



GOVERNOR'S OFFICE OF
BUDGET AND PROGRAM PLANNING

Fiscal Note 2023 Biennium

Bill # HB0423

Title: Revise laws to provide for additional screening of newborn infants

Primary Sponsor: Lenz, Dennis R

Status: As Amended

- Significant Local Gov Impact
 Needs to be included in HB 2
 Technical Concerns
 Included in the Executive Budget
 Significant Long-Term Impacts
 Dedicated Revenue Form Attached

FISCAL SUMMARY

	<u>FY 2022</u> <u>Difference</u>	<u>FY 2023</u> <u>Difference</u>	<u>FY 2024</u> <u>Difference</u>	<u>FY 2025</u> <u>Difference</u>
Expenditures:				
General Fund	\$1,030,058	\$0	\$0	\$0
State Special Revenue	\$1,436	\$230,635	\$233,551	\$237,059
Federal Special Revenue	\$0	\$0	\$0	\$0
Revenue:				
General Fund	\$0	\$0	\$0	\$0
State Special Revenue	\$0	\$229,449	\$232,347	\$235,837
Federal Special Revenue	\$0	\$0	\$0	\$0
Net Impact-General Fund Balance:	<u>(\$1,030,058)</u>	<u>\$0</u>	<u>\$0</u>	<u>\$0</u>

Description of fiscal impact: As amended, HB 423 results in a cost to establish and support the proposed newborn screening advisory committee for per diem and travel as well as updates and maintenance to associated administrative rules. The amendments increase the committee size from 6 members to 8 members, and require that the committee recommend Krabbe disease testing be added to the newborn screening panel provided for each infant born in Montana, which results in new testing costs for Krabbe disease.

FISCAL ANALYSIS

Assumptions:

- HB 423 requires the committee recommend the addition of Krabbe disease to newborn screening panels in Montana. There are few labs nationally that have the capability to do this screening, therefore the department assumes the screening would be done by the State Public Health Lab (SPHL).

2. The SPHL is not currently equipped to test for Krabbe disease. To include this test, the department assumes the following:
 - a. New 1.0 FTE Clinical Lab Technologist to be trained and run the testing instruments.
 - b. The new FTE and a current lab employee would be required to attend a minimum of a two-week training at CDC in Atlanta or another qualified lab, estimated at \$5,000 each for training and travel costs.
 - c. The SPHL would be required to purchase the Perkin Elmer Q Sight MS/MS Lab Instrument to perform the Krabbe test, at an estimated cost of \$285,000, plus an annual \$28,500 service agreement.
 - d. The SPHL must do validation sample testing with the instrument to ensure accurate test results. This requires a minimum of six months and costs \$273,000 for approximately 1,300 patient samples per month at \$35 per patient sample charged by Perkin Elmer, the instrument manufacturer, for validation. A minimum of six months of test kits for the validation study costs \$49,920.
 - e. The SPHL would be required to purchase the Panthera punch instrument to accommodate the increase in blood spot requirements, adjusting the punch shape and size in order to maximize the quality of the punch and use of the limited sample. The estimated cost of this is \$85,000, plus an annual \$8,500 service agreement.
 - f. To efficiently automate testing with the Q Sight MS/MS instrument and the Panthera punch instrument, the SPHL would be required to purchase the Autodelphia instrument, estimated at \$98,000 with an annual \$9,800 service agreement.
3. The ongoing costs for testing kits would be approximately \$99,840 annually (\$6.40 per test kit per 15,600 infants born in Montana and possible retests), and \$2,000 annually for testing consumables. Test kit and consumable pricing increases approximately 3% annually.

	2022	2023	2024	2025
1.0 FTE Clinical Lab Technologist	80,498	77,754	77,505	77,754
Cost of training for 2 staff (2 weeks to CDC or another lab)	10,000	-	-	-
Q Sight MS/MS Lab Instrument (equipment) required	285,000			
Validation Sample Testing (minimum 6 months with Perkin Elmer)	273,000			
Kits for validation study (minimum 6 months)	49,920			
Annual Q Sight MS/MS service agreement	28,500	28,500	28,500	28,500
Panthera punch instrument (equipment) required	85,000			
Annual Panthera service agreement	8,500	8,500	8,500	8,500
Autodelphia instrument (equipment) to automate testing	98,000			
Annual Autodelphia service agreement	9,800	9,800	9,800	9,800
Annual cost of testing kits	99,840	102,835	105,920	109,098
Annual cost of testing consumables	2,000	2,060	2,122	2,185
Total	1,030,058	229,449	232,347	235,837

4. The addition of Krabbe disease to the newborn screening panel would require the SPHL to increase the Newborn Screening Panel fee to account for the additional costs of Krabbe testing. The SPHL increases the fee to approximately cover costs, at \$15.00 per test for a total of \$229,138 in FY 2022, \$226,394 in FY 2023, \$226,145 in FY 2024, and \$226,394 in FY 2025.

Annual cost for testing	229,138	229,449	232,347	235,837
Cost per patient, increase NBS test cost to offset annual testing cost	14.69	14.71	14.89	15.12

Fiscal Note Request – As Amended

(continued)

5. The department assumes the increased revenues for the NBS panel fee will not be commensurate with expenditures until year two, FY 2023. Therefore, the initial equipment outlay and year one, FY 2022 operating costs would require general fund.
6. To establish the newborn screening advisory committee, operating costs are estimated to include two meetings per year for eight members, resulting in per diem cost of \$30.50 per member, per meeting, for a total of \$488 per year; and mileage of 100 miles per member at \$0.56 cents per mile for a total estimated mileage cost of \$448 per year. These ongoing operating expenditures of \$936 would be funded with 100% state special revenue newborn screening funds.
7. The department estimates ten pages of associated rulemaking in the passage of this bill at \$50 per page for a FY 2022 cost of \$500, with an ongoing cost in following years estimated at five pages of associated rulemaking at \$250 per year for any new testing established by the committee expected to affect rule definitions. Rulemaking expenditures would be funded with 100% state special revenue funds.
8. Ongoing operating costs are inflated by 1.5% per year in FY 2024 and FY 2025.

	<u>FY 2022</u> <u>Difference</u>	<u>FY 2023</u> <u>Difference</u>	<u>FY 2024</u> <u>Difference</u>	<u>FY 2025</u> <u>Difference</u>
<u>Fiscal Impact:</u>				
FTE	1.00	1.00	1.00	1.00
<u>Expenditures:</u>				
Personal Services	\$80,498	\$77,754	\$77,505	\$77,754
Operating Expenses	\$481,560	\$151,695	\$154,842	\$158,083
Equipment	\$468,000	\$0	\$0	\$0
TOTAL Expenditures	<u>\$1,030,058</u>	<u>\$230,635</u>	<u>\$233,551</u>	<u>\$237,059</u>
<u>Funding of Expenditures:</u>				
General Fund (01)	\$1,030,058	\$0	\$0	\$0
State Special Revenue (02)	\$0	\$230,635	\$233,551	\$237,059
Federal Special Revenue (03)	\$0	\$0	\$0	\$0
TOTAL Funding of Exp.	<u>\$1,030,058</u>	<u>\$230,635</u>	<u>\$233,551</u>	<u>\$237,059</u>
<u>Revenues:</u>				
General Fund (01)	\$0	\$0	\$0	\$0
State Special Revenue (02)	\$0	\$229,449	\$232,347	\$235,837
Federal Special Revenue (03)	\$0	\$0	\$0	\$0
TOTAL Revenues	<u>\$0</u>	<u>\$229,449</u>	<u>\$232,347</u>	<u>\$235,837</u>
<u>Net Impact to Fund Balance (Revenue minus Funding of Expenditures):</u>				
General Fund (01)	(\$1,030,058)	\$0	\$0	\$0
State Special Revenue (02)	\$0	(\$1,186)	(\$1,204)	(\$1,222)
Federal Special Revenue (03)	\$0	\$0	\$0	\$0

Technical Notes:

1. An alternative to the SPHL performing the tests would be to send Krabbe tests to an outside lab. This would require that the SPHL purchase the Panthera punch instrument to accommodate the increase in blood spot requirements, estimated cost of \$85,000, plus an annual \$8,500 service agreement. For approximately 15,600 infants born and estimated retests at \$35 per test, plus daily shipping costs, would cost approximately \$562,300 annually. The department assumes the increased revenues for the NBS panel fee will not be commensurate with expenditures until year two, FY 2023. Therefore, the initial equipment outlay and year one, FY 2022 operating costs would require general fund expenditure.

	2022	2023	2024	2025
Alternate-cost to send out tests	546,000	546,000	546,000	546,000
Shipping costs for samples	7,800	7,800	7,800	7,800
Panthera punch instrument (equipment) required	85,000			
Annual Panthera service agreement	8,500	8,500	8,500	8,500
Total	647,300	562,300	562,300	562,300

NOT SIGNED BY SPONSOR

_____ 3/10/21 _____ KA _____ 3/3/21
Sponsor's Initials *Date* *Budget Director's Initials* *Date*