



RON CHAPMAN, MD, MPH
Director

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



EDMUND G. BROWN JR.
Governor

ACTION: Notice of Proposed Rulemaking
Title 17, California Code of Regulations

SUBJECT: Newborn Screening Panel Fee Increase, DPH-11-020E

Notice is hereby given that the California Department of Public Health (Department) will conduct written public proceedings 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 this notice. Section 124977(d)(1) of the Health and Safety Code provides that for the purposes of the Administrative Procedure Act, the adoption of these regulations shall be deemed an emergency and necessary for the immediate preservation of the public peace, health and safety, or general welfare. These regulations are now in effect. This notice of proposed rulemaking commences a rulemaking to make the regulations permanent.

PUBLIC HEARING:

Date and Time: September 07, 2012 -- 10:00 am to 12 noon

Place: 1500 Capitol Ave, Sacramento, California 95814

Purpose: For the public to provide input regarding the proposed action

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 a public hearing.

To request such services or copies of materials in an alternate format, please write to Dawn Basciano, Office of Regulations, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377, or call (916) 440-7367, or use the California Relay Service by dialing 711.

WRITTEN COMMENT PERIOD: Any written comments pertaining to these regulations, regardless of the method of transmittal, must be received by the Office of Regulations by 5 p.m. on September 07, 2012, 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-11-020E" in the subject line to facilitate timely identification and review of the comment; or
2. By fax transmission: (916) 440-5747; or
3. By mail to: Office of Regulations, California Department of Public Health, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377; or hand-delivered to: 1616 Capitol Avenue, Sacramento, CA 95814. It is requested but not required that written comments sent by mail or hand-delivered be submitted in triplicate.

All comments, including email 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.

AUTHORITY AND REFERENCE: **Authority:** Sections 124977, 124996, 125000, 131050, 131051, and 131200, Health and Safety Code. **Reference:** Sections 124977, 124996, 125000 and 125001, Health and Safety Code.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW: Health and Safety Code (HSC) Sections 124977 and 125001 enacted by Assembly Bill (AB) 395 (Pan, Chapter 461, Statutes of 2011), requires the expansion of the Newborn Screening program (NBS) panel to include severe combined immunodeficiency (SCID) and other T-cell lymphopenias. The Department proposes to revise Subchapter 9, Testing for Heritable Disorders, Group 3, Newborn Screening Fee Collection, Title 17, California Code of Regulation (CCR), Division 1, Chapter 4, Section 6508, to raise the Newborn Screening fee from \$101.75 to \$111.70.

The Newborn Screening Program (NBS) administered by the Department provides organized quality-assured screening of 500,000 births annually in California for several genetic disorders. The Newborn Screening panel screens for over 75 disorders that include amino acid disorders such as phenylketonuria, organic acid disorders, fatty acid oxidation disorders, galactosemia, congenital hypothyroidism, congenital adrenal hyperplasia, sickle cell anemia, cystic fibrosis, and biotinidase deficiency and other hemoglobinopathies.

Early detection of SCID by newborn screening can significantly minimize and even prevent an undue financial burden being placed on the families and/or the health care system as a result of treating patients with immunodeficiency complications. SCID,

unlike the other disorders on the screening panel, is the only disorder where early medical treatment may eliminate the disease in a patient.

Sections 124977 and 124996, HSC, require that the program be "fully supported from fees collected." This fee may be adjusted by the Department's Director as needed to meet costs. A fee increase is required to provide revenue to ensure the expansion to SCID is fully implemented and sufficient resources are available on an ongoing basis. This funding will support expenditures associated with the ongoing workload of processing biospecimens at the CDPH Genetic Disease Laboratory, staff needed to perform the screening, testing chemicals, equipment acquisition, IT upgrades and supplies used to assay the results. Funding will also be utilized to support follow-up costs for screen positive cases, such as case management, diagnostic work-up, confirmatory processing, provider and family education, informative result mailers as well as incorporation and maintenance on an on-going basis of SCID into the Screening Information System (SIS).

EVIDENCE SUPPORTING THAT THE PROPOSED REGULATORY ACTION IS COMPATIBLE WITH EXISTING STATE REGULATIONS: The proposed regulatory action is compatible with existing state regulations that mandate that the Newborn Screening Program (NBS) administered by the Department according to HSC Code Sections 125000, 125001, and 125025 must provide organized quality-assured screening of all births in California for several genetic disorders. Disorders mandated for testing are established in HSC Sections 124977, 125000, 125001 and 125025, and in Title 17, California Code of Regulations (CCR), Section 6501. The Newborn Screening panel screens for over 75 disorders that include amino acid disorders such as phenylketonuria, organic acid disorders, fatty acid oxidation disorders, galactosemia, congenital hypothyroidism, congenital adrenal hyperplasia, sickle cell anemia, cystic fibrosis, and biotinidase deficiency and other hemoglobinopathies. Assembly Bill (AB) 395 (Pan, Chapter 461, Statutes of 2011) requires the expansion of the Newborn Screening program (NBS) panel to include severe combined immunodeficiency (SCID) and other T-cell lymphopenias.

HSC Sections 124977 and 124996 require that the program be "fully supported from fees collected." This fee may be adjusted by the Department's Director as needed to meet costs. The program previously collected \$101.75 for each newborn tested. The fees collected from the institution of birth are deposited in a special fund called the Genetic Disease Testing Fund (GDTF). The GDTF is used to pay expenses of program operations including costs of supplies, forms, educational materials and contracts with private vendors for laboratory analysis, tracking and follow-up of positive test results, data processing and fee collection.

EVIDENCE SUPPORTING THE FINDING OF NO SIGNIFICANT ADVERSE ECONOMIC IMPACT ON ANY BUSINESS: The requirement that the Newborn Screening fee be increased to \$111.70 will have no significant adverse economic impact on any business. It is unlikely that a \$9.95 increase in newborn screening fees that are paid by the institution of birth to the Department is sufficient to require any significant increase in premiums for health insurance charged to businesses.

Currently, there are no existing federal regulations or statutes applicable to this proposed regulation.

FORMS INCORPORATED BY REFERENCE: N/A

MANDATED BY FEDERAL LAW OR REGULATIONS: N/A

OTHER STATUTORY REQUIREMENTS: N/A

FISCAL IMPACT ESTIMATE:

A. Fiscal Effect on Local Government: None.

B. Fiscal Effect on State Government:

The newborn screening panel has been a covered benefit of public and private insurance programs and required for all newborns since 1980. Medi-Cal fee-for-service (FFS Medi-Cal): Approximately 45 percent of babies born in California per year are FFS Medi-Cal eligible or approximately 238,335 out of 529,633 births. State costs are estimated to be $\$9.95 \times 238,335$ up to $\$2,371,432.00$ annually of which 50 percent is covered by Federal Funding resulting in a cost of $\$1,185,712.00$ per year resulting in (an approximate cost of $\$595,000.00$ for the remainder of the current fiscal year – Attachment 1).

FY 2011-2012: The potential cost of the current fiscal year is $119,167 \times \$9.95 \div 2 = \$592,585.00$ (6 months of 50% of the total fee of $\$9.95$ for 45% of total births).

FY 2012-2013 and ongoing years: 45% of 529,633 births ($238,335 \times \$9.95$) $\div 2$ (50% of total fee funded by state government) = $\$1,185,712.00$.

C. Fiscal Effect on Federal Funding of State Programs:

The federal Medi-Cal program reimbursement for newborn screening fees is 50 percent of the total charge resulting in a Federal Funding impact of approximately $\$1,185,717.00$ per year. Approximately 238,335 births are expected to be eligible or Medi-Cal in California.

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

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

DETERMINATIONS

ECONOMIC IMPACT ANALYSIS: The Department has made an initial determination that the emergency regulations will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. The Department has determined that the emergency regulations will not significantly affect the following: the creation or elimination of jobs within the State of California, the creation of new businesses or the elimination of existing businesses within the State of California or the expansion of businesses currently doing business within the State of California.

The Department has made the determination that this emergency action will benefit the health and welfare of the residents of California. Early detection of SCID by newborn screening can significantly minimize and even prevent an undue financial burden being placed on the families and/or the health care system as a result of treating patients with immunodeficiency complications. SCID, unlike the other disorders on the screening panel, is the only disorder where early medical treatment may eliminate the disease in a patient.

The American Academy of Pediatrics indicates that early screening for SCID is critically important as data show that SCID infants who receive a related donor bone marrow transplant (BMT) within the first 14 weeks of life are significantly more likely to survive and have fewer problems over time than those who receive care later in infancy or who have already developed an infection. SCID and other T-cell lymphopenias occur in approximately 1 in 23,000 births in the state of California. The average lifetime cost for an undiagnosed, or late diagnosed SCID case is conservatively estimated at approximately \$2.2 million per child, anecdotal information predicts that the expected incidence of SCID and related T-cell lymphopenias in California is 18 children per year, for a cost that may exceed \$40,000,000.

The Department has made the initial determination that this emergency action would not have a significant benefit or adverse impact on California worker's safety or have any effect on the state's environment.

EFFECT ON SMALL BUSINESSES: The Department has determined there would be an effect on those small businesses that choose to participate in the Newborn Screening Program. There may be a small economic impact on some small businesses.

LOCAL MANDATE DETERMINATION: The Department has determined that the emergency regulations will not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by Part 7 (commencing with Section 17500) of Division 4 of the Government Code.

HOUSING COSTS DETERMINATION: The Department has determined that the emergency regulations will not impact housing costs.

STATEMENT OF THE RESULTS OF THE ECONOMIC IMPACT ANALYSIS: The Department has made the determination that this emergency action will benefit the health and welfare of the residents of California. Early detection of SCID by newborn screening can significantly minimize and even prevent an undue financial burden being placed on the families and/or the health care system as a result of treating patients with immunodeficiency complications. SCID, unlike the other disorders on the screening panel, is the only disorder where early medical treatment may eliminate the disease in a patient.

The American Academy of Pediatrics indicates that early screening for SCID is critically important as data show that SCID infants who receive a related donor bone marrow transplant (BMT) within the first 14 weeks of life are significantly more likely to survive and have fewer problems over time than those who receive care later in infancy or who have already developed an infection. SCID and other T-cell lymphopenias occur in approximately 1 in 23,000 births in the state of California. The average lifetime cost for an undiagnosed, or late diagnosed SCID case is conservatively estimated at approximately \$2.2 million per child, anecdotal information predicts that the expected incidence of SCID and related T-cell lymphopenias in California is 18 children per year, for a cost that may exceed \$40,000,000.

The Department has made the initial determination that this emergency action would not have a significant benefit or adverse impact on California worker's safety or have any effect on the state's environment.

COST IMPACTS ON REPRESENTATIVE PERSON OR BUSINESS:

Private Person: Health insurance plans in California cover the cost of the newborn screening fee. Uninsured participants will be responsible for 100 percent of the total fee of \$111.70, the total costs to private persons are unknown. The maximum newborn screening fee increase that an individual with or without partial health insurance would incur, is \$9.95. No adverse economic impact on individuals was reported to CDPH when past newborn screening fee increases were made.

Business: CDPH has made an initial determination that this emergency action 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. It is unlikely that a \$9.95 increase to the newborn screening fees is sufficient to require any significant increase in premiums for health insurance charged to covered beneficiaries. No adverse economic impact on businesses was reported to CDHP when past newborn screening fee increases were made.

BUSINESS REPORT: N/A

ALTERNATIVES STATEMENT: 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, would be as effective and less burdensome to affected private persons than the proposed action or would be more cost-effective to affected private persons and equally effective in implementing the statutory or other provision of law. The Department invites interested persons to comment with respect to alternatives to the proposed regulations at the scheduled hearing or during the written comment period.

CONTACT PERSON: Robin Cooley, Genetic Disease Screening Program, (510) 412-1500. All other inquiries concerning the action described in this notice may be directed to Alana McKinzie, Office of Regulations, at (916) 440-7689, or to the designated backup contact person, Dawn Basciano (916) 440-7367.

In any inquiries or written comments, please identify the action by using the Department regulation package identifier, DPH-11-020E.

AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF REGULATIONS:

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 noted above, 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) 440-7367 (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.

AVAILABILITY OF CHANGED OR MODIFIED TEXT: 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.

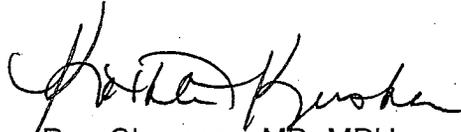
FINAL STATEMENT OF REASONS: A copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations.

INTERNET ACCESS: Materials regarding the action described in this notice (including this public notice, the regulation text, 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 and Opportunity for Public Participation, Regulations, Proposed.

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

DPH-11-020E

Date:


Ron Chapman, MD, MPH
Director