

## INITIAL STATEMENT OF REASONS

### **Summary of Regulatory Action**

The California Department of Public Health (Department) is the successor to the Department of Health Services pursuant to Health and Safety Code (HSC) sections 131050 and 131051. HSC section 131200 authorizes the Department to promulgate regulations for the execution of its duties.

### **Policy Statement Overview**

#### ***Problem Statement:***

The Department revised Subchapter 9, Testing for Heritable Disorders, Group 3, Newborn Screening Fee Collection, Title 17, California Code of Regulation (17 CCR), Division 1, Chapter 4, Section 6508 that raised the Newborn Screening Fee as an emergency amendment from \$111.70 to \$129.25.

The Newborn Screening (NBS) Program (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 of 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 6508. 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, and severe combined immune deficiency.

HSC sections 124977 and 125001, enacted by Assembly Bill (AB) 1559 (Pan, Chapter 565, Statutes 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). This increases the cost of the program, in part, because this addition requires new equipment, specific reagents, IT upgrades, and additional staff to screen for ALD.

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. The program previously collected \$111.70 for each newborn tested. 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.

ALD is a rare X-chromosome genetic disorder (which affects mostly boys) that can cause injury to the brain, nerves, and adrenal glands. People with ALD do not generate enough of the protein that breaks down very long chain fatty acids (VLCFA). The

myelin sheath, which acts as insulation around the nerves, is made up of these fatty acids; buildup of the VLCFA prevents the brain from communicating with the body. The first signs of ALD are behavioral and it is often misdiagnosed as attention deficit disorder, but it rapidly leads to a vegetative state and ultimately death. The childhood form is the most severe and affects boys between the ages of two and eight years old. The slightly milder adult version affects men in their 20s and 30s. 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. Cord blood and bone marrow transplants performed at a very early stage in the disease have proven to treat the patient, enabling a healthy life.

***Benefits and Objectives (Goals):***

An early diagnosis through newborn screening coupled with appropriate treatment can slow the progress of the disease before some irreversible disease processes have begun. An early diagnosis is the first step in an appropriate ALD 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 ALD and helps parents make informed life choices, including reproductive and health plan decisions.

The cost of including ALD to the NBS 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 ALD without an increase in fees, appropriation authority and associated staffing.

Because the Program is fully fee supported - as required by state statute, a fee increase is required to provide revenue to ensure that 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 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 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. The additional expenditures are described in the dollar amounts in Attachment 1 to the Std. 399 form. The comments are based on past experience with implementation of newborn screening expansions, information collected from discussions with vendors and comparison of costs for similar services in other states and the private sector.

**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.

**Evaluation as to whether the Regulations are Inconsistent or Incompatible 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 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 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, Statutes 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.

**Reasonable Alternatives to the Regulation and the Agency's Reasons for Rejecting Those Alternatives**

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.

**Reasonable Alternatives to the 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.

**Technical, Theoretical, and/or Empirical Study, Reports or Documents Relied Upon:** None.

**STATEMENTS OF DETERMINATION**

**Alternatives Statement**

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 emergency action was taken, would be as effective and less burdensome to affected private persons than the emergency 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 program and to protect the public interest in maintaining a statewide screening program.

**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.

**Significant Statewide Adverse Economic Impact on Business, Including the Ability to Compete**

The Department has made the initial determination that this regulatory 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 numbers 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.

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

**Local Mandate**

The Department has determined that the 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.

**Effect on Small Business**

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 Cost**

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

**Reporting Requirements**

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