

FINAL STATEMENT OF REASONS

The information contained in the Initial Statement of Reasons (ISOR) at the time of the Public Notice and the Supplemental Statement of Reasons (SSOR) at the time of the Notice of Public Availability remains unchanged with the exception of the following modifications. The ISOR and SSOR are incorporated by reference in the Final Statement of Reasons.

SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE INITIAL 45-DAY NOTICE PERIOD

The Department mailed the notice of proposed regulations to those persons specified in Government Code section 11346.4(a)(1) through (6). This regulation was made available to the public from June 24, 2016 through August 8, 2016, ending at 5:00 p.m. A request for a public hearing was not received and, thus, no public hearing was held. The written proceeding produced two comments from those noted below.

List of Commenters during Initial 45-day Proceeding

(Written testimony)

- 1) Mary Earhart
- 2) Yvonne Kellar-Guenther, Denver, CO

Commenter 1: "My Homebirth clients have difficulty getting their babies screened. Hospitals turn them away (Indio) because baby wasn't born there and the pediatrician who wrote a request does not have privileges there. A baby born at a birth center in Riverside County couldn't get her baby screened near her home in Imperial County, the hospital in Imperial turned her away and her pediatrician refused to order it, saying he would call child protective services if aquamephyton wasn't given (parents refused it and there were no signs of disease). Two others gave up after endless run arounds. Years ago we only had to take home born babies to the health department to register them and access local screening. The health department even made a home visit (1980) to offer it to rural clients. Thank you for mentioning midwives. I am a provider but have not been screening newborns because of billing concerns, getting letters from NBS because Marian Dillard retired and no one else in your office will give me an offset for Medi-Cal nonpayment (I'm told I can't get reimbursed because I am not a lab). I now need Medi-Cal denials to prove non-payment for every patient, which would require me to pay my billing service to submit fruitless invoices...so as the cost of screening went up I dropped it from my practice. I do very few births as I am retiring, but there needs to be easy access throughout the state and in every county regardless of place of birth. Simple fix. Let's get these babies screened."

Department Response: The Department thanks the commenter for taking the time to review the regulations and comment; however, since the comment is outside the scope of the regulations no changes to the regulation text was made. The Department appreciates the indication of support for the amended proposal.

Commenter 2: “I would like to see the regulations specify that blood spot specimens should be collected between 24 and 48 hours of birth.”

Department Response: In response to the commenter’s suggestion and to reflect the U.S. Department of Health and Human Services’ 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 is aligning the collection time from 96 hours to 48 hours to comply with current national standards for Newborn Screening by amending section 6505(a)(1).

COMMENTS RECEIVED DURING THE PERIOD THE MODIFIED TEXT WAS AVAILABLE TO THE PUBLIC

The Department mailed the modified text of the regulations with a notice of public availability to those persons specified in subsections (a)(1) through (4) of Section 44 of Title 1 of the CCR. The notice of availability and the modified text were available to the public from December 20, 2016 through January 3, 2017, at the Department’s Office of Legal Services, 1415 L Street, Suite 500, Sacramento, CA, between the hours of 8:00 a.m. and 5:00 p.m. and on the Department’s web site. There was one comment received from the commenter noted below.

List of Commenters during the 15-day Public Availability

(Written testimony)

- 1) Keri LeBlanc

Comment: “I RECOMMEND DELETION OF THIS PHRASE: 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. I WOULD REPLACE WITH THE FOLLOWING: Physicians attending critically ill newborns who require special care SHOULD COLLECT AN INITIAL newborn screening specimen with initial labs, and may repeat the collection once the baby is stabilized if results indicate repeating.

Definitely AGREE WITH THE FOLLOWING:

(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.”

Department Response: The Department has reviewed the request and determined no change is indicated because collecting NBS specimens with initial lab work will result in all inadequate specimens as initial labs are collected prior to 12 hours of age. Regulations exist that address the collection of NBS specimens for critically ill infants. In addition, the indication of support for the amended proposal is appreciated.

STATEMENTS OF DETERMINATIONS

ALTERNATIVES CONSIDERED

The Department has determined that no alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective and less burdensome to affected private persons than the adopted regulation, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

LOCAL MANDATE DETERMINATION

The Department has determined that the regulations will not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by Part 7 (commencing with section 17500) of Division 4 of the Government Code.

IMPACT ON BUSINESS

The Department has determined that the proposed regulations would not have any significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.