



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



TOMÁS J. ARAGÓN, MD, DrPH
Director and State Public Health Officer

GAVIN NEWSOM
Governor

NOTICE OF PUBLIC HEARING
Title 17, California Code of Regulations
Newborn Screening Program Fee Increase (DPH-23-004)
Notice Mailed: May 14th, 2024

NOTICE IS HEREBY GIVEN that the California Department of Public Health 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 hold a virtual public hearing on June 24, 2024. (See below for further details). Please consider submitting written public comments to Regulations@cdph.ca.gov or by fax: (916) 440-5747 or mail: California Department of Public Health, 1415 L Street, Suite 500, Sacramento, CA 95814. Written comments can be submitted now and will be accepted after the hearing until July 24th, 2024. The public will also be able to provide public comment when prompted during the hearing.

To request copies of the regulatory proposal in an alternate format, please contact Jasmine Fullwood, CDPH Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814, or at (916) 558-1710 or email Regulations@CDPH.CA.Gov, or use the California Relay Service by dialing 711.

PUBLIC HEARING

The hearing will be held via Microsoft Teams®, on June 24, 2024, from 11:00 A.M. to 12:00 P.M.

Attendees should use the following URL:

https://teams.microsoft.com/dl/launcher/launcher.html?url=%2F%20%2Fmeetup-join%2F19%3Ameeting_MmNINDdmOGEtMTFjMi00NmVhLThjMGYtNDRiZDFhNDIzYTlj%40thread.v2%2F0%3Fcontext%3D%257b%2522Tid%2522%253a%25221f311b51-f6d9-4153-9bac-55e0ef9641b8%2522%252c%2522Oid%2522%253a%252244621d52-0bc7-4ff8-9f05-b04383296617%2522%257d%26CT%3D1715114180774%26OR%3DOutlook-

[Body%26CID%3D702285E0-2AB7-4F4A-B26D-C7E8BE4606B9%26anon%3Dtrue&type=meetup-join&deeplinkId=f34be152-8310-4953-a7fe-aa0c791294ca&directDI=true&msLaunch=true&enableMobilePage=true&suppressPrompt=true](https://www.cdph.ca/Programs/OPA/Pages/B0D702285E0-2AB7-4F4A-B26D-C7E8BE4606B9%26anon%3Dtrue&type=meetup-join&deeplinkId=f34be152-8310-4953-a7fe-aa0c791294ca&directDI=true&msLaunch=true&enableMobilePage=true&suppressPrompt=true)

Meeting ID: 232 348 093 369

Passcode: BxqeUB

Those who do not have access to a computer may call in using the following information:

Call in only: (916) 306-8051 Phone Conference ID: 394 578 328#

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. 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, include your name and your mailing address or email address. All comments, including email or fax transmissions, should include the regulation package identifier, DPH-23-004 Newborn Screening Program Fee. 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.

AUTHORITY AND REFERENCE

Authority for the proposed regulatory change is provided under 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.

Background and Policy Statement Overview

The Department proposes to amend the Newborn Screening Program's (NBS Program's) all-inclusive program participation fee by \$15.00, increasing the current fee of \$211.00 to \$226.00 (\$225.00 plus the \$1.00 fee for the specimen collection form). Regulations pertaining to this fee are contained in 17 CCR, Division 1, Chapter 4, section 6508, subdivision (b). This increase is necessary to support the addition of two new disorders: mucopolysaccharidosis type II (MPS II) and guanidinoacetate methyltransferase (GAMT) deficiency, into the Newborn Screening panel. HSC section 124977, subdivision (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.

Problem Statement

HSC section 125001(d) requires the NBS Program to expand statewide screening of newborns to include diseases that are detectable in blood samples within two years of being adopted by the federal Recommended Uniform Screening Panel (RUSP). Mucopolysaccharidosis type II (MPS II) and Guanidinoacetate Methyltransferase (GAMT) deficiency were added to the RUSP on August 2, 2022, and January 4, 2023, respectively. CDPH is required to include MPS II to the California NBS panel by August 2024, and the GAMT deficiency by January 2025.

By August 2024, CDPH will incorporate screening for both MPS II and GAMT deficiency into the Newborn Screening panel. Screening for these additional diseases will require start-up costs, additional laboratory equipment and personnel, changes to the Screening Information System (SIS), follow-up systems, and the addition of new confirmatory testing. To provide sufficient revenues to offset these additional expenditures, GDSP must raise its program participation fee from \$211.00 to \$226.00. This increase includes a \$1 fee for the specimen collection form.

Because the NBS Program is fully fee supported, as required by state statute, the proposed fee increase is necessary to provide revenue to ensure services are not interrupted and sufficient resources are available to the NBS Program on an ongoing basis.

Objectives (Goals):

The broad objectives of this regulatory action are to:

- Meet the national standard of care as recommended by the federal Advisory Committee on Heritable Disorders in Newborns and Children, aligning the NBS Program with the most up-to-date research, technology, laboratories, public health standards and practices, and to maintain compliance with the statutory mandates of HSC section 125001(d).
- Prevent any interruptions to NBS Program services so that the program can continue to carry out day-to-day operations intended to provide better health outcomes for California's newborn population.
- Continue funding for the processing of biospecimens at the Department's Genetic Disease Laboratory.
- Continue funding for provider and family education, informative result mailers, and ongoing support for the Screening Information System (SIS), resulting in improved information and health outcomes for the people of California.

Benefits:

Anticipated benefits from this regulatory action are:

- Program will continue to carry out day-to-day operations intended to provide better health outcomes for California's newborn population.

- Program will be able to support ongoing costs for the reagent kits, laboratory supplies, newborn screening specimen test request forms, contracts with regional screening laboratories, regional area service centers (including follow-up at special care centers), and confirmatory testing and technology that enable effective and efficient newborn screening.
- Necessary resources and treatment for disorders in newborns may be identified and delivered in a timelier manner, potentially reducing the risk of morbidity and mortality for infants and children, as well as reducing fiscal burdens to the public health care system.

Other Statutory Requirements

None.

Local Mandate

The Department has determined that this rulemaking does not impose a mandate on local agencies or school districts, nor are there any cost for which reimbursement is required by part 7 (commencing with section 17500) of Division 4 of the Government Code.

Alternatives Statement

The Department has determined that there is no reasonable alternative that would be more effective in carrying out the purpose for which the action is proposed; would be as effective and less burdensome to affected persons than the proposed action; or would be more cost-effective to affected persons and equally effective in implementing the statutory policy or other provision of law. California statute requires the Department to fund the operations of the NBS Program and protect the public interest in maintaining a statewide NBS Program. To the Department's knowledge, the emergency regulatory action is the most efficient way of keeping the NBS Program operational so that it may continue to reduce the risk of morbidity and mortality for infants and children and reduce any related fiscal burdens to the public health care system.

CONTACT PERSON

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

All other inquiries concerning the action described in this notice may be directed to Jasmine Fullwood, Office of Regulations, at Jasmine.Fullwood@cdph.ca.gov, 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-23-004.

INTERNET ACCESS

Materials regarding the action described in this notice (the text of the emergency regulation) are available via the Internet and may be accessed at <https://www.cdph.ca.gov/Programs/OLS/Pages/DPH-23-004.aspx> by clicking on these links, in the following order: Programs, Office of Regulations, Proposed Regulations.