

**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.

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.

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.

(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 a facility which is contracted with the Department to provide regional newborn screening services.

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.

(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 - (6/16)) NBS-I (E).

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.

(11) Adopt §6500.51 to read:

**§6500.51. Newborn Screening Test.**

“Newborn Screening Test” means a biochemical or other assay of blood spots collected from an infant for the purpose of determining whether the newborn might be 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.

(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) 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.

(15) 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**

(16) Amend §6501 to read:

**§6501. Scope of Newborn Testing.**

Except for provisions in §6501.2 and §6502, ~~E~~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, 125000, 125001 and 131200, Health and Safety Code. Reference: Sections 124975, 124980, 125000, 125001, 125025, 131050, 131051 and 131052, Health and Safety Code.

(17) 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 - (6/16)) NBS-I (F). 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 (06/16) - English version or CDPH 4459(SP) (06/16) - Spanish version. These forms are hereby incorporated by reference.

(c) 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.

(18) Amend §6505 to read:

**§6505. Collection of Newborn Screening Specimens.**

(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 - (6/16)) NBS-I (E) pursuant to §6501.5(a) and §6504.4(b). This specimen collection shall occur after 12 hours but no later than 48 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 - (6/16)) NBS-I (E) 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 - (6/16)) NBS-I (E) pursuant to §6501.5(a) and §6504.4(b).

(3) ensure that specimens are given, on the same-day or next business day of the designated carrier, to a carrier contracted with the Department or contracted with a newborn screening laboratory or to another same-day or overnight delivery service for transport to the assigned newborn screening laboratory.

(4) 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 (06/16) 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 - (6/16)) NBS-I (E) pursuant to §6501.5(a) and §6504.4(b), unless a copy of the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (6/16)) NBS-I (E), or a copy of the NEWBORN SCREENING TEST REFUSAL (NBS-TR) CDPH 4459 (06/16), 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 - (6/16)) NBS-I (E) pursuant to §6501.5(a) and §6504.4(b).

(3) ensure that specimens are given, on the same or next business day of the designated carrier, to a carrier contracted with the Department or contracted with a newborn screening laboratory or to another same-day or overnight delivery service for transport to the assigned newborn screening laboratory.

(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 - (6/16)) NBS-I (E) pursuant to §6501.5(a) and §6504.4(b) unless a copy of the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (6/16)) NBS-I (E) or a copy of the NEWBORN SCREENING TEST REFUSAL

(NBS-TR) CDPH 4459 (06/16), or a newborn screening result is found in the infant's medical record.

(2) ensure that specimens are given, on the same or next business day of the designated carrier, to a carrier contracted with the Department or contracted with a newborn screening laboratory or to another same-day or overnight delivery 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) 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.

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.

(19) Amend §6506 to read:

**§6506. Verification of Receipt of Newborn Screening Specimens by the Department.**

(a) 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 - (06/16)) NBS-I (E) pursuant to §6501.5(a) nor a copy of a completed NEWBORN SCREENING TEST REFUSAL (NBS-TR) CDPH 4459 (06/16) - English version or CDPH 4459 (SP) (6/16) - Spanish version pursuant to §6501.2 and §6501.5(b) present in the newborn's medical record, the 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 - (6/16)) NBS-I (E) 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 another overnight carrier for transport to the assigned newborn screening laboratory on the same or next business day of the designated carrier.

(b) 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, 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 §6506.6 to read:

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

(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 - (6/16)) NBS-I (E).

(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 - (6/16)) NBS-I (E) pursuant to §6501.5(a) and §6504.4(b).

(2) ensure the specimen is given, on the same or 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 another same-day or overnight carrier 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 - (6/16)) NBS-I (E) pursuant to §6501.5(a) and §6504.4(b).

(2) ensure the specimen is given, on the same or 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 another same-day or overnight carrier 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, 125000, 125001 and 131200, Health and Safety Code. Reference: Sections 124975, 124980, 125000, 125001, 125025, 131050, 131051 and 131052, Health and Safety Code.

(21) Amend §6506.8 to read:

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

(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, 125000, 125001 and 131200, Health and Safety Code. Reference: Sections 124975, 124980, 125000, 125001, 125025, 131050, 131051 and 131052, Health and Safety Code.

(22) Amend Section 6506.10 to read:

**§6506.10. Use of Newborn Screening Contracted Laboratories for Repeat and Confirmatory Specimens.**

(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 same or next business day of the designated carrier, by a carrier contracted with the Department or contracted with a newborn screening laboratory or by same-day or overnight carrier, 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, 125000, 125001 and 131200, Health and Safety Code. Reference: Sections 124975, 124980, 125000, 125001, 125025, 131050, 131051 and 131052, Health and Safety Code.