

## 2017-19 Biennium Budget Decision Package

**FINAL**

**Agency:** 303 Department of Health

**Decision Package Code/Title:** NC Expand Newborn Screening Panel

**Budget Period:** 2017-19

**Budget Level:** PL-Performance Level

**Agency Recommendation Summary Text:** In 2017, the State Board of Health added Pompe disease and MPS-I to the mandatory newborn screening panel. 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 for both of these heritable conditions.

**Fiscal Summary:** Decision package total dollar and FTE cost/savings by year, by fund, for 4 years. Additional fiscal details are required below.

Operating Expenditures	FY 2018	FY 2019	FY 2020	FY 2021
Fund 001-7	0	683,000	843,000	843,000
<b>Total Cost</b>	<b>0</b>	<b>683,000</b>	<b>843,000</b>	<b>843,000</b>
Staffing	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>
FTEs	0.0	2.5	3.2	3.2
<b>Revenue</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>
Fund 001-7	0	634,500	846,000	846,000
<b>Object of Expenditure</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>
A - Salaries and Wages	0	139,000	181,000	181,000
B - Employee Benefits	0	48,000	63,000	63,000
C - Personal Service Contracts	0	40,000	40,000	40,000
E - Goods and Services	0	379,000	486,000	486,000
G - Travel	0	0	0	0
J - Capital Outlays	0	74,000	70,000	70,000
N - Grants, Benefits & Client Svc	0	0	0	0
T- Intra-Agency Reimbursements	0	3,000	3,000	3,000

## Package Description

Approximately 90,000 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.

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 28 conditions<sup>1</sup>. The SBOH voted in August 2017 to add two new 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 during the third quarter of 2018. An 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 Department of Health (DOH) requests a fee increase and corresponding expenditure authority to begin mandatory testing for Pompe disease and MPS-I.

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.

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<sup>1</sup> 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 is preparing to begin universal newborn screening for X-ALD during the first quarter of 2018. This will bring the number of conditions on the mandatory panel to 29.

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).

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**Base Budget: If the proposal is an expansion or alteration of a current program or service, provide information on the resources now devoted to the program or service.** Please include annual expenditures and FTEs by fund and activity (or provide working models or backup materials containing this information).

The current base budget for the Newborn Screening Program consists of 30 FTE and \$7,701,000 per fiscal year from General Fund Local, Activity A011. These funds are used to test babies born in Washington to detect and prevent the developmental impairments and life-threatening illness associated with congenital disorders that are specified by the State Board of Health. The program provides appropriate follow-up and referral of those infants who screen positive to assure prompt diagnostic and treatment services. In addition, NBS provides long-term tracking of affected children to assure continued access to appropriate comprehensive health care.

**Decision Package expenditure, FTE and revenue assumptions, calculations and details:** Agencies must clearly articulate the workload or policy assumptions used in calculating expenditure and revenue changes proposed.

Revenue:

As of September 2016, the Newborn Screening Program tests infants born in Washington for 28 disorders and collects \$76.10 per baby screened. In 2017, the legislature approved increasing the fee by \$8.10 per baby to implement newborn screening for X-linked adrenoleukodystrophy, which is anticipated to start during the first quarter of 2018. This proposal will increase the newborn screening fee by \$9.40 from \$84.20 to \$93.60 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 2018.

Using a formula based on OFM's November 2015 Components of Population Change: 2000 – 2040, the anticipated number of infants screened is expected to be about 90,000 babies born. The estimated revenue for 2018-2019 = 90,000 x \$9.40 at 9 months = \$634,500. Estimated ongoing revenue is \$846,000 per year. This revenue estimate is ongoing but will fluctuate each year based on the number of births.

Expenditures:

Starting in September 2018 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 550 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 0.2 FTE Health Services Consultant 2 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 2 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 \$405,000 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 1.0 FTE to assist with increased division and agency workload.

FY 2019 – 2.8 FTE, \$683,000 and FY 2020 and ongoing, 3.2 FTE and \$843,000.

## **Decision Package Justification and Impacts**

### **What specific performance outcomes does the agency expect?**

Describe and quantify the specific performance outcomes the agency expects as a result of this funding change. ([results washington link](#))

The fee increase will allow the newborn screening laboratory to test all babies for Pompe disease and MPS-I. It will also allow for follow-up staff to ensure appropriate clinical response for babies with abnormal or unsuitable results (Results Washington goal area: Healthy and Safe Communities). Both Pompe disease and MPS-I are conditions that can cause early death or lifelong disability if not detected and treated prior to the manifestation of symptoms. Babies with these conditions need diagnostic and clinical services provided by cardiologists, neurologists and biochemical geneticists. All babies born in Washington State have access to specialty care providers through Seattle Children's Hospital. These providers operate a satellite clinic in Spokane to serve patients on the eastern side of Washington. It is estimated that the screening program will help diagnose 1 baby with infantile Pompe disease and 0.4 babies with MPS-I each year, saving one baby with infantile Pompe disease from dying every 4.5 years.

### **Performance Measure detail:**

**N/A**

**Fully describe and quantify expected impacts on state residents and specific populations served:**

Babies born in Washington State and their families will be impacted by this decision package. Only 34 percent of babies with Pompe disease and 19 percent of babies with MPS-I have a positive family history of the condition. Because newborn screening is mandatory per state law (RCW 70.83), it will provide an opportunity for early identification for all babies with these conditions.

**What are other important connections or impacts related to this proposal?** Please complete the following table and provide detailed explanations or information below:

Impact(s) To:		Identify / Explanation
Regional/County impacts?	No	Identify:
Other local gov't impacts?	No	Identify:
Tribal gov't impacts?	No	Identify:
Other state agency impacts?	Yes	<b>Identify:</b> Medicaid pays the newborn screening fee for approximately half of the babies born in Washington State. The staff at the Health Care Authority are aware of the planned increase in fee for Pompe disease and MPS-I screening. Our point of contact at HCA is Jean Bui.
Responds to specific task force, report, mandate or exec order?	Yes	<b>Identify:</b> The State Board of Health considered recommendations from the Newborn Screening Advisory Committee to add Pompe disease and MPS-I to the mandatory newborn screening panel. The State Board of Health voted to accept this recommendation in August 2017.
Does request contain a compensation change?	No	Identify:
Does request require a change to a collective bargaining agreement?	No	Identify:
Facility/workplace needs or impacts?	Yes	<b>Identify:</b> The Newborn Screening Program will need to modify the existing laboratory space to prepare for routine testing of all newborns for Pompe disease and MPS-I.
Capital Budget Impacts?	No	Identify:
Is change required to existing statutes, rules or contracts?	Yes	<b>Identify:</b> The State Board of Health will be responsible for changes to the newborn screening rule (WAC 246.650). The statute does not require modification. Current specialty care physician consulting contracts with Seattle Children's Hospital will need to be modified to account for their technical support for Pompe disease and MPS-I diagnoses.
Is the request related to or a result	No	<b>Identify lawsuit (please consult with Attorney General's</b>

of litigation?		Office):
Is the request related to Puget Sound recovery?	No	If yes, see budget instructions Section 14.4 for additional instructions
Identify other important connections		The Newborn Screening Program will work with stakeholders (WSHA and the midwifery community) and the Health Care Authority to facilitate a smooth transition when screening for Pompe disease and MPS-I begins.

**Please provide a detailed discussion of connections/impacts identified above.**

The State Board of Health has statutory authority to decide what conditions are on the mandatory newborn screening panel. In August 2017, the Board approved adding Pompe disease and MPS-I to the mandatory newborn screening panel. The cost for adding screening for these two conditions cannot be absorbed by the current newborn screening fee.

The Newborn Screening Program works closely with its stakeholders to ensure quality services are available to all babies born in Washington State. The Washington State Hospital Association and the Midwifery Associations in Washington are important partners in adding new tests to the mandatory panel and paying the increased fee for testing. The Health Care Authority is a partner agency directly impacted by a change in the newborn screening fee because Medicaid pays for approximately half of all of babies born in Washington State. The Newborn Screening Fee Advisory Committee includes members from these stakeholders and from insurance companies and works with the Department to plan for implementing fee adjustments.

**What alternatives were explored by the agency and why was this option chosen?**

The alternative would be to not implement screening for Pompe disease and MPS-I per the State Board of Health requirements. This option puts the department at risk of not following WAC and also in the untenable position of explaining to advocacy groups why the department decided not to test their children contrary to Board of Health requirements. Although there would be no need to raise the fee for this option, there may be liability if a baby were to die from the (undetected) condition.

**What are the consequences of not funding this request?**

About 28 percent of babies with Pompe disease are at risk of life-threatening cardiac arrest absent early diagnosis. The remaining patients with Pompe disease will develop a less-severe form of the disease, manifesting after infancy. Approximately 71 percent of babies with MPS-I are at risk of severe brain damage absent early diagnosis. The remaining patients with MPS-I will develop a less-severe form of the disease, manifesting in late childhood.

If this request is not funded, babies with Pompe disease may die who would otherwise be saved through early diagnosis and medical intervention. Babies with MPS-I may have permanent and severe intellectual disabilities who would otherwise have had a normal Intelligence Quotient through early diagnosis and medical intervention.

**How has or can the agency address the issue or need in its current appropriation level?**

The newborn screening program operates on fee-for-service. Without additional appropriation authority, the department cannot spend the additional fee revenue proposed in this decision package.

**Other supporting materials:** Please attach or reference any other supporting materials or information that will help analysts and policymakers understand and prioritize your request.

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

No 

Yes Continue to IT Addendum below and follow the directions on the bottom of the addendum to meet requirements for OCIO review.)