

## FINDING OF EMERGENCY

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 as per Health and Safety Code section 124977, subdivision (c)(1). The Health and Safety Code (HSC) also provides authority for the California Department of Public Health (Department) to adopt emergency regulations under HSC section 124977, subdivision (d)(1).

The Department's Genetic Disease Screening Program (GDSP) administers the Newborn Screening Program (NBS Program) 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 Title 17 of the California Code of Regulations (17 CCR) section 6508, subdivision (b). The NBS Program screens for over 80 different genetic or heritable disorders including: amino acid disorders such as phenylketonuria, hemoglobinopathies, organic acid disorders, fatty acid oxidation disorders, galactosemia, congenital hypothyroidism, congenital adrenal hyperplasia, sickle cell disease, cystic fibrosis, biotinidase deficiency, severe combined immune deficiency, adrenoleukodystrophy, mucopolysaccharidosis type I, Pompe disease, spinal muscular atrophy, mucopolysaccharidosis type II, and guanidinoacetate methyltransferase.

HSC sections 124977 and 124996 require that the NBS Program be "fully supported from fees collected." The program participation fee may be adjusted by the Department's Director as needed to meet costs. The NBS Program currently collects \$211.00 for each newborn tested (\$210.00, plus \$1.00 for the specimen form).

HSC section 124977, subdivision (d) authorizes the Department to adopt emergency regulations to implement and make specific 17 CCR, Division 1, Chapter 4, Subchapter 9 (Testing for Heritable Disorders), Group 3 (Newborn Screening Program), changes to Article 4 (Program Participation Fee).

HSC section 124977, subdivision (d)(1) states: "For the purposes of the Administrative Procedure Act, the adoption shall be deemed an emergency and necessary for the immediate preservation of the public peace, health and safety, or general welfare. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, these emergency regulations shall not be subject to the review and approval of the Office of Administrative Law. Notwithstanding Sections 11346.1 and 11349.6 of the Government Code, the department shall submit these regulations directly to the Secretary of State for filing. The regulations shall become effective immediately upon filing by the Secretary of State. Regulations shall be subject to public hearing within 120 days of filing with the Secretary of State and shall comply with sections 11346.8 and 11346.9 of the Government Code or shall be repealed."

HSC section 124977, subdivision (d)(2) states: "The Office of Administrative Law shall provide for the printing and publication of these regulations in the California Code of

Regulations. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the regulations adopted pursuant to this chapter shall not be repealed by the Office of Administrative Law and shall remain in effect until revised or repealed by the department.”

### **Technical, Theoretical, and/or Empirical Study, Reports or Documents Relied Upon**

Department of Finance Demographic Research Unit (DRU) Birth Projections Population Projections (Baseline 2020), [Birth Projections](https://dof.ca.gov/Forecasting/Demographics/Projections/) <<https://dof.ca.gov/Forecasting/Demographics/Projections/>> (as of July 19, 2023)

### **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 that services are not interrupted and that 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 reagents 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 Determination**

The Department has determined that this rulemaking does 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.

**Fiscal Impact**

The Department has made the following determinations concerning the fiscal impact of this regulatory proposal.

**A. Costs to Local Agency or School District**

None.

**B. Costs or Savings to State Agencies**

None.

**C. Non-Discretionary Costs or Savings Imposed on Local Agencies**

None.

**D. Costs or Savings to Federal Funding to the State**

None.

**Reasonable Alternatives**

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, this 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.