

2017-19 Biennium Budget Decision Package

FINAL

Agency: 303 Department of Health

Decision Package Code/Title: D1 Increase Newborn Screening Fee

Budget Period: 2017-19

Budget Level: PL-Performance Level

Agency Recommendation Summary Text:

The Department of Health requests a fee increase to add X-linked adrenoleukodystrophy (X-ALD) to the mandatory newborn screening panel. X-ALD, is a deadly genetic disease that affects 1 in 18 000 boys. Early diagnosis of X-ALD, through newborn screening is the key to saving lives, without treatment; most boys with the severe form of X-ALD will die before the age ten.

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	900,000	980,000	980,000	980,000
Total Cost	900,000	980,000	980,000	980,000
Staffing	FY 2018	FY 2019	FY 2020	FY 2021
FTEs	4.0	4.9	4.9	4.9
Revenue	FY 2018	FY 2019	FY 2020	FY 2021
Fund 001-7	686,000	922,000	922,000	922,000
Object of Expenditure	FY 2018	FY 2019	FY 2020	FY 2021
A - Salaries and Wages	228,000	285,000	285,000	285,000
B - Employee Benefits	80,000	100,000	100,000	100,000
C - Personal Service Contracts	40,000	40,000	40,000	40,000
E - Goods and Services	383,000	391,000	391,000	391,000
J - Capital Outlays	164,000	158,000	158,000	158,000
T - Intra-Agency Reimb	5,000	6,000	6,000	6,000

Package Description

More than 89,000 babies are born in the 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 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 add X-linked adrenoleukodystrophy (X-ALD) to the mandatory newborn screening panel. X-ALD, is a deadly genetic disease that affects 1 in 18,000 boys. This brain disorder destroys myelin, the protective sheath that surrounds the brain's neurons -- the nerve cells that allow us to think and to control our muscles. Early diagnosis of X-ALD, through newborn screening is the key to saving lives, without treatment; most boys with the severe form of X-ALD will die before the age ten.

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. The SBOH voted in January, 2016, to add a new condition, X-linked adrenoleukodystrophy (X-ALD), to the mandatory newborn screening panel. This will be a new test that does not fit into the existing testing platforms used by the laboratory. As such it will require additional personnel, additional space, and new equipment. The existing newborn screening fee will not provide sufficient funds to add X-ALD to laboratory operations; a fee increase is required to implement testing, which is scheduled to start during the fourth quarter of 2017. The additional fee will be added to the existing fee and will be ongoing as long as X-ALD is included on the newborn screening panel.

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 27.0 FTE and \$5.6 million direct dollar and 15.8 FTE and \$1.2 million to assist with increased division and agency workload 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.

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 twenty-eight disorders and collects \$76.10 per baby screened. The proposal will increase the newborn screening fee by \$10.00 from \$76.10 to \$86.10 per baby screened.

The anticipated implementation date to begin screening infants for X-ALD will be the fourth quarter of 2017 (October 1, 2017).

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 is Number of births x \$10.00. Estimated number of births for 2017-2018 = 91,484 x \$10.00 at 9 months = \$686,130. Estimated number of births for 2018-2019 = 92,248 x \$10.00 = \$922,480

The estimated 2017-19 biennium revenue total is estimated to be \$1,608,610. This revenue estimate will increase every year ongoing but will fluctuate each year based on the number of births.

Expenditures:

Starting in September of Fiscal Year (FY) 2018 and ongoing, the Newborn Screening Laboratory will begin screening for X-ALD.

- This will require 1.0 FTE Chemist 2 to perform the daily laboratory analyses for X-ALD 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.
- 1.0 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.
- 1.0 FTE Health Services Consultant 2 (HSC2) 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 babies diagnosed with X-ALD 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 HSC2 position is also responsible for educating primary care providers and the general public about X-ALD 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 \$200,000 per year. There will also be a cost to purchase two mass spectrometers of about \$157,500 per year through a five year lease purchase with the State Treasurer's Office. Equipment maintenance will be about \$112,500 per year. Additionally, \$40,000 per year will be needed for clinical specialist contracts for referrals; one each on retainer in eastern and western WA to provide clinical expertise on a particular disorder and treatment plan.

In addition, estimated total expenditures include 1.7 FTE to assist with increased division and agency workload.

FY 2018 – 4.0 FTE, \$900,000 and FY 2019 and ongoing, 4.9 FTE and \$980,000.

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.

The fee increase will allow the newborn screening laboratory to test all babies for X-ALD and for follow-up staff to ensure appropriate clinical response for babies with abnormal or unsuitable results (Results Washington goal area: Healthy and Safe Communities). X-ALD is a condition that can cause early death or lifelong disability if not detected and treated prior to the manifestation of symptoms. Babies with X-ALD need diagnostic and clinical services provided by endocrinologists, neurologists and biochemical geneticists; all babies born in Washington State have access to specialty care providers through Seattle Children’s Hospital. It is estimated that the screening program will help diagnose three babies with X-ALD each year and save one baby from dying every three years.

Performance Measure detail:

Is this DP essential to implement a strategy identified in the agency’s strategic plan?

Goal 2: Ensure all children in Washington achieve their highest health potential

Objective 1: Give all babies a planned, healthy start in life

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. It is estimated that only 23 percent of babies with X-ALD have a positive family history of this condition. Because newborn screening is mandatory per state law (RCW 70.83), it will provide an opportunity for early identification for all babies with X-ALD.

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	Identify: 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 X-ALD screening.
Responds to specific task force, report, mandate or exec order?	Yes	Identify: The State Board of Health considered recommendations from the Newborn Screening Advisory Committee to add X-ALD to the mandatory newborn screening panel. The State Board of Health voted to accept

		this recommendation in January of 2016.
Does request contain a compensation change?	Yes	Identify:
Does request require a change to a collective bargaining agreement?	No	Identify:
Facility/workplace needs or impacts?	Yes	Identify: The Newborn Screening Program will need to modify the existing laboratory space to prepare for routine testing of all newborns for X-ALD.
Capital Budget Impacts?	No	Identify: A capital budget project is already underway for newborn screening laboratory expansion – there will be no additional impacts to the ongoing project from this decision package (assuming capital budget funding is re-appropriated).
Is change required to existing statutes, rules or contracts?	Yes	Identify: 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 X-ALD diagnosis.
Is the request related to or a result of litigation?	No	Identify lawsuit (please consult with Attorney General’s 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 X-ALD 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 January 2016, the Board accepted the recommendation from the multidisciplinary Newborn Screening Advisory Committee to add X-ALD. The cost for adding screening for X-ALD 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 X-ALD 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 80 percent of babies with X-ALD develop adrenal insufficiency within the first two years of life and are at risk of a life-threatening adrenal crisis absent early diagnosis. Before ten years of age, about 35 percent of boys with X-ALD will develop the most severe form of the disease that causes irreversible brain damage and potentially death. The remaining patients with X-ALD will develop a less-severe form of the disease, manifesting in adulthood. If this request is not funded, babies with X-ALD may die that would otherwise be saved 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.)