2019-21 Biennium Budget
Decision Package

Agency: 303 - Department of Health
Decision Package Code-Title: 2A - Conduct Mandated Newborn Screening
Budget Session: 2019-21 Regular
Budget Level: Policy Level
Contact Info: Ryan Black
(360) 236-4530
ryan.black@doh.wa.gov

Agency Recommendation Summary

In 2017, the State Board of Health initiated administrative rules to add Pompe disease and MPS-I to the mandatory newborn screening panel. When these rules are adopted, the Department of Health is required to begin testing for both of these heritable conditions. Additional expenditure authority and a fee increases is necessary for the Department of Health's Newborn Screening Laboratory to conduct the required blood sample testing.

Fiscal Summary

Dollars in Thousands

Operating Expenditures	**FY 2020**	**FY 2021**	**FY 2022**	**FY 2023**
Fund 001 - 7	$701	$905	$905	$905
Total Expenditures	**$701**	**$905**	**$905**	**$905**
Biennial Totals		**$1,606**		**$1,810**
Staffing	**FY 2020**	**FY 2021**	**FY 2022**	**FY 2023**
FTEs	2.6	3.6	3.6	3.6
Average Annual		**3.1**		**3.6**
Object of Expenditure	**FY 2020**	**FY 2021**	**FY 2022**	**FY 2023**
Obj. A	$158	$209	$209	$209
Obj. B	$55	$73	$73	$73
Obj. C	$30	$40	$40	$40
Obj. E	$374	$500	$500	$500
Obj. J	$74	$70	$70	$70

Object of Expenditure	FY 2020	FY 2021	FY 2022	FY 2023
Obj. T	$10	$13	$13	$13

Revenue	FY 2020	FY 2021	FY 2022	FY 2023
001 - 0597	$685	$914	$914	$914
Total	**$685**	**$914**	**$914**	**$914**
Biennial Totals		**$1,599**		**$1,828**

Package Description

Approximately 87,000 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 mission to protect and improve the health of people in Washington State.

The Department of Health (DOH) requests a fee increase to concurrently add Pompe disease and MPS-I to the mandatory newborn screening panel.

Infantile Pompe disease is a deadly genetic disease that affects 1 in 89,000 babies. This neuromuscular disorder causes accumulation of glycogen within the cellular lysosomes, resulting in progressive muscle weakness and cardiac problems. Early diagnosis of infantile Pompe disease through newborn screening improves survival, as well as cardiac and gross motor function. Without early treatment, infants with Pompe disease have a greater likelihood of passing away early in life, and becoming wheelchair and/or ventilator-dependent. There is also a later-onset form of Pompe that manifests after infancy, typically in adulthood with milder symptoms.

MPS-I is a genetic disease that affects 1 in 50,000 babies. This multi-system disorder causes mucopolysaccharides (complex sugars) to accumulate within the cellular lysosomes, resulting in progressive skeletal disease and cognitive decline. Early diagnosis of MPS-I through newborn screening improves cognitive outcomes and may attenuate orthopedic and other manifestations. Without early treatment, infants with MPS-I have a greater likelihood of experiencing severe intellectual disability due to advanced neurologic disease. There is a later-onset form of MPS-I that manifests in late childhood with milder symptoms.

Per RCW 70.83.050 The Washington State Board of Health (SBOH) determines the conditions to be tested in the Washington State newborn screening panel. There are currently 29 conditions[1]. The SBOH voted in

August 2017 to add two news conditions, Pompe disease and MPS-I, to the mandatory newborn screening panel. These new tests will require additional personnel, additional space, and additional equipment capacity. The existing newborn screening fee will not provide sufficient funds to add Pompe disease and MPS-I to laboratory operations; a fee increase is required to implement testing, which is scheduled to start on or before October 2019. The additional fee will be added to the existing fee and will be ongoing as long as Pompe and MPS-I are 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 2017 legislative session, the newborn screening fee was increased by $8.10 per baby to add a different, life-threatening condition called X-linked adrenoleukodystrophy (X-ALD). The department started universal newborn screening for X-ALD in March 2018.

Assumptions and Calculations

Expansion or alteration of a current program or service:
During the 2015-17 biennium, the total expenses of the Newborn Screening General Fund – Local account (MI 16101716) was $12,307,206. Total revenue during this period was $13,280,975.

Through FM 11 of the 2017-19 biennium, the total expenses of the Newborn Screening General Fund – Local account is $6,282,836. Total revenue during this period was is $7,051,268

Detailed assumptions and calculations:
Revenue:

The Newborn Screening Program tests infants born in Washington for 29 disorders. The Department of Health (DOH) requests a fee increase to add Pompe disease and mucopolysaccharidosis type I (MPS-I) to the mandatory newborn screening panel.This proposal will increase the newborn screening fee by $10.50 from $84.20 to $94.70 per baby screened.

The anticipated implementation date to begin screening infants for Pompe disease and MPS-I will be the third quarter of calendar year 2019.

Using the past year as an estimate, the anticipated number of infants screened is expected to be approximately 87,000 babies born. The estimated revenue for 2019-2020= 87,000 x $10.50 at 9 months = $685,125. Estimated ongoing revenue is $913,500 per year. This revenue estimate is ongoing but will fluctuate each year based on the number of births.

Expenditures:

Starting in September 2019 and ongoing, the Newborn Screening Laboratory will begin screening for Pompe disease and MPS-I.This will require 1.0 FTE Chemist 2 to perform the daily laboratory analyses for about 175,000 specimens per year or about 560 per day. The testing time is expected to take six hours each day, the remaining time is used to receive and process specimens in the mornings. A 0.2 FTE Chemist 3 will be needed to review the laboratory testing and release and report final results for all specimens.This position is also responsible for instrument maintenance and will troubleshoot any instrument or assay performance issues. A 0.4 FTE Health Services Consultant 3 will be responsible for reviewing all results and coordinating follow-up and referral activities for those infants who screen positive to assure prompt diagnostic and treatment services.Because some screen-positive babies for Pompe disease and MPS-I have an uncertain prognosis, the follow-up position will also establish a long-term follow-up program to track outcomes over time and ensure that patients receive appropriate long-term care and support.The HSC 3 position is also responsible for educating primary care providers and the general public about Pompe disease and MPS-I 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 $407,000 per year. There will also be a cost to purchase one mass spectrometer (including equipment maintenance) of about $70,000 per year through a five year lease purchase with the State Treasurer's Office. Equipment maintenance will be about $54,000 per year. Additionally, $40,000 per year will be needed for clinical specialist contracts for referrals.

In addition, estimated total expenditures include 1.4 FTE during FY20 and 2.0 FTE in FY21 to assist with increased division and agency workload.

FY 2020 – 2.6 FTE, $701,000 and FY 2021 and ongoing, 3.6 FTE and $905,000.

Workforce Assumptions:
See attached 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 Pompe disease and MPS-I prevents death and disability of affected newborns.

This proposal would add additional fee based revenue and expenses to Newborn Screening. Additional revenue will be $10.50 per baby born in WA 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 that babies with Pompe disease and MPS-I will be saved from death and permanent disability. Pompe disease is a deadly genetic condition that affects 1:89,000 births. Early diagnosis of Pompe disease is the key to saving lives because without treatment, babies with the severe form of Pompe disease die within the first two years. MPS-I is a severe genetic condition that affects 1:50,000 births.Early diagnosis of the severe form of MPS-I is the key to preventing irreversible neurocognitive damage by treating early.

Other Collateral Connections

Intergovernmental:
The WA State Board of Health conducted a public vote on August 9, 2017 and recommended adding Pompe and MPS-1 to the mandatory screening panel. Prior to this meeting, the ad hoc Newborn Screening Advisory Committee held two public meetings and conducted a closed ballot vote, ultimately recommending adding both conditions to the mandatory screening panel. The Health Care Authority pays for approximately half of the births in Washington State through the Medicaid program and had two representatives serving on the advisory committee during the formal review of these two candidate conditions.

Stakeholder response:
WA State Hospital Association – Unknown; closed ballot voting

Biochemical geneticists – Unknown; closed ballot voting

WA State Nurses Association - 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

Insurance companies - Unknown; closed ballot voting

Bioethicists – Unknown; closed ballot voting

Community members - Unknown; closed ballot voting

Legal or administrative mandates:
The State Board of Health 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 August 9, 2017 to consider the recommendations from the Washington State Newborn Screening Advisory Committee to add both Pompe disease and MPS-I. The Board heard a report about the advisory committee's findings, held a discussion about the proposed additions and voted unanimously to include both conditions to the mandatory newborn screening panel in Washington State.

Chapter 246-650 WAC specifies the conditions all newborns must be tested for in Washington. The Board filed aCR-101 Pre proposal Statement of Inquiry for Chapter 246-650 WAC, Newborn Screening, on October 31, 2017. The CR-101 announces to the public that the Board is considering adding Pompe disease and Mucopolysaccharidosis type I (MPSI) to the list of mandatory conditions for newborn screening conducted by the Department of Health (Department); creating a new section outlining critical congenital heart disease screening requirements for hospitals and health care providers attending a birth outside of a hospital to align with RCW 70.83.090;updating language concerning the use and release of dried blood spots to align with the federal Newborn Screening Saves Lives Reauthorization Act of 2014; and improving clarity and usability of the rules.

In order to add Pompe and MPS Ito the newborn screening panel, the legislature must give the Department 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. The legislature did not approve the fee increase during the 2018 legislative session and therefore this rule making is delayed until the funding is approved.

Changes from current law:
N/A

State workforce impacts:
N/A

State facilities impacts:
N/A

Puget Sound recovery:
N/A

Agency Questions

Did you include cost models and backup assumptions?
See attached documents.

Reference Documents

- Conduct Mandated NBS - Pompe & MPS-1 Fee_Adjustment_4_year_Cycle.xlsx

- Conduct Mandated NBS - Revenue Calculation.xlsx
- Conduct Mandated Newborn Screening- FNCal -090418.xlsm
- MPSI overview for advisory committee.pdf
- Pompe overview for advisory committee.pdf

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