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

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TITLE 17. CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
NOTICE OF PROPOSED RULEMAKING
Newborn Screening Program Participation Fee (DPH-17-016EFP)
Notice published: July 27, 2018

NOTICE IS HEREBY GIVEN that the California Department of Public Health (Department) has adopted the regulations described in this notice on an emergency basis, and they are now in effect. The purpose of this regulatory proposal is to make the emergency regulations permanent after considering all comments, objections, and recommendations regarding the regulations.

PUBLIC PROCEEDINGS

The Department is conducting a 45-day written public comment period and will hold a public hearing (pursuant to Health and Saf. Code § 124977, subd. (c)(1), within 120 days from the emergency effective date of July 19, 2018, OAL Emergency Filing No. 2018-0713-02EFP, 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 action described in the Informative Digest. The Department requests, but does not require tht persons who make oral comments at the hearing also submit a written copy of their testimony at the hearing.

Date and Time:	September 11, 2018 from 1:30 p.m to 2:30 p.m.
Place:	East End Complex, 1500 Capitol Avenue, Hearing Room 167, 1st floor Sacramento, CA 95814
Purpose:	To hear comments about this action.

ASSISTIVE SERVICES

For individuals with disabilities, the Department will provide assistive services such as the conversion of written materials into Braille, large print, audiocassette, and computer disk. For public hearings, assistive services can include sign-language interpretation, real-time captioning, note takes, reading or writing assistance. To request these assistive services, please call (916) 440-7673 (or California Relay at 711 or 1-800-735-2929), email Regulations@cdph.ca.gov or write to the Office of Regulations at the address noted above. Note: The range of assistive services available may be limited if requests are received less than 10 business days prior to a public hearing.

WRITTEN COMMENT PERIOD

Written comments relevant to this proposal, regardless of the method of transmittal, must be received by the Office of Regulations by **September 10, 2018 by 5:00 p.m**. to be considered. Comments received afterwards will not be considered timely.

Written comments may be submitted by mail (to address next), facsimile (FAX) at (916) 636-6220 or by e-mail to Regulations@cdph.ca.gov. **Please include the package identifier DPH-17-016E**.

California Department of Public Health
Office of Regulations
1415 L Street, Suite 500
Sacramento, CA 95814

The Department will consider all comments received regarding the proposal equally, whether submitted in writing or through oral testimony at a public hearing.

AUTHORITY AND REFERENCE

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

INFORMATIVE DIGEST/ POLICY STATEMENT OVERVIEW

This regulatory emergency amendment increased the Newborn Screening (NBS) Program's all-inclusive program participation fee from $129.25 to $141.25 in Title 17, California Code of Regulations (17 CCR), Division 1, Chapter 4, Subchapter 9, Group 3, Article 4, Newborn Screening Fee Collection, section 6508, subdivision (b). The increase is necessary for the expansion of statewide screening of newborns to include screening for Mucopolysaccharidosis Type I (MPS I) and Pompe disease.

Problem Statement:

The California Department of Public Health's (Department) Genetic Disease Screening Program (GDSP) administers the NBS Program, as mandated by Health and Safety Code sections 125000, 125001, and 125025 to provide organized, quality assured screenings for all births in California for several genetic disorders. Disorders mandated for testing are established in Health and Safety Code sections 124977, 125000, 125001 and 125025, and in 17 CCR section 6508, subdivision (b). The NBS Program panel screens for over 80 disorders that include amino acid disorders such as phenylketonuria, hemoglobinopathies, organic acid disorders, fatty acid oxidation disorders, galactosemia, congenital hypothyroidism, congenital adrenal hyperplasia, sickle cell anemia, cystic fibrosis, biotinidase deficiency, severe combined immune deficiency, and adrenoleukodystrophy.

Senate Bill (SB) 1095 (Chapter 393, Statutes of 2016) established Health and Safety Code section 125001, subdivision (d) and required the GDSP to expand statewide screenings of newborns by adding new tests within two years of the disease screen being adopted by the federal Recommended Uniform Screening Panel (RUSP). At the time the bill was chaptered, there were two disorders on the RUSP that were not on the NBS Program panel: MPS I and Pompe disease, which were added to the RUSP in 2016 and 2015, respectively. Therefore, as

specified in state statutes, the Department is required to add these disorders to the NBS Program panel by August 30, 2018.

Health and Safety Code sections 124977 and 124996 require the NBS Program to be “fully supported from fees collected.” The Department’s Director may adjust this fee as needed to meet costs. The NBS Program previously collected $129.25 for each newborn tested. The fees collected from the institution of birth are deposited into 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.

To begin screening for Pompe disease and MPS I, a test method for each disorder must be developed by the Department. In Fiscal Year (FY) 2017-2018, the 2017 Budget Act included $2.25 million in one-time Local Assistance funding and $139,000 in State Operations funding to plan, prepare for, and incorporate MPS I and Pompe disease into the Screening Information System and support one Research Scientist II to start-up test method development activities.

The FY 2018-2019 Budget Change Proposal for routine screening for Pompe and MPS I to support SB 1095 to expand the NBS Program was approved to add fifteen positions to address the routine testing and ongoing workload associated with the addition of Pompe disease and MPS I. An increase in Local Assistance expenditure authority was approved to purchase the consumables, supplies, and reagents related to the ongoing screening and testing activities. The FY 2018-2019 Budget Change Proposal authorizing the expansion of the NBS Program and the November and May Revision Estimates authorizing Local Assistance expenditures were approved by the Department of Finance and the Legislature during the FY 2018-2019 budget building process. All of the expenditure authority was included in the budget that was signed by the Governor on June 27, 2018.

The Department’s GDSP works to improve the quality of testing by preventing false negative tests and keeping false positive test rates as low as possible. Incorporating new testing strategies to reduce false positive test rates to prevent unnecessary stress and anxiety for parents is vital. By coupling the primary screening method with a second linked test that is more specific than the original method, the Department can improve diagnostic specificity (fewer false positives) without reducing sensitivity (the rate of false negatives). A second-tier test uses the same blood specimen from the original test, eliminating that additional burden to families or hospital personnel, and measures additional metabolites that either strongly supports the presumption of a true positive case or shows that the patient does not have the disorder.

In FY 2017-2018, the 2017 Budget Act included a one-time increase of $300,000 in State Operations expenditure authority, and a one-time transfer of $330,000 from Local Assistance to State Operations expenditure authority, for the purpose of mass spectrometry equipment and testing method development. These one-time increases provided expenditure authority for the initial start-up activities for second-tier testing.

The FY 2018-2019 Budget Change Proposal was approved to support the workload associated with Second-Tier Newborn Testing. A shift of $460,000 from Local Assistance to State Operations was approved to fund three positions to perform the ongoing second-tier testing that will begin in FY 2018-2019. The FY 2018-2019 Budget Change Proposal was approved by the

Department of Finance and the Legislature during the FY 2018-2019 budget building process. All of the expenditure authority was included in the budget that was signed by the Governor on June 27, 2018.

Pompe disease is an inherited disorder caused by the buildup of a complex sugar called glycogen in the body's cells. The accumulation of glycogen in certain organs and tissues, especially in muscles, impairs their ability to function normally.

MPS I is a condition that affects many parts of the body. Children with MPS I often have no signs or symptoms of the condition at birth, but it is a progressive disease if not treated early. Individuals with MPS I may have a large head (macrocephaly), heart valve abornormalities, and an enlarged liver and spleen.

Benefits and Objectives (Goals):
California newborns and their families will benefit from the expansion of statewide screening of newborns by adding new tests within two years of the disease screen being adopted by the federal Recommended Uniform Screening Panel (RUSP). An early diagnosis through newborn screening coupled with appropriate treatment can slow the progress of the diseases before some irreversible disease processes have begun. An early diagnosis is the first step in an appropriate medical care treatment plan. An early diagnosis provides parents with more time to become educated about how to provide the best possible care for a child with either condition and helps parents make informed life choices, including reproductive and health plan decisions.

The cost of including the new disorders to the NBS Program panel requires complicated and labor-intensive development activities, all of which require the highest standards of medical and scientific procedures and protocols. New equipment is necessary as well as additional staff to run the test. The Department cannot absorb the additional workload associated with adding both disorders without an increase in fees, appropriation authority, and associated staffing.

This rulemaking is in response to changes in technology, testing methodologies, and the expansion of the NBS Program. Because the NBS Program is fully fee supported as required by state statute, a fee increase is required to provide revenue to ensure the expansion to Pompe disease and MPS I is fully implemented and that sufficient resources are available on an ongoing basis. This funding will support expenditures associated with the ongoing workload of processing biospecimens at the Department's Genetic Disease Laboratory; staff needed to perform the screening; testing chemicals; equipment acquisition; IT upgrades; and supplies used to run the assay. 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 Pompe and MPS I into the Screening Information System.

The Legislature has found that timely implementation of changes in genetic screening programs and continuous maintenance of quality statewide services requires expeditious regulatory action and administrative procedures (Health and Saf. Code § 124977, subd. (c)(1).) The Health and Safety Code provides authority for the Department to adopt emergency regulations. Health and Safety Code section 124977, subdivision (d)(1) specifies that 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, and that the regulations shall not be subject to the

review and approval of the Office of the Administrative Law (OAL); shall be submitted directly to the Secretary of State for filing; and shall become effective immediately upon filing by the Secretary of State. Health and Safety Code section 124977, subdivision (d)(1) also requires the Department to conduct a public hearing within 120 days of filing with the Secretary of State, and to submit to the OAL the adopted regulation, a final statement of reasons, and an updated informative digest. Health and Safety Code section 124977, subdivision (d) (2) specifies that this emergency regulation shall not be repealed by the OAL and shall remain in effect until revised or repealed by the Department.

The GDSP will continue to monitor NBS Program revenues and expenses in order to determine whether future increases or decreases in the NBS Program's participation fees are warranted.

Specific Discussion of Regulatory Action
Section 6508, subdivision (b), Newborn Screening Fee Collection.

The regulation amended the section to increase the program's participation fee for Newborn Screening from $129.25 to $141.25. The amendment increases the Newborn Screening Program participation fee as necessary for the expansion of statewide screening of newborns to include screening for MPS I, and Pompe disease.

Comparable Federal Regulations or Statutes
These regulatory changes do not conflict with or duplicate any federal or state statutes, regulations, or policies.

Evaluation of Inconsistency/Incompatibility with Existing State Regulations
The Department evaluated whether the regulation is inconsistent or incompatible with existing state regulations. This evaluation included a review of the Department's existing state regulations and those regulations specific to newborn screening fee regulations. An Internet search of other state agency regulations was also performed and it was determined that no other state agency regulation addressed the same subject matter and that this proposal was not inconsistent or incompatible with other state regulations. Therefore, the Department has determined that this regulation is not inconsistent or incompatible with existing state regulations.

This regulatory action is compatible with existing state regulations that mandate that the NBS is administered by the Department's GDSP according to Health and Safety Code sections 125000, 125001, and 125025 to provide organized, quality-assured screening of all births in California for several genetic disorders. Disorders mandated for testing are established in Health and Safety Code sections 124977, 125000, 125001 and 125025 of 17 CCR, section 6501. The NBS 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, severe combined immune deficiency, and adrenoleukodystrophy.

Local Mandate
The Department has determined that these 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.

Technical, Theoretical, and/or Empirical Study, Reports or Documents Relied Upon (Govt. Code 11346.1(b)(2)
Department of Finance Demographic Research Unit (DRU) Birth Projections for calendar year 1990-2040, (Birth Projections).

Documents/Forms Incorporated by Reference: None.

Mandated by Federal Law or Regulations: These regulatory changes do not conflict with or duplicate any federal or state statutes, regulations or policies.

Other Statutory Requirements: Not applicable.

FISCAL IMPACT ESTIMATE

Costs to any Local or School District Requiring Reimbursement Pursuant to section 17500 et seq.
No costs because this regulation does not affect local agencies or schools.

Costs or Savings Impact to any State Agency
The Medi-Cal program will incur approximately $2,506,000 in additional costs annually as a result of the screening fee increase of which $1,253,000 will be General Fund costs. This cost was incorporated into the Medi-Cal base as an ongoing cost.

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

Costs or Savings in 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 $2,506,000, and of that, $1,253,000 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%).

Statement of the Results of the Economic Impact Assessment (GC § 11346.5(a)(10) and 11346.3(b))

(b)(1) The Department has determined that the rulemaking will not significantly affect the following pursuant to Government Code Sections 11346.3, subd. (b)(1), (A) through (D):

(A) **The Creation or Elimination of Jobs within the State of California**
The regulation will not create or eliminate jobs in California. The impact to insurers in processing the participation fee increase, and to insurance/health plan members, will be minimal.

(B) **The Creation of New Businesses or the Elimination of Existing Businesses within the State of California.** The regulation will not create new businesses or eliminate existing businesses within the State of California. The cost impact to insurers

of $12.00 for each covered newborn is unlikely to have a significant impact on any affected business, or insurance/health plan members.

(C) **The Expansion of Businesses Currently Doing Business within the State of California.** The regulation will not expand businesses within the state of California. The impact to insurers in processing the participation fee increase will be minimal.

(D) **Worker Safety** This regulation does not affect worker safety because it does not affect workers;
California's Environment This regulation does not affect the State's environment. The Department has determined that the rulemaking impacts the following pursuant to Government Code section 11346.3, subdivision (b)(1)(D):

1. **Health and Welfare of California Residents**. The regulation is expected to increase and strengthen the health and welfare of California residents. An increase in the participation fee for the NBS Program ensures that the NBS Program remains self-sufficient and protects statewide access to newborn screening and follow-up services, thereby reducing the emotional and financial burden of disability and death caused by genetic and congenital disorders.

2. The amendment increases the NBS Program participation fee as necessary for the NBS Program to expand statewide screening of newborns to include screening for MPS I, and Pompe disease.

ALTERNATIVES STATEMENT (11346.5(A)(13)):
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 policy or other provision of law.

The Department has made an initial determination that there are no acceptable alternatives to the regulation to fund the operations of the NBS Program and protect the public interest in maintaining a statewide Newborn Screening Program. There is no alternative to compliance with SB 1095 and HSC 125001, which requires the Department to add Mucopolysaccharidosis Type I and Pompe disease to the California Newborn Screening Program panel by August 30, 2018. 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 out the purposes for which the regulations are being written.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING THE ABILITY OF CALIFORNIA TO COMPETE WITH BUSINESSES IN OTHER STATES (11346.5(A)(7)):
The Department has made a determination that the 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 impact to insurers in

processing the change in the participation fee will be minimal. The cost impact to insurers of $12.00 for each covered newborn is unlikely to have a significant impact on any affected business. It is unlikely that the fee increase would be sufficient to require any significant increase in premiums charged to insurance/health plan members.

COST IMPACT ON REPRESENTATIVE PERSON OR BUSINESS (11346.5(A)(9))

There would be a cost increase of $12.00 per NBS test in the NBS Program participation fee for those businesses providing health coverage to women delivering newborns.

While the Department directly bills hospitals and midwives, the Newborn 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 $5,739,852 (478,321 estimated numbers of newborns to be screened in FY 2018-19 X $12.00).

It is unlikely that a $12.00 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.

COMPARABLE FEDERAL REGULATIONS OR STATUTES (G.C. 11346.2 (C))

These regulatory changes do not conflict with or duplicate any federal or state statutes, regulations or policies.

SMALL BUSINESS (1 CCR 4(A) AND (B))

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.

EFFECT ON HOUSING COSTS (GC 11346.5(A)(12)

The Department has determined that the rulemaking has no impact on housing costs.

BUSINESS REPORT (11346.5)(A), (11; 11346.3(D))

The Department has determined that the rulemaking would have no new or additional reporting requirements applicable to businesses.

CONTACT PERSONS

Inquiries concerning the subject matter in this notice may be directed to Sara Goldman of the Department's Genetic Disease Screening Program at (510) 412-1460. For inquiries related to the regulatory process, to Laurel Prior, Office of Regulations, at (916) 440-7673.

AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF REGULATIONS, AND RULEMAKING FILE

The Department will have the entire rulemaking file available for inspection and copying throughout the rulemaking process at its office at the above address. As of the date this notice

is published in the Notice Register, the rulemaking file consists of this notice, the proposed text of the regulations, initial statement of reasons, and information upon which proposed rulemaking is based. Copies may be obtained by contacting the Office of Regulations at Regulations@cdph.ca.gov or by phone at (916) 558-1710.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

After considering all timely and relevant comments received, the Department may adopt the proposed regulations substantially as described in this notice. If the Department makes modifications that are sufficiently related to the originally proposed text, it will make the modified text (with the changes clearly indicated) available to the public for at least 15 days before the Department adopts the regulations as revised. Please send requests for copies of any modified regulations to the Office of Regulations at Regulations@cdph.ca.gov. The Department will accept written comments on the modified regulations for 15 days after the date on which they are made available.

AVAILABILITY OF THE 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 the Initial Statement of Reasons, and the regulations text are available via the Internet and may be accessed by clicking on these links, in the following order, from the the Department's Webpage click on Programs, Office of Regulations, then Proposed Regulations.