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

January 19, 2011

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

Prior to this amendment, the newborn screening regulations provided that babies born in Colorado would be screening for a total of thirty-four disorders. Within the last year, the Health Resources and Services Administration Advisory Committee on Heritable Disorders in Newborns and Children voted unanimously to recommend adding Severe Combined Immunodeficiency (SCID) to the core panel for universal screening of all newborns in the United States. Additionally, the Colorado Newborn Screening Advisory Committee has concluded that SCID warrants inclusion in the first screen panel of disorders.

The Colorado Newborn Screening statute specifies the criteria for the inclusion of disorders for newborn screening. These criteria are:

1. "Condition for which the test is designed presents a significant danger to the health of the infant or his family." With Severe Combined Immunodeficiency, babies suffer genetic defects that impair that impair normal T-cell development necessary for immune response. SCID babies typically appear normal at birth, but acquire multiple life-threatening infections, such as pneumonia, meningitis, and septicemia, within a few months. SCID is sometimes referred to as "bubble boy disease".

2. "Condition is amenable to treatment." Early diagnosis and treatment with a bone-marrow transplant markedly improves long-term outcomes.

3. "Incidence of the condition is sufficiently high to warrant screening." A conservative estimate of the prevalence of SCID is 1/66,000 births. Estimates range from 1/40,000 to 1/100,000.[1]

4. "The test to detect the condition meets commonly accepted standards of reliability." T-cell lymphopenia as determined using Real-time quantitative polymerase chain reaction assay (RT-qPCR) measuring T-cell excision circles (TRECs) performed on dried blood spots. RT-PCR is widely accepted as a standard methodology in laboratories for measuring infectious agents and currently in the CDPHE lab to perform cystic fibrosis DNA analysis.

5. "Cost-benefit consequences of screening are acceptable." Cost per test is estimated to be $6.49 per newborn including follow-up. This cost benefit is comparable to the other disorders currently screened for in Colorado.

[1] Lipstein E., Knapp AA, Perrin JM. Evidence Review: severe combined immunodeficiency (SCID) 2009 Nov 20.

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: On January 21, 2010, the Health Resources and Services Administration Advisory Committee on heritable Disorders in Newborns and children voted unanimously to recommend adding SCID to the core panel for universal screening of all newborns in the United States.

Alternative Rules Considered and Why Rejected: None