



STATE OF CALIFORNIA—HEALTH AND HUMAN SERVICES AGENCY
California Department of Public Health



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NOTICE OF PROPOSED RULEMAKING
Title 17, California Code of Regulations
DPH-17-019E Newborn Screening Program
Notice Published: June 14, 2019

NOTICE IS HEREBY GIVEN that the California Department of Public Health (Department) announces a public comment period. This notice of proposed rulemaking commences a rulemaking to make the emergency regulations permanent after considering all comments, objections, and recommendations regarding the regulations.

PUBLIC PROCEEDINGS

The Department is conducting a 45-day written public comment period and will hold a public hearing (pursuant to HSC section 124977(d)(1)), within 120 days from the emergency effective date of May 30, 2019, during which time any interested person or such person's duly authorized representative may present statements, arguments or contentions (all of which are hereinafter referred to as comments) relevant to the action described in this notice.

PUBLIC HEARING

At the hearing, any person may present statements or arguments orally or in writing relevant to the proposed action described in the Informative Digest. The Department requests, but does not require that persons who make oral comments at the hearing also submit a written copy of their testimony at the hearing.

Date & Time: July 30, 2019 at 9:00 a.m.

Place: 1415 L Street, Suite 500, Room 1001, Sacramento, CA 95814

Purpose: To hear comments about this action.

An agenda for the public hearing will be posted at the time and place of the hearing.

For individuals with disabilities, the Department shall provide, upon request, assistive services such as sign-language interpretation, real-time captioning, note takers, reading or writing assistance, and conversion of written public hearing materials into Braille, large print, and audiocassette or computer disk. Please note that the range of assistive services available may be limited if requests are received without adequate preparation time prior to the public hearing.

To request such services or copies of materials in an alternate format, please write or call Hannah Strom-Martin, California Department of Public Health, Office of

Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814, (916) 440-7371, or email hannah.strom-martin@cdph.ca.gov, or use the California Relay Service by dialing 711 at no cost.

WRITTEN COMMENT PERIOD

Written comments pertaining to this proposal, regardless of the method of transmittal, must be received by the Office of Regulations by **5:00 p.m. on July 30, 2019**, which is hereby designated as the close of the written comment period. Comments received after this date will not be considered timely.

Written comments may be submitted as follows:

- 1) By email to: regulations@cdph.ca.gov. It is requested that email transmission of comments, particularly those with attachments, contain the regulation package identifier “DPH-17-019E” in the subject line to facilitate timely identification and review of the comment;
- 2) By fax transmission to: (916) 636-6220;
- 3) By United States Postal Service to: California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814;
- 4) Hand-delivered to: California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814.

All submitted comments should include the regulation package identifier “**DPH-17-019E Newborn Screening Program**,” the author’s name, and the author’s mailing address.

AUTHORITY AND REFERENCE

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.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Summary of Proposal

The 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.

Background

The Department's Genetic Disease Screening Program (GDSP), previously called the Genetic Disease Branch (GDB), administers a statewide Newborn Screening Program (NBSP) in order to screen newborns 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 treatable 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.

Anticipated Benefits

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.

STATEMENTS OF DETERMINATION AND ECONOMIC IMPACT ASSESSMENT

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

The Department has made a determination that these regulations are neither inconsistent or incompatible with other state regulations. After conducting a review for any regulations that would relate to or affect this area, the Department has concluded that these are the only regulations that concern the NBSP.

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.

Other nondiscretionary cost or savings imposed on local agencies

None.

Cost or Savings in Federal Funding to the State

None.

Significant effect on housing costs

None.

Significant Statewide Adverse Economic Impact Directly Affecting Business and Individuals

The proposed action will not directly affect businesses statewide, including small businesses. As a result the Department concludes that the adverse economic impact, including the ability of California businesses to compete with businesses in other states, will not be significant.

Results of the Economic Impact Assessment

The Department has determined that the proposed regulatory action would have no significant economic impact upon the following:

- 1) The creation or elimination of jobs within the State of California.
- 2) The creation of new businesses or the elimination of existing businesses within the State of California.
- 3) The competitive advantages or disadvantages of businesses currently doing business within the State of California.
- 4) The increase or decrease of investment in the state.
- 5) The incentive for innovation in products, materials, and processes.

Benefits of the Proposed Regulation

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 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.

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.

Effect on Small Business

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

Consideration of Reasonable Alternatives

The Department has determined that no reasonable alternative considered or otherwise identified or brought to its attention:

- 1) Would be more effective in carrying out the purpose for which the action is proposed.
- 2) Would be as effective or less burndensome to affected private persons; or
- 3) Would be more cost-effective in implementing this statutory policy.

Contact Person

Inquiries regarding the proposed regulatory action can be directed to Hannah Strom-Martin within the Department's Office of Regulations at (916) 440-7371 or via email at: hannah.strom-martin@cdph.ca.gov, or to the designated backup contact, Linda Cortez at (916) 440-7367.

Availability of Statement of Reasons and Text of Regulations

The Department has prepared and has available for public review the text of the regulations, Initial Statement of Reasons, and all other information upon which the rulemaking is based at the address noted above, which will also be the location of any public records, including reports, documentation, and other material related to the proposed regulations (rulemaking file). The Department will have the entire rulemaking file available for inspection and copying throughout the rulemaking process at its office at the above address. As of the date this notice is published in the Notice Register, the rulemaking file consists of this notice, the proposed text of the regulations, the initial statement of reasons, and the proposed Newborn screening form (CDPH-4409). Copies may be obtained by contacting Hannah Strom-Martin at the address or phone number listed above.

Availability of Changed or Modified Text

After holding the hearing and considering all timely and relevant comments received, the Department may adopt the proposed regulations substantially as described in this notice. If the Department makes modifications which are sufficiently related to the originally proposed text, it will make the modified text (with the changes clearly indicated) available to the public for at least 15 days before the Department adopts the

regulations as revised. Please send requests for copies of any modified regulations to the attention of Hannah Strom Martin at the address indicated above.

In order to request that a copy of this public notice or the regulation text be mailed to you, please call (916) 558-1710 (or the California Relay Service at 711), send an email to regulations@cdph.ca.gov, or write to the Office of Regulations at the address previously noted. Upon specific request, these documents will be made available in Braille, large print, audiocassette, or computer disk.

Final Statement of Reasons

A copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations.

Internet Access

Materials regarding the action described in this notice (including this Public Notice, Initial Statement of Reasons, Regulation Text and Informative Digest) may be accessed online at the [Department's Website \(www.cdph.ca.gov\)](http://www.cdph.ca.gov) by clicking on the following links, in the following order: Programs, [Office of Regulations](#), [Proposed Regulations](#).