COMMITTEE REPORT

April 4, 2019

**H. 3036**

Introduced by Reps. McCravy, Parks, West, Gagnon, Martin, Hiott, Burns, Huggins, G.R. Smith, Trantham, Ridgeway, Thayer, W. Cox, Toole, Johnson, Jefferson, Clary and Gilliard

S. Printed 4/4/19--H.

Read the first time January 8, 2019.

**THE COMMITTEE ON MEDICAL,**

**MILITARY, PUBLIC AND MUNICIPAL AFFAIRS**

To whom was referred a Bill (H. 3036) to amend the Code of Laws of South Carolina, 1976, so as to enact “Dylan’s Law”; and by adding Section 44‑37‑35 so as to require, etc., respectfully

**REPORT:**

That they have duly and carefully considered the same and recommend that the same do pass with amendment:

Amend the bill, as and if amended, by striking all after the enacting words and inserting:

/ SECTION 1. This act may be known and cited as “Dylan’s law”.

SECTION 2. Chapter 37, Title 44 of the 1976 Code is amended by adding:

“Section 44‑37‑35. (A) Neonatal testing conducted pursuant to Section 44‑37‑30 must include testing for the following:

(1) Krabbe disease;

(2) Pompe disease; and

(3) Hurler syndrome.

(B) The department shall require additional lysosomal storage disorders to be tested upon the recommendations of the Newborn Screening Advisory Committee and in accordance with Section 44‑37‑30 pursuant to a duly promulgated regulation as testing for such disorders becomes available.”

SECTION 3. Section 44-37-30 of the 1976 Code is amended by adding an appropriately lettered subsection at the end to read:

“( ) The department shall establish the Newborn Screening Advisory Committee to review the feasibility and advisability of including additional metabolic, genetic, and congenital disorders in the neonatal testing conducted pursuant to this section. The committee must be multidisciplinary and composed of members deemed appropriate by the department.”

SECTION 4. This act takes effect upon approval by the Governor. /

Renumber sections to conform.

Amend title to conform.

LEON HOWARD for Committee.

**STATEMENT OF ESTIMATED FISCAL IMPACT**

**Explanation of Fiscal Impact**

**Amended by House Medical, Military, Public, and Municipal Affairs Health and Environmental Affairs Subcommittee on March 27, 2019**

**State Expenditure**

This amendment requires DHEC to add tests for 3 neonatal genetic disorders and diseases to the existing newborn screening program. These additional tests for lysosomal storage disorders will be conducted in accordance with the existing newborn screening program statutes and regulations. Expenditures for the existing newborn screening program totaled $8,100,000 in FY 2017-18, while reimbursements from hospitals and physicians totaled $6,944,000. This resulted in general fund appropriations offsetting the deficit of $1,156,000 in FY 2017-18.

DHEC indicates that the additional neonatal testing for Krabbe disease, Pompe disease, and Hurler syndrome will require additional general fund expenditures for salaries and fringe benefits of $247,146 and 3.00 FTEs for the Newborn Screening Program to provide the following services:

 FTE for a Program Coordinator II to collaborate with the state laboratory, primary care providers, hospitals, and medical geneticists regarding newborn screening policies and procedures with emphasis on protocols related to lysosomal storage disorders, and to notify hospital neonatal intensive care units and physician offices regarding patients with abnormal lab results.

 FTEs for a Laboratory Technologist II position to perform newborn screening tests for lysosomal storage disorders using tandem mass spectrometry and other ancillary equipment.

 FTE for a Laboratory Technologist III position to supervise and train the other technologists on the lysosomal storage disorder testing methodology.

Additional recurring general fund operating expenditures of $289,871 in FY 2019-20 include testing reagents, other testing supplies, confirmatory testing, and a medical consultant. Total recurring general fund expenditures in FY 2019-20 for salaries, fringe benefits, and other operating expenses will total $537,017.

**State Revenue**

While DHEC bills hospitals and physicians to fund a portion of the existing newborn screening program, they indicate that increased reimbursements may not be available since the additional screenings are not included on the recommended uniform screening panel of disorders specified by the U.S. Secretary of the Department of Health and Human Services. As such, these additional tests may not be reimbursed by health plans. Additionally, DHEC indicates that they work with hospitals in advance of adding new tests to determine fee increases, and current agreements may preclude a fee increase until 2020. Since additional reimbursements from hospitals and physicians may not be available to offset the additional expenditures, DHEC indicates that the department will require additional general fund resources of $537,017 to administer the additional tests.

**Introduced on January 8, 2019**

**State Expenditure**

This bill requires DHEC to add tests for six neonatal genetic disorders and diseases to the existing newborn screening program. These additional tests for lysosomal storage disorders will be conducted in accordance with the existing newborn screening program statutes and regulations. Expenditures for the newborn screening program totaled $8,100,000 in FY 2017-18 while reimbursements from hospitals and physicians totaled $6,944,000. This resulted in general fund appropriations offsetting the deficit of $1,156,000 in FY 2017-18.

DHEC indicates that the specified neonatal testing will require additional general fund expenditures for salaries and fringe benefits of $361,094 and 5.00 FTEs for the Newborn Screening Program to provide the following services.

 FTE for a Program Coordinator II to collaborate with the state laboratory, primary care providers, hospitals, and medical geneticist regarding newborn screening policies and procedures with emphasis on protocols related to lysosomal storage disorders. Notifies hospital neonatal intensive care units and physician offices regarding patients with abnormal lab results.

 3.00 FTEs for Laboratory Technologist II positions to perform newborn screening tests for lysosomal storage disorders using tandem mass spectrometry, and other ancillary equipment.

 FTE for a Laboratory Technologist III position to supervise and train the other technologists on the lysosomal storage disorder testing methodology.

Additional recurring general fund other operating expenditures of $627,646 in FY 2019-20 include testing reagents, other testing supplies, confirmatory testing, and a medical consultant. Total recurring general fund expenditures in FY 2019-20 for salaries, fringe benefits, and other operating expenses will total $988,740.

DHEC indicates that non-recurring general fund expenditures will increase by $112,836 in FY 2019-20 for general office supplies, office equipment, and renovation of office space. Total additional recurring and non-recurring general fund expenditures will total $1,101,576 in FY 2019-20. As discussed below, DHEC indicates that the department will require additional general fund resources as additional reimbursements from hospital and physicians may not be available.

**State Revenue**

While DHEC bills hospitals and physicians to fund a portion of the existing newborn screening program, they indicate that increased reimbursements may not be available since the additional screenings are not included on the recommended uniform screening panel of disorders specified by the U.S. Secretary of the Department of Health and Human Services. As such, these additional tests may not be reimbursed by health plans. Additionally, DHEC indicates that they work with hospitals in advance of adding new tests to determine fee increases and current agreements may preclude a fee increase until 2020. Therefore, additional reimbursements may not be available to offset the additional expenditures.

Frank A. Rainwater, Executive Director

Revenue and Fiscal Affairs Office

**A** **BILL**

TO AMEND THE CODE OF LAWS OF SOUTH CAROLINA, 1976, SO AS TO ENACT “DYLAN’S LAW”; AND BY ADDING SECTION 44‑37‑35 SO AS TO REQUIRE NEONATAL TESTING FOR CERTAIN GENETIC DISORDERS AND DISEASES AND FOR OTHER PURPOSES.

Be it enacted by the General Assembly of the State of South Carolina:

SECTION 1. This act may be known and cited as “Dylan’s law”.

SECTION 2. Chapter 37, Title 44 of the 1976 Code is amended by adding:

“Section 44‑37‑35. (A) Neonatal testing conducted pursuant to Section 44‑37‑30 must include testing for the following:

(1) Krabbe disease;

(2) Fabry disease;

(3) Gaucher disease;

(4) Pompe disease;

(5) Hurler syndrome; and

(6) Niemann‑Pick disease.

(B) The department shall require additional lysosomal storage disorders to be tested in accordance with Section 44‑37‑30 pursuant to a duly promulgated regulation as testing for such disorders becomes available.”

SECTION 3. This act takes effect upon approval by the Governor.

‑‑‑‑XX‑‑‑‑