



Karen L. Smith, MD, MPH
Director and State Public Health Officer

State of California—Health and Human Services Agency
California Department of Public Health



EDMUND G. BROWN JR.
Governor

NOTICE OF PROPOSED RULEMAKING
Title 17, California Code of Regulations
DPH-09-010E Newborn Screening
Notice Published: June 24, 2016

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 March 23, 2016, OAL Emergency Filing No. 2016-0323-02 EFP), 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 and Time: July 6, 2016 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 hearing location.

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. Note: 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 Linda M. Cortez, California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814, (916) 440-7807, or email to Linda.Cortez@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 August 8, 2016**, 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-09-010E” in the subject line to facilitate timely identification and review of the comment;
2. By fax transmission: (916) 440-5747;
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-09-010E**”, author’s name and mailing address.

AUTHORITY AND REFERENCE

The Department is proposing to adopt, amend, or repeal the proposed rulemaking under the authority provided in sections 124977, 124980, 125000, 125001, 125025, 131050, 131051, and 131200 of the Health and Safety Code. The Department is proposing to implement, interpret, and make specific sections 124116, 124977, 124980, 125000, 125001, 125025, 131050, 131051, and 131200 of the Health and Safety Code.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

The purpose of this rulemaking proposal is to make permanent the emergency regulations which clarified and made specific Health and Safety Code sections 124977 and 125001 and updated the newborn screening (NBS) regulations in order to protect the health, and prevent unnecessary death of newborns born in California. These regulations are needed to address the changes in medical technology and incorporate necessary changes in the NBS requirements for newborn’s physicians, midwives, perinatal health facilities/hospitals, and other out-of-hospital newborn screening providers.

POLICY STATEMENT OVERVIEW

Problem Statement: The California NBS Program has expanded its testing panel three times since the current regulations were developed, from four (4) tests detecting 29 diverse disorders to eight (8) tests detecting 80 diverse disorders. (See attached list of Disorders Detectable by NBS Program as of January 1, 2012.) The requirements for screening have changed because the new disorders are so diverse and require different standards and practices. These necessary changes are not reflected in the current NBS regulations.

Objectives: The broad objectives of this proposed regulatory action are to accomplish the following:

- Include the expansion of NBS which occurred in 2005 and 2007, resulting in a substantial increase in the number of disorders for which newborns are tested
- Include the expansion of NBS which occurred in 2012 to include testing for an additional disorder - Severe Combined Immunodeficiency (SCID)
- Change technology, terminology, medical standards, and practices that have occurred in the field of newborn screening internationally, nationally, and in California since the last NBS regulations were written

Benefits: The benefits anticipated by the adoption of these regulations are:

- Providing protection of public health and safety by expanding upon existing regulation provisions
- Improved provisions for early detection, follow-up and referrals for diagnosis and early treatment
- Providing early treatment, preventing illness, disability and even death to infants
- Identifying detailed responsibilities of parties involved in 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 is not inconsistent or incompatible with other state regulations.

Existing regulations provide for the means of newborn screening, including test methods, and instructions to various medical personnel and providers but they don't identify the expansions of the NBS Program occurring in 2005, 2007, and 2012, which have resulted in a substantial increase in the number of disorders for which newborns are tested or the changing technology, terminology, medical standards and practices

that have occurred in the field of newborn screening since the last NBS Program regulations were written.

Therefore, the Department has determined that this proposal, if adopted, would not be inconsistent or incompatible with existing state regulations.

MANDATED BY FEDERAL LAW OR REGULATIONS

Currently, there are no existing federal regulations or statutes applicable to the 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).

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. COST OR SAVINGS TO ANY STATE AGENCY:** No fiscal impact exists because this regulation does not affect any state entity or program. The costs for provider education on regulation changes are included in program's budget.
- B. COST TO ANY LOCAL AGENCY:** No fiscal impact exists because this regulation does not affect any local entity or program.
- C. COST OR SAVINGS ON FEDERAL FUNDING OF STATE PROGRAMS:** No fiscal impact exists because this regulation does not affect any federal entity or program.
- D. OTHER NONDISCRETIONARY COST OR SAVINGS IMPOSED ON LOCAL AGENCIES:** No fiscal impact exists because this regulation does not affect any local entity or program.

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.

EFFECT ON SMALL BUSINESSES

The Department has determined that the regulations will have no significant effect on small businesses as this proposal addresses the changes in the medical field and screening requirements that already exist for newborn's physicians, midwives, perinatal health facilities/hospitals, and other out-of-hospital newborn screening providers. The additional screens are to be collected at the same time.

HOUSING COSTS

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

BUSINESS REPORTING REQUIREMENT

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

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING THE ABILITY TO COMPETE

The Department has made an initial determination that this proposal would not have a significant statewide adverse economic impact directly affecting California business enterprises or individuals, including the ability of California businesses to compete with businesses in other states.

RESULTS OF THE ECONOMIC IMPACT ASSESSMENT

The Department has determined that the regulation would not significantly impact the creation or elimination of jobs, the creation of new businesses or the elimination of existing businesses, or the expansion of businesses currently doing business within the State of California. This regulation does not affect worker safety or California's environment. As stated previously in the Informative Digest/Policy Statement Overview, this regulation will benefit the health and welfare of California residents. The regulations expand upon existing regulation provisions and will provide provisions for early detection, follow-up, and referrals for diagnosis and treatment which will lead to early treatment, preventing illness, disability, and even death to infants.

ALTERNATIVES INFORMATION

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 action is proposed or would be as effective and less burdensome to affected private persons than the proposed action or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provisions of law.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDIES, REPORTS OR DOCUMENTS RELIED UPON

California Department of Public Health, Genetic Disease Screening Program, Newborn Screening Program. (Updated January 1, 2012). *Disorders Detectable by NBS Program as of January 1, 2012.*

CONTACT PERSON

Inquiries regarding the substance of the regulation described in this notice may be directed to Robin Thomas, Genetic Disease Screening Program, Center for Family Health, (510) 412-1519.

All other inquiries concerning the action described in this notice may be directed to Linda M. Cortez, Office of Regulations, (916) 440-7807, or the designated backup contact person, Dawn Basciano, (916) 440-7367.

In any inquiry or written comment, please identify the action by using the Department regulation package identifier “DPH-09-010E”.

AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF REGULATIONS

The Department has prepared and has available for public review an initial statement of reasons for the proposed regulations, all the information upon which the proposed regulations are based, and the text of the proposed regulations. The Office of Regulations, at the address noted above, will be the location of public records, including reports, documentation, and other material related to the proposed regulations (rulemaking file).

In order to request that a copy of this public notice, the regulation text, and the initial statement of reasons or alternate formats for these documents be mailed to you, please call (916) 440-7807 (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.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

The full text of any regulation which is changed or modified from the express terms of the proposed action will be made available by the Department's Office of Regulations at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

AVAILABILITY OF 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, the regulation text, and the initial statement of reasons) are available via the Internet and may be accessed at www.cdph.ca.gov by clicking on these links, in the following order: Decisions Pending & Opportunities for Public Participation, Proposed Regulations.