

FILE PRINT

STATE OF CALIFORNIA—OFFICE OF ADMINISTRATIVE LAW

NOTICE PUBLICATION/REGULATIONS SUBMISSION

(See instructions on reverse)

For use by Secretary of State only

STD. 400 (REV. 01-2013)

OAL FILE NUMBERS	NOTICE FILE NUMBER Z-2016-0927-05	REGULATORY ACTION NUMBER 2017-0725-03FP	EMERGENCY NUMBER
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ENDORSED - FILED
in the office of the Secretary of State
of the State of California

SEP 06 2017
1:55 P.M.

For use by Office of Administrative Law (OAL) only

2017 JUL 25 A 11: 37
OFFICE OF
ADMINISTRATIVE LAW

NOTICE	REGULATIONS
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AGENCY WITH RULEMAKING AUTHORITY
CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

AGENCY FILE NUMBER (if any)
DPH-16-015E

A. PUBLICATION OF NOTICE (Complete for publication in Notice Register)

1. SUBJECT OF NOTICE	TITLE(S)	FIRST SECTION AFFECTED	2. REQUESTED PUBLICATION DATE
3. NOTICE TYPE <input type="checkbox"/> Notice re Proposed Regulatory Action <input type="checkbox"/> Other	4. AGENCY CONTACT PERSON	TELEPHONE NUMBER	FAX NUMBER (Optional)
OAL USE ONLY	ACTION ON PROPOSED NOTICE <input type="checkbox"/> Approved as Submitted <input type="checkbox"/> Approved as Modified <input type="checkbox"/> Disapproved/Withdrawn	NOTICE REGISTER NUMBER	PUBLICATION DATE

B. SUBMISSION OF REGULATIONS (Complete when submitting regulations)

1a. SUBJECT OF REGULATION(S) NEWBORN SCREENING PARTICIPATION FEE	1b. ALL PREVIOUS RELATED OAL REGULATORY ACTION NUMBER(S) 2016-0630-02 EFP
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2. SPECIFY CALIFORNIA CODE OF REGULATIONS TITLE(S) AND SECTION(S) (Including title 26, if toxics related)

SECTION(S) AFFECTED (List all section number(s) individually. Attach additional sheet if needed.)	ADOPT
	AMEND 6508
	REPEAL

TITLE(S)
17

3. TYPE OF FILING

<input type="checkbox"/> Regular Rulemaking (Gov. Code §11346)	<input type="checkbox"/> Certificate of Compliance: The agency officer named below certifies that this agency complied with the provisions of Gov. Code §§11346.2-11347.3 either before the emergency regulation was adopted or within the time period required by statute.	<input type="checkbox"/> Emergency Readopt (Gov. Code, §11346.1(h))	<input type="checkbox"/> Changes Without Regulatory Effect (Cal. Code Regs., title 1, §100)
<input type="checkbox"/> Resubmittal of disapproved or withdrawn nonemergency filing (Gov. Code §511349.3, 11349.4)	<input type="checkbox"/> Resubmittal of disapproved or withdrawn emergency filing (Gov. Code, §11346.1)	<input checked="" type="checkbox"/> File & Print	<input type="checkbox"/> Print Only
<input type="checkbox"/> Emergency (Gov. Code, §11346.1(b))		<input checked="" type="checkbox"/> Other (Specify) HSC SECTION 124977(d)	

4. ALL BEGINNING AND ENDING DATES OF AVAILABILITY OF MODIFIED REGULATIONS AND/OR MATERIAL ADDED TO THE RULEMAKING FILE (Cal. Code Regs. title 1, §44 and Gov. Code §11347.1)

5. EFFECTIVE DATE OF CHANGES (Gov. Code, §§ 11343.4, 11346.1(d); Cal. Code Regs., title 1, §100)

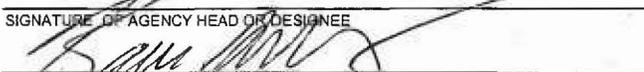
<input type="checkbox"/> Effective January 1, April 1, July 1, or October 1 (Gov. Code §11343.4(a))	<input type="checkbox"/> Effective on filing with Secretary of State	<input type="checkbox"/> \$100 Changes Without Regulatory Effect	<input checked="" type="checkbox"/> Effective other (Specify) HSC SECTION 124977(d)
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6. CHECK IF THESE REGULATIONS REQUIRE NOTICE TO, OR REVIEW, CONSULTATION, APPROVAL OR CONCURRENCE BY, ANOTHER AGENCY OR ENTITY

<input type="checkbox"/> Department of Finance (Form STD. 399) (SAM §6660)	<input type="checkbox"/> Fair Political Practices Commission	<input type="checkbox"/> State Fire Marshal
<input type="checkbox"/> Other (Specify)		

7. CONTACT PERSON LINDA M. CORTEZ	TELEPHONE NUMBER 916-440-7807	FAX NUMBER (Optional) 916-440-5747	E-MAIL ADDRESS (Optional) linda.cortez@cdph.ca.gov
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8. I certify that the attached copy of the regulation(s) is a true and correct copy of the regulation(s) identified on this form, that the information specified on this form is true and correct, and that I am the head of the agency taking this action, or a designee of the head of the agency, and am authorized to make this certification.

SIGNATURE OF AGENCY HEAD OR DESIGNEE 	DATE 6/28/17
TYPED NAME AND TITLE OF SIGNATORY KARIN S. SCHWARTZ, DEPUTY DIRECTOR AND CHIEF COUNSEL	

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ENDORSED APPROVED
SEP 06 2017
Office of Administrative Law

Title 17. Public Health
Division 1. State Department of Health Services
Chapter 4. Preventive Medical Service
Subchapter 9. Testing for Heritable Disorders
Group 3. Newborn Screening Program
Article 4. Newborn Screening Participation Fee

Amend Section 6508 to read:

§ 6508. Newborn Screening Fee Collection.

(a) Perinatal licensed health facilities and birth attendants shall obtain from the Department a sufficient supply of specimen collection forms to permit collection of a blood specimen from each newborn required to be tested under this Group.

(b) The Department shall collect a fee for each specimen record form provided and a program participation fee for all services provided. The fee for a specimen form shall be \$1 and for program services shall be \$129.25 except for a comprehensive prepaid group practice direct health care service plan with 20,000 or more births in the last completed calendar year for which complete statistics are available, which elects to provide testing, follow-up and/or counseling services to its members. The fee for such plans shall be equal to the Department's cost of administration of the newborn screening program, to be determined by reducing the \$129.25 program service fee by the annual statewide average per infant contracted cost of laboratory testing, follow-up and/or counseling services rendered during the previous fiscal year. In order to qualify for this special fee a medical group serving a comprehensive prepaid group practice direct care service plan with 20,000 or more births shall sign a written agreement which contains the same standards and conditions, except as to payment or where specifically waived, as are applicable to the newborn screening laboratories and Newborn

Screening Area Service Centers, adhere to the regulations governing the program, and to submit to monitoring and evaluation of compliance. Failure to comply with these conditions after being given written notification and 30 days to correct deviations shall result in loss of the option. In the event the option is lost the State shall designate appropriate contractors to provide services.

The provisions of this section shall apply even if the newborn is part of a State-approved demonstration project.

(c) Birth attendants and physicians attending newborns who are under six days of age and who were not born in perinatal licensed health facilities and not subsequently admitted to perinatal licensed health facilities shall obtain a sufficient supply of specimen record forms to permit collection or shall arrange for a collection of a blood specimen from each such newborn attended.

(d) Birth attendants and physicians attending newborns and perinatal licensed health facilities shall not charge parents or third parties responsible for medical care coverage fees for participation in the newborn screening program in addition to those specified in this section, except for reasonable fees for costs of blood specimen collection and handling which shall not exceed \$6.

(e) The perinatal licensed health facility shall make available to the responsible physician, at no additional charge, specimen collection services or a specimen record form for obtaining either a repeat specimen for an inadequate specimen or a specimen on a newborn discharged without the test having been obtained.

Note: Authority cited: Sections 124977, 124996, 125000, 131050, 131051 and 131200, Health and Safety Code. Reference: Sections 124977, 124996, 125000 and 125001, Health and Safety Code.

**STATEMENT OF COMPLIANCE WITH
HEALTH AND SAFETY CODE SECTION 124977**

The California Department of Public Health has complied with section 124977 subdivision (d)(1) of the Health and Safety Code by holding a public hearing on October 18, 2016, within 120 days of filing the prior emergency regulations with the Secretary of State on July 1, 2016, and complied with sections 11346.8 and 11346.9 of the Government Code.