

INFORMATIVE DIGEST

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

The Newborn Screening (NBS) Program is administered by the Department. H&S Code section 125000 requires screening of all newborns for heritable and congenital disorders and section 125025 requires screening for sickle cell anemia. Testing for hemoglobinopathies, phenylketonuria, hypothyroidism and galactosemia is mandated in Title 17, California Code of Regulations, Division 1, Chapter 4, section 6501.

The Fiscal Year 2004-05 State budget authorized the expansion of NBS to include tandem mass spectrometry screening for fatty acid oxidation, amino acid and organic acid disorders and congenital adrenal hyperplasia. Senate Bill 1103 (Chapter 228, Statutes of 2004) amended H&S Code section 125001 to include this expansion of disorders.

The Fiscal Year 2006-07 State budget authorized the expansion of NBS to include cystic fibrosis and biotinidase deficiency testing. Assembly Bill 1807 (Health Trailer Bill, Chapter 48, Statutes of 2006) amended H&S Code section 124977 to include this expansion of disorders.

Assembly Bill 395 (Pan, Chapter 461, Statutes of 2011) required testing for Severe Combined Immunodeficiency beginning in January 2012. With the exception of fee increases there have been no additional changes to these regulations.

H&S Code section 124980 provides the Director shall establish any regulations and standards for hereditary disorders programs as the director deems necessary to promote and protect the public health and safety.

H&S Code section 124977(d) further provides for regulations issued on an emergency basis to be exempt from review and approval of the Office of Administrative Law (OAL). However, OAL shall provide for the printing and publication of these regulations in the California Code of Regulations. The Department shall submit these regulations directly to the Secretary of State for filing and the regulations become effective immediately upon filing by the Secretary of State.

The purpose of the regulations is to establish appropriate criteria and standards for newborn screening and update the changes in medical technology, testing, methodologies and the expansion of the NBS Program to assure rapid intervention in order to prevent death or disability in newborns. Newborn screening regulations have not been substantively changed since the early 1990's. The program has added over 40 new conditions to the screening panel. Many are rare, complex conditions that

require treatment within the first few days of life. Continuing to use the current regulations as written will increase the population of infants with developmental disability, illness or neonatal death.

The emergency regulation will expand upon existing regulation provisions and improve provisions for early detection, follow up and referrals for diagnosis and early treatment, preventing illness, disability, and even death for infants.

The emergency regulation will further detail responsibilities of parties involved in newborn screening services, such as hospitals, physicians, and NBS contracted laboratories. This is needed to address the changes in medical technology and to assure rapid intervention in order to prevent death or disability in newborns and infants.

The benefits anticipated by the adoption of these regulations are the protection of public health and safety by expanding upon existing regulation provisions and improving provisions for early detection, follow-up and referrals for diagnosis and treatment. This early detection will lead to early treatment, preventing illness, disability and even death to infants. These regulations will further detail responsibilities of parties involved in the newborn screening services, such as hospitals, physicians, and NBS contracted laboratories.

Evaluation of Inconsistency and Incompatibility with Existing State Regulations

The Department evaluated this proposal as to whether the proposed regulations are inconsistent or incompatible with existing state regulations. This evaluation included a review of the Department's existing general regulations and California Children's Services regulations. An internet search of other state agency regulations was also performed and it was determined that no other state 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 proposal, if adopted, would not be inconsistent or incompatible with existing state regulations.

Forms Incorporated by Reference

1. CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH-4409-(11/12)) NBS-I (D).
2. NEWBORN SCREENING TEST REFUSAL (NBS-TR) CDPH 4459 (06/11) – English version or CDPH 4459 (SP) (06/11) – Spanish version.
3. HOSPITAL REPORT OF NEWBORN SCREENING SPECIMEN NOT OBTAINED (NBS-NO) CDPH 4089 (01/11).
4. NOTIFICATION OF REGISTRATION OF BIRTH WHICH OCCURRED OUT OF A LICENSED HEALTH FACILITY (NBS-OH) CDPH 4460 (01/09).

This emergency regulatory action adopts sections 6500.03, 6500.05, 6500.9, 6500.21, 6500.33, 6500.43, 6500.50, 6500.51, 6500.55, 6500.58, 6500.71, 6500.78 and 6501.5.

This emergency regulatory action amends sections 6500.35, 6500.39, 6500.45, 6501, 6505, 6506, 6506.6, 6506.8 and 6506.10.

This emergency regulatory action repeals sections 6500.65 and 6500.67.

Authority

Sections 124977, 124980, 125000, 125001, 125025, 131050, 131051 and 131200, Health and Safety Code.

Reference

Sections 124116, 124977, 124980, 125000, 125001, 125025, 131050, 131051 and 131200, Health and Safety Code.

Mandated by Federal Law or Regulations

N/A

Other Statutory Requirements

N/A

Mandate on Local Agency or School District

The Department has determined that the regulation would 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 Estimate

A. FISCAL IMPACT ON LOCAL AGENCIES:

The Department has made an initial determination that the proposed regulations would not have a fiscal impact on any local agency or school district.

B. FISCAL IMPACT ON STATE AGENCIES:

The Department has determined that the proposed regulations would not have a fiscal impact on any state agency.

C. OTHER NONDISCRETIONARY COST OR SAVINGS IMPOSED ON LOCAL AGENCIES:

The Department has determined that the proposed regulations would not impose nondiscretionary costs or savings on local agencies.

D. FISCAL IMPACT ON FEDERAL FUNDING TO THE STATE:

The Department has made an initial determination that the proposed regulations would not have a fiscal impact in federal funding to the State.

Housing Costs Determination

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

Significant Statewide Adverse Economic Impact on Business

The Department has determined that the proposed regulatory action would have no significant adverse economic impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states.

Mandate on Local Agency or School Districts

The Department has determined that the regulation would 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.

Economic Impact Analysis

The Department has determined that the regulation would 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 not 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, worker safety, and the state's environment.** The proposal will significantly increase the benefits to the health and welfare of newborns born in California as it outlines protocols for the timely collection of newborn screening specimens; prompt testing, diagnosis and treatment when disorders are found. The proposal would not significantly affect worker safety in the State of California. The proposal would not affect the state's environment.

Cost Impacts on Representative Person or Business

The Department is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Business Report

The Department has determined that there is no business report to be filed.

Effect on Small Businesses

The Department has determined that the regulations will have no significant effect on small businesses.