

**State of California
Office of Administrative Law**

In re:
Department of Public Health

Regulatory Action:

Title 17, California Code of Regulations

Adopt sections: 6500.03, 6500.05, 6500.9,
6500.21, 6500.33, 6500.43,
6500.50, 6500.51, 6500.55,
6500.58, 6500.71, 6500.78,
6501.5

Amend sections: 6500.35, 6500.39, 6500.45,
6501, 6505, 6506, 6506.6,
6506.8, 6506.10

Repeal sections: 6500.65, 6500.67

**AMENDED NOTICE OF FILING AND
PRINTING ONLY OF EMERGENCY
REGULATIONS**

Government Code Section 11343.8

OAL Matter Number: 2016-0323-02EFP

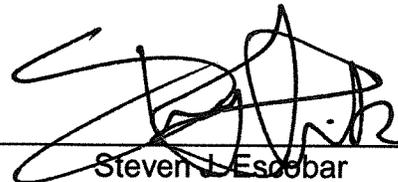
**OAL Matter Type: Emergency File and Print
Only (EFP)**

This emergency rulemaking by the Department of Public Health (the "Department") adopts, amends, and repeals several sections in title 17 of the California Code of Regulations. Specifically, these regulatory changes revise Newborn Screening Program requirements for newborn's physicians, midwives, perinatal health facilities/hospitals, and other out-of-hospital newborn screening providers. These regulations also update the scope of testing to accommodate the expanded list of disorders for which testing is done, as well as update definitions, optimal timing, specific details regarding specimen collection, and follow-up requirements to accommodate practice and technology changes in newborn screening.

OAL filed these emergency regulations with the Secretary of State on April 4, 2016, and will publish the emergency regulations in the California Code of Regulations.

This amended notice (1) adds section 6501.5 to the list of sections adopted in this rulemaking to accurately reflect the regulations filed with the Secretary of State; (2) clarifies that the notice is for filing and printing only of emergency regulations; and (3) states the date the regulations were filed with the Secretary of State.

Date: April 5, 2016



Steven J. Escobar
Attorney

For: Debra M. Cornez
Director

Original: Dr. Karen Smith
Copy: Charlet Archuleta

EMERGENCY

(See instructions on reverse)

For use by Secretary of State only

STD. 400 (REV. 01-2013)

OAL FILE NUMBERS	NOTICE FILE NUMBER Z-	REGULATORY ACTION NUMBER	EMERGENCY NUMBER 2016-0323-02 EFP
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For use by Office of Administrative Law (OAL) only	
NOTICE	REGULATIONS

ENDORSED - FILED
 in the office of the Secretary of State
 of the State of California

APR 04 2016
 3:09 PM

AGENCY WITH RULEMAKING AUTHORITY Department of Public Health	AGENCY FILE NUMBER (if any) DPH-09-010E
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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	1b. ALL PREVIOUS RELATED OAL REGULATORY ACTION NUMBER(S)
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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 6500.03, 6500.05, 6500.9, 6500.21, 6500.33, 6500.43, 6500.50, 6500.51, 6500.55, 6500.58, 6500.71, 6500.78, AMEND 6500.35, 6500.39, 6500.45, 6501, 6505, 6506, 6506.6, 6506.8, 6506.10 REPEAL 6500.65, 6500.67
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 §11349.3, 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) <u>Emergency Regs HSC 124977(d)</u>	

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) <u>Health & Safety Code §124977(d)(1)</u>

6. CHECK IF THESE REGULATIONS REQUIRE NOTICE TO, OR REVIEW, CONSULTATION, APPROVAL OR CONCURRENCE BY, ANOTHER AGENCY OR ENTITY			
<input checked="" 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 Charlet Archuleta	TELEPHONE NUMBER (916) 445-9403	FAX NUMBER (Optional) (916) 440-5747	E-MAIL ADDRESS (Optional) charlet.archuleta@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 3/22/16
TYPED NAME AND TITLE OF SIGNATORY Karin S. Schwartz, Deputy Director and Chief Counsel	

For use by Office of Administrative Law (OAL) only
ENDORSED APPROVED
APR 04 2016
Office of Administrative Law

156-04-04-2016 per agency request



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

ADDENDUM

DPH-09-010E Newborn Screening

Notice Publication/Regulations Submission (STD. 400)

- B. Submission of Regulations
- 2. Specify California Code of Regulations Title(s) and Section(s)

Title(s): 17

Sections Affected: Adopt 6501.5



TEXT OF REGULATIONS

ARTICLE 1. DEFINITIONS

(1) Adopt §6500.03 to read:

§6500.03. California Children's Services (CCS).

"California Children's Services (CCS)" means a State and County program providing medically necessary benefits as defined in Title 22, Division 2, Subdivision 7, Chapter 1, §41452 to persons under 21 years of age with physically handicapping conditions who meet medical, financial and residential eligibility requirements for the CCS program.

Note: Authority cited: Sections 20, 100275, 123805, 124980, 125000 and 131200, Health and Safety Code. Reference: Sections 123830, 123835, 123845, 123865, 123870, 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(2) Adopt §6500.05 to read:

§6500.05. Confirmatory Test.

“Confirmatory Test” means a laboratory test done to prove or disprove the presence of a specific condition identified by the newborn screening test. This test is performed on a specimen other than the screening specimen.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.
Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(3) Adopt §6500.9 to read:

§6500.9. Early Specimen.

“Early Specimen” means a newborn screening specimen collected from a newborn who is less than 12 hours of age.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.
Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(4) Adopt §6500.21 to read:

§6500.21. Infant.

“Infant” means a child 29 days through 12 months old.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.
Reference: Sections 124116, 124975, 124980, 125000, 131050, 131051 and 131052,
Health and Safety Code.

(5) Adopt §6500.33 to read:

§6500.33. Lost to Follow-Up.

“Lost to Follow-Up” means the inability of the Newborn Screening Area Service Center to locate the newborn or infant for follow-up because:

(a) there is no response to attempts to locate the parents or legal guardian after a minimum of 1 phone call and 1 certified letter using available contact information; and

(b) the Newborn Screening Area Service Center and the Department believe that reasonable attempts have been made to locate the infant.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.
Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(6) Amend §6500.35 to read:

§6500.35. Newborn.

“Newborn” means a child less than 29 days old ~~an infant 30 days of age and under.~~

Note: Authority cited: Sections 124980, 125000, and 131200, Health and Safety Code. Reference: Sections 124116, 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(7) Amend §6500.39 to read:

§6500.39. Newborn's Physician.

"Newborn's physician" means the physician caring for the newborn or infant in the perinatal licensed health facility's normal newborn nursery or neonatal intensive care unit or in the outpatient community after discharge responsible for the care of the newborn after discharge from the hospital.

Note: Authority cited: Sections 124980, and 125000, and 131200, Health and Safety Code. Reference: Sections 124975, 124980, and 125000, 131050, 131051 and 131052, Health and Safety Code.

(8) Adopt §6500.43 to read:

§6500.43. Newborn Screening.

“Newborn Screening” means the testing of infants to identify those at increased risk for certain genetic and other congenital disorders for which early identification and treatment may prevent disability and/or death.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.
Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(9) Amend §6500.45 to read:

§6500.45. Newborn Screening Area Service Center.

~~“Newborn Screening Area Service Center” means an institution, corporation, hospital or university medical center:~~

~~(a) Having specialized expertise;~~

~~(b) Designated by the Department to serve a specific geographic area of the State; and~~

~~(c) Contracted with the Department to provide follow-up, referral and diagnosis of a preventable heritable or congenital disorder.~~

“Newborn Screening Area Service Center” means a facility which is contracted with the Department to provide regional newborn screening services.

Note: Authority cited: Sections 124980, and 125000 and 131200, Health and Safety Code. Reference: Sections 124975, 124980, and 125000, 131050, 131051 and 131052, Health and Safety Code.

(10) Adopt §6500.50 to read:

§6500.50. Newborn Screening Specimen.

"Newborn Screening Specimen" means a blood sample taken from an infant that is collected on CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D).

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code. Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(12) Adopt §6500.55 to read:

§6500.55. Out-of-Hospital Newborn Screening Providers.

“Out-of-Hospital Newborn Screening Providers” means:

(a) all healthcare professionals including, but not limited to, licensed midwives (LM), certified nurse midwives (CNM), registered nurses (RN), physician assistants (PA), pediatric nurse practitioners (PNP), physicians/medical doctors (MD), doctors of osteopathy (DO), and naturopathic doctors (ND), who are licensed or certified by the State to provide maternal care and to deliver pregnant women in alternative settings other than perinatal licensed health facilities including, but not limited to, private homes and clinics; and

(b) staff of health care entities, such as clinics and free-standing independent laboratories that are authorized by the Department to collect newborn screening specimens in alternative settings other than perinatal licensed health facilities.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.
Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(13) Adopt §6500.58 to read:

§6500.58. Perinatal Licensed Health Facility Staff.

“Perinatal Licensed Health Facility Staff” means the individuals working in the laboratory, maternal, or nursery departments of perinatal licensed health facilities who collect the newborn screening specimens.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.
Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(14) Repeal §6500.65 as follows:

~~§6500.65. Recall Specimen.~~

~~"Recall specimen" means a specimen collected from a newborn because the initial test or combination of tests was positive for any of the disorders covered by this Group.~~

~~Note: Authority cited: Sections 124980 and 125000, Health and Safety Code.
Reference: Sections 124980 and 125000, Health and Safety Code.~~

(15) Repeal §6500.67 as follows:

~~§6500.67. Recall Test.~~

~~"Recall test" means a test ordered collected from a newborn because the initial test or combination of tests was positive for any of the disorders covered by this Group.~~

~~Note: Authority cited: Sections 124980 and 125000, Health and Safety Code.
Reference: Sections 124980 and 125000, Health and Safety Code.~~

(16) Adopt §6500.71 to read:

§6500.71. Screening Information System (SIS).

“Screening Information System (SIS)”, in this Group, means the Department Newborn Screening Program’s database and associated screens that:

(a) list the newborn screening specimens that have been received by the Department for testing; and

(b) provide for reporting of those specimens that are missing.

This system is to be used to verify receipt of specimens and report those that have not been received pursuant to §6506.

Note: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code.
Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

(17) Adopt §6500.78 to read:

§6500.78. This Group.

“This Group” means Group 3. Newborn Screening Program in the official California Code of Regulations as follows: 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.

NOTE: Authority cited: Sections 124980, 125000 and 131200, Health and Safety Code. Reference: Sections 124975, 124980, 125000, 131050, 131051 and 131052, Health and Safety Code.

ARTICLE 2. TESTING AND FOLLOW-UP PROGRAM REQUIREMENTS

(18) Amend §6501 to read:

§6501. Scope of Newborn Testing.

Except for provisions in §6501.2 and §6502, Each newborn born in California shall be tested for galactosemia, hereditary hemoglobinopathies, phenylketonuria, and primary congenital hypothyroidism and disorders authorized for testing in Health and Safety Codes 124977, 124980 and 125001 in accordance with procedures in this Group.

Note: Authority cited: Sections 124977, 124980, 124996, and 125000, 125001 and 131200, Health and Safety Code. Reference: Sections 124975, 124980, 125000, 125001, and 125025, 131050, 131051 and 131052, Health and Safety Code.

(19) Adopt §6501.5 to read:

§6501.5. Required Newborn Screening Forms.

The following newborn screening forms from the Department shall be utilized in accordance with provisions in this Group:

(a) For all newborn screening specimen collection pursuant to §6505(a)(1), §6505(a)(2), §6505(b)(1), §6505(b)(2), §6505(c)(1), §6506(a), §6506.6(a), §6506.6(b)(1) and §6506.6(c)(1): CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D). This form is hereby incorporated by reference.

(b) For parents or legally appointed guardians who object to a newborn screening test pursuant to §6501.2: NEWBORN SCREENING TEST REFUSAL (NBS-TR) CDPH 4459 (06/11) - English version or CDPH 4459(SP) (6/11) - Spanish version. This form is hereby incorporated by reference.

(c) For perinatal licensed health facility staff or birth attendants who have not obtained a newborn screening specimen pursuant to §6505(a)(4), §6505(b)(4), §6506(a) or §6506.2: HOSPITAL REPORT OF NEWBORN SCREENING SPECIMEN NOT OBTAINED (NBS – NO) CDPH 4089 (01/11). This form is hereby incorporated by reference.

(d) For county registrars who register infants born outside of a perinatal licensed health facility or who are not attended by a birth attendant pursuant to §6505(d): NOTIFICATION OF REGISTRATION OF BIRTH WHICH OCCURRED OUT OF A LICENSED HEALTH FACILITY (NBS-OH) CDPH 4460 (01/09). This form is hereby incorporated by reference.

Note: Authority cited: Sections 124977, 124980, 124996, 125000, 125001 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, 125000, 125001, 125025, 131050, 131051 and 131052, Health and Safety Code.

(20) Amend §6505 to read:

§6505. Collection of Newborn Screening Specimens.

~~(a) Birth attendants, laboratories and hospitals shall collect specimens using the technique for blood collection distributed by the Department.~~

~~(b) Physicians or birth attendants who are caring for newborns born in perinatal licensed health facilities shall have blood specimens collected using Department approved specimen collection forms in accordance with criteria distributed by the Department including the following:~~

~~(1) A specimen must be collected from any untested infant prior to blood transfusion.~~

~~(2) For newborns discharged before six days of age, a blood specimen shall be obtained as close to the time of discharge from the perinatal licensed health facility as is practical regardless of age or feeding history, unless the newborn is transferred for continuing care to another perinatal licensed health facility on or before the sixth day of age. Perinatal licensed health facilities which discharge infants before 24 hours of age may request a waiver from this requirement documenting how such newborns will be tested on or before 6 days of age. Such alternative testing schedules must be approved in writing by the Department.~~

~~(3) For newborns remaining in perinatal licensed health facilities beyond five days of age, a blood specimen shall be obtained from the newborn on the sixth day of age regardless of feeding history.~~

~~(4) For newborns received by transfer on or before six days of age, the receiving hospital shall obtain a blood specimen as close to discharge as possible, and if not discharged by the sixth day, a blood specimen shall be obtained on the sixth day of life.~~

~~(c) For newborns not born in a perinatal licensed health facility but admitted to a perinatal licensed health facility within the first six days of age, a specimen shall be obtained as close to discharge as possible, and if not discharged by the sixth day of life, a blood specimen shall be obtained on the sixth day of life unless the newborn's physician has evidence that the specimen was previously obtained and records the results of the test in the newborn's medical record.~~

~~(d) For newborns not born in a perinatal licensed health facility but admitted to a perinatal licensed health facility after six days of age but within the first 30 days of age, a blood specimen shall be obtained within 48 hours after admission unless the newborn's physician has evidence that the specimen was previously obtained and records the results of the test in the newborn's medical record.~~

~~(e) Physicians attending sick newborns who exhibit symptoms suggestive of galactosemia, hypothyroidism or phenylketonuria (PKU), in addition to immediate diagnostic tests from local laboratory sources, shall have a blood specimen collected from the newborn and submitted to a newborn screening laboratory using forms purchased from the Department.~~

~~(f) Physicians attending critically ill newborns who require special care may postpone collection of a blood specimen until the newborn's emergency life-threatening condition is stabilized.~~

~~(g) Birth attendants or physicians attending newborns not born in a perinatal licensed health facility and not subsequently admitted to a licensed health facility during the first six days of age, shall have a blood specimen collected from the newborn between the~~

~~second and sixth days of age and submitted to a newborn screening laboratory using forms obtained from the Department.~~

~~(h) If a newborn is born outside of a perinatal licensed health facility and the birth is not attended by a birth attendant and the newborn is not subsequently admitted to a perinatal licensed health facility within the first ten days of age, the person required to register the birth shall arrange for a blood specimen to be collected and submitted to a newborn screening laboratory between the second and tenth day of age.~~

~~(i) Initial specimens shall be collected using a Department-approved form and shall be placed in the United States mail or other approved channel of transmittal to the assigned Department-approved laboratory as soon as possible, but not later than 12 hours after they are obtained.~~

(a) For each newborn born in a perinatal licensed health facility, the perinatal licensed health facility staff shall:

(1) collect the newborn screening specimen, using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) pursuant to §6501.5(a) and §6504.4(b). This specimen collection shall occur after 12 hours but no later than 96 hours of age prior to discharge or transfer of the newborn unless the newborn's condition is life-threatening and the collection cannot be done safely.

Physicians attending critically ill newborns who require special care may postpone collection of a newborn screening specimen until the newborn's emergency condition is stabilized. The receiving perinatal licensed health facility staff shall then collect the newborn screening specimen using the Instructions for Collecting Adequate Blood

Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM

(NBS-TRF) (CDPH – 4409 - (11-12)) NBS-I (D) pursuant to §6501.5(a) and §6504.4(b)

as soon as the newborn's condition is stabilized. Any specimen collected on a newborn prior to 12 hours of age is an early specimen and another specimen shall be collected after 12 hours of age pursuant to §6505(a)(2) and §6506.6.

(2) collect a newborn screening specimen prior to red blood cell transfusion when the newborn is stable, even if the newborn is under 12 hours of age, using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH – 4409 - (11-12)) NBS-I (D) pursuant to §6501.5(a) and §6504.4(b).

(3) ensure that specimens are given, on the next business day of the designated carrier, to a carrier contracted with the Department or contracted with a newborn screening laboratory or to the United States Postal Service for transport to the assigned newborn screening laboratory.

(4) complete the HOSPITAL REPORT OF NEWBORN SCREENING SPECIMEN NOT OBTAINED (NBS-NO) CDPH-4089 (01/11) pursuant to §6501.5(c), in the event the newborn screening specimen is not collected prior to transfer to another perinatal licensed health facility and there is no copy of the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409- (11-12)) NBS-I (D) in the newborn's medical record.

(5) Collection of a newborn screening specimen under this section shall not apply if the parent or legal guardian has signed a copy of the NEWBORN SCREENING TEST REFUSAL (NBS-TR) CDPH 4459 (06/11) pursuant to 6501.5(b).

(b) For infants not born in a perinatal licensed health facility, but admitted to a perinatal licensed health facility at any time after birth, the perinatal licensed facility staff shall:

(1) obtain a newborn screening specimen within 48 hours of admission, using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) pursuant to §6501.5(a) and §6504.4(b), unless a copy of the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D), or a copy of the NEWBORN SCREENING TEST REFUSAL (NBS-TR) CDPH 4459 (06/11), or a newborn screening result is found in the infant's medical record or the physician has a record of the screening specimen having been collected.

(2) collect a newborn screening specimen prior to red blood cell transfusion, even if the newborn is under 12 hours of age, using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) pursuant to §6501.5(a) and §6504.4(b).

(3) ensure that specimens are given, on the next business day of the designated carrier, to a carrier contracted with the Department or contracted with a newborn screening laboratory or to the United States Postal Service for transport to the assigned newborn screening laboratory.

(4) complete the HOSPITAL REPORT OF NEWBORN SCREENING SPECIMEN NOT OBTAINED (NBS-NO) CDPH-4089 (01/11) pursuant to 6501.5(c), in the event the newborn screening specimen is not collected.

(c) For infants not born in a perinatal licensed health facility and not admitted to a perinatal licensed health facility after birth, out-of-hospital newborn screening providers shall:

(1) collect a newborn screening specimen within 48 hours of the first contact with the infant using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) pursuant to §6501.5(a) and §6504.4(b) unless a copy of the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) or a copy of the NEWBORN SCREENING TEST REFUSAL (NBS-TR) CDPH 4459 (06/11), or a newborn screening result is found in the infant's medical record.

(2) ensure that specimens are given, on the next business day of the designated carrier, to a carrier contracted with the Department or contracted with a newborn screening laboratory or to the United States Postal Service for transport to the assigned newborn screening laboratory.

(d) For infants born outside of a perinatal licensed health facility and not subsequently admitted to a perinatal licensed health facility, when the birth is being registered at the county registrar's office, the person in the county registrar's office required to register the birth shall notify the Department of the birth the next business day after the birth is registered using the NOTIFICATION OF REGISTRATION OF BIRTH WHICH OCCURRED OUT OF A LICENSED HEALTH FACILITY (NBS-OH) CDPH 4460 (01/09) pursuant to §6501.5(d).

(e) A newborn screening specimen may be collected on a child over 1 year of age with prior authorization from the Department.

(f)(i) The blood specimen and information obtained during the testing process becomes the property of the State and may be used for program evaluation or research by the Department or Department-approved scientific researchers without identifying the person or persons from whom these results were obtained, unless the person or his/her legally authorized representative specifically prohibits such use in writing.

Note: Authority cited: Sections 124977, 124980, 124996, and 125000, 125001 and 131200, Health and Safety Code. Reference: Sections 124975, 124980, and 125000, 125001, 125025, 131050, 131051 and 131052, Health and Safety Code.

(21) Amend §6506 to read:

§6506. Medical Record Review Verification of Receipt of Newborn Screening

Specimens by the Department.

~~(a) Perinatal licensed health facilities shall review each newborn's medical record within 14 days from the date of discharge to determine that the results of required tests are filed in the newborn's medical record, or that a parent's or legal guardian's signed refusal has been filed in the newborn's medical record.~~

Perinatal licensed health facility staff and out-of-hospital newborn screening providers shall check the Department Screening Information System (SIS) within 7 days after the date of birth to verify that the newborn screening specimen has been received by the Department. This applies to all infants for whom perinatal licensed health facilities and out-of-hospital newborn screening providers have responsibility for newborn screening pursuant to §6505(a), (b) and (c). If a specimen has not been received and there is neither a copy of the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) pursuant to §6501.5(a) nor a copy of a completed NEWBORN SCREENING TEST REFUSAL (NBS-TR) CDPH 4459 (06/11) - English version or CDPH 4459(SP) - Spanish version pursuant to §6501.2 and 6501.5(b) present in the newborn's medical record, the staff shall complete a HOSPITAL REPORT OF NEWBORN SCREENING SPECIMEN NOT OBTAINED (NBS - NO) CDPH 4089 (01/11) pursuant to §6501.5(c). If a specimen has not been received and the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) is present in the newborn's medical record, staff shall enter a missing specimen report into the Screening Information System (SIS), and

if the newborn has not been discharged, collect a newborn screening specimen on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) pursuant to §6501.5(a) and §6504.4(b) within 24 hours.

This specimen shall be given to a carrier contracted with the Department or contracted with a newborn screening laboratory or to the United States Postal Service for transport to the assigned newborn screening laboratory on the next business day of the designated carrier.

~~(b) Whenever a perinatal licensed health facility determines that a specimen has been obtained, but there are no results available in the newborn's medical record the facility shall send written notification within five days to the Department.~~

If a perinatal licensed health facility or a group of perinatal licensed health facilities has an internal computerized system in place to identify specimens received by their designated newborn screening laboratory, and this system has the same criteria to verify receipt of newborn screening specimens as the Department's Screening Information System (SIS) as described in §6500.71(a) and (b), then their system rather than SIS may be used to verify receipt of their specimens.

Note: Authority cited: Sections 124977, 124980, and 125000, 125001 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, and 125000, 125001, 125025, 131050, 131051 and 131052, Health and Safety Code.

(22) Amend §6506.6 to read:

§6506.6. Follow-Up to Reports of Inadequate and Early Newborn Screening

Specimens.

~~When the newborn's physician is notified by the laboratory by telephone that a specimen is inadequate, the physician so notified shall make every reasonable effort to have an adequate specimen obtained within five days of notification. If the newborn's physician so notified, cannot obtain the repeat specimen, the physician shall notify the Newborn Screening Area Service Center as soon as possible by telephone. Such telephone notification shall be noted in the newborn's physician's records specifying the date of notification, the person notified and the information provided.~~

(a) For those specimens identified by the Newborn Screening Area Service Center as early, or where the infant's age at time of specimen collection cannot be determined, the Newborn Screening Area Service Center shall verify with the collecting person or facility the dates and times of birth and specimen collection written on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D).

(b) Upon notification by the Newborn Screening Area Service Center that the specimen is verified as an early specimen, the perinatal licensed health facility staff, birth attendant, out-of-hospital newborn screening provider, or newborn's physician shall:

(1) collect a repeat specimen within 48 hours of notification, using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) pursuant to §6501.5(a) and §6504.4(b).

(2) ensure the specimen is given, on the next business day of the designated carrier, to a carrier contracted with the Department or contracted with a newborn screening laboratory or is transported by the United States Postal Service to the assigned newborn screening laboratory.

(c) When the perinatal licensed health facility staff, the birth attendant, out-of-hospital newborn screening provider, or the newborn's physician is notified by the Newborn Screening Area Service Center that a specimen is an inadequate specimen, the perinatal licensed health facility, the birth attendant, out-of-hospital newborn screening provider, or the newborn's physician shall:

(1) collect a repeat specimen within 48 hours of notification, using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (11-12)) NBS-I (D) pursuant to §6501.5(a) and §6504.4(b).

(2) ensure the specimen is given, on the next business day of the designated carrier, to a carrier contracted with the Department or contracted with a newborn screening laboratory or is transported by the United States Postal Service to the assigned newborn screening laboratory.

(d) If a repeat specimen for either an early or an inadequate specimen cannot be obtained, the perinatal licensed health facility staff, birth attendant, out-of-hospital newborn screening provider, or newborn's physician shall notify the Newborn Screening Area Service Center by phone, fax, or e-mail within 48 hours regarding the status of the collection and also again when the specimen has been collected and sent to the Department.

(e) Nothing in this section imposes the duty on the newborn's physician to find the infant if the infant is determined by the Newborn Screening Area Service Center to be lost to follow-up.

Note: Authority cited: Sections 124977, 124980, and 125000, 125001 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, and 125000, 125001, 125025, 131050, 131051 and 131052, Health and Safety Code.

(23) Amend §6506.8 to read:

§6506.8. Follow-Up to Reports of Initial Positive Results.

~~When the newborn's physician is notified by telephone by the Department-approved Newborn Screening Area Service Center of an initial positive test result, the newborn's physician shall obtain an adequate recall blood specimen from the newborn and submit it to the designated laboratory within 48 hours. If the recall specimen cannot be obtained within 48 hours, the newborn's physician shall notify the Newborn Screening Area Service Center by telephone. Such telephone notification shall be noted in the newborn's physician's records, specifying the date of notification, the person notified and the information provided.~~

(a) When the newborn's physician is notified by a Newborn Screening Area Service Center of a positive test result, the physician shall, within 48 hours of notification:

(1) Consult with a medical specialist from a California Children's Services (CCS) center or a CCS-paneled medical specialist, and upon the specialist's advice, shall refer the infant to a CCS center or a CCS paneled medical specialist for confirmatory testing and/or evaluation, diagnosis, and treatment; and

(2) Instruct the parents about medically necessary recommendations to care for the infant.

(b) Nothing in this section imposes the duty on the newborn's physician to find the infant if the infant is determined by the Newborn Screening Area Service Center to be lost to follow-up.

Note: Authority cited: Sections 124977, 124980, and 125000, 125001 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, and 125000, 125001, 125025, 131050, 131051 and 131052, Health and Safety Code.

(24) Amend Section 6506.10 to read:

§6506.10. Use of Newborn Screening Contracted Laboratories for Repeat and Recall Confirmatory Specimens Collection and Transmittal.

~~Repeat and recall specimens required by this Group shall be collected on Department approved forms, placed in appropriate containers, and shall be placed in the United States mail or other approved channel of transmittal to the assigned Department-approved laboratory as soon as possible, but not later than 12 hours after they have been obtained.~~

(a) When repeat or confirmatory tests are required, the newborn's physician will ensure that:

(1) Repeat or confirmatory specimens are collected within 48 hours;

(2) Specimens are placed in containers appropriate for the specified test; and

(3) Specimens are transported, on the next business day of the designated carrier, by a carrier contracted with the Department or contracted with a newborn screening laboratory or by the United States Postal Service, to the assigned newborn screening laboratory.

(b) Nothing in this section imposes the duty on the newborn's physician to find the infant if the infant is determined by the Newborn Screening Area Service Center to be lost to follow-up.

Note: Authority cited: Sections 124977, 124980, and 125000, 125001 and 131200, Health and Safety Code.

Reference: Sections 124975, 124980, and 125000, 125001, 125025, 131050, 131051 and 131052, Health and Safety Code.

NBS COPY

CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) State of California - Health and Human Services Agency California Department of Public Health

FOR STATE USE ONLY

ADDRESSOGRAPH HERE



SN 29 000 001 32

Check Digits

BABY'S INFORMATION PLEASE PRINT USING ALL CAPITAL LETTERS

BABY'S LAST NAME, FIRST NAME, STREET ADDRESS, APT, CITY, ZIP

BIRTH ORDER IF MULTIPLE A, B, C, etc.

MOTHER'S INFORMATION/LEGAL GUARDIAN INFORMATION

MOTHER'S LAST NAME, MOTHER'S BIRTH DATE, FIRST NAME, MAIDEN NAME, MOM PHONE, ALTERNATE/EMERGENCY # PHONE

MOTHER'S SSN: LAST 4 DIGITS

THIS BABY IS A WARD OF THE COURT - CONTACT INFORMATION

NAME, PHONE

NEWBORN'S PHYSICIAN INFORMATION

PHYSICIAN LAST NAME, FIRST NAME, STREET ADDRESS, SUITE, CITY, ZIP, PHY PHONE LIC# OR NPI

RACE/ETHNICITY: FILL ALL THAT APPLY

- WHITE, CHINESE, VIETNAMESE, OTHER S.E. ASIAN, MIDDLE EASTERN, HAWAIIAN, SAMOAN, HISPANIC, JAPANESE, CAMBODIAN, FILIPINO, ASIAN-EAST INDIAN, GUAMANIAN, NATIVE AMERICAN, BLACK, KOREAN, LAOTIAN (LAOS), OTHER (Specify)

PRIMARY LANGUAGE: (Fill only ONE circle)

- ENGLISH, SPANISH, OTHER (Specify)

FACILITY/SUBMITTER DRAWING SPECIMEN

FACILITY NAME, HOSPITAL/SUBMITTER CODE, INITIALS OF COLLECTOR

NEWBORN'S BIRTH DATE:

MMDDYY HOUR

DATE SPECIMEN COLLECTED:

MMDDYY HOUR

BIRTH WEIGHT:

GMS

ALL FEEDINGS SINCE BIRTH: (Fill only ONE circle)

- ONLY HUMAN MILK, ONLY FORMULA, HUMAN MILK & FORMULA

TYPE OF SPECIMEN:

- HEELSTICK, OTHER: (Specify)

SEX:

- MALE, FEMALE

GESTATIONAL AGE AT DELIVERY:

WEEKS

NPO AT TIME OF COLLECTION?

- NO, YES

REASON FOR TEST: (Fill only ONE circle)

- INITIAL SPECIMEN, REPEAT OF INADEQUATE OR EARLY (<12 HRS) INITIAL SPECIMEN, OTHER REPEAT: (Specify)

NURSERY TYPE:

- NICU, REG. NURSERY/FCC/RI, HOME BIRTH, OTHER: (Specify)

NEWBORN ON TPN/HYPERAL OR AMINO ACIDS AT TIME OF COLLECTION?

- NO, YES

IF COLLECTED AT <12 HRS OF AGE, REASON:

- TO BE TRANSFUSED, OTHER: (Specify)

RBC TRANSFUSION BEFORE COLLECTION:

- NO, YES - if YES, date/time transfusion completed

MMDDYY HOUR

MEDICAL RECORD/EHR#

HOSPITAL ORDER #

PLEASE SEE PRIVACY NOTIFICATION WITHIN To reorder, request form NBS-TRF from the Genetic Disease Screening Program, Newborn Screening Branch (510) 412-1542 (CDPH - 4409 - (11-12)) NBS-1 (D)

Whatman 903™

LOT 6937912/W113

2015-11

CALIFORNIA NBS Job # 6937912-007.1 02-05-13 First Proof

CUSTOMER APPROVED NOT APPROVED SIGNATURE NAME: DATE: EBF DATE: SIGNATURE

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Perf Does Not Print

Part 1 - 21# White CB - 6" x 11 1/4" (±1/16") - Prints Black and Red 185 Inks & Laser Code 3 of 9 Barcode with Mod 9 DR (1-9) and Mod 7 DR (0-6) Check Digits

Sender's Copy

ADDRESSOGRAPH HERE

CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) State of California - Health and Human Services Agency California Department of Public Health

FOR STATE USE ONLY

Check Digits

SN 29 000 001 32

BABY'S INFORMATION PLEASE PRINT USING ALL CAPITAL LETTERS

Grid for baby's information with birth order indicator (A, B, C, etc.)

MOTHER'S INFORMATION/LEGAL GUARDIAN INFORMATION

MOTHER'S BIRTH DATE

Grid for mother's information including SSN and alternate emergency contact

THIS BABY IS A WARD OF THE COURT - CONTACT INFORMATION

Grid for court ward information

NEWBORN'S PHYSICIAN INFORMATION

Grid for newborn's physician information

RACE/ETHNICITY: FILL ALL THAT APPLY

- White, Chinese, Vietnamese, Other S.E. Asian, Middle Eastern, Hawaiian, Samoan, Hispanic, Japanese, Cambodian, Filipino, Asian-East Indian, Guamanian, Native American, Black, Korean, Laotian (Laos), Other (Specify)

PRIMARY LANGUAGE: (Fill only ONE circle)

- English, Spanish, Other (Specify)

FACILITY/SUBMITTER DRAWING SPECIMEN

Grid for facility and submitter information

NEWBORN'S BIRTH DATE:

Grid for newborn's birth date

DATE SPECIMEN COLLECTED:

Grid for date specimen collected

BIRTH WEIGHT:

Grid for birth weight in grams

ALL FEEDINGS SINCE BIRTH: (Fill only ONE circle)

- Only Human Milk, Only Formula, Human Milk & Formula

TYPE OF SPECIMEN:

- Heelstick, Other (Specify)

SEX:

- Male, Female

REASON FOR TEST: (Fill only ONE circle)

- Initial Specimen, Repeat of inadequate or early (<12 hrs) initial specimen, Other repeat (Specify)

GESTATIONAL AGE AT DELIVERY:

Grid for gestational age at delivery in weeks

NPO AT TIME OF COLLECTION?

- No, Yes

IF COLLECTED AT <12 HRS OF AGE, REASON:

- To be transfused, Other (Specify)

NURSERY TYPE:

- NICU, Reg. Nursery/FCC/IRI, Home Birth, Other (Specify)

NEWBORN ON TPN/HYPERAL OR AMINO ACIDS AT TIME OF COLLECTION?

- No, Yes

RBC TRANSFUSION BEFORE COLLECTION:

- No, Yes - if YES, date/time transfusion completed

MEDICAL RECORD/EHR#

Grid for medical record/EHR number

HOSPITAL ORDER #

Grid for hospital order number

CALIFORNIA NBS Job # 6937912-007.1 02-05-13 First Proof

CUSTOMER APPROVED/NOT APPROVED SIGNATURE NAME DATE EBF DATE SIGNATURE

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Perf Does Not Print

Part 2 - 17# Canary CFB - 6" x 11 1/4" (+/- 1/16") - Prints Black Ink & Black Serial Number with Mod 9 DR (1-9) and Mod 7 DR (0-6) Check Digits

010-10-11, 2011

Parent's Copy

ADDRESSOGRAPH HERE

CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) State of California - Health and Human Services Agency California Department of Public Health

FOR STATE USE ONLY

Check Digits

SN 29 000 001 32

BABY'S INFORMATION PLEASE PRINT USING ALL CAPITAL LETTERS

Grid for baby's information including name, sex, date of birth, and birth order.

MOTHER'S INFORMATION/LEGAL GUARDIAN INFORMATION

MOTHER'S BIRTH DATE

Grid for mother's information including name, birth date, SSN, and alternate/emergency contact.

THIS BABY IS A WARD OF THE COURT - CONTACT INFORMATION

NEWBORN'S PHYSICIAN INFORMATION

Grid for newborn's physician information including name, address, and phone number.

RACE/ETHNICITY: FILL ALL THAT APPLY

- White, Chinese, Vietnamese, Other S.E. Asian, Middle Eastern, Hawaiian, Samoan, Hispanic, Japanese, Cambodian, Filipino, Asian-East Indian, Guamanian, Native American, Black, Korean, Laotian (Laos), Other (Specify).

PRIMARY LANGUAGE: (Fill only ONE circle)

- English, Spanish, Other (Specify).

FACILITY/SUBMITTER DRAWING SPECIMEN

Grid for facility/submitter information including name, address, and hospital code.

NEWBORN'S BIRTH DATE:

Grid for newborn's birth date.

BIRTH WEIGHT:

Grid for birth weight in grams.

SEX:

- Male, Female.

GESTATIONAL AGE AT DELIVERY:

Grid for gestational age at delivery in weeks.

NURSERY TYPE:

- NICU, Reg. Nursery/FCC/RI, Home Birth, Other (Specify).

ALL FEEDINGS SINCE BIRTH: (Fill only ONE circle)

- Only Human Milk, Only Formula, Human Milk & Formula.

NPO AT TIME OF COLLECTION?

- No, Yes.

NEWBORN ON TPN/HYPERAL OR AMINO ACIDS AT TIME OF COLLECTION?

- No, Yes.

DATE SPECIMEN COLLECTED:

Grid for date specimen collected.

TYPE OF SPECIMEN:

- Heelstick, Other (Specify).

REASON FOR TEST: (Fill only ONE circle)

- Initial Specimen, Repeat of inadequate or early (<12 hrs) initial specimen, Other repeat (Specify).

IF COLLECTED AT <12 HRS OF AGE, REASON:

- To be transfused, Other (Specify).

RBC TRANSFUSION BEFORE COLLECTION:

- No, Yes - if YES, date/time transfusion completed.

MEDICAL RECORD/EHR#

Grid for medical record/EHR number.

HOSPITAL ORDER #

Grid for hospital order number.

PLEASE SEE PRIVACY NOTIFICATION WITHIN To reorder, request form NBS-TRF from the Genetic Disease Screening Program, Newborn Screening Branch (510) 412-1542 (CDPH - 4409 - (11-12)) NBS-1 (D)

Whatman 903™

LOT 6937912/W113

2015-11

Part 3 - 20# Pink CF - 6" x 11 1/4" (±1/16") - Prints Black Ink & Black Serial Number with Mod 9 DR (1-9) and Mod 7 DR (0-6) Check Digits

CALIFORNIA NBS Job # 6937912-007.1 02-05-13 First Proof

CUSTOMER APPROVED NOT APPROVED SIGNATURE NAME: DATE: EBF DATE: SIGNATURE

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NOTICE OF INFORMATION AND PRIVACY PRACTICES
California Department of Public Health (CDPH)
Genetic Disease Screening Program
Newborn Screening Branch

Please Review Carefully

This notice describes how personal and medical information about you or your newborn may be used and disclosed and how you can get access to this information.

Department's Legal Duty

Federal and State laws restrict the use, maintenance, and disclosure of personal and medical information obtained by a State agency and requires certain notices to individuals whose information is maintained. In compliance with these laws, you and those providing information are notified of the following:

Department Authority and Purpose for the Newborn Screening Program

The CDPH collects information related to newborn screening as permitted in Health and Safety Code Sections 124980, 125000, 125001, 125025, and 125030. This information is collected electronically and includes such things as your name, address, medical care given to you and your newborn. Testing is required by law (Health and Safety Code Section 125000) and regulations (17 CCR 6500 through 6510) and if the required information is not provided, serious illness or permanent damage for affected newborns could result.

If you have religious objections to this testing, you may say "no" to the testing in writing and sign a form advising you that your hospital, doctor, and clinic staff are not responsible if your baby develops problems because those disorders were not identified and treated early.

Uses and Disclosure of Health Information

The CDPH uses health information about you or your newborn for screening, to provide health care services, to obtain payment for screening, for administrative purposes, and to evaluate the quality of care that you or your newborn receives. Some of this information is retained for as long as 21 years. The information will not be sold.

The law also allows the Department to use or give out information we have about you or your newborn for the following reasons:

- For research studies unless you specifically request in writing that your information or specimen not be used.
- To organizations, which help us in our operations, such as collecting fees.

The Department may change its policies at any time subject to applicable laws and regulations. You may request a copy of our current policies or obtain more information about our privacy practices by contacting the Chief of the Genetic Disease Screening Program at 850 Marina Bay Parkway, F175, Richmond, CA 94804 or consulting our website at

www.cdph.ca.gov/programs/pages/privacyoffice.aspx

Individual Rights and Access to Information

The Newborn Screening Program must have your written permission to use or give out personal or health information about you for any reason that is not described in this notice. You can revoke your authorization at any time, except if the Newborn Screening Program has already acted because of your permission by contacting the Chief of the Genetic Disease Screening Program at 850 Marina Bay Parkway, F175, Richmond, CA 94804.

(continued on next page)

Perf Does Not Print

Part 3 Back - Prints Black Ink - Spot Glue Indicated in Green Between Parts 3 and 4 Does Not Print

CALIFORNIA NBS
Job # 6937912-007.1
02-05-13
First Proof

CUSTOMER
APPROVED <input type="checkbox"/>
NOT APPROVED <input type="checkbox"/>
SIGNATURE
NAME:
DATE:
EBF
DATE:
SIGNATURE

Note: This PDF form layout is produced to a 1:1 scale. All copy and construction features are shown in their proper position per your specifications. Production variances will result in a potential ± 1/16" (1.6mm) tolerance.

Perf Does Not Print

You have the right to look at or receive a copy (you will be charged) of your or your newborn's health information and receive a list of instances where we have disclosed health information about you or your newborn for reasons other than screening, payment or related administrative purposes.

You have a right to have information in your or your child's records changed if information is missing or you believe the information is incorrect. If the information you want to change did not come from Newborn Screening Program, we may not be able to change it, but we will keep a copy of your request with our records.

You have a right to ask that Newborn Screening Program contact you only in writing or at a different address, post office box, or telephone number. Newborn Screening Program will contact you the way you have asked if this is necessary to keep you safe.

You have a right to ask the Newborn Screening Program not to use or share your or your newborn's information in the ways listed in this notice. However, Newborn Screening Program may not retaliate, take away your health benefits, or hurt you in any way if you choose to file a complaint or use any of your privacy rights in this notice.

The information on this form is maintained by the California Department of Public Health, Genetic Disease Screening Program. Please address correspondence to the Chief of the Genetic Disease Screening Program, 850 Marina Bay Parkway, F175, Mail Stop 8200, Richmond, California, 94804 (510-412-1502).

Copies and Other Languages
To get a copy of this notice in other languages, Braille, large print, audiocassette or computer disk, please call or write the Privacy Officer at the address and number listed below.

Important: Newborn Screening Program does not have complete copies of your health records. If you want to look at, get a copy of, or change your health records, please contact your doctor, clinic, or health plan.

Notices
This privacy notice is from the Newborn Screening Program. You may get other privacy notices from your doctor and other health care programs.

How Do You Use Your Rights
If you believe that we have not protected your or your newborn's privacy or have violated any of your or your newborn's rights you may file a complaint by calling or writing: Privacy Officer, California Department of Public Health, P.O. Box 997377, Sacramento, CA 95899-7377, 916-440-7671 or 877-421-9634 TTY/TDD. Or visit our website at:

www.cdph.ca.gov/program/pages/privacyoffice.aspx
Or

You may also contact the Regional Manager, Department of Health and Human Services, Office for Civil Rights at 90 7th Street, Suite 4-100, San Francisco, CA, 94103, telephone 800-368-1019 or U.S. Office for Civil Rights at 866-OCR-PRIV (866-627-7748) or 866-788-4989 TTY.

(continued on back)

Part 4 - 20# Blue Bond - 6" x 11 1/4" (±1/16") - Prints Black Ink

CALIFORNIA NBS
Job # 6937912-007.1
02-05-13
First Proof

CUSTOMER	
APPROVED <input type="checkbox"/>	
NOT APPROVED <input type="checkbox"/>	
SIGNATURE	
NAME:	
DATE:	
EBF	
DATE:	
SIGNATURE	

Note: This PDF form layout is produced to a 1:1 scale. All copy and construction features are shown in their proper position per your specifications. Production variances will result in a potential ± 1/16" (1.6mm) tolerance.

**Questions & Answers About the Storage of the
Newborn Screening Bloodspots**

Why is my baby's blood spot collection card stored by the Genetic Disease Screening Program (GDSP)?

The main reason GDSP stores the used blood spots is to develop new tests to add to the newborn screening testing panel and to provide quality control for testing on an on-going basis. When the Newborn Screening Program began in the early 1980s, we tested for 3 disorders. The stored specimens were used anonymously to develop the new tests, so that we now screen for about 80 disorders. Newborn Screening blood spot cards are **not** "DNA cards". Your child's DNA is not analyzed for our initial screening tests and his/her "DNA profile" is not stored. There is no personal information on the dried blood spot card, only a unique non-identifying number.

What if I do not want my baby's blood spot collection card used by the Genetic Disease Screening Program? What are my options?

If you decide not to allow the GDSP to use your child's unidentified dried blood spot, you may request that the specimen not be used for research and/or be destroyed by our laboratory. Please realize that if you make this choice, the spot will no longer be available should you or your doctor need it for any further health concerns with your child. Please submit this request in writing to: Chief of the Genetic Disease Screening Program, 850 Marina Bay Parkway, F175, Richmond, CA 94804.

For more information please visit our website at www.cdph.ca.gov/programs/nbs or if you have additional questions you can email us at NBSNews@cdph.ca.gov or call (510) 412-1502.

Attention Parents

- 1) Review the information on the pink copy of your baby's newborn screening test request form. **Notify the hospital if your name, address and/or phone or the name, address and phone number of your baby's doctor is not correct.**
- 2) **Take the pink copy of this form when you go to your baby's first check up.** This will help the doctor locate your baby's newborn screening results.

Thank You

For copies of the Notice of Information and Privacy Practices in Spanish and other languages please visit the Newborn Screening Program website at: www.cdph.ca.gov/programs/nbs

Para una copia de la NOTIFICACIÓN DE PRÁCTICAS DE INFORMACIÓN Y PRIVACIDAD por favor visite nuestro sitio web del Programa del Análisis de Recién Nacidos en www.cdph.ca.gov/programs/nbs

CALIFORNIA NBS
Job # 6937912-007.1
02-05-13
First Proof

Part 4 Back - Prints Black Ink

CUSTOMER
APPROVED <input type="checkbox"/>
NOT APPROVED <input type="checkbox"/>
SIGNATURE
NAME:
DATE:
EBF
DATE:
SIGNATURE

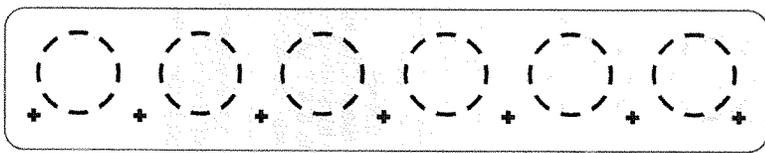
Note: This PDF form layout is produced to a 1:1 scale. All copy and construction features are shown in their proper position per your specifications. Production variances will result in a potential $\pm 1/16"$ (1.6mm) tolerance.

Perf Does Not Print

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29 000 001 32

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CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
NEWBORN SCREENING

LOT# 6937912/W113

2015-11

Revision Date: 11/12
Whatman 903

CDPH USE ONLY

SN

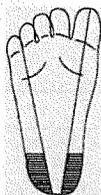
SN

DO NOT DETACH

INSTRUCTIONS FOR COLLECTING ADEQUATE BLOOD SPECIMENS

Puncture site is indicated by shaded areas on heel. Do not collect from side or back of foot.

*NO COURIER PLASTIC BAGS



COLLECT SAMPLE FROM
SHADED AREA

- | | |
|--------------|-------------------------------------|
| RIGHT | ACCEPTABLE |
| | Circle filled and evenly saturated |
| WRONG | UNACCEPTABLE |
| | Layering |
| | Insufficient, multiple applications |
| | Serum rings present |

NOTE:

*Do not use capillary tubes for collection of blood spot specimen.
Do not collect blood from antecubital space or dorsal hand vein.
Do not handle blood collection area of specimen collection card prior to, during, or following sampling.*

1. Position infant's foot to increase blood flow. Warming of the heel is optional.
2. Clean skin with alcohol and either air-dry or wipe dry with sterile gauze.
3. Puncture heel with sterile disposable lancet, using a firm, quick stab. If using an automated lancet device, place it firmly against the heel prior to device activation.
4. Allow a large drop of blood to accumulate and wipe away with sterile gauze.
5. Allow a second large drop of blood to accumulate. Apply gentle pressure to heel and ease intermittently so blood flows freely.
6. Apply the blood drop to one side of the specimen collection paper until the circle is filled COMPLETELY when viewed from both sides. Do not press collection paper against puncture site. Allow blood to fill circle by natural flow. **Do not apply blood to both sides of the paper.**
7. Fill the first circle completely before moving on to the next circle. Repeat procedure for each circle.
8. Allow blood spots to air-dry at room temperature for at least three hours. Keep away from direct light (sun or lamp) and heat.
9. Do not close specimen collection form while blood spots are still wet. Do not allow wet specimens to come in contact with each other.
10. **DO NOT PUT SPECIMEN IN PLASTIC BAG.**

ADDITIONAL INSTRUCTIONS ARE CONTAINED IN "BLOOD COLLECTION ON FILTER PAPER FOR NEWBORN SCREENING PROGRAMS", 5th EDITION (CLSI DOCUMENT LA4-A5)

PRINT ONLY, USE ALL CAPITAL LETTERS, USE BLACK OR BLUE INK ONLY.

Perf Does Not Print

Part 5 - 125# White Tag - 6" X 11 1/4" (±1/16") - Prints Black and Red 185 Inks & 2 Black Serial Numbers with Mod 9 DR (1-9) and Mod 7 DR (0-6) Check Digits

Part 6 - Whatman 903 Lot W113
6" x 2 1/4" (±1/16)

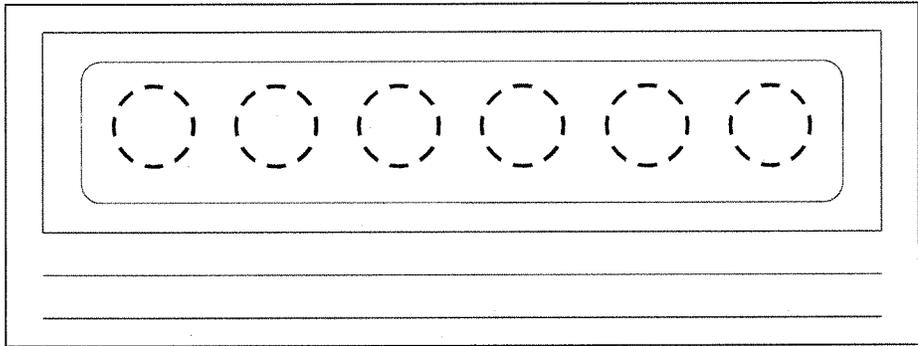
Prints Bio Black 586 Ink
Green Lines Indicate Gluing
Between Parts 5 & 6 with EBF
Glue #1001 and Do Not Print

CALIFORNIA NBS
Job # 6937912-007.1
02-05-13
First Proof

CUSTOMER	
APPROVED <input type="checkbox"/>	
NOT APPROVED <input type="checkbox"/>	
SIGNATURE	
NAME:	
DATE:	
EBF	
DATE:	
SIGNATURE	

Note: This PDF form layout is produced to a 1:1 scale. All copy and construction features are shown in their proper position per your specifications. Production variances will result in a potential ± 1/16" (1.6mm) tolerance.

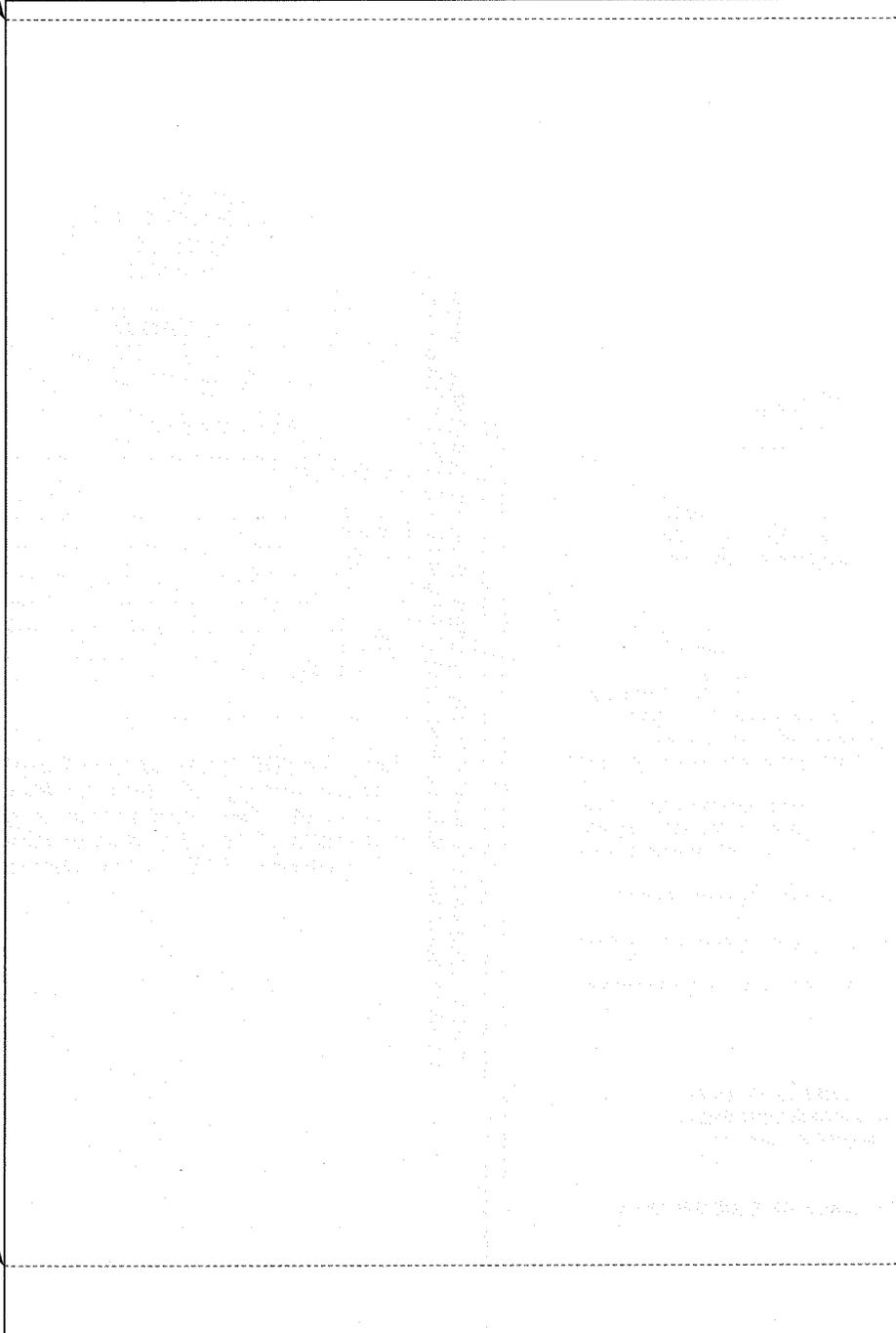
Perf Does Not Print



Part 6 Back
 Prints Bio Black 586 Ink
 Green Lines Indicate Gluing
 Between Parts 6 & 7 with EBF
 Glue #1001 and Do Not Print

Part 7 Back - 125# White Tag
 6" x 2 1/4" (±1/16")
 No Printing on Face or Back

Perf Does Not Print



Part 5 Back - No Printing

CALIFORNIA NBS
 Job # 6937912-007.1
 02-05-13
 First Proof

CUSTOMER	
APPROVED <input type="checkbox"/>	
NOT APPROVED <input type="checkbox"/>	
SIGNATURE	
NAME:	
DATE:	
EBF	
DATE:	
SIGNATURE	

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DO NOT WRITE IN THIS AREA
DO NOT HANDLE FILTER PAPER

THIS AREA MAY BE USED TO ADHERE A STICKER
 CONTAINING THE INFANT'S FACILITY INFORMATION

Revision Date: 11/12

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
NEWBORN SCREENING

INSTRUCTIONS FOR COMPLETION OF FORM

PLEASE PRINT AND USE BLUE OR BLACK BALL POINT PEN

1. **NEWBORN'S NAME:** Name as entered on birth certificate, last name first. If multiple birth, indicate A, B, C, etc.
2. **MOTHER'S INFORMATION:** Name as entered on birth certificate, last name first. Please also include mother's maiden name and last 4 digits of social security number. If mother does not have a social security number, enter 9999.
3. **THIS BABY IS A WARD OF THE COURT – CONTACT INFORMATION:** Answer YES if newborn is a ward of the court and provide contact information for person responsible for baby's care at time of collection.
4. **NEWBORN'S PHYSICIAN INFORMATION:** Obtain from mother the name of the physician responsible for continuing care of the newborn after discharge.
5. **NEWBORN'S PHYSICIAN'S LICENSE NUMBER OR NPI NUMBER:** Enter the physician's California license number or national provider identification number.
6. **RACE/ETHNICITY:** As entered for both parents on birth certificate. These data are required by Government Code 8310.5. Check ALL that apply.
7. **PRIMARY LANGUAGE:** Please indicate primary language spoken; this helps determine if an interpreter is needed.
8. **FACILITY DRAWING SPECIMEN:** Name and code number must be entered to ensure correct reporting of results.
9. **NEWBORN'S BIRTH DATE (AND TIME):** As entered on the birth certificate. All time is to be entered by the 24 hour clock, e.g., 8:30 a.m. is 0830; 9:01 p.m. is 2101.
10. **BIRTH WEIGHT:** In grams, as entered on birth certificate.
11. **GESTATIONAL AGE:** Enter gestational age at time of birth in weeks.
12. **NURSERY TYPE:** Check NICU, Regular Nursery, which includes Family Centered Care (FCC) or Rooming In (RI), Home Birth, or other.
13. **ALL FEEDING SINCE BIRTH:** Include all feeding from birth to collection. Human milk includes breastfeeding, mother's own expressed milk and banked human milk. If newborn has had neither human milk, nor formula leave this section blank.
14. **NPO AT TIME OF COLLECTION?:** Answer YES if newborn is NPO (i.e., is taking nothing by mouth) at time of specimen collection.
15. **NEWBORN ON TPN/HYPERAL or AMINO ACIDS AT TIME OF COLLECTION?:** Answer YES if newborn is being given TPN (total parenteral nutrition, aka hyperalimentation) or amino acids at time of specimen collection.
16. **DATE SPECIMEN COLLECTED:** Date and hour of specimen collection. This refers to the time the specimen is collected from the newborn.
17. **TYPE OF SPECIMEN:** Please check only one box. If "OTHER" type of specimen is checked, please specify the type of specimen.
18. **IF COLLECTED AT <12 HRS OF AGE, REASON?:** If this specimen is being collected prior to the newborn being 12 hours of age, indicate why.
19. **RBC TRANSFUSION BEFORE COLLECTION:** Please indicate whether the newborn was transfused with RED BLOOD CELLS and the date and time the last transfusion ended prior to specimen collection. DO list intrauterine transfusions. DO NOT list fresh frozen plasma, albumin, platelets, or cryoprecipitate as transfusion. DO NOT list transfusions that occurred after the specimen was collected.
20. **MEDICAL RECORD NUMBER:** Enter number used in medical records department of facility collection specimen.
21. **INITIALS OF COLLECTOR:** Enter initials of person drawing the specimen.
22. **DISTRIBUTION:** Original MUST remain attached to specimen. Facility drawing the specimen should retain and file the yellow copy in the newborn's chart. The pink copy should be given to the newborn's parent(s) with instructions to give to the newborn's physician.

PLEASE SEE PRIVACY NOTIFICATION WITHIN

Part 8 Back - 20# White Bond - 6" x 11 1/4" - Prints Black and Red 185 Inks

CALIFORNIA NBS
 Job # 6937912-007.1
 02-05-13
 First Proof

CUSTOMER	
APPROVED <input type="checkbox"/>	
NOT APPROVED <input type="checkbox"/>	
SIGNATURE	
NAME:	
DATE:	
EBF	
DATE:	
SIGNATURE	

Note: This PDF form layout is produced to a 1:1 scale. All copy and construction features are shown in their proper position per your specifications. Production variances will result in a potential ± 1/16" (1.6mm) tolerance.

S.J.E., 04-04-2016

NOTICE OF INFORMATION AND PRIVACY PRACTICES
California Department of Public Health (CDPH)
Genetic Disease Screening Program, Newborn Screening Branch
Please Review Carefully

This notice describes how personal and medical information about you or your newborn may be used and disclosed and how you can get access to this information.

Department's Legal Duty

Federal and State laws restrict the use, maintenance, and disclosure of personal and medical information obtained by a State agency and requires certain notices to individuals whose information is maintained. In compliance with these laws, you and those providing information are notified of the following:

Department Authority and Purpose for the Newborn Screening Program

The CDPH collects information related to newborn screening as permitted in Health and Safety Code Sections 124980, 125000, 125001, 125025, and 125030. This information is collected electronically and includes such things as your name, address, medical care given to you and your newborn. Testing is required by law (Health and Safety Code Section 125000) and regulations (17 CCR 6500 through 6510) and if the required information is not provided, serious illness or permanent damage for affected newborns could result. If you have religious objections to this testing, you may say "no" to the testing in writing and sign a form advising you that your hospital, doctor, and clinic staff are not responsible if your baby develops problems because those disorders were not identified and treated early.

Uses and Disclosure of Health Information

The CDPH uses health information about you or your newborn for screening, to provide health care services, to obtain payment for screening, for administrative purposes, and to evaluate the quality of care that you or your newborn receives. Some of this information is retained for as long as 21 years. The information will not be sold.

The law also allows the Department to use or give out information we have about you or your newborn for the following reasons:

- For research studies unless you specifically request in writing that your information or specimen not be used.
- To organizations, which help us in our operations, such as collecting fees.

The Department may change its policies at any time subject to applicable laws and regulations. You may request a copy of our current policies or obtain more information about our privacy practices by contacting the Chief of the Genetic Disease Screening Program at 850 Marina Bay Parkway, F175, Richmond, CA 94804 or consulting our website at www.cdph.ca.gov/programs/pages/privacyoffice.aspx.

Individual Rights and Access to Information

The Newborn Screening Program must have your written permission to use or give out personal or health information about you for any reason that is not described in this notice. You can revoke your authorization at any time, except if the Newborn Screening Program has already acted because of your permission by contacting the Chief of the Genetic Disease Screening Program at 850 Marina Bay Parkway, F175, Richmond, CA 94804.

You have the right to look at or receive a copy (you will be charged) of your or your newborn's health information and receive a list of instances where we have disclosed health information about you or your newborn for reasons other than screening, payment or related administrative purposes.

You have a right to have information in your or your child's records changed if information is missing or you believe the information is incorrect. If the information you want to change did not come from Newborn Screening Program, we may not be able to change it, but we will keep a copy of your request with our records.

You have a right to ask that Newborn Screening Program contact you only in writing or at a different address, post office box, or telephone number. Newborn Screening Program will contact you the way you have asked if this is necessary to keep you safe.

You have a right to ask the Newborn Screening Program not to use or share your or your newborn's information in the ways listed in this notice. However, we may not be able to comply with your request.

Newborn Screening Program may not retaliate, take away your health benefits, or hurt you in any way if you choose to file a complaint or use any of your privacy rights in this notice.

The information on this form is maintained by the California Department of Public Health, Genetic Disease Screening Program. Please address correspondence to the Chief of the Genetic Disease Screening Program, 850 Marina Bay Parkway, F175, Mail Stop 8200, Richmond, California, 94804 (510-412-1502).

Copies and Other Languages

To get a copy of this notice in other languages, Braille, large print, audiocassette or computer disk, please call or write the Privacy Officer at the address and number listed below.

Important: Newborn Screening Program does not have complete copies of your health records. If you want to look at, get a copy of, or change your health records, please contact your doctor, clinic, or health plan.

Notices: This privacy notice is from the Newborn Screening Program. You may get other privacy notices from your doctor and other health care programs.

How Do You Use Your Rights

If you believe that we have not protected your or your newborn's privacy or have violated any of your or your newborn's rights you may file a complaint by calling or writing: Privacy Officer, California Department of Public Health, P.O. Box 997377, Sacramento, CA 95899-7377, 916-440-7671 or 877-421-9634-TTY/TDD. Or visit our website at: www.cdph.ca.gov/program/pages/privacyoffice.aspx

Or

You may also contact the Regional Manager, Department of Health and Human Services, Office for Civil Rights at 90 7th Street, Suite 4-100, San Francisco, CA, 94103, telephone 800-368-1019 or U.S. Office for Civil Rights at 866-OCR-PRIV (866-627-7748) or 866-788-4989 TTY.

NOTIFICACIÓN DE PRÁCTICAS DE INFORMACIÓN Y PRIVACIDAD Departamento de Salud Pública de California
División de Enfermedades Genéticas
Programa de Análisis de Recién Nacidos

Esta notificación describe la manera en que se puede usar y revelar la información personal y médica sobre usted o su recién nacido y cómo usted puede obtener acceso a esta información. Léala con atención.

Obligación legal del Departamento. Leyes federales y estatales restringen el uso, el mantenimiento y la revelación de información personal y médica obtenida por una entidad del estado y requiere ciertas notificaciones a las personas cuya información mantiene. En cumplimiento de estas leyes, se notifica lo siguiente a usted y a los que proporcionan la información:

Autoridad del Departamento y Propósito del Programa de Análisis de Recién Nacidos. El Departamento de Salud Pública obtiene información relativa a los análisis de recién nacidos según lo permiten las Secciones 124980, 125000, 125001, 125025 y 125030 del Código de Salud y Seguridad. Esta información se obtiene electrónicamente e incluye datos como su nombre completo, dirección y la atención médica que obtuvieron usted y su recién nacido. El análisis es requerido por ley (Sección 125000 del Código de Salud y Seguridad) y reglamentaciones (17 CCR 6500 a 6510) y si la información requerida no se proporciona, podría resultar en que los recién nacidos afectados desarrollen incapacidades permanentes o mueran. Si tiene objeciones religiosas al análisis, puede decir "no" al análisis por escrito y firmar un formulario que le indica que el personal tanto de su hospital, como de su médico y clínica no son responsables si su bebé tiene problemas porque esas enfermedades no se identificaron y trataron temprano.

Usos y revelación de información sobre la salud. El Departamento de Salud Pública usa la información sobre su salud o la de su recién nacido para hacer el análisis, proporcionar servicios de atención de la salud, obtener pagos por el análisis, para fines administrativos y para evaluar la calidad de la atención que recibe usted o su recién nacido. Parte de esta información se retiene por hasta 21 años. La información no se venderá.

La ley también permite que el Departamento use o proporcione la información que tengamos sobre usted o su recién nacido por los siguientes motivos:

- Para estudios de investigación, a menos que usted solicite específicamente por escrito que la información sobre usted no se use.
- A organizaciones que nos ayuden en nuestras operaciones, por ejemplo para cobranzas.

Aparte de lo que antecede, la información es confidencial y no se entregará sin su autorización por escrito. Si usted firma una autorización para revelar información, puede revocar esa autorización más adelante para parar las revelaciones y los usos futuros, poniéndose en contacto con la persona indicada a continuación.

El Departamento puede cambiar sus normas en cualquier momento, sujeto a las leyes y reglamentaciones aplicables. Si lo desea, puede solicitar una copia de nuestras normas vigentes u obtener más información sobre nuestras prácticas de privacidad, poniéndose en contacto con la persona indicada a continuación o consultando nuestro sitio web, www.dhs.ca.gov/nbs. También puede solicitar una copia impresa de esta notificación.

Derechos individuales y acceso a la información. Usted tiene derecho a ver o a recibir una copia (se le cobrará) de la información sobre su salud o la de su recién nacido y a recibir una lista de las instancias en que hayamos revelado información sobre su salud o la de su recién nacido por motivos aparte de hacer análisis, obtener pagos o para fines administrativos afines. Si le parece que la información en sus datos o en los de su recién nacido es incorrecta o está incompleta, tiene derecho a solicitar correcciones. Tiene derecho a hacernos pedidos razonables de que nos pongamos en contacto con usted únicamente por escrito o en una dirección, casilla postal o número de teléfono diferentes.

Puede solicitar por escrito que restrinjamos la revelación de la información sobre usted o su recién nacido para fines de tratamiento de salud, pagos y fines administrativos. No estamos obligados a acceder a su pedido.

Quejas. Si le parece que no hemos protegido su privacidad o la de su recién nacido o que hemos violado alguno de sus derechos o los de su recién nacido, puede presentar una queja llamando o escribiendo a: **Privacy Officer**, CA Department of Public Health, P.O. Box 997413, Sacramento, CA 95899-7413, (916) 445-4646 ú (877) 735-2929 TTY/TDD. O visite nuestro sitio web: www.dhs.ca.gov/privacyoffice/NPP/default.htm

También puede ponerse en contacto con el secretario del Departamento de Salud y de Servicios Humanos, Oficina de Derechos Civiles, en la siguiente dirección: Secretary of the Department of Health and Human Services, Office for Civil Rights, 50 United Nations Plaza, Room 322, San Francisco, CA, 94102; teléfono 800-368-1019. O puede llamar a la Oficina de Derechos Civiles de Estados Unidos, al 866-OCR-PRIV (866-627-7748) ú 866-788-4989 TTY.

El Departamento no le puede quitar sus beneficios de atención de la salud ni hacer nada que le haga daño de ninguna manera si usted opta por presentar una queja o usar alguno de los derechos de privacidad en esta notificación.

Contacto con el Departamento - La información en este formulario es mantenida por el Departamento de Salud Pública, División de Enfermedades Genéticas. Escribe al Jefe de la División de Enfermedades Genéticas, 850 Marina Bay Parkway, F175, Mail Stop 8200, Richmond, California, 94804 (510-412-1502).

NOTIFICATION OF REGISTRATION OF BIRTH WHICH OCCURRED OUT OF A LICENSED HEALTH FACILITY (NBS-OH)

THIS FORM IS USED FOR CLINICAL FOLLOW-UP
PLEASE SEND THIS FORM IMMEDIATELY AFTER REGISTERING THE BIRTH (DO NOT BATCH MAIL).

PLEASE PRINT USING ALL CAPITAL LETTERS

TO: LOCAL HEALTH OFFICER AND CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
DATE OF REGISTRATION: MONTH DAY YEAR

FROM: BIRTH REGISTRAR OF COUNTY OR CITY

WE HAVE REGISTERED THE FOLLOWING BIRTH WHICH OCCURRED OUT OF A LICENSE HEALTH FACILITY

NEWBORN'S NAME (as shown on the birth certificate): LAST FIRST SEX
MALE FEMALE

MOTHER'S COMPLETE NAME: LAST FIRST MAIDEN

CURRENT ADDRESS: NUMBER STREET APARTMENT

CITY STATE ZIP CODE

BIRTH WEIGHT (grams) BIRTH DATE: MONTH DAY YEAR BIRTH HOUR (24 hour clock)

PARENT'S TELEPHONE NUMBER (indicate area code)

HAS A NEWBORN SCREENING TEST BEEN DONE? YES NO

IF YES, WHERE WAS THE TEST DONE?

DATE OF TEST: MONTH DAY YEAR

NEWBORN'S PRIMARY CARE PROVIDER NAME: LAST FIRST

ADDRESS: NUMBER STREET SUITE

CITY STATE ZIP CODE

TELEPHONE NUMBER:

FILL BOX(es) IF APPROPRIATE: INFANT EXPIRED PARENTS REFUSED NEWBORN SCREENING TEST REFUSAL FORM SIGNED (ATTACH NBS-TR)

Please complete this form and mail **immediately** to:
WHITE- CA Department of Public Health, Newborn Screening Program, 850 Marina Bay Pkwy, F175, Richmond, CA 94804
YELLOW-Local Health Officer
PINK-Retain for your files

PLEASE SEE PRIVACY NOTIFICATION ON REVERSE

To reorder, request form NBS-OH from the Genetic Disease Screening Program, Newborn Screening Program (510) 412-1542.
CDPH 4460 (01/09)

per agency
request

S.J.E., 04-04-2016

NOTICE OF INFORMATION AND PRIVACY PRACTICES
California Department of Public Health (CDPH) Genetic Disease Screening Program
Newborn Screening Branch

Please Review Carefully

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If you have religious objections to this testing, you may say "no" to the testing in writing and sign a form advising you that your hospital, doctor, and clinic staff are not responsible if your baby develops problems because those disorders were not identified and treated early.

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The law also allows the Department to use or give out information we have about you or your newborn for the following reasons:

- For research studies unless you specifically request in writing that your information or specimen not be used.
- To organizations, which help us in our operations, such as collecting fees.

The Department may change its policies at any time subject to applicable laws and regulations. You may request a copy of our current policies or obtain more information about our privacy practices by contacting the Chief of the Genetic Disease Screening Program at 850 Marina Bay Parkway, F175, Richmond, CA 94804 or consulting our website at www.cdph.ca.gov/programs/pages/privacyoffice.aspx.

Individual Rights and Access to Information

The Newborn Screening Program must have your written permission to use or give out personal or health information about you for any reason that is not described in this notice. You can revoke your authorization at any time, except if the Newborn Screening Program has already acted because of your permission by contacting the Chief of the Genetic Disease Screening Program at 850 Marina Bay Parkway, F175, Richmond, CA 94804.

You have the right to look at or receive a copy (you will be charged) of your or your newborn's health information and receive a list of instances where we have disclosed health information about you or your newborn for reasons other than screening, payment or related administrative purposes.

You have a right to have information in your or your child's records changed if information is missing or you believe the information is incorrect. If the information you want to change did not come from Newborn Screening Program, we may not be able to change it, but we will keep a copy of your request with our records.

You have a right to ask that Newborn Screening Program contact you only in writing or at a different address, post office box, or telephone number. Newborn Screening Program will contact you the way you have asked if this is necessary to keep you safe.

You have a right to ask the Newborn Screening Program not to use or share your or your newborn's information in the ways listed in this notice. However, we may not be able to comply with your request.

Newborn Screening Program may not retaliate, take away your health benefits, or hurt you in any way if you choose to file a complaint or use any of your privacy rights in this notice.

The information on this form is maintained by the California Department of Public Health, Genetic Disease Screening Program. Please address correspondence to the Chief of the Genetic Disease Screening Program, 850 Marina Bay Parkway, F175, Mail Stop 8200, Richmond, California, 94804 (510-412-1502).

Copies and Other Languages

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Notices

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How Do You Use Your Rights

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Or

You may also contact the Regional Manager, Department of Health and Human Services, Office for Civil Rights at 90 7th Street, Suite 4-100, San Francisco, CA, 94103, telephone 800-368-1019 or U.S. Office for Civil Rights at 866-CCR-PRIV (866-627-7748) or 866-788-4989 TTY.

HOSPITAL REPORT OF NEWBORN SCREENING SPECIMEN NOT OBTAINED (NBS-NO)

PLEASE PRINT USING ALL CAPITAL LETTERS

FOR OFFICE USE ONLY

DATE: MONTH DAY YEAR

FROM: (Give hospital name) _____

HOSPITAL CODE: R

TO: PHYSICIAN'S NAME: LAST FIRST

PHYSICIAN'S ADDRESS: NUMBER STREET SUITE

CITY STATE ZIP CODE

TELEPHONE NUMBER (indicate area code) EXTENSION

NEWBORN'S NAME: LAST FIRST

SEX: MALE FEMALE MULTIPLE BIRTHS: A B C D

ADDRESS: NUMBER STREET APARTMENT

CITY STATE ZIP CODE

MEDICAL RECORD NUMBER

BIRTH WEIGHT (grams) BIRTH DATE: MONTH DAY YEAR BIRTH HOUR (24 HOUR CLOCK)

MOTHER'S NAME: LAST FIRST MOTHER'S BIRTH DATE: MONTH DAY YEAR

TELEPHONE NUMBER (indicate area code) OTHER TELEPHONE NUMBER FOR FAMILY

The above newborn was discharged/transferred on MONTH DAY YEAR without a newborn screening specimen taken because (fill one box):

- Newborn Expired
- Parents refused to have specimen collected. Fill out NBS-TR (Screening Test Refusal). Put original in chart and send a copy of the signed test refusal with this form to the California Department of Public Health, Newborn Screening Branch
- Transferred to the following receiving hospital on or before six days of age

HOSPITAL CITY

Other Reason (specify):

INSTRUCTIONS: This form must be completed by the perinatal licensed health facility when it has been determined that an infant was discharged without obtaining a newborn screening specimen. Send copies to:

- WHITE:** California Department of Public Health
Newborn Screening Branch
850 Marina Bay Parkway, F175
Mail Stop 8200
Richmond, CA 94804
- YELLOW:** M.D. of record.
- PINK:** Receiving hospital (if transferred)
- GOLDENROD:** Retain for your files

To the Physician: California Code of Regulations Section 6506.2(b), states:

"When the newborn's physician is notified by telephone by the perinatal licensed health facility that a newborn was discharged from the perinatal licensed health facility before a specimen was taken, the newborn's physician shall make every reasonable effort to have a specimen obtained within five days of notification. If the newborn's physician cannot obtain the specimen, the Newborn Screening Area Service Center shall be notified by the newborn's physician by telephone. Such telephone notification shall be noted in the newborn's physician's records, specifying the date of notification, the person notified and the information provided."

If you have questions, please call your NBS follow-up coordinator (listed on the bottom of every NBS result mailer.)

PLEASE SEE PRIVACY NOTIFICATION ON REVERSE

To reorder, request form NBS-NO from the Genetic Disease Screening Program, Newborn Screening Branch at (510) 412-1542.

per agency
request

J.J.E., 04-04-2016

OFFICE OF INFORMATION AND PRIVACY PRACTICES
California Department of Public Health (CDPH)
Genetic Disease Screening Program, Newborn Screening Branch
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Federal and State laws restrict the use, maintenance, and disclosure of personal and medical information obtained by a State agency and requires certain notices to individuals whose information is maintained. In compliance with these laws, you and those providing information are notified of the following:

Department Authority and Purpose for the Newborn Screening Program

The CDPH collects information related to newborn screening as permitted in Health and Safety Code Sections 124980, 125000, 125001, 125025, and 125030. This information is collected electronically and includes such things as your name, address, medical care given to you and your newborn. Testing is required by law (Health and Safety Code Section 125000) and regulations (17 CCR 6500 through 6510) and if the required information is not provided, serious illness or permanent damage for affected newborns could result. If you have religious objections to this testing, you may say "no" to the testing in writing and sign a form advising you that your hospital, doctor, and clinic staff are not responsible if your baby develops problems because those disorders were not identified and treated early.

Uses and Disclosure of Health Information

The CDPH uses health information about you or your newborn for screening, to provide health care services, to obtain payment for screening, for administrative purposes, and to evaluate the quality of care that you or your newborn receives. Some of this information is retained for as long as 21 years. The information will not be sold.

The law also allows the Department to use or give out information we have about you or your newborn for the following reasons:

- For research studies unless you specifically request in writing that your information or specimen not be used.
- To organizations, which help us in our operations, such as collecting fees.

The Department may change its policies at any time subject to applicable laws and regulations. You may request a copy of our current policies or obtain more information about our privacy practices by contacting the Chief of the Genetic Disease Screening Program at 850 Marina Bay Parkway, F175, Richmond, CA 94804 or consulting our website at www.cdph.ca.gov/programs/pages/privacyoffice.aspx.

Individual Rights and Access to Information

The Newborn Screening Program must have your written permission to use or give out personal or health information about you for any reason that is not described in this notice. You can revoke your authorization at any time, except if the Newborn Screening Program has already acted because of your permission by contacting the Chief of the Genetic Disease Screening Program at 850 Marina Bay Parkway, F175, Richmond, CA 94804.

You have the right to look at or receive a copy (you will be charged) of your or your newborn's health information and receive a list of instances where we have disclosed health information about you or your newborn for reasons other than screening, payment or related administrative purposes.

You have a right to have information in your or your child's records changed if information is missing or you believe the information is incorrect. If the information you want to change did not come from Newborn Screening Program, we may not be able to change it, but we will keep a copy of your request with our records.

You have a right to ask that Newborn Screening Program contact you only in writing or at a different address, post office box, or telephone number. Newborn Screening Program will contact you the way you have asked if this is necessary to keep you safe.

You have a right to ask the Newborn Screening Program not to use or share your or your newborn's information in the ways listed in this notice. However, we may not be able to comply with your request.

Newborn Screening Program may not retaliate, take away your health benefits, or hurt you in any way if you choose to file a complaint or use any of your privacy rights in this notice.

The information on this form is maintained by the California Department of Public Health, Genetic Disease Screening Program. Please address correspondence to the Chief of the Genetic Disease Screening Program, 850 Marina Bay Parkway, F175, Mail Stop 8200, Richmond, California, 94804 (510-412-1302).

Copies and Other Languages

To get a copy of this notice in other languages, Braille, large print, audiocassette or computer disk, please call or write the Privacy Officer at the address and number listed below.

Important: Newborn Screening Program does not have complete copies of your health records. If you want to look at, get a copy of, or change your health records, please contact your doctor, clinic, or health plan.

Notices: This privacy notice is from the Newborn Screening Program. You may get other privacy notices from your doctor and other health care programs.

How Do You Use Your Rights

If you believe that we have not protected your or your newborn's privacy or have violated any of your or your newborn's rights you may file a complaint by calling or writing: Privacy Officer, California Department of Public Health, P.O. Box 997377, Sacramento, CA 95899-7377, 916-440-7671 or 877-421-9634 TTY/TDD. Or visit our website at www.cdph.ca.gov/program/pages/privacyoffice.aspx.

Or

You may also contact the Regional Manager, Department of Health and Human Services, Office for Civil Rights at 90 7th Street, Suite 4-100, San Francisco, CA, 94103, telephone 800-368-1019 or U.S. Office for Civil Rights at 866-OCR-PRIV (866-627-7748) or 866-788-4989 TTY.

9702-10-10-2015
per agency
request