

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

Amend Section 6500.50 as follows:

Section 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).

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.

Amend section 6501.5 to read as follows:

Section 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 or religious refusal pursuant to §6501.2, §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). This form is hereby incorporated by reference.

(b) 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.

Amend Section 6505 to read as follows:

Section 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) 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) 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) 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) Not collect a newborn screening specimen under this section if the parent or legal guardian has executed a refusal of the newborn screening test on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH-4409) pursuant to §6501.2.

(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) pursuant to §6501.5(a) and §6504.4(b), unless a religious refusal pursuant to §6501.2 is executed, or a newborn screening result is found in the infant's

medical record, or the physician has a record that the screening specimen has 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) 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 between 12 and 48 hours of birth using the Instructions for Collecting Adequate Blood Specimens on the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH-4409) pursuant to §6501.5(a) and §6504.4(b) unless a religious refusal pursuant to §6501.2 is executed, 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.

Amend Section 6506 to read as follows:

Section 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 not a copy of the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH-4409) pursuant to §6501.2 or §6501.5(a) 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) 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 collected specimen has not been received, the staff shall enter a missing specimen report into the SIS.

(c) 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.

Amend Section 6506.6 to as read follows:

Section 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).

(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) 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) 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.