



2020 Supplemental Budget Decision Package

Agency: 303 - Department of Health
Decision Package Code-Title: B6 - Conduct Mandated Newborn Screening
Budget Session: 2020 Supp
Budget Level: Policy Level
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Agency Recommendation Summary

In 2019, the State Board of Health added spinal muscular atrophy to the list of diseases screened through the state's mandatory newborn screening panel. The Washington State Department of Health requests additional spending appropriation and authority to increase the test fee to support the department's Newborn Screening Laboratory to conduct this new, required blood sample testing for this heritable condition.

Fiscal Summary

Dollars in Thousands

Operating Expenditures	FY 2020	FY 2021	FY 2022	FY 2023
Fund 001 - 1	\$6	\$0	\$0	\$0
Fund 001 - 7	\$0	\$360	\$357	\$361
Total Expenditures	\$6	\$360	\$357	\$361
Biennial Totals		\$366		\$718
Staffing	FY 2020	FY 2021	FY 2022	FY 2023
FTEs	0.0	2.3	2.3	2.3
Average Annual		1.2		2.3
Object of Expenditure	FY 2020	FY 2021	FY 2022	FY 2023
Obj. A	\$3	\$172	\$172	\$172
Obj. B	\$1	\$62	\$62	\$62
Obj. C	\$0	\$20	\$20	\$20
Obj. E	\$2	\$86	\$88	\$92
Obj. J	\$0	\$5	\$0	\$0
Obj. T	\$0	\$15	\$15	\$15

Revenue	FY 2020	FY 2021	FY 2022	FY 2023
001 - 0597	\$0	\$360	\$357	\$361
Total	\$0	\$360	\$357	\$361
Biennial Totals		\$360		\$718

Package Description

Approximately 83,000 babies are born in Washington State each year. The Newborn Screening Laboratory tests blood samples from each of these babies for heritable conditions. This provides an opportunity for medical intervention prior to the babies becoming sick, thereby preventing permanent disability and death. The Newborn Screening Program significantly contributes to the Department of Health's (DOH) mission to protect and improve the health of people in Washington State.

In 2019, the Washington State Board of Health (SBOH) filed a CR-101 Preproposal Statement of Inquiry to change Washington Administrative Code (WAC) to add spinal muscular atrophy (SMA) to the mandatory newborn screening panel. However, DOH needs additional expenditure and fee authority to perform the screening.

Spinal muscular atrophy is a genetic disease that results in the progressive degradation of the nerve cells in the spinal cord. SMA affects about one in 10,000 babies. Early identification provides the opportunity for life-saving treatment which enables babies with SMA to reach many of the regular motor development milestones. Approximately 55 percent of babies with SMA have the most severe form of the disease, which presents with muscle weakness and respiratory insufficiency; without treatment these infants will die within two years of birth. Another 35 percent of babies with SMA have a less severe form impacting their motor development; without treatment these infants will never stand or walk. The remaining 10 percent of babies with SMA have a mild and late-onset form presenting with muscle weakness in adulthood.

RCW 70.83.050 provides authority to the SBOH to determine the conditions to be tested in the Washington State newborn screening panel. Currently, there are 29 tested conditions^[1]. The SBOH convened a technical advisory committee in April 2019. The committee is comprised of stakeholders representing public health, patient care, health plans, advocacy organizations, and family members impacted by these conditions. They evaluated SMA using the SBOH's established criteria of available screening, available diagnostic testing and treatment, prevention potential and medical rationale, public health rationale, and evaluation of cost-benefit. The committee unanimously recommended adding SMA to the newborn screening panel. In June 2019 the SBOH voted to initiate rule-making to add SMA to the mandatory newborn screening panel. This new test requires additional personnel and additional equipment capacity. The existing newborn screening fee will not provide sufficient revenue to add SMA to laboratory and follow-up operations; a fee increase is required to implement testing, which is scheduled to start on or before October 2021. The additional fee will be added to the existing fee and will be ongoing as long as SMA is included on the newborn screening panel. Early identification and treatment of affected infants supports Goal 2, Objective 1 of the Agency's Strategic Plan to give all babies a planned, healthy start in life.

The newborn screening fee is charged to hospitals and is ultimately passed on to consumers or their insurance carriers. For out-of-hospital births, the fee is charged to the parents' insurance company or paid out-of-pocket. The newborn screening fee is generally paid by insurance (private, Medicaid, etc.). The one-time fee covers the first and all subsequent tests (i.e. the fee is per newborn, not per test).

[1] Historical note: During the 2019 legislative session, the newborn screening fee was increased by \$10.50 per baby to add two lysosomal storage diseases: Pompe disease and MPS-I. The department anticipates starting universal newborn screening for these conditions before the end of 2019.

Assumptions and Calculations

Expansion or alteration of a current program or service:

During the 2015-2017 biennium, the total expenses of the Newborn Screening General Fund – Local account was \$12,307,206. Total revenue during this period was \$13,280,975.

Through fiscal month 22 of the 2017-2019 biennium, the total expenses of the Newborn Screening General Fund – Local account is \$13,289,348. Total revenue during this period was \$13,612,739. The projected total expenses at the end of the biennium for the General Fund–Local account is \$14,711,561. The projected total revenue during this period is \$14,775,035.

Detailed assumptions and calculations:

DOH requests a fee increase to screen for spinal muscular atrophy. This proposal will increase the newborn screening fee by \$4.30 from \$94.70 to \$99.00 per baby screened.

The anticipated implementation date to begin screening infants for SMA is July 1, 2020. Depending on the timing of legislative approval and length of time required for the rule-making process, DOH may need additional time to implement within the third quarter of calendar year 2020.

Using the past year as an estimate, the anticipated number of infants screened is expected to be approximately 83,000 babies. The estimated additional annual revenue needed for fiscal year 2021 and beyond is \$356,900 (83,000 babies x \$4.30 per baby). This revenue estimate is ongoing but will fluctuate each year based on the number of births.

Expenditures:

Starting fiscal year 2021, the Newborn Screening Laboratory will begin screening for SMA. The standard laboratory work, including specimen processing and testing, will be part of the existing work flow, and will be performed by existing staff. This will require 0.5 FTE Chemist 3 to oversee the laboratory testing, review findings and report final results for all specimens (about 175,000 specimens per year or about 560 per day). This position is responsible for writing technical procedures and monthly quality control reports, instrument maintenance and troubleshooting any instrument or assay performance issues. Additionally, a 1.0 FTE Epidemiologist 1 (Epi 1) will be needed to manage the case work of all out-of-range SMA screening results and assure proper medical care is taken for each baby to prevent death and disability. Because some screen-positive babies for SMA have an uncertain prognosis, the follow-up position will also establish a long-term follow-up program to track outcomes over time and ensure patients receive appropriate long-

term care and support. The Epi 1 position is also responsible for educating primary care providers and the general public about SMA and performing epidemiological surveillance work to monitor screen positive results and disease trends over time.

There will be additional costs for expendable testing supplies and materials of about \$77,000 per year. Additionally, \$20,000 per year will be needed for clinical specialist contracts for referrals.

One time costs in fiscal year 2020 will be required for the SBOH to update newborn screening rules to include SMA. SBOH will require \$6,000 to complete rules, including development and stakeholder outreach. Cost for one day of Attorney General time is included.

In addition, estimated total expenditures include 0.8 FTE during fiscal year 2021 and 0.8 FTE in fiscal year 2022 to assist with increased division and agency workload.

Fiscal year 2020 - \$6,000, Fiscal year 2021 – 2.3 FTE, \$360,000; Fiscal year 2022, 2.3 FTE and \$357,000; Fiscal year 2023, 2.3 FTE and \$361,000.

Workforce Assumptions:

See financial calculator (FNCAL)

Strategic and Performance Outcomes

Strategic framework:

Early identification and treatment of affected infants supports Goal 2, Objective 1 of the Agency's Strategic Plan to give all babies a planned, healthy start in life. Early identification and treatment of SMA prevents death and disability of affected newborns.

This proposal would add additional fee based revenue and expenses to Newborn Screening – Local fund source (Master Index 16101716). Additional revenue will be \$4.30 per baby born in Washington State. Additional expenses for the cost of testing would include staff time, supplies, and equipment maintenance.

Performance outcomes:

For a relatively small investment in screening costs, the department anticipates babies with SMA will be saved from death and permanent disability. SMA is a deadly genetic disorder that affects 1 in 10,000 babies. Early diagnosis of SMA is the key to preventing death and permanent disability.

Other Collateral Connections

Intergovernmental:

The SBOH conducted a public vote on June 12, 2019 and recommended adding SMA to the mandatory screening panel. Prior to this meeting, the ad hoc Newborn Screening Advisory Committee held one public meeting and conducted a closed ballot vote, unanimously recommending adding SMA to the mandatory screening panel. The Washington State Health Care Authority pays for approximately half of the births in Washington State through the Medicaid program and had one representative serving on the advisory committee during the formal review.

Stakeholder response:

Neurologists – Unknown; closed ballot voting

March of Dimes Foundation - Unknown; closed ballot voting

Save Babies Through Screening Foundation - Unknown; closed ballot voting

Midwives - Unknown; closed ballot voting

Naturopathic physicians - Unknown; closed ballot voting

Insurance companies - Unknown; closed ballot voting

American Indian Health Commission - Unknown; closed ballot voting

Commission on Hispanic Affairs - Unknown; closed ballot voting

Community members - Unknown; closed ballot voting

WA State Hospital Association – unable to attend

Legal or administrative mandates:

The SBOH has statutory authority from RCW 70.83.050 to “adopt rules and regulations necessary to carry out the intent of [the newborn screening] chapter” of the state law. The Board held a public meeting on June 12, 2019 to consider the recommendations from the Washington State Newborn Screening Advisory Committee to add SMA. The Board heard a report about the advisory committee’s findings, held a discussion about the proposed additions and voted unanimously to include SMA to the mandatory newborn screening panel in Washington State.

Chapter 246-650 WAC specifies the conditions that all newborns must be tested for in Washington. The Board will need to file a CR-101 Preproposal Statement of Inquiry for Chapter 246-650 WAC, Newborn Screening, next. The CR-101 announces to the public the Board is considering adding spinal muscular atrophy (SMA) to the list of mandatory conditions for newborn screening conducted by the Department.

In order to add SMA to the newborn screening panel, DOH needs the authority to increase to the newborn screening fee. This fee is collected for every infant and covers laboratory testing, follow-up services, and support for specialty care clinics that provide treatment for children diagnosed with rare conditions identified through screening.

Changes from current law:

This request does not require any changes to statutes or rules.

State workforce impacts:

This request does not impact existing collective bargaining.

State facilities impacts:

This request does not impact facilities and workplace needs.

Puget Sound recovery:

This request is not related to Puget Sound recovery efforts.

Reference Documents

- PL B6 Conduct Mandated Newborn Screening-FNCAL.xlsm

IT Addendum

Does this Decision Package include funding for any IT-related costs, including hardware, software, (including cloud-based services), contracts or IT staff?

No