

SUPPLEMENTAL STATEMENT OF REASONS

The California Department of Public Health (the Department) has instituted changes to these proposed regulations, as discussed below. These changes are either initiated by the Department or are in response to comments that were received during the 45-day public comment period that ended on August 8, 2016.

Detailed Discussion of the Changes

The Department is proposing to:

Repeal form CDPH 4089 (01/11) HOSPITAL REPORT OF NEWBORN SCREENING SPECIMEN NOT OBTAINED (NBS-NO) from the list of forms incorporated by reference because the Newborn Screening Program is now requesting a newborn screening test request form for every baby born and form CDPH 4089 will no longer be used. Any field from form CDPH 4089 not already duplicated has been added to the revised form CDPH – 4409 (6/16) NBS-I (F) CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF).

Amend form CDPH - 4409 - (6/16) NBS-I (F) CALIFORNIA NEWBORN SCREENING TEST REQUEST FORM (NBS-TRF), incorporated by reference, to include fields not already duplicated from form CDPH 4089 (01/11) HOSPITAL REPORT OF NEWBORN SCREENING SPECIMEN NOT OBTAINED (NBS-NO). Additionally, the Notice of Information and Privacy Practices has been updated for clarity and readability, to include updated program authority citations, remove obsolete mailing codes, and to update the privacy website link.

Amend form CDPH 4459 (06/16) – English version and CDPH 4459 (SP) (06/16) – Spanish version NEWBORN SCREENING TEST REFUSAL (NBS-TR), incorporated by reference, to include identifying information contained on form CDPH - 4409 - (6/16) NBS-I (F) when the newborn screening test is refused. Additionally, the notification regarding the Important Information for Parents about Newborn Test Screening has been revised to be more readable and use appropriate medical terminology. Corrections to the program name and mailing information are also made.

Amend Section 6501.5(a) & (b) to identify the amended forms CDPH - 4409 - (6/16) NBS-I (F), CDPH 4459 (06/16), and CDPH 4459 (SP) (06/16). A non-substantial correction to grammar is also made.

Delete subsection (c) since form CDPH 4089 (01/11) will no longer be used. The revised version of form CDPH – 4409 (6/16) NBS-I (F) includes information from the obsolete form. Subsection **(d)** has been redesignated to be subsection (c).

Amend Section 6505 to identify the revised forms CDPH - 4409 - (6/16) NBS-I (F), CDPH 4459 (06/16), and CDPH 4459 (SP) (06/16) as previously discussed.

Amend subsection (a)(1) specifying the collection time of the Newborn Screen is updated to reflect the U.S. Department of Health and Human Services' (HHS) Advisory Committee on Heritable Disorders in Newborns and Children recommendation of a newborn screening collection be completed between 24 and 48 hours after birth. The Department proposes to align the collection time from 96 hours to 48 hours to comply with current national standards for Newborn Screening. References to revised form CDPH - 4409 - (6/16) NBS-I (F) have also been updated.

Amend subsection (a)(3) to clarify the references to the carrier for shipping the Newborn Screen. The change removes a specific carrier and identifies same-day delivery as an option. It also provides clarification that same-day or overnight delivery service is the preferred delivery method due to the nature of the newer NBS tests and HHS' recommendation described previously in subsection (a)(1).

Delete subsection (a)(4) since form CDPH 4089 (01/11) will no longer be used. The revised version of form CDPH – 4409 (6/16) NBS-I (F) includes information from the obsolete form. Subsection **(a)(5)** has been redesignated to be subsection (a)(4).

Amend subsection (b)(3) to clarify the references to the carrier for shipping the Newborn Screen. The change removes a specific carrier and now includes same-day delivery as an option. It also provides clarification that same-day or overnight delivery service is the preferred delivery method due to the nature of the newer NBS tests and HHS' recommendation described previously in subsection (a)(1).

Delete subsection (b)(4) since form CDPH 4089 (01/11) will no longer be used. The revised version of form CDPH – 4409 (6/16) NBS-I (F) includes information from the obsolete form.

Amend subsection (c)(2) to clarify the references to the carrier for shipping the Newborn Screen. The change removes a specific carrier and now includes same-day delivery as an option. It also provides clarification that same-day or overnight delivery service is the preferred delivery method due to the nature of the newer NBS tests and HHS' recommendation described previously in subsection (a)(1).

Amend Section 6506 to identify the revised forms CDPH - 4409 - (6/16) NBS-I (F), CDPH 4459 (06/16), and CDPH 4459 (SP) (06/16) as previously discussed. References to form CDPH 4089 (01/11) HOSPITAL REPORT OF NEWBORN SCREENING SPECIMEN NOT OBTAINED (NBS-NO) is deleted because the Newborn Screening Program is now requesting a newborn screening test request form for every baby born, and form CDPH 4089 will no longer be used as stated above. References to the carrier for shipping the Newborn Screen is also updated to remove a specific carrier and now includes same-day delivery as an option, as well as clarification that same-day or overnight delivery service is the preferred delivery method due to the nature of the newer NBS tests and HHS' recommendation described previously in section 6505(a)(1). Non-substantial grammatical

corrections are also made.

Amend Section 6506.6 to identify the revised forms CDPH - 4409 - (6/16) NBS-I (F) as previously discussed. References to the carrier for shipping the Newborn Screen is also updated to remove a specific carrier and now includes same-day delivery as an option. It also provides clarification that same-day or overnight delivery service is the preferred delivery method due to the nature of the newer NBS tests and HHS' recommendation made in section 6505(a)(1). Non-substantial grammatical corrections are also made.

Amend Section 6506.10 to update references to the carrier for shipping the Newborn Screen. Reference to a specific carrier have been deleted and now includes same-day delivery as an option. It also provides clarification that same-day or overnight delivery service is the preferred delivery method due to the nature of the newer NBS tests and HHS' recommendation described previously in section 6505(a)(1).