

COMMITTEE ON LEGISLATIVE RESEARCH  
OVERSIGHT DIVISION

**FISCAL NOTE**

L.R. No.: 1522-02  
Bill No.: Perfected HB 716  
Subject: Children and Minors; Health Care; Health Department; Health Care Professionals  
Type: Original  
Date: April 15, 2009

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Bill Summary: This legislation establishes the Brady Alan Cunningham Newborn Screening Act which adds Lysosomal Storage Diseases to the list of required newborn screenings.

**FISCAL SUMMARY**

<b>ESTIMATED NET EFFECT ON GENERAL REVENUE FUND</b>			
FUND AFFECTED	FY 2010	FY 2011	FY 2012
<b>Total Estimated Net Effect on General Revenue Fund</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>

<b>ESTIMATED NET EFFECT ON OTHER STATE FUNDS</b>			
FUND AFFECTED	FY 2010	FY 2011	FY 2012
<b>Total Estimated Net Effect on <u>Other</u> State Funds</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>

Numbers within parentheses: ( ) indicate costs or losses. This fiscal note contains 8 pages.

<b>ESTIMATED NET EFFECT ON FEDERAL FUNDS</b>			
<b>FUND AFFECTED</b>	<b>FY 2010</b>	<b>FY 2011</b>	<b>FY 2012</b>
<b>Total Estimated Net Effect on <u>All</u> Federal Funds</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>

<b>ESTIMATED NET EFFECT ON FULL TIME EQUIVALENT (FTE)</b>			
<b>FUND AFFECTED</b>	<b>FY 2010</b>	<b>FY 2011</b>	<b>FY 2012</b>
<b>Total Estimated Net Effect on FTE</b>	<b>0</b>	<b>0</b>	<b>0</b>

Estimated Total Net Effect on All funds expected to exceed \$100,000 savings or (cost).

Estimated Net Effect on General Revenue Fund expected to exceed \$100,000 (cost).

<b>ESTIMATED NET EFFECT ON LOCAL FUNDS</b>			
<b>FUND AFFECTED</b>	<b>FY 2010</b>	<b>FY 2011</b>	<b>FY 2012</b>
<b>Local Government</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>

## FISCAL ANALYSIS

### ASSUMPTION

#### ***Section 191.333:***

Officials from the **Office of the Secretary of State (SOS)** state many bills considered by the General Assembly include provisions allowing or requiring agencies to submit rules and regulations to implement the act. The SOS is provided with core funding to handle a certain amount of normal activity resulting from each year's legislative session. The fiscal impact for this fiscal note to the SOS for Administrative Rules is less than \$2,500. The SOS recognizes that this is a small amount and does not expect that additional funding would be required to meet these costs. However, the SOS also recognizes that many such bills may be passed by the General Assembly in a given year and that collectively the costs may be in excess of what the office can sustain with the core budget. Therefore, the SOS reserves the right to request funding for the cost of supporting administrative rules requirements should the need arise based on a review of the finally approved bills signed by the governor.

**Oversight** assumes the SOS could absorb the costs of printing and distributing regulations related to this proposal. If multiple bills pass which require the printing and distribution of regulations at substantial costs, the SOS could request funding through the appropriation process. Any decisions to raise fees to defray costs would likely be made in subsequent fiscal years.

Officials from the **University of Missouri (UM)** assume the proposed legislation would have no significant financial impact if UM continues with the same process of UM staff obtaining the blood sample and sending it in to the state to run the tests.

Officials from the **Department of Social Services** state the MO HealthNet Division (MHD) was billed for 14,351 newborn screenings in FY08 by the state health lab. Currently, newborn screenings are reimbursed by the MHD for the federal portion only. The general revenue portion is included in the DHSS budget.

The fiscal impact to the MHD is expected to be greater than \$100,000 in federal funds. However, it is unknown what the rate for the additional newborn screenings will be. If rates are increased by \$12.00, the result would be \$172,212 (\$12 times 14,351) and \$111,094 in federal funds. The fiscal impact to the MHD for FY10 is calculated for ten months or unknown but greater than \$92,578 (\$172,212 divided by 12 times 10 months or \$143,510 times .6451).

ASSUMPTION (continued)

Officials from the **Department of Health and Senior Services** state approximately 80,000 babies are born each year in Missouri. According to the Centers for Disease Control and Prevention (CDC), the collective incidence of lysosomal storage disorders (LSD) is 1:7,700 to 1:10,000 births. As a result of this data, the Department assumes that approximately eight to ten infants will be confirmed positive each year for at least one form of lysosomal storage disorder. For each infant that is confirmed positive, it is anticipated that there would be ten infants that would have an abnormal newborn screen result requiring follow-up and additional testing.

Based on the new testing requirements proposed by this legislation, DHSS assumes that the current State Public Health Laboratory will need capital improvements, including:

- Chemical fume hood and accessories - \$15,000;
- Fume hood installation, compressed air lines, air duct connection, and Triatek hood monitor - \$15,000;
- Electrical work to run six 30 amp 220V receptacles on emergency power - \$10,000;
- Venting and duct work for two liquid handlers and for two tandem mass spectrometers to connect into the ceiling vent that pulls from the chemical fume hood - \$10,000;
- Carpentry work and built-in lab furniture needed to retro-fit and accommodate the needs for lab benches and cabinet space in two rooms - \$20,000; and
- One two-door refrigerator, one minus 30 degree freezer, one pH meter, four multi channel hand-pipeters, certified laboratory glassware, and other standard ancillary laboratory equipment needed for lab work areas - \$20,000.

The costs of these improvements are based on the costs incurred for similar items/services paid for during the construction of the State Public Health Laboratory.

Additional laboratory equipment will also be needed for the increased number of tests that will be performed. Laboratory equipment leasing estimates were obtained from the current vendor and include equipment and maintenance and consumable parts for: two tandem mass spectrometry systems including two gas generators; two incubators; two auto-samplers; two High Performance Liquid Chromatography (HPLC) delivery systems; two vacuum pumps; two robotic liquid handlers; and Specimen Gate data suite enhancements to add additional analysts and merging data from new equipment. The Department estimates that the total leasing cost will be \$348,210.

ASSUMPTION (continued)

The Department assumes that the CDC will continue to provide support at no charge in the form of necessary reagents, standards, controls, and proficiency test samples needed for the testing and quality control of each specific LSD that would be screened for and reported. If the CDC does not continue to supply these items, the Department would seek additional funding through the appropriations process.

The Department estimates that three additional FTE will be required to carry out the provisions of the proposed legislation:

- One Senior Public Health Lab Scientist (\$40,212, Grade A26, Range G) to oversee the LSD testing laboratory section and assure accurate and timely testing and reporting of the newborn screening samples for this disorder category. This person would need complete understanding of the tandem mass spectrometry testing through all pre-analytical, analytical, and post analytical parameters. They will be in charge of scrutinizing all test results and quality control aspects while applying LSD decision schemes and algorithms for the detection of at-risk infants for these disorders. They will contact the contracted genetic referral centers to refer positive screens for diagnostic confirmation and continually work with DHSS newborn screening follow-up staff and the genetics advisory board to implement, sustain and continually improve upon the entire screening process for this disorder category;
- Two Public Health Laboratory Scientists (\$35,952, Grade A23, Range G) will be responsible for the daily sample preparation, sample testing, instrument monitoring, maintenance and trouble shooting for the mass spectrometers; all support instrumentation in the LSD laboratory section; and assist the senior scientist in producing accurate and timely testing and reporting for the LSD testing laboratory section.

Standard expense and equipment costs have been requested for all three FTE.

As a result of the proposed legislation, the Department of Health and Senior Services will be required to contract with the four genetic tertiary centers (Cardinal Glennon Medical Center for Children, St. Louis Children's Hospital, University Hospitals and Clinics, and Children's Mercy Hospital) to track and follow-up on newborns who have an abnormal lysosomal storage disorder newborn screen result; provide consultation to health care providers on what confirmatory tests to order and course of medical care; ensure that either the infant has returned for a repeat newborn screen or has had confirmatory testing; ensure that those infants who are confirmed positive are entered into a system of health care; offer medical, nutritional, and genetic counseling to families of affected infants; provide long-term follow-up of identified children in

ASSUMPTION (continued)

their respective genetic center; provide consultation to the department's newborn screening laboratory on appropriate testing methodology; research each of the lysosomal storage disorders; and develop informational material (pamphlets, fact sheets) on these disorders to distribute to parents, health care providers, and the general public.

DHSS currently has contracts with all four genetic tertiary centers to provide follow-up for newborns with many other disorders detected through newborn screening. This is performed through a genetics counselor. The addition of disorders to the newborn screening panel cannot be absorbed by the current contract. The Department estimates that the current contracts will be increased by the following amount:

Genetics Counselor

Salary of a genetics counselor = \$50,000

Fringe benefits at 44.06 percent = \$22,030

Total personnel costs = \$72,030 per genetics counselor (salary and fringe benefits)

\$72,030 per genetics counselor X 4 genetic tertiary centers = \$288,120

Geneticists Consultation fee:

The salary of a geneticist is approximately \$160,000. It is anticipated that 10 percent of their time they provide consultation on state newborn screened disorders, resulting in a cost of \$64,000 (\$160,000 x 10 percent x 4 genetic tertiary centers).

The Department assumes that there will not be any official test results available until FY 2012; therefore follow-up by the genetics counselors will not be needed until then.

The Department will need to revise and reprint the newborn screening pamphlet to include the additional lysosomal storage disorders for which newborns are screened. The estimated cost is \$7,000 (100,000 pamphlets x \$0.07 per pamphlet). The Department assumes that the pamphlets will be updated once more information is received on testing for lysosomal storage disorders; therefore the cost is shown in FY 2011.

Section 191.333.4 of the proposed legislation allows DHSS to increase newborn screening fees in order to cover the additional cost of the expanded newborn screening test required in the legislation. Very few states are currently screening for the types of disorders set forth in the proposed legislation. Based on this information and previous history of expanding newborn screening requirements, the SPHL estimates that it may take up to two years to produce official test results. Funding from General Revenue will be needed the first year for program start-up until the testing can be implemented and additional costs billed for the new testing. Beginning in

ASSUMPTION (continued)

FY 2011, newborn screening fees would be increased by \$8 to cover the cost of testing. Based on the number of newborn screening blood specimens tested in FY 2008, total newborn screening fees for FY 2011 would be approximately \$654,040 (\$8 x 81,755). In FY 2012, newborn screening fees would be increased by an additional \$5 to cover the costs of follow-up provided by the genetic tertiary centers; this would result in newborn screening fees of approximately \$1,062,815 (\$13 x 81,755). These fees are deposited into the Missouri Public Health Services Fund. FY 2011 and FY 2012 costs for the proposed legislation will be covered by the increase in fees.

Oversight was unable to obtain fiscal impact responses from the affected agencies. However, Oversight assumes the costs for the agencies would be beyond the fiscal note period. Oversight assumes that the income, expenses, and transfers would occur in FY 13.

**Oversight** notes that the income and cost to the Missouri Public Health Services Fund (MPHS) are estimates and the underlining goal is to charge a fee increase to cover cost and not realize a savings. **Oversight** also assumes expenses occurring in FY13 would be borrowed from General Revenue Fund and paid back in FY14 and FY15.

<u>FISCAL IMPACT - State Government</u>	FY 2010 (10 Mo.)	FY 2011	FY 2012
	<u>\$0</u>	<u>\$0</u>	<u>\$0</u>

<u>FISCAL IMPACT - Local Government</u>	FY 2010 (10 Mo.)	FY 2011	FY 2012
	<u>\$0</u>	<u>\$0</u>	<u>\$0</u>

FISCAL IMPACT - Small Business

No direct fiscal impact to small businesses would be expected as a result of this proposal.

FISCAL DESCRIPTION

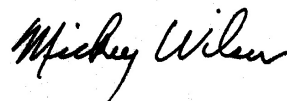
**Section 191.333:**

The proposed legislation establishes the Brady Alan Cunningham Newborn Screening Act which adds Lysosomal Storage Diseases to the list of required newborn screenings starting July 1, 2012.

This legislation is not federally mandated, would not duplicate any other program and would not require additional capital improvements or rental space.

SOURCES OF INFORMATION

Department of Health and Senior Services  
Department of Social Services  
Office of the Secretary of State  
University of Missouri



Mickey Wilson, CPA  
Director  
April 15, 2009