

INITIAL STATEMENT OF REASONS

Summary of Proposal

The California Department of Public Health (Department) proposes to amend sections 6500.50, 6501.5, 6505, 6506, and 6506.5 of the California Code of Regulations (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). Additionally, the Department proposes changes to section 6505 subdivision (c)(1) in order to clarify the newborn screening collection process for infants born out-of-hospital.

Background

The Department's Genetic Disease Screening Program (GDSP), previously called the Genetic Disease Branch (GDB), administers a statewide Newborn Screening Program (NBSP) 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 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 changes to CCR sections 6500.50, 6501.5, 6505, 6506 and 6506.6. These changes will have the ultimate result of consolidating the information found on forms CDPH-4409 and CDPH-4459 into a single form, and will clarify the collection process for infants born out-of-hospital.

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.

Detailed discussion of each regulatory section proposed to be amended:

Amend CCR sections 6500.50; 6501.5 subdivision (a); 6505 subdivisions (a)(1)-(2), (a)(4), (b)(1)-(2), and (c)(1); 6506 subdivision (a); 6506.6 subdivisions (a), (b)(1) and (c)(1): The Department proposes to amend the above-named sections in order to reflect that an outdated form number and date-citation have been removed from the footer of the California Newborn Screening Test Request Form (CDPH – 4409). This change shall be reflected in all relevant portions of the above-named regulatory sections and their subdivisions as applicable. This change is necessary in order to accommodate the consolidation of form CDPH-4409 with the NBSP's Test Refusal Form (CDPH-4459) as discussed below.

Amend sections 6501.5 subdivision (b), 6505 subdivisions (a)(4), (b)(1), (c)(1), and 6506 subdivision (a): In an effort to reduce repetitive paperwork and to ensure each infant born in California has had an opportunity to have a newborn screen collected, the Department proposes to incorporate the Newborn Screening Test Refusal form (CDPH 4459) as a part of form CDPH – 4409. In accordance with the Legislature's intent under The Hereditary Disorders Act (HSC §§ 124975 – 124996) this change will reduce excess paperwork and allow for better tracking and timely notification of infants not screened. CDPH 4459 is currently mailed several weeks or months after an infant is born, missing a critical intervention window which may ultimately result in harm to the infant.

These regulatory proposals follow the successful consolidation, in 2017, of the old Newborn Screening Test - Not Obtained form (CDPH-4089) as part of form CDPH-4409. Regulatory section 6506 subdivision (b) was added to the CCR at this time to ensure a missing report would be entered into the Screening Information System if a previously collected specimen had not been received. This scenario was missing from the previous version of the regulation.

Amend section 6505 subdivision (c)(1): The department proposes new language to this section in order to clarify that out-of-hospital newborn screening providers must collect a newborn screening between 12 and 48 hours of the infant's birth. The previous version of this provision contradicted the requirements specified in subdivision (a) of this section.

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.

Other Statutory Requirements

None.

Local Mandate

The Department has determined that this regulatory action 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 Assessment

The Department has determined that there shall be no significant costs or savings to any local or state agency, or to any school district as a result of the proposed regulations, nor is any impact upon federal funding to the state anticipated.

Housing Costs

The Department has determined that this regulatory action would have no impact on housing costs.

Economic Impact Assessment

The Department has made the determination that the regulation would not significantly impact the following:

- 1) **The creation or elimination of jobs within the State of California.** Because the proposed action imposes no fees and is related to the internal program policies of the NBSP only, the Department does not anticipate any significant impact upon the creation or elimination of jobs within the state.
- 2) **The creation of new businesses or the elimination of existing businesses within the State of California.** Because the proposed action imposes no fees and is related to the internal program policies of the NBSP only, the Department does not anticipate any significant impact upon the creation of new businesses or elimination of existing businesses within the state.
- 3) **The expansion of businesses currently doing business within the State of California.** Because the proposed action imposes no fees and is related to the internal program policies of the NBSP only, the Department does not anticipate any significant impact affecting the expansion of businesses currently doing business within the state.

- 4) **The benefits of the regulation to the health and welfare of California residents, worker safety, and the state's environment.** The benefits anticipated by the adoption of these regulations are the protection of public health and safety by facilitating the timely collection, testing, diagnosis, and treatment of disorders known to cause developmental disabilities, death, or other medical complications in California's infants. As described in the discussion of proposed amendments, by reducing paperwork, these regulations will eliminate duplicative responsibilities for parties involved in the NBS services (such as hospitals, physicians, and NBS contracted laboratories) and will provide a more timely notification of infants not screened, which will improve intervention times. The proposal would not significantly affect worker safety in the State of California and would not affect the state's environment.

Evidence Supporting Finding of No Significant Statewide Adverse Economic Impact Directly Affecting Business

The proposed changes would consolidate information from two forms used by the NBSP into a single form and clarify an existing NBSP process with the intention of reducing administrative redundancies that may affect the health and wellbeing of California's newborns. While these regulations may improve workflow for parties involved in the NBS services (such as hospitals, physicians, and NBS contracted laboratories) these changes are not anticipated to significantly alter how the NBSP does business, or to result in any additional costs. The Department concludes that the economic impact of this regulatory proposal, including the ability of California businesses to compete with businesses in other states, would not be significant.

Estimated Benefits

The benefits anticipated by the adoption of these regulations are the protection of public health and safety by facilitating the timely collection, testing, diagnosis, and treatment of disorders known to cause developmental disabilities, death, or other medical complications in California's infants. As described above, by reducing paperwork, these regulations will eliminate duplicative responsibilities for parties involved in the NBS services (such as hospitals, physicians, and NBS contracted laboratories) and will provide a more timely notification of infants not screened, which will improve intervention times.

Cost Impacts On Representative Person Or Business

The Department is unaware of any cost impacts that a representative private person or business would incur in reasonable compliance with the proposed action.

Business Report

None required.

Effect on Small Business

Because the proposed action imposes no fees and is related to the internal program policies of the NBSP only, it shall have no financial impact upon small businesses.

Alternatives Considered

No alternatives were proposed or considered that seemed less burdensome or more effective in carrying out the Department's regulatory intent.