian personal beliefs; any exemptions to immunization that are taken will reduce costs to private persons. Therefore, the total costs to private persons are unknown.

Small Businesses: For the one-year 7th through 12th grade requirement in FY 2011-2012, the estimated costs to private schools would be up to \$360,000 (up to 240,000 private schools x \$1.50 per pupil for record checks). For the ongoing 7th grade requirement, the estimated annual costs to private schools would be up to \$60,000 (40,000 pupils x \$1.50 per record check).

E. Other Nondiscretionary Cost or Savings Imposed on Local Agencies: None

DETERMINATIONS: The Department has determined that the regulations would impose a mandate on local agencies or school districts. There may be costs for which reimbursement is required by Part 7 (commencing with Section 17500) of Division 4 of the Government Code. These regulations do impose a mandate on schools. Schools may be reimbursed if the Commission on State Mandates determines that this is a reimbursable state mandated cost. This cost is determined by the Commission.

The Department has made an initial determination that the regulations would not have a significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

The Department has determined that the regulations would not significantly affect the following:

- (1) The creation or elimination of jobs within the State of California.
- (2) The creation of new businesses or the elimination of existing businesses within the State of California.
- (3) The expansion of businesses currently doing business within the State of California.

The Department has determined that the regulations would affect small business.

The Department has determined that the regulations will have no impact on housing costs.

The proposed emergency regulation imposes a reporting requirement for schools with 7th through 12th grades, as well as an ongoing reporting requirement for schools with a 7th grade, to provide data on pertussis immunization to the California Department of Public Health. The Department finds that it is necessary for the protection of the health, safety, or welfare of the people of the State of California that the regulation applies to businesses.

ADDITIONAL STATEMENTS AND COMMENTS: In accordance with Government Code Section 11346.5(a)(13), the Department must determine that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed action.

15-DAY PUBLIC COMMENT PERIOD

Any written comments pertaining to the clarification and updated information, regardless of the method of transmittal, must be received by the Office of Regulations by 5:00 p.m. on December 21, 2011, which is hereby designated as the close of the written comment period. Comments received after this date will not be considered timely. Persons wishing to use the California Relay Service may do so at no cost by dialing 711.

Written comments may be submitted as follows:

1. By email to: regulations@cdph.ca.gov;
2. By fax transmission: (916) 440-5747;
3. By mail to: Office of Regulations, California Department of Public Health, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377; or
4. Hand delivered to: 1616 Capitol Avenue, Sacramento, CA 95814

All comments, including e-mail or fax transmissions, should include the author's name and U.S. Postal Service mailing address in order for the Department to provide copies of any notices for proposed changes to the regulation text on which additional comments may be solicited.

Materials regarding the action described in this notice (including this public notice, the regulation text, and the Initial Statement of Reasons (ISOR)) that are available via the Internet may be accessed at www.cdph.ca.gov by clicking on these links, in the following order: Decisions Pending and Opportunity for Public Participation, Regulations, Proposed.

To request that a copy of this public notice, the regulation text, and the ISOR or alternate formats for these documents be mailed to you, please call (916) 440-7439 (or the California Relay Service at 711), send an email to regulations@cdph.ca.gov, or write to the Office of Regulations at the address previously noted. Upon specific request, these documents will be made available in Braille, large print, audiocassette, or computer disc.

Any inquiries or written comments should contain the regulation package identifier, DPH-10-004E.

CONTACT INFORMATION:

Questions regarding the subject matter of the regulation should be directed to:

Dr. John Talarico
Center for Infectious Diseases
California Department of Public Health
(510) 620-3737

Questions regarding the regulatory process described in this notice should be directed to:

Miko Sawamura, Staff Services Manager II
Office of Regulations
(916) 440-7690

In the event the contact person named above is unavailable, inquiries should be directed to:

Coleen Keelan, Associate Governmental Program Analyst
Office of Regulations
(916) 440-7439

AUTHORITY: Sections 120330, 120335, and 131200, Health and Safety Code

REFERENCE: Sections 120325, 120335, 120365, 120370, and 120375, Health and Safety Code