

**STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY FOR**
Amendments to Rules and Regulations Pertaining to Newborn Screening

May 17, 2012

Basis and Purpose: Under Section §25-4-1004(1) (b) C.R.S., the Board of Health has the authority to promulgate and make changes to the Newborn Screening rules and regulations regarding procedures, testing and reporting, quality assurance, and the disorders for the FIRST screen. The Executive Director is vested with the authority to make changes to the SECOND screen under §25-4-1004.5 C.R.S.

The proposed changes involve the revision of the procedures for sample collection and delivery to the laboratory, specifically, the limited use of USPS for delivery (it will be disallowed for the first screen but allowed for the second screen), and the effect on testing quality and timeliness of reporting of results. The guidelines referenced for sample collection are outlined in the Clinical and Laboratory Standards Institute (CLSI) document: *Blood Collection on Filter Paper for Newborn Screening. Approved Standard – fifth Edition* LA4-A5 Vol. 27 No. 20. Input was also solicited from other state’s newborn screening programs, stakeholders, and the Colorado Newborn Screening Advisory Committee to align the associated regulatory language with best practice.

Specific Statutory Authority: These rules are promulgated pursuant to the following statutes: Sections 25-4-801 through 25-4-804 and 25-4-1001 through 25-4-1006 (not including Section 25-4-1004.7) C.R.S (1998), the Newborn Screening Regulations are established.

Major Factual and Policy Issues Encountered: The USPS will likely implement cost savings measures in the near future aimed at reducing their deficit and resulting in the delayed delivery of first class mail.

Alternative Rules Considered and Why Rejected: None

STATE OF COLORADO

John W. Hickenlooper, Governor
Christopher E. Urbina, MD, MPH
Executive Director and Chief Medical Officer

Dedicated to protecting and improving the health and environment of the people of Colorado

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Colorado Department
of Public Health
and Environment

NOTICE OF PUBLIC RULE-MAKING HEARING BEFORE THE EXECUTIVE DIRECTOR AND CHIEF MEDICAL OFFICER OF THE COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

NOTICE is hereby given pursuant to the provisions of Section 24-4-103, C.R.S., that the Executive Director/Chief Medical Officer of the Colorado Department of Public Health and Environment will conduct a public rule-making hearing on **July 2, 2012** in the Sabin-Cleere Conference Room of the Colorado Department of Public Health and Environment, Bldg. A, First Floor, 4300 Cherry Creek Drive, South, Denver, CO 80246, to consider the promulgation of a change to 5 CCR 1005-4, Newborn Screening Regulations.- Rules And Regulations of the Executive Director Colorado Department of Public Health and Environment- Implementation Of Second Newborn Screening. The rulemaking hearing will commence at 2:30 p.m.

The purpose of this hearing is to receive public comments on the proposed amendment to the regulations for the Second Newborn screen. The proposed amendments will revise the sample collection and submission requirements.

The proposed rules have been developed by the Laboratory Services Division of the Colorado Department of Public Health and Environment pursuant to Section (25-4-1004(1)(b), C.R.S. Copies of the proposed rules may be obtained by contacting the Colorado Department of Public Health and Environment, Laboratory Services Division, 8100 Lowry Bld., Denver, CO 80230, (303) 692-3090. The proposed amendments will also be available on the Department's Web site at <http://www.cdphe.state.co.us/>.

The Executive Director/Chief Medical Officer encourages all interested persons to participate in the hearing by providing written data, views, or comments, or by making oral comments at the hearing. At the discretion of the Executive Director and Chief Medical Officer, oral testimony at the hearing may be limited to five minutes or less depending on the number of persons wishing to comment.

The Executive Director/Chief Medical Officer requests submission of written materials no later than seven days prior to the hearing date, to allow him sufficient time to review the comments prior to the meeting. Persons wishing to submit written comments or views should submit them to:

Executive Director and Chief Medical Officer
ATTN: Jamie Thornton, Program Assistant
Colorado Department of Public Health and Environment
4300 Cherry Creek Drive South EDO-A5
Denver, Colorado 80246-1530
FAX: 303-691-7702, e-mail: Jamie.Thornton@state.co.us

The proposed revisions to be considered at the hearing, together with the proposed statement of basis and purpose, specific statutory authority and regulatory analysis will be available for inspection at the above address by any person at least five working days prior to the hearing.

Dated this 3 / day of May 2012.

Christopher E. Urbina, MD
Executive Director and Chief Medical Officer