

**METHODOLOGY TO INDICATE CHANGES TO
DPH-09-010E NEWBORN SCREENING**

Changes to the regulations are indicated as follows:

- Deleted text is indicated by double strike-through (~~strike-through~~).
- Additions to the regulation text are indicated by double underline (underline).

TEXT OF REGULATIONS

ARTICLE 2. TESTING AND FOLLOW-UP PROGRAM REQUIREMENTS

(1) 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 - (~~41-126/16~~)) NBS-I (~~DF~~). 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 (~~06/1106/16~~) - English version or CDPH 4459(SP) (~~6/1106/16~~) - Spanish version. ~~This~~These forms ~~is~~are 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.

(2) 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 - (~~11-126/16~~)) NBS-I (~~DF~~) pursuant to §6501.5(a) and §6504.4(b). This specimen collection shall occur after 12 hours but no later than ~~96~~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~~11-12~~)) NBS-I (FD) 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 - ~~(6/1644-12)~~) NBS-I
(~~FD~~) 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 ~~the United States Postal Service~~ another same-day or overnight delivery 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.~~

~~(54)~~ 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 (06/164) 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 - ~~(11-126/16)~~) NBS-I (~~FD~~) 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-~~

~~426/16~~) NBS-I (~~FD~~), or a copy of the NEWBORN SCREENING TEST REFUSAL (NBS-TR) CDPH 4459 (06/16~~4~~), 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 - (~~41-426/16~~)) NBS-I (~~FD~~) 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 ~~the United States Postal Service~~ another same-day or overnight delivery 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 - (~~41-426/16~~)) NBS-I (~~FD~~) pursuant to §6501.5(a) and §6504.4(b) unless a copy of

the CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF) (CDPH - 4409 - (~~11-126/16~~)) NBS-I (~~FD~~) or a copy of the NEWBORN SCREENING TEST REFUSAL (NBS-TR) CDPH 4459 (06/16~~4~~), 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 ~~the United States Postal Service~~ another same-day or overnight delivery service for transport to the assigned newborn screening laboratory.

(d) through (f) *No change to previous noticed text.*

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.

(3) 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 - ~~(11-12)~~(16)) NBS-I (~~FD~~) pursuant to §6501.5(a) nor a copy of a completed NEWBORN SCREENING TEST REFUSAL (NBS-TR) CDPH 4459 (06/16~~4~~) - 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 ~~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 - (~~6/1641-42~~)) NBS-I (~~FD~~) 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~~ another overnight carrier for transport to the assigned newborn screening laboratory on the same or next business day of the designated carrier.

(b) *No change to previously noticed text.*

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.

(4) 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 - ~~(6/1644-12)~~) NBS-I (~~FD~~).

(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 - ~~(6/1644-12)~~) NBS-I (~~FD~~) 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 ~~the United States Postal Service~~ 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 - (~~6/1611-12~~)) NBS-I (~~FD~~) 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 ~~the United States Postal Service~~ another same-day or overnight carrier to the assigned newborn screening laboratory.

(d) and (e) *No change to previously noticed text.*

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.

(5) 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 ~~the United States Postal Service~~ same-day or overnight carrier, to the assigned newborn screening laboratory.

(b) *No change to previously noticed text.*

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.