



KAREN L. SMITH, MD, MPH
Director and State Public Health Officer

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



EDMUND G. BROWN JR.
Governor

NOTICE OF PROPOSED RULEMAKING
Title 17, California Code of Regulations
DPH-11-004 Pre-kindergarten and School Immunization Requirements
Notice Published: March 10, 2017

Notice is hereby given that the California Department of Public Health (Department) is proposing the regulations described below. This notice of proposed rulemaking commences a rulemaking to make the regulations permanent after considering all comments, objections, and recommendations regarding the proposal.

PUBLIC PROCEEDINGS

The Department is conducting a 45-day written public proceeding during which time any interested person or such person's duly authorized representative may present statements, arguments, or contentions (all of which are hereinafter referred to as comments) relevant to the action described in the Informative Digest/Policy Statement Overview section of this notice.

PUBLIC HEARING

The Department will hold a public hearing, during which time any interested person may present statements or arguments, orally or in writing, relevant to the proposed action described in this notice. The Department requests but does not require that persons who make oral comments at the hearing also submit a written copy of their testimony at the hearing.

Date and Time: April 24, 2017 at 9:00 a.m.
Place: Auditorium at 1500 Capitol Avenue, Sacramento, CA 95814
Purpose: To hear comments about this regulatory proposal

An agenda for the public hearing will be posted at the time and place of the hearing location.

For individuals with disabilities, the Department will provide assistive services such as sign-language interpretation, real-time captioning, note takers, reading, or writing assistance, and conversion of written public hearing materials into Braille, large print, audiocassette, or computer disk. Note: The range of assistive services available may be limited if requests are received less than ten business days prior to public hearing.

To request such services or copies of material in an alternate format, please write or call: Linda M. Cortez, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA



95814, at (916) 440-7807, email to linda.cortez@cdph.ca.gov, or use the California Relay Service by dialing 711.

WRITTEN COMMENT PERIOD

Any written comments pertaining to this proposal, regardless of the method of transmittal, must be received by Office of Regulations by 5:00 p.m. on April 24, 2017, 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. It is requested that email transmission of comments, particularly those with attachments, contain the regulation package identifier “DPH-11-004 Immunizations Regulations” in the subject line to facilitate timely identification and review of the comment;
2. By fax transmission to: (916) 440-5747;
3. By postal service or hand delivery to: California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814.

All comments should include the regulation package identifier, “DPH-11-004 Immunization Regulations,” and author’s name and mailing address.

AUTHORITY AND REFERENCE

The Department proposes to amend or repeal the regulation sections identified under the authority provided in sections 120330, 120335, and 131200 of the Health and Safety Code (HSC). This proposal implements, interprets, or makes specific, sections: 8263(e) and 49061 of the Education Code, and sections 120325, 120335, 120340, 120360, 120370, and 120375 of the HSC.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Problem Statement: Current regulations are out of date and inconsistent with statutory requirements passed during the past seven years. The Governor signed into law Assembly Bill (AB) 354, AB 2109, and Senate Bill (SB) 277, to better protect the public from vaccine-preventable diseases. In summary, AB 354 removed statutory dates and age restrictions for Haemophilus influenzae type b (Hib), mumps, pertussis, hepatitis B, and varicella immunizations. It also amended statute by requiring full immunization against pertussis for pupils advancing or being admitted to 7th grade beginning July 1, 2012. AB 2109 changed the criteria to obtain a personal beliefs exemption from immunization requirements for pupils beginning January 1, 2014. SB 277 eliminates the option for new pupils to obtain personal beliefs exemptions in 2016 and future years.

Objectives (Goals): Broad objectives for this proposed regulatory action are to update the regulations in order to be consistent with:

- AB 354 amendments
- AB 2109 requirements
- SB 277 requirements
- The age and vaccine dose recommendations of the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP)

Benefits: Anticipated benefits, including nonmonetary benefits to the protection of public health and safety, worker safety, the environment, from this proposed regulatory action are to:

- Protect the public's health by reducing outbreaks of vaccine-preventable diseases in schools.
- Prevent vaccine-preventable diseases and their potentially severe consequences.
- Reduce health care, local health department, and family costs associated with vaccine-preventable diseases.
- Provide clear guidance to pre-kindergarten facilities and school staff implementing immunization requirements.

DETERMINATION OF INCONSISTENCY AND INCOMPATIBILITY WITH EXISTING STATE REGULATIONS

The Department evaluated whether the proposed regulations are inconsistent or incompatible with existing state regulations. This evaluation included a review of the Department's existing general regulations, as well as the California Department of Education's (CDE) and the Department of Social Services' (DSS) regulations. The proposed regulations intentionally align with CDE regulation and therefore are not inconsistent or incompatible. DSS regulations are relevant to and mirror the regulations put forth by the Department. DSS is aware of the Department's proposal to amend its immunization regulations and plans to revise its corresponding regulations accordingly.

MANDATED BY FEDERAL LAW OR REGULATIONS

This regulatory proposal does not duplicate or conflict with any existing federal law or regulation.

BUSINESS REPORTING REQUIREMENTS

The Department finds it is necessary for the health, safety, or welfare of the people of this state that proposed section 6075, which requires a report, apply to businesses. Because many schools are moving towards electronic recordkeeping and submission of reports, the proposed regulation will be amended to allow electronic storage of specific required immunization information. The amended regulations specify the required fields, which can be recorded in any paper or electronic form. In addition, the amended regulations list the annual reporting requirement data elements and allow the electronic submission of annual assessment reports through the Department's Immunization Branch website.

LOCAL MANDATE

Existing regulations in Title 17, California Code of Regulations, sections 6000 through 6075 and the governing statutes in HSC sections 120325 through 120380, may impose a mandated cost for pupil immunization assessment by schools pursuant to Government Code sections 17514 and 17561. The State Controller's Office may be required to reimburse public school districts for the additional costs associated with the new immunization requirement to check for two doses of the varicella vaccine at kindergarten through 12th grade admission and, until the year 2024, at 7th grade. This reimbursement is based on estimated workload costs to implement the regulation. Schools already check for other required immunizations at kindergarten and at 7th grade, including the first dose of varicella vaccine that is currently required, the additional workload of the new requirements would be small.

If a test claim for reimbursement is submitted, the Commission on State Mandates will determine whether the costs are reimbursable.

FISCAL IMPACT ESTIMATES

A. Cost or Savings to any State Agency:

Department of Health Care Services (DHCS) Costs: Medi-Cal and Child Health and Disability Prevention Program (CHDP)

DHCS costs are not anticipated to increase because of these regulations. The California Healthy Families Program has transitioned its beneficiaries to DHCS Medi-Cal Managed Care health plans; thus, the beneficiaries are eligible for the Vaccine for Children Program (VFC) vaccine at no cost to the State. As most Medi-Cal fee-for-service beneficiaries will have transitioned to managed care, the vaccine administration fees will usually be included in the provider's managed care capitation rate. In addition, the Patient Protection and Affordable Care Act (ACA) requires coverage for all ACIP-recommended vaccines. Similar coverage requirements apply to the Medi-Cal Program – both fee-for-service and Medi-Cal managed care. Because the proposed regulations do not impose requirements beyond the ACIP recommendations, the proposed regulations will have no additional fiscal effect for students eligible for Medi-Cal or CHDP or previously eligible for the Healthy Families Program.

Department of Public Health Costs

Additional staff time at a cost of \$24,000 annually will be needed to implement the proposed regulations. These costs can be absorbed by the Department.

Department of Education Costs

Additional staff time at a cost of \$27,200 annually will be needed to implement the proposed regulations. These costs will be absorbed by CDE.

State Controller's Office (SCO) – Commission on State Mandates (CSM)

Public school districts may be able to claim funds from the SCO for implementing immunization requirements in HSC sections 120325 through 120380. This potential cost would only occur if both a test claim is submitted to the state and is approved by

the CSM. However, at this time it is not certain that a test claim would be filed and approved. The potential reimbursement is unknown at this time but would be marginal since schools already check for other required immunizations at kindergarten and 7th grade.

B. Cost to any Local Agency or School District:

Schools incur costs in implementing immunization requirements. Public school districts may file a test claim to the CSM and, if approved, file an invoice with the SCO for mandated cost reimbursement based on workload estimates.

C. Other Nondiscretionary Cost or Savings Imposed on Local Agencies:

Costs of Immunization by Local Public Health Departments (LHDs)

LHD costs are estimated to be at most \$4,644 for FY 2016-2017 and decreasing annually over time.

D. Cost or Savings in Federal Funding to the State:

There is no fiscal effect on federal funding of state programs.

COST IMPACTS ON REPRESENTATIVE PERSON OR BUSINESS

There should be no additional costs for private persons because of these proposed regulations. The provisions of the ACA include full coverage with no co-payments or deductibles of ACIP-recommended immunizations. The Department is not aware of any cost impacts that businesses would necessarily incur in reasonable compliance with the proposed action.

HOUSING COSTS

The Department has determined that the proposed regulations would not have an impact on housing costs.

EFFECT ON SMALL BUSINESS

Additional costs because of the proposed regulations for private schools, which are considered small businesses, are estimated to be similar to mandated cost estimate calculations of \$0.65 per pupil for kindergarten, and no additional cost per pupil for 7th grade. Currently, private schools are already checking all kindergarten and 7th grade students for other required immunizations, so the process for checking immunizations is already in place. The estimated cost of the proposed regulations for private schools with kindergarten is \$26,000 for FY 2016-2017 and annually thereafter.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE

The Department has made an initial determination that the proposed regulatory action would not have significant, statewide adverse economic impact directly affecting California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states. The private schools that are considered small businesses will incur some costs due to the proposed regulations; however, these costs will neither impose an undue burden nor have a significant

economic impact. Thus, there will be no significant adverse economic impact on California businesses.

RESULTS OF THE ECONOMIC IMPACT ASSESSMENT

The Department has made an initial determination that these regulations would not significantly affect the creation or elimination of jobs, the creation of new businesses or the elimination of existing businesses, or the expansion of businesses currently doing business within California. The proposed regulation would better protect children and adolescents from vaccine-preventable diseases. With fewer cases of vaccine-preventable disease in the pre-kindergarten and school settings, staff and communities will also be better protected from exposure to these diseases.

ALTERNATIVES CONSIDERED

The Department must determine that no other 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 this regulatory action is proposed, would be as effective and less burdensome to affected private persons than this action, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The Department considered not proposing any regulation changes other than those necessary to be consistent with amendments to HSC section 120365. However, the Department has decided to propose amendments to the regulations because over the years:

- Applicable statutes have been amended
- National recommendations of the ACIP, AAP, and AAFP have been updated
- Laboratory technologies have evolved
- Recordkeeping systems have advanced
- The Department has received feedback from schools that the current immunization requirement tables are confusing and inconsistent with national recommendations

CONTACT PERSON

Inquiries regarding the substance of the proposed regulations described in this notice may be directed to Amber Christiansen of the Immunization Branch, Center for Infectious Diseases, at (510) 620-3759.

All other inquiries concerning the action described in this notice may be directed to Linda M. Cortez, Office of Regulations, at (916) 440-7807, or to the designated backup contact, Julia Robinson at (916) 445-2529.

AVAILABILITY STATEMENTS

The Department has prepared and has available for public review an initial statement of reasons for the proposed regulations, all the information upon which the proposed regulations are based, and the text of the proposed regulations. The Office of

Regulations, at the address previously noted, will be the location of public records, including reports, documentation, and other material related to the proposed regulations (rulemaking file).

In order to request that a copy of this public notice, the regulation text, and the initial statement of reasons or alternate formats for these documents be mailed to you, please call (916) 440-7807 (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 disk.

The full text of any regulation which is changed or modified from the express terms of the proposed action will be made available by the Department's Office of Regulations at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

A copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations.

INTERNET ACCESS

Materials regarding the action described in this notice (including this public notice, the text of the proposed regulations, and the initial statement of reasons) 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 & Opportunities for Public Participation, Proposed Regulations.