First Regular Session Seventieth General Assembly STATE OF COLORADO

REREVISED

This Version Includes All Amendments Adopted in the Second House HOUSE BILL 15-1281

LLS NO. 15-0698.01 Kristen Forrestal x4217

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A BILL FOR AN ACT

101 CONCERNING NEWBORN CONGENITAL HEART DEFECT SCREENING

102 THROUGH THE USE OF PULSE OXIMETRY, AND, IN CONNECTION

103 THEREWITH, MAKING AN APPROPRIATION.

Bill Summary

(Note: This summary applies to this bill as introduced and does not reflect any amendments that may be subsequently adopted. If this bill passes third reading in the house of introduction, a bill summary that applies to the reengrossed version of this bill will be available at <u>http://www.leg.state.co.us/billsummaries.</u>)

The bill requires all newborns born in a a birthing center that is below an elevation of 7,000 feet to be screened for congenital health defects using pulse oximetry prior to the infant leaving the health facility. The state board of health is required to promulgate rules for pulse oximetry at birthing centers at or above 7,000 feet when the board SENATE 3rd Reading Unamended May 6, 2015

> Reading Unamended May 5, 2015

2nd

SENATE

HOUSE 3rd Reading Unamended April 21, 2015

> Amended 2nd Reading April 16, 2015

HOUSE

receives confirmation of appropriate calibration of pulse oximetry instruments. The bill requires each birthing facility to report the results of the screening to the department of public health and environment and allows the state board of health to promulgate rules.

1 *Be it enacted by the General Assembly of the State of Colorado:* 2 **SECTION 1. Legislative declaration.** (1) The general assembly 3 finds and declares that: 4 (a) Congenital heart defects are structural abnormalities of the 5 heart that are present at birth; 6 (b) Congenital heart defects range in severity from simple 7 problems, such as holes between chambers of the heart, to severe 8 malformations, such as the complete absence of one or more chambers or 9 valves: 10 (c) Some critical congenital heart defects can cause severe and 11 life-threatening symptoms, which require intervention within the first 12 days of life; 13 (d) Critical congenital heart defects are the number one killer of 14 infants with birth defects: 15 (e) According to the United States secretary of health and human 16 services' discretionary advisory committee on heritable disorders in newborns and children, critical congenital heart disease affects 17 18 approximately 7 to 9 of every 1,000 live births in the United States and 19 Europe; 20 (f) Hospital costs for all individuals with congenital heart disease 21 can total \$2.6 billion per year; 22 (g) Current methods for detecting critical congenital heart defects 23 generally include prenatal ultrasound screening. These screenings alone

identify less than half of all cases. Critical congenital heart defect cases
 are often missed during routine clinical exams performed prior to a
 newborn's discharge from a birthing facility, but repeated clinical
 examinations can identify many affected newborns.

5 (h) Pulse oximetry is a noninvasive test that estimates the 6 percentage of hemoglobin in blood that is saturated with oxygen and, 7 when performed on newborns in delivery centers, is effective at detecting 8 critical, life-threatening congenital heart defects that otherwise go 9 undetected by current screening methods; and

(i) Newborns with abnormal pulse oximetry results require
immediate confirmatory testing and intervention. Many newborn lives
could potentially be saved by earlier detection and treatment of critical
congenital heart defects if birthing facilities in Colorado were required to
perform this simple, noninvasive newborn screening in conjunction with
current critical congenital heart disease screening methods.

16 (2) Therefore, it is the intent of the general assembly to require
17 that birthing facilities perform critical congenital heart defect screening
18 using pulse oximetry.

SECTION 2. In Colorado Revised Statutes, add 25-4-1004.3 as
follows:

21 25-4-1004.3. Newborn heart defect screening - pulse oximetry
22 - rules. (1) (a) ON AND AFTER JANUARY 1, 2016, A BIRTHING FACILITY
23 THAT IS BELOW SEVEN THOUSAND FEET OF ELEVATION SHALL TEST ALL
24 INFANTS BORN IN THE FACILITY FOR CRITICAL CONGENITAL HEART
25 DEFECTS USING PULSE OXIMETRY.

26 (b) UPON RECEIPT OF THE CONFIRMATION OF THE APPROPRIATE
27 ALGORITHM FOR THE PULSE OXIMETRY READING FROM THE NEWBORN

-3-

1 SCREENING COMMITTEE, THE NEWBORN SCREENING COMMITTEE SHALL 2 EVALUATE WHETHER PULSE OXIMETRY TESTING IN BIRTHING FACILITIES AT 3 OR ABOVE SEVEN THOUSAND FEET ELEVATION MEETS THE CRITERIA IN 4 SECTION 25-4-1004. UPON CONFIRMATION FROM THE COMMITTEE THAT 5 THE CRITERIA HAVE BEEN MET, THE STATE BOARD OF HEALTH SHALL 6 PROMULGATE RULES PURSUANT TO SECTION 25-4-1004 TO ENSURE THAT 7 ALL NEWBORNS BORN AT OR ABOVE SEVEN THOUSAND FEET ELEVATION 8 ARE SCREENED FOR CRITICAL CONGENITAL HEALTH DEFECTS.

9 (c) THE CRITICAL CONGENITAL HEART DEFECT SCREENING USING
10 PULSE OXIMETRY MUST BE PERFORMED ON EVERY NEWBORN PRIOR TO THE
11 NEWBORN'S RELEASE FROM THE BIRTHING FACILITY.

12 (2) EACH BIRTHING FACILITY SHALL REPORT THE RESULTS OF THE
13 PULSE OXIMETRY SCREENINGS TO THE DEPARTMENT OF PUBLIC HEALTH
14 AND ENVIRONMENT. THE STATE BOARD OF HEALTH MAY PROMULGATE
15 RULES FOR THE IMPLEMENTATION OF THIS SECTION.

16 (3) AS USED IN THIS SECTION, A "BIRTHING FACILITY" MEANS A
17 GENERAL HOSPITAL OR BIRTHING CENTER LICENSED OR CERTIFIED
18 PURSUANT TO SECTION 25-1.5-103 AND THAT PROVIDES BIRTHING AND
19 NEWBORN CARE SERVICES.

20 **SECTION 3.** Appropriation. For the 2015-16 state fiscal year, 21 \$32,386 is appropriated to the department of public health and 22 environment for use by the center for health and environmental 23 information. This appropriation is from the newborn screening and 24 genetic counseling cash funds created in section 25-4-1006 (1), C.R.S., 25 and is based on an assumption that the center will require an additional 26 0.2 FTE. To implement this act, the center may use this appropriation for 27 the birth defects monitoring and prevention program.

SECTION 4. Act subject to petition - effective date. This act 1 2 takes effect at 12:01 a.m. on the day following the expiration of the 3 ninety-day period after final adjournment of the general assembly (August 4 5, 2015, if adjournment sine die is on May 6, 2015); except that, if a referendum petition is filed pursuant to section 1 (3) of article V of the 5 6 state constitution against this act or an item, section, or part of this act within such period, then the act, item, section, or part will not take effect 7 8 unless approved by the people at the general election to be held in 9 November 2016 and, in such case, will take effect on the date of the official declaration of the vote thereon by the governor. 10