

FINDING OF EMERGENCY

Health and Safety Code (HSC) section 124977, subdivision (d) authorizes the California Department of Public Health (Department) to adopt emergency regulations to interpret and make specific the Newborn Screening Program (NBSP) contained in Title 17, Division 1, Chapter 4, Subchapter 9, Group 3 of the California Code of Regulations (CCR), in accordance with Chapter 3.5 (commencing with § 11340) of Part 1 of Division 3 of Title 2 of the Government Code. HSC Section 124977, subdivision (d)(1) specifies that this 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 § 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 (OAL). 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. These 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with the Secretary of State and shall comply with sections 11346.8 and 11346.9 of the Government Code or shall be repealed.

Additionally, HSC section 124977, subdivision (d)(2) provides that the OAL shall provide for the printing and publication of these regulations in the CCR and, notwithstanding Chapter 3.5 (commencing with section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, if adopted, these regulations shall not be repealed by the OAL and shall remain in effect until revised or repealed by the Department.

The emergency regulatory amendments proposed below would consolidate two forms used by the NBSP: the Newborn Screening Test Request Form (CDPH-4409) and the Test Refusal Form (CDPH-4459) into a single form in order to reduce administrative redundancies that may affect the health and wellbeing of California's newborns.

Summary of Proposal

The Department proposes to amend sections 6500.50, 6501.5, 6505, 6506, and 6506.5 of the CCR in order to consolidate two forms used by the Newborn Screening Program (NBSP): the Newborn Screening Test Request Form (CDPH-4409) and the Test Refusal Form (CDPH-4459). The proposed changes are needed in order to reduce administrative redundancies that may affect the health and wellbeing of California's newborns. The preservation of the health and wellbeing of newborns is one of the intentions of the Legislature under governing statute (The Hereditary Disorders Act, Health and Safety Code sections 124975 – 124996).

Informative Digest

The Department's Genetic Disease Screening Program (GDSP), previously called the Genetic Disease Branch (GDB), administers the NBSP in order to screen for specific treatable, heritable disorders. This program is implemented by regulations in CCR, Title 17, Division 1, Chapter 4, Subchapter 9, Group 3, Articles 1, 2 and 3.

The NBSP currently oversees the screening of all live births in California (approximately 500,000 annually). Disorders screened for by the program have varying degrees of severity and, if identified early, can be treated before they cause serious health problems, or even death.

In order to continue to maximize the NBSP's ability to screen for disorders impacting the health and wellbeing of California's newborns, the Department proposes the regulatory changes discussed below.

Policy Statement Overview

Problem Statement: Updates affecting the NBSP's screening forms are needed in order to maximize the NBSP's ability to effectively screen for heritable disorders in newborns.

Objective (Goals): In order to eliminate redundancies, reduce paperwork, and accommodate changes to the NBSP so that it may continue to effectively collect, screen and report specimens, the Department proposes amendments to CCR sections 6500.50, 6501.5, 6505, 6506 and 6506.6. These amendments will have the ultimate result of consolidating the information found on forms CDPH-4409 and CDPH-4459 into a single form.

Benefits of the Proposed Regulatory Changes

The Department anticipates that the proposed changes will:

- 1) Support and facilitate timely specimen collection, testing, diagnosis, and treatment known to prevent death, intellectual and developmental disabilities, and other medical complications in infants in California.
- 2) Maintain clear, non-redundant, and current written requirements for providers (hospitals/perinatal health facilities, physicians, midwives) and county birth registrars regarding NBSP procedures.
- 3) Protect the health and welfare of newborns born in California.

Authority

Authority for the proposed regulatory changes is provided in Health and Safety Code (HSC) sections 124975, 124977, 124980, 124985, 124990, 124995, 125000, 125001, 125005, 125025, 125030, and 125035. This proposal implements, interprets and makes specific sections 124977, 124980, 124996, and 125001, 131050, and 131051 of the HSC Code.

Determination of Local Mandate

The Department has determined that the proposed regulations 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.

Evaluation as to Whether the Proposed Regulations are Inconsistent or Incompatible with Existing State Regulations

The Department evaluated 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 an internet search of other state agency regulations. The Department determined that no other state regulation addressed the same subject matter, and that this proposal, if adopted, would be neither inconsistent or incompatible with other state regulations.

Fiscal Impact Estimate

The Department has determined that this regulatory proposal would have no significant impact on:

- 1) Any costs or savings to any state agency;
- 2) The reimbursable cost to any local government agency;
- 3) Any nondiscretionary costs or savings to state or local government agencies; or
- 4) Any costs or savings in federal funding to the state.