



Agency Recommendation Summary

The Department of Health requests a proposed fee increase that will 1) reduce inequities in specimen transit time, reducing the time to diagnosis for babies with newborn screening conditions, 2) add a new condition mandated by the State Board of Health, 3) reduce missed cases and improve time to diagnosis for cystic fibrosis through expanded DNA testing, and 4) expand electronic NBS test ordering and results reporting capacity. Babies born in Washington State benefit from newborn screening to detect 32 congenital disorders that can cause death or permanent disability.

Fiscal Summary

Fiscal Summary <i>Dollars in Thousands</i>	Fiscal Years		Biennial	Fiscal Years		Biennial
	2024	2025	2023-25	2026	2027	2025-27
Staffing						
FTEs	5.2	5.2	5.2	5.3	5.3	5.3
Operating Expenditures						
Fund 001 - 7	\$1,637	\$1,679	\$3,316	\$1,738	\$1,800	\$3,538
Total Expenditures	\$1,637	\$1,679	\$3,316	\$1,738	\$1,800	\$3,538
Revenue						
001 - 0597	\$1,637	\$1,679	\$3,316	\$1,738	\$1,800	\$3,538
Total Revenue	\$1,637	\$1,679	\$3,316	\$1,738	\$1,800	\$3,538

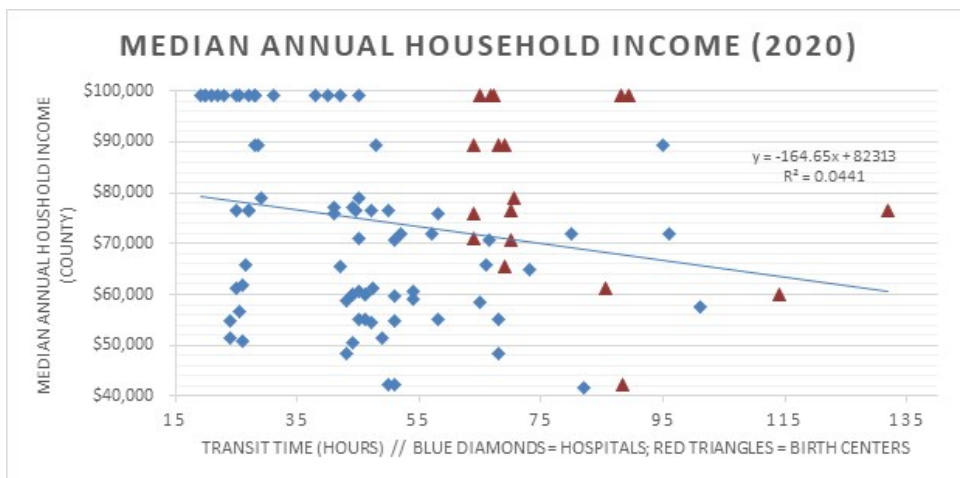
Decision Package Description

What is the problem, opportunity, or priority you are addressing with the request?

The proposed newborn screening (NBS) fee increase will strengthen services in four critical areas: specimen delivery from hospitals and birthing centers to the Public Health Laboratories, new testing required by the State Board of Health, DNA testing for cystic fibrosis and NBS electronic test ordering and results.

Specimen delivery from hospitals and birthing centers to the Public Health Laboratories (PHL): Delays in transport and processing of NBS specimens can cause death or permanent disability in babies with NBS conditions due to delayed screening and diagnosis. [RCW 70.83.020](#) requires hospitals and health care providers attending a birth outside of a hospital to collect a NBS specimen prior to 48 hours of age and delivered to the PHL within 72 hours of collection. Birth facilities/providers are currently responsible for transporting NBS specimens to the PHL. They use a variety of methods, including USPS, FedEx and other couriers. Not every facility/provider can afford an overnight delivery option, which creates disparities in delivery time based on the financial situation of the birthing hospital or attending provider for out-of-hospital births.

During 2020 (the most recent full year of data we have) we received specimens from 79,223 babies. More than 7,800 babies' specimens were delivered outside of the required 72-hour window. Of the 175 babies diagnosed with newborn screening conditions from the first specimen, 15 (8.5%) had delayed diagnosis because NBS specimen transit was greater than 72 hours. This is dangerous. The health of babies should not depend on the mail system.



Delayed transit places babies at higher risk of death and disability because of later testing and diagnosis. Specimens from babies from less affluent parts of the state and babies born outside of hospitals have slower transit times (see chart). Addressing this inequity will save lives.

New testing required by the State Board of Health (SBOH): Ornithine transcarboxylase deficiency (OTCD) is a urea cycle disorder that is deadly in the first weeks of life. The biggest impact is for boys (X-linked inheritance) and early diagnosis and treatment are critical to prevent death and permanent disability.

In October 2021, the SBOH directed the Department of Health to add OTCD to the mandatory NBS panel. This decision came after a multidisciplinary technical advisory committee reviewed OTCD using the [SBOH's criteria for candidate NBS conditions](#).

DNA testing for cystic fibrosis (CF): The NBS program added screening for CF in 2006. The original screening strategy in Washington State was to identify babies with persistent elevation of immunoreacted trypsinogen (IRT) from two screening samples (abbreviated IRT/IRT). Over the years, DOH has added a limited amount of DNA testing to improve the screening performance.

Currently, 43 states and Washington, D.C. reflex to a DNA test if the original NBS specimen has elevated IRT (IRT/DNA). This protocol speeds up diagnosis and treatment because only one NBS specimen is required for the process. The expanded DNA testing also will increase test sensitivity from the current 95-96% level to about 97-98%. Published data demonstrates that babies with CF have improved health with earlier identification (reference available upon request). The pediatric pulmonology consultants at Seattle Children's Hospital want us to diagnose babies earlier and have expressed willingness to write a letter of support or have their lobbyists advocate for a fee increase to make the needed changes. Faster diagnoses yield healthier babies with CF.

The median age at CF DNA results (the prompt to make a referral for diagnostic testing) in the current CF screening algorithm is 21 days of age. This can be dramatically improved by adopting the IRT/DNA strategy, which would speed up the process by 12 days (improving median age at referral to 9 days of age). This will allow affected babies to receive treatment much sooner and improve clinical outcomes. The change will also simplify our testing and follow-up algorithms.

NBS electronic test ordering and results (ETOR): Previous federal and local NBS funding was used to develop a NBS ETOR system (funding ended in 2021). One pilot hospital is almost ready to go live with this program. This request adds funding for continued onboarding of other birth hospitals to the NBS health information exchange.

Our staff are frequently asked about ETOR capacity, so we know there is an interest in the community.

The onboarding process requires consistent collaboration between DOH, the vendor and the partner facility's IT department. Lessons learned from the pilot project will pay dividends as this service is expanded.

A NBS fee increase of \$20.00/baby will provide the services listed below.

1. A courier service will be implemented to provide overnight delivery for specimens from all hospitals and birthing centers. This portion of the fee increase will purchase the courier service and pay for FTE support to monitor the contract and ensure the vendor meets the deliverables for on-time delivery. Expected results are expedited diagnosis and treatment of babies with NBS conditions and a reduction in death and permanent disability through faster delivery of specimens to the DOH.

2. All newborns will be screened for OTCD. Follow-up services will be provided for babies with positive screens. This portion of the fee increase will fund FTEs (to perform testing, follow-up and NBS-related operations), testing standards, reagents, consumables and diagnostic support from the biochemical genetics team at Seattle Children's Hospital. Expected results are a reduction in death and permanent disability for babies born with OTCD in Washington State.

3. Second-tier DNA testing will be expanded for babies with positive screening results for CF to expedite diagnosis and treatment. This portion of the fee increase will fund FTEs (to perform testing, follow-up and NBS-related operations), testing standards, reagents and consumables. This plan will quadruple our current capacity for DNA testing and follow-up case management. Expected results are an improved screening sensitivity (reduction in false negative results) and a faster time to referral/diagnosis by approximately two weeks.

4. The NBS ETOR system will expand beyond the pilot hospital and over time will become available to all hospitals, clinical laboratories and birthing centers who wish to participate. The ETOR system was purchased with previous funds and the maintenance and operations cost is already a part of the standing NBS budget. This portion of the fee increase will pay for the FTEs to continue the onboarding process for additional facilities. Expected results are eliminating the chance of transcription errors and saving staff time and printing co.

What alternatives did you explore and why was this option chosen?

We considered piggy-backing with the courier system established for COVID-19 samples through the CDC's ELC grant. The federal funding for the courier expires in 2023 and there is no guarantee that the courier service will be extended/renewed. The status quo puts babies at risk for delays based on where they are born; babies born in less affluent counties and babies born outside of hospitals have a longer specimen transit time and are at higher risk from bad outcomes from slow specimen delivery. DOH has recommended that specimen submitters use a courier system for many years. While the transit time statistics have improved over the years, they are still at unacceptable rates of 8.0% late deliveries from hospital births and 43.1% late deliveries from out-of-hospital births.

There are no legitimate alternatives to complying with the State Board of Health's direction to add OTCD to the mandatory screening panel. Alternatives to increasing the NBS fee would be to reassign existing staff to expanded CF DNA testing. We don't have staffing or budget capacity to do this without stopping required testing of other mandated screens. Another alternative is to send specimens to an outside laboratory, which would be costly and would introduce delays. If there is no fee increase, our best alternative is the status quo, which is slow to diagnosis for babies with CF. Over the years, DOH has made many changes to improve the screening and follow-up protocols, and additional changes require a financial investment for staffing and testing supplies. More details are included in the other supporting materials section.

The NBS ETOR expansion project was not chosen among the recent proposals for the 2022 CDC workforce development grant. If the NBS ETOR expansion is not included in the fee increase, only one hospital will benefit from the infrastructure developed using a combination of past federal grant money and local NBS funds.

Assumptions and Calculations

Expansion, Reduction, Elimination or Alteration of a current program or service:

The Newborn Screening Program tests for 32 disorders. The Department of Health requests a fee increase to add OTCD to the mandatory screening panel. This proposal will increase the Newborn Screening Fee by \$1.26/baby. The anticipated implementation date to begin screening

infants for OTCD is July 1, 2023. Based on historical birth rates the anticipated number of infants screened is expected to be approximately 84,000 per year. The estimated revenue for 2023-2024 is $84,000 * \$1.26 = \$105,840$. Estimated ongoing revenue is $84,000 * \$1.26 = \$105,840$ per year. This revenue estimate is ongoing but will fluctuate each year based on the number of births.

Detailed Assumptions and Calculations:

During the 2017-19 biennium, the total expenses of the Newborn Screening General Fund – Local account (MI 16101716) was \$14,695,141. Total revenue during this period was \$14,698,359.

During the 2019-21 biennium, the total expenses of the Newborn Screening General Fund – Local account (MI 16101716) was \$16,520,280. Total revenue during this period was \$16,511,691.

A statewide courier service would be selected using the competitive bid process. The Department of Health requests a fee increase of \$9.53 per baby to add the courier service. A current quote from UPS estimated \$721,644.00/yr. This would provide overnight delivery for specimens from all hospitals and birthing centers. A HSC3 would manage the bid and selection process, as well as continued contract management and deliverables enforcement. A 5% increase was applied each year to the contract cost due to inflation assumptions. The estimated revenue for 2023-2024 is $84,000 * \$9.53 = \$800,520$. Estimated ongoing revenue is $84,000 * \$9.53 = \$800,520$ per year. This revenue estimate is ongoing but will fluctuate each year based on the number of births.

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To incorporate a second-tier DNA test for the diagnosis of cystic fibrosis in infants this proposal will increase the Newborn Screening Fee by \$6.29/baby. This will allow the screening to be dramatically improved, reducing diagnosis from 23 days of age to 9 days of age. The anticipated implementation date to begin screening infants for CF DNA is July 1, 2023. Based on historical birth rates the anticipated number of infants screened is expected to be approximately 84,000 per year. The estimated revenue for 2023-2024 is $84,000 * \$6.29 = \$528,360$. Estimated ongoing revenue is $84,000 * \$6.29 = \$528,360$ per year. This revenue estimate is ongoing but will fluctuate each year based on the number of births.

To continue and expand electronic test ordering and reporting (ETOR) this proposal will increase the Newborn Screening Fee by \$2.92/baby. This includes one pilot hospital and continued expansion to all other birth facilities to the NBS health information exchange. The anticipated implementation date to begin ETOR is July 1, 2023. Based on historical birth rates the anticipated number of infants screened is expected to be approximately 84,000 per year. The estimated revenue for 2023-2024 is $84,000 * \$2.92 = \$245,280$. Estimated ongoing revenue is $84,000 * \$2.92 = \$245,280$ per year. This revenue estimate is ongoing but will fluctuate each year based on the number of births. Estimated expenditures include salary, benefit, and related costs to assist with administrative workload activities. These activities include policy and legislative relations; information technology; budget and accounting services; human resources; contracts; procurement, risk management, and facilities management.

Workforce Assumptions:

Workforce Assumptions FY24 Projections Only					
FTE	Job Classification	Salary	Benefits	Startup Costs	FTE Related Costs
0.8	HEALTH SERVICES CONSULTANT 2	\$52,000.00	\$22,000.00	\$3,000.00	\$6,000.00
0.4	CHEMIST 2	\$26,000.00	\$11,000.00	\$1,000.00	\$3,000.00
0.3	CHEMIST 3	\$22,000.00	\$8,000.00	\$1,000.00	\$2,000.00
0.2	EPIDEMIOLOGIST 2 (NON-MEDICAL)	\$21,000.00	\$7,000.00	\$1,000.00	\$2,000.00
1.0	EPIDEMIOLOGIST 1	\$89,000.00	\$33,000.00	\$4,000.00	\$8,000.00
0.5	MANAGEMENT ANALYST 4	\$44,000.00	\$17,000.00	\$2,000.00	\$4,000.00
0.1	HEALTH SERVICES CONSULTANT 3	\$8,000.00	\$3,000.00	\$0.00	\$1,000.00
1.3	FISCAL ANALYST 2	\$69,000.00	\$33,000.00	\$0.00	\$0.00
0.8	HEALTH SERVICES CONSULTANT 1	\$40,000.00	\$19,000.00	\$0.00	\$0.00
5.2		\$371,000.00	\$153,000.00	\$12,000.00	\$26,000.00

Estimated expenditures include salary, benefit, and related costs to assist with administrative workload activities. These activities include policy and legislative relations; information technology; budget and accounting services; human resources; contracts; procurement; risk management, and facilities management.

Strategic and Performance Outcomes

Strategic Framework:

The NBS fee increase request aligns with the Governor's Health and Safe Communities and Efficient, Effective, and Accountable Government goals. It also is in harmony with DOH's strategic plans for transformations in Data, Information, Technology Innovations and Equity, Diversity, Inclusion.

Health and Safe Communities:

* A courier service providing next-day delivery of NBS specimens will expedite testing, diagnosis and treatment of babies with all NBS conditions, reducing the chance of tragic outcomes from delayed sample transport.

* Screening all babies for OTCD will reduce death and permanent disability for babies born with this condition.

* Expanding the CF DNA testing will improve the test sensitivity (fewer false negatives) and shorten the time to diagnosis and treatment for babies with CF and improving their health and cognitive outcomes.

Efficient, Effective, and Accountable Government:

* The courier service increases efficiency by providing next-day delivery of NBS specimens for all newborns, no matter where they are born. It creates accountability within the system to ensure uniformity in expedited specimen delivery.

* Expanded DNA testing will decrease time to diagnosis and treatment for many babies with CF. It will also streamline and simplify the laboratory and follow-up protocols, which reduces the chance of human error.

* The current paper-based system for ordering NBS tests and reporting results is costly and archaic. Expanding the NBS ETOR system improves efficiency by integrating NBS results into the baby's medical record. This system increases DOH's accountability because submitters will be able to track the progress of reporting.

HEALTH AND WELLNESS All Washingtonians have the opportunity to attain their full potential of physical, mental, and social health and well-being. NBS results will be integrated into the baby's medical records, saving resources and removing the chance for transcription errors.

Performance Outcomes:

1. Performance outcomes will be measured by monitoring specimen transit time. The vendor will be obligated to provide next-day delivery of all NBS specimens per the contract, so we anticipate the compliance rates to dramatically increase from current levels (as described above). Our compliance and education specialist will work with hospitals, birth centers and midwives to implement the courier system and establish a routine procedure for our contracts specialist to monitor vendor performance.

2. Babies with positive OTCD screens are at risk for death and disability. Performance outcomes for OTCD screening will include laboratory testing turn-around time and time from results to referral by the follow-up staff. Our internal quality assurance goals for this testing platform are for 100% of specimens to be reported within five days of receipt. Since OTCD is a life-threatening condition, we expect for the time from results to referral to be within hours.

3. Expanded CF DNA testing seeks to decrease the age at referral for diagnostic testing. Similar to OTCD deficiency, performance outcomes are turn-around-time for testing and time from results to referral by the follow-up staff. Our internal quality assurance goals for the CF DNA testing platform are for 100% of specimens to be reported within seven days of receipt. We expect for the time from results to referral to be \leq one business day.

4. Performance outcomes for the NBS ETOR project will be number of submitters participating in the program over time. We are hopeful to add networks of providers in groups (e.g. all the Multi-care hospitals and clinics could join at one time).

Equity Impacts

Community outreach and engagement:

DOH did not conduct community outreach and engagement about this proposal. Anecdotally we know that some hospitals use snail mail to deliver newborn screening specimens because they do not have the budget to employ a courier service.

Disproportional Impact Considerations:

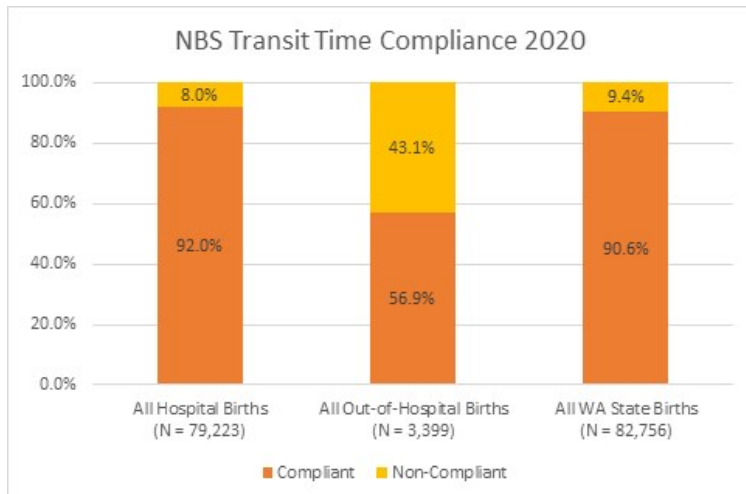
No target populations or communities are excluded or would be negatively impacted by this proposal.

Target Populations or Communities:

Newborn screening specimen transit times in Washington State vary depending on where a baby is born. This proposal will fund an overnight courier system to ensure expedited delivery of specimens for all babies, no matter where they are born. This proposal will benefit babies born in less affluent parts of the state and babies born outside of hospitals.

Babies born in more affluent areas of the state have faster delivery of specimens to the NBS laboratory than their counterparts in less affluent parts of the state. The data for specimen transit time show that median income by county predicts speed of delivery of NBS specimens (see chart above).

Specimens for babies born outside of a hospital are much less likely to be delivered within the 72-hour time period described in the [NBS law](#) (see chart below). Birthing centers and individual midwives have fewer resources than hospitals to ensure timely delivery of NBS specimens.



Implementing a courier service would create equity by providing overnight delivery for all NBS specimens, not just for the hospitals that can afford this service (current system). Birthing centers will be included in the courier system and individual midwives will be able to drop off specimens to a hospital/birthing center to take advantage of the overnight delivery service.

Other Collateral Connections

Puget Sound Recovery:

N/A

State Workforce Impacts:

N/A

Intergovernmental:

N/A

Stakeholder Response:

The biochemical genetics specialists will be supportive of the changes to improve outcomes for babies with OTCD through universal screening.

For approximately six years the pediatric pulmonologists at Seattle Children's Hospitals have advocated for expanded DNA testing for CF to detect more babies with CF and facilitate treatment faster. While we have made progress, we lag behind most of the country in use of CF DNA testing. The pulmonologists have expressed willingness to write a letter of support for the fee increase and employ their lobbyist to make visits to legislators in Olympia.

Hospitals typically bundle the NBS fee with the charges for a birth, so an increase in the NBS fee will impact their level of reimbursement. However, the courier service will save hospitals on current shipping costs. The Washington State Hospital Association has participated in each NBS technical advisory committee during the past 20 years. They have been supportive of the growth of the NBS program.

Advocacy organizations such as the March of Dimes Foundation and Save Babies Through Screening have participated in the advisory committees and support the expansion of NBS.

State Facilities Impacts:

All additional testing described in this proposal can be performed on existing equipment at the Public Health Laboratories.

Changes from Current Law:

Upon legislative approval of the budget, the State Board of Health will lead efforts to amend WAC Section 246-650 to include omithine transcarboxylase deficiency OTCD. The other activities and goals of this decision package are operational in nature and will not require administrative code changes.

Legal or Administrative Mandates:

N/A

Reference Documents

- [FinancialCalculator_2023-25_ver24.0 -NEWBORN SCREENING.xlsm](#)
- [NBS 2022 fee increase information 2022-08-16.xlsx](#)
- [Timeline of changes to the CF NBS protocols.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

Objects of Expenditure

Objects of Expenditure <i>Dollars in Thousands</i>	Fiscal Years		Biennial	Fiscal Years		Biennial
	2024	2025	2023-25	2026	2027	2025-27
Obj. A	\$371	\$372	\$743	\$375	\$378	\$753
Obj. B	\$154	\$154	\$308	\$156	\$157	\$313
Obj. C	\$722	\$758	\$1,480	\$796	\$835	\$1,631
Obj. E	\$333	\$351	\$684	\$367	\$386	\$753
Obj. J	\$13	\$0	\$13	\$0	\$0	\$0
Obj. N	\$20	\$20	\$40	\$20	\$20	\$40
Obj. T	\$24	\$24	\$48	\$24	\$24	\$48

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