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NOTICE OF PUBLIC HEARING
Title 17, California Code of Regulations
Newborn Screening Program Fee Increase 2020 (DPH-19-012E)
Notice Mailed: August 10, 2020

NOTICE IS HEREBY GIVEN that the California Department of Public Health (Department) has adopted the regulations described in this notice on an emergency basis. Health & Safety Code (HSC) section 124977(d)(1) provides that, for the purpose of the Administrative Procedures 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 and this notice of public hearing is pursuant to HSC 124977(d)(1) to consider comments, objections, and recommendations regarding the regulation.

PUBLIC PROCEEDINGS

The Department will conduct a 45-day written public comment period at a later date during which time any interested person or such person's duly authorized representative may present written statements, arguments or contentions (all of which are hereinafter referred to as comments) relevant to the action described in this notice.

To request copies of the regulatory proposal in an alternate format, please contact Linda M. Cortez at CDPH Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814, or at (916) 440-7807, or email to Linda.Cortez@cdph.ca.gov, or use the California Relay Service by dialing 711.

PUBLIC HEARING

The hearing will be held via WebEx on August 20, 2020, from 9:00 a.m. to 10:00 a.m.
Attendees should use the following URL: https://cdph-conf.webex.com/cdph-conf/j.php?MTID=mb0b306ffbea2b811e9ba161be146371a
Access code: 145041103812
Password: j4yMPpaD7Z3

During the hearing, any person may present oral statements or arguments relevant to the proposed action described in this notice. The Department requests but does not require persons who make oral comments during the hearing to also submit a written copy of their testimony by email to Regulations@cdph.ca.gov, eFax to (916) 636-6220, or postal service or hand delivered to California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814-7377. An agenda for the public hearing will be made available upon request.

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, and audiocassette or computer disk. Note: The range of assistive services available may be limited if requests are received without adequate preparation time prior to the public hearing.

All comments, including email or fax transmissions, should include the regulation package identifier, DPH-19-012E Newborn Screening Program Fee Increase 2020, along with your name and your mailing address or email address in order for the Department to provide copies of any notices for proposed changes to the regulation text of which additional comments may be solicited.

Authority and Reference

Authority for the proposed regulatory changes is provided in sections 124977, 124996, 125000, 131050, 131051 and 131200 of the Health and Safety Code. This proposal implements, interprets and makes specific sections 124977, 124996, 125000 and 125001 of the Health and Safety Code.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Summary of Proposal

This regulatory proposal is to amend the Newborn Screening (NBS) Program's all-inclusive program participation fee from $141.25 to $176.25 in Title 17, California Code of Regulations (17 CCR), Division 1, Chapter 4, section 6508. The increase is necessary for the expansion of statewide screening of newborns to include screening for Spinal Muscular Atrophy (SMA).

Background/Authority

The California 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 & Saf. Code § 124977 subd. (c)(1).) The NBS Program is administered by the Department's Genetic Disease Screening Program (GDSP), as mandated by HSC 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 HSC sections 124977, 125000, 125001 and 125025, and in 17 CCR, section 6501. The NBS 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 (ALD).

Senate Bill (SB) 1095 (Chapter 393, Statutes of 2016) established HSC section 125001(d) and required the NBS Program to expand 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). Since this mandate was introduced,

the NBS Program added screening for two disorders to the NBS panel in August 2018 – Mucopolysaccharidosis (MPS) Type I and Pompe disease – requiring NBS fee increases in July 2018 to support the additional expenditures.

On July 2, 2018, SMA was added to the federal RUSP by the Secretary of the U.S. Department of Health and Human Services (HHS) which requires the GDSP to implement newborn screening for the disorder in California by July 2020.

This addition will allow California to meet the national standard of care as recommended by the federal Advisory Committee on Heritable Disorders in Newborns and Children and the HHS and will bring the NBS Program into alignment with the most up-to-date research, technology, laboratory, public health standards, and practices, as well as HSC section 125001(d). Similar to MPS Type I and Pompe disease, GDSP will need to increase fees to offset the additional expenditures of needing to screen for SMA.

Additionally, over the past two years, GDSP has been experiencing an increase in the contracted rates for screening which can be attributed to normal costs of doing business. There has been an increase in the referrals for case management and coordination and diagnostic services. Additional contract rate increases with regional testing laboratories for ALD rollout, Area Service Centers, specialized follow-up centers, and diagnostic testing labs, as well as scientific supply companies are expected in future budget years. These rates and caseload increases were included in prior, current, and budget year estimates, and although additional budget authority was authorized, fees were not increased to offset the additional expenditures.

HSC sections 124977 and 124996 require the NBS Program be “fully supported from fees collected.” This fee may be adjusted by the Department’s Director as needed to meet costs. The NBS Program previously collected $142.25 for each newborn tested ($1.00 is for the specimen form). 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.

Policy Statement Overview

Problem Statement: SMA is a genetic disorder characterized by weakness and wasting (atrophy) in muscles used for movement (skeletal muscles). It is caused by a loss of specialized nerve cells, called motor neurons that control muscle movement. The weakness tends to be more severe in the muscles that are close to the center of the body (proximal) compared to muscles away from the body’s center (distal). SMA is a neurodegenerative disorder characterized by progressive muscle weaking and wasting due to the gradual loss of motor neurons, or nerve cells, that control muscles. Depending on the type of SMA, the age of onset and severity of the disorder can vary.

Benefits and Objectives (Goals):

Newborn screening can help identify the existence of SMA before symptoms begin and can enable early treatment. This will improve patient outcomes. An early diagnosis

through newborn screening, coupled with appropriate treatment, can slow the progress of the disease before some irreversible disease processes have begun. 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 the condition and helps parents make informed life choices, including future 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 this disorder without an increase in fees, appropriation authority and associated staffing.

Because the NBS Program is fully fee supported, as required by state statute, a fee increase is required to provide revenue to ensure that the expansion to SMA screening 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, staffing needs to perform the screening, testing chemicals, and equipment acquisition. Funding will also be used 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, and incorporation and maintenance on an on-going basis of SMA into the Screening Information System.

Specific Discussion of Regulatory Action

Section 6508(b). Newborn Screening Fee Collection. The proposed regulation to subdivision (b) amends the program's participation fee for the Newborn Screening panel fee from $141.25 to $176.25. This amendment is necessary because an increase of $35.00 is required to fully support the current NBS Program and the additional service expansions necessary to implement SMA screening components. The expansion of statewide screening of newborns includes additional expenditures due to an increased rate in referrals for case management and diagnostic services, as well as increases in contract rates for regional testing labs and scientific companies.

Evaluation as to Whether the Proposed Regulations Are Inconsistent or Incompatible with Existing State and Federal 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 Program is administered by the Department's GDSP according to HSC 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 HSC sections 124977, 125000, 125001 and 125025, and 17 CCR section 6501. The NBS 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, severe combined immune deficiency, ALD, MPS Type I, and Pompe disease.

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

Department of Finance Demographic Research Unit (DRU) Birth Projections for Fiscal Years 2010/2011 through 2022/2023, (Birth Projections).

Mandated by Federal Law or Regulations

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

Fiscal Impact Estimate

A. Costs to any Local or School District Requiring Reimbursement Pursuant to section 17500 et seq.: No fiscal impact exists because this regulation does not affect any local entity or program.
B. Costs or Savings to any State Agency: The Medi-Cal program will incur approximately $8,563,000 in additional costs annually as a result of the screening fee increase of which $4,282,000 will be General Fund costs. This cost was incorporated into the Medi-Cal base as an ongoing cost.
C. 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 $8,563,000, and of that, $4,282,000 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%).
D. 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.

Significant Statewide Adverse Economic Impact

The Department has made the initial determination that this emergency regulatory action will 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 directly bills hospitals and midwives and 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 $15,885,415 (453,869 estimated numbers of newborns to be screened in Fiscal Year 2020/2021 X $35.00).

It is unlikely that a $35.00 increase in newborn screening fees, paid by the hospital of birth to the Department, is enough 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.

Cost Impact 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 (except for religious objection) and will continue to be under these regulations.

There would be a cost increase of $35.00 per NBS test in the NBS Program participation fee for those businesses providing health coverage to newborns.

Statement of the Results of the Economic Impact Assessment

The Department has determined that the rulemaking will not significantly impact the following:

A. The Creation or Elimination of Jobs within the State: 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: The regulation will not create new businesses or eliminate existing businesses within the State. The cost impact to insurers of $35.00 for each covered newborn is unlikely to have a significant impact on any affected business, or insurance/health plan members.
C. The Benefits of the Regulation to Worker Safety and the State's Environment: This regulation does not affect worker safety because it does not impact workers nor does it affect the state's environment.

The Department has determined that the benefits of the regulation are expected to increase and strengthen the health and welfare of California residents. An increase in the participation fee expands statewide screening of newborns to include screening for SMA and ensures 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.

Effect on Housing Costs

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

Effect on Small Business

The Department has determined that the rulemaking has no impact on small businesses that provide health insurance to newborns.

Alternatives Statement

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 emergency 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 itself has made an initial determination that there are no acceptable alternatives to the regulations to protect the public interest. However, the Department invites interested persons to present alternatives with respect to the proposed regulation during the public comment period.

CONTACT PERSON

Inquiries regarding the substance of the proposed regulations described in this notice may be emailed to Sara Goldman, Genetic Disease Screening Branch, at Sara.Goldman@cdph.ca.gov.

All other inquiries concerning the action described in this notice may be directed to Linda M. Cortez, Office of Regulations, at Linda.Cortez@cdph.ca.gov, or (916) 440-7807, or to the designated backup contact person, Michael Boutros, Chief of the Office of Regulations, at Michael.Boutros@cdph.ca.gov.

In any inquiries or written comments, please identify the action by using the Department regulation package identifier, DPH-19-012E.

INTERNET ACCESS

Materials regarding the action described in this notice (including this notice, the text of the emergency regulations, and the finding of emergency) are available via the Internet and may be accessed at www.cdph.ca.gov by clicking on these links, in the following order: Programs, Office of Regulations, Proposed Regulations.