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

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NOTICE OF PROPOSED RULEMAKING

Title 17, California Code of Regulations
Newborn Screening Participation Fee DPH-16-015
Notice Published: October 7, 2016

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

PUBLIC PROCEEDINGS

The Department is conducting a 45-day written comment period and will hold a public hearing, 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.

PUBLIC HEARING

At the hearing, any person may present statements or arguments orally or in writing relevant to the proposed action described in the Informative Digest. 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:	October 18, 2016, 1:30 PM – 02:30 PM
Place:	East End Complex 1500 Capitol Avenue Hearing Room Sacramento, CA 95814
Purpose:	To hear comments about this action.

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

For individuals with disabilities, the Department shall provide upon request, 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 Laurel Prior, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814, or call (916) 440-7673, email Laurel.Prior@cdph.ca.gov, or use the California Relay Service by dialing 711.

WRITTEN COMMENT PERIOD

Written comments pertaining to this proposal must be received by the Office of Regulations by **5:00 pm on November 21, 2016,** which is hereby designated as the close of the written comment period. Comments received after this date will not be considered timely.

Written comments may be submitted as follows:

1. By email to: regulations@cdph.ca.gov. Please place the regulation identifier "DPH-16-015" in the subject line;
2. By FAX transmission to: (916) 440-5747;
3. By United States Postal Service to: California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814; or
4. Hand-delivered to: Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814.

All submitted comments should contain the regulation package identifier: **DPH-16-015**, author's name and mailing address.

AUTHORITY AND REFERENCE

Authority: sections 124977, 124996, 125000, 131050, 131051, and 131200 of the Health and Safety Code. Reference: sections 124977, 124966, 125000, and 125001 of the Health and Safety Code.

INFORMATIVE DIGEST / POLICY STATEMENT OVERVIEW

The Department revised Subchapter 9, Testing for Heritable Disorders, Group 3, Newborn Screening Fee Collection, in Title 17, California Code of Regulations (17 CCR), Division 1, Chapter 4, section 6508, to raise the Newborn Screening fee from $111.70 to $129.25 that became effective on July 1, 2016.

The Newborn Screening (NBS) Program is administered by the California Department of Public Health's (Department) Genetic Disease Screening Program (GDSP). Health and Safety Code (HSC) section 125000 requires screening of all newborns for heritable and congenital disorders and Section 125025 requires screening for sickle cell anemia. Testing for hemoglobinopathies, phenylketonuria, hypothyroidism and galactosemia is mandated in 17 CCR, Division 1, Chapter 4, Section 6508.

HSC section 124980 provides the director shall establish any regulations and standards for hereditary disorders programs as the director deems necessary to promote and protect the public health and safety.

HSC sections 124977 and 125001 enacted by Assembly Bill (AB) 1559 (Pan, Chapter 565, Statues of 2014) require the expansion of statewide screening of newborns to include screening for adrenoleukodystrophy (ALD) as soon as ALD is adopted by the federal Recommended Uniform Screening Panel (RUSP). ALD was added to the RUSP in February 16, 2016.

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. A fee increase is required to provide revenue to ensure the expansion to ALD is fully implemented and sufficient resources are available on an ongoing basis. This funding will support expenditures associated with the ongoing workload of processing newborn screening specimens at the Department's Genetic Disease Laboratory, staff needed to perform the screening, testing chemicals, equipment acquisition, information technology upgrades and supplies used to assay the results. Funding will also be utilized to support follow-up costs for screen positive cases, such as provider notification and case follow-up, diagnostic work-up, confirmatory processing, provider and family education, informative result mailers as well as incorporation and maintenance on an on-going basis of ALD into the Screening Information System (SIS).

Section 6508 Newborn Screening Fee Collection
Subsection (b) was revised to raise the Newborn Screening panel fee from $ 111.70 to $129.25. This revision is necessary because an increase of $17.55 is required to fully support the current program and the additional service expansions necessary to implement ALD screening components.

EVALUATION AS TO WHETHER THE REGULATIONS ARE INCONSISTENT OR INCOMPATIBILITY WITH EXISTING STATE REGULATIONS

The Department evaluated whether the regulation was inconsistent or incompatible with existing state regulations. This evaluation included a review of the Department's existing state regulations and those regulations specific to prenatal screening regulations. An Internet search of other state agency regulations was conducted and it was determined that no other state agency regulation addressed the same subject matter and that this proposal would not be inconsistent or incompatible with other state regulations. Therefore, the Department determined that this regulation is not inconsistent or incompatible with existing state regulations.

The regulatory action is compatible with existing state regulations that mandate that the program is administered by the Department according to HSC 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 of 17 CCR, section 6501. The program screens over 80 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, biotinidase deficiency, hemoglobinopathies, and severe combined immune deficiency.

Assembly Bill (AB) 1559 (Pan, Chapter 565, Statues of 2014) requires the expansion of statewide screening of newborns to include screening for adrenoleukodystrophy (ALD) as soon as ALD is adopted by the federal Recommended Uniform Screening Panel (RUSP). ALD was added to the RUSP on February 16, 2016.

MANDATED USE OF SPECIFIC TECHNOLOGIES OR EQUIPMENT

The technology that will be employed is the only testing method available for ALD screening and so no other technologies would be more effective in carrying out the mandated addition to the screening panel.

MANDATED BY FEDERAL LAW OR REGULATIONS

Currently, there are no existing federal regulations or statutes applicable to the regulations.

DOCUMENTS RELIED UPON

Not applicable.

DOCUMENTS INCORPORATED BY REFERENCE

Not applicable.

FORMS INCORPORATED BY REFERENCE

Not applicable.

OTHER STATUTORY REQUIREMENTS

Not applicable.

FISCAL IMPACT ESTIMATE

A. Fiscal Impact on Local Government:
The Department has made an initial determination that these regulations would not have a fiscal impact on any local entity or program.

B. Fiscal Impact on State Agencies:
The Medi-Cal program will incur approximately $3,847,000 in additional costs annually as a result of the screening fee increase. Of the $3,847,000, $1,923,500 will be General Fund costs. This cost was incorporated into the Medi-Cal base as an ongoing cost.

C. Other Nondiscretionary Costs or Savings Imposed on Local Agencies:
The Department has determined that the proposed regulations would not impose nondiscretionary costs or savings on local agencies.

D. Fiscal Impact on Federal Funding to the State:
The Department has made an initial determination that the proposed regulations will have an estimated annual cost to the Medi-Cal program of $3,847,000, and of that, $1,923,500 in General Fund costs. This cost was incorporated into the Medi-Cal base as an ongoing cost. Medi-Cal is funded in part from both state and federal funds (usually Federal Financial Participation in Medi-Cal is 50%).

E. Other Nondiscretionary Costs or Savings Imposed on Local Agencies:
Not applicable.

F. Estimated Benefits
The benefits anticipated by the adoption of these regulations are the protection of

public health and safety by expanding upon existing regulation provisions and the improvement of provisions for early detection, follow up and referrals for ALD diagnosis and treatment. Unless treated before symptoms show, children affected with ALD will die within a few months to a few years. Early detection and treatment provides dramatically better quality of life for the affected individuals and their families.

REASONABLE ALTERNATIVES TO THE PROPOSED REGULATORY ACTION THAT WOULD LESSEN ANY ADVERSE IMPACT ON SMALL BUSINESS

No reasonable alternatives considered by the Department or that otherwise have been identified and brought to the attention of the Department would be more effective in carrying the purposes for which the regulations are being written or would be as effective as and less burdensome to affected private persons or small businesses than the action taken.

EVIDENCE SUPPORTING THE FINDING OF NO SIGNIFICANT ADVERSE ECONOMIC IMPACT ON ANY BUSINESS, INCLUDING THE ABILITY TO COMPETE

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

While the Department directly bills hospitals and midwives, the screening test is generally covered by health insurance and health plans and their capitated medical groups and health insurers. As such the hospitals and midwives are generally reimbursed for the cost of the screening test and the health plans and health insurers account for the increase in the form of increased premiums and such increases are typical for health care costs in any given year.

The total annual costs of this regulation are estimated to be $8,724,000 (497,083 estimated number of newborns to be screened in FY 2016-17 X 17.55) of this total; the total estimated to be covered by health plans and health insurers in the private sector is $4,877,000.

It is unlikely that a $17.55 increase in newborn screening fees, paid by the hospital of birth to the Department, is sufficient to require any significant increase in premiums for health insurance charged to businesses. Past increases in newborn screening fees had no adverse business impacts that were reported to the Department.

STATEMENTS OF DETERMINATION

A. 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:

1. **The creation or elimination of jobs within the State of California.** The proposal may result in the creation of jobs but its extent cannot be estimated.

2. **The creation of new businesses or the elimination of existing businesses within the State of California**. The proposal may result in the creation of new businesses but its extent cannot be estimated. The proposal should neither result in the elimination of any existing businesses.

3. **The expansion of businesses currently doing business within the State of California.** The proposal may result in the expansion of businesses currently doing business with the State of California but its extent cannot be estimated.

4. **The benefits of the regulation to the health and welfare of California residents** - The Department has made the determination that this emergency action will benefit the health and welfare of the residents of California. Early detection of ALD 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 adrenal and neurological complications.

   According to the California Department of Health Care Services, between 2004 and 2013, the cost of treating 22 children with the disease in the California Children's Services program was slightly more than $100,000 per child, during that nine-year period.

5. **The benefits of the regulation to worker safety, and the state's environment.** The Department has made the initial determination that this emergency action will not have a significant benefit or adverse impact on California worker's safety or have any effect on the state's environment.

B. 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.

C. ALTERNATIVES CONSIDERED

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 policy or other provision of law.

The Department has determined that there are no reasonable alternatives to the technologies chosen to implement ALD screening. The technology that will be employed is the only testing method available for ALD screening and so no other

technologies would be more effective in carrying out the mandated addition to the screening panel.

D. LOCAL MANDATE

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.

E. HOUSING COSTS

The Department has determined that the emergency regulations will not impact housing costs.

Cost Impacts on Representative Person or Business

The Department has determined that there is no cost effect on private persons. The NBS specimen collection is mandatory now (with the exception of religious objection) and will continue to be under these regulations.

California Department of Public Health (CDPH) has made an initial determination that this emergency action would not have a significant statewide adverse economic impact directly affecting businesses.

While CDPH directly bills hospitals and midwives, the screening test is generally covered by health insurance and health plans and their capitated medical groups and health insurers. As such the hospitals and midwives are generally reimbursed for the cost of the screening test and the health plans and health insurers account for the increase in the form of increased premiums and such increases are typical for health care costs in any given year.

The total annual costs of this regulation are estimated to be $8,724,000 (497,083 estimated number of newborns to be screened in FY 2016-17 X 17.55) of this total, the total estimated to be covered by health plans and health insurers in the private sector is $4,877,000.

The Department is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

CONTACT INFORMATION

Inquiries regarding the substance of the regulation described in this notice may be directed to Robin Thomas, Nurse Consultant Specialist III, Genetic Disease Screening Program, at (510) 412-1519.

All other inquiries concerning the action described in this notice may be directed to Laurel Prior, Office of Regulations, at (916) 440-7673.

In any inquiries or written comments, please identify the action by using the Department regulation package identified, **DPH-16-015.**

AVAILABILITY STATEMENTS

The Department has prepared and has available for public review an initial statement of reasons for the regulation, all the information upon which the amendments to the regulation are based upon and the text of the regulations. The Office of Regulations is located at 1415 L Street, Suite 500, Sacramento, CA 95814, and is the location of the 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, please call (916) 440-7673 (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 that 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 regulation text of the proposed regulations, and the initial statement of reasons) are available via the Internet and may be accessed at www.cdph.ca.gov by clicking on these links, in the following order: Decisions Pending & Opportunity for Public Participation, Proposed Regulations.