DRAFT

Oregon Health Authority
Northwest Regional Newborn Bloodspot Screening Advisory Board

Meeting Summary **March 3, 2026**

Location

Videoconference

Quorum

Board attendees constituted a quorum for the meeting.

Board Members Attending

Elizabeth Powers, MD, FAAFP, Chair, Representative of birthing center or hospital
Angela Douglas, MD, Vice Chair, Representative of a statewide association of pediatricians
Cheryl Grabham, Representative of advocacy association regarding newborns with medical or rare disorders
Andrea Keating, LDM, CPM, Representative of a statewide association of midwives
Marilyn Hartzell, M.Ed. Family Representative
Sheevaun Khaki, MD, Representative of a statewide association of pediatricians
Rusha Grinstead, Representative of Medicaid or insurance industry
Mort Murry, MD, Representative of advocacy association regarding newborns with medical or rare disorders
Kara Stirling, MD, Representative of a birthing center or hospital

Board Members Absent

Amy Yang, MD, Contracted medical consultant
Sherly Paul, Representative of a statewide association of nurses

NBS Program Staff

Patrice Held, PhD, Newborn Screening Program Manager
Kasfian Khan, OSPHL Legislative and Community Engagement Coordinator
Sarah King, OSPHL Client Services Coordinator
Sharon Willis OPSHL- Laboratory Manager
Kristi Murphy- OHA Genetic Counselor Newborn Screening
Sara Etienne- OHA

Guests

Alyssa Rapp- Newborn Screening Data Analyst

Members of the Public

Lesa Brackbill- Parent advocate

Emilia Wilburn, Orchard Therapeutics

Jensen Strategies Facilitation Team

Erik Jensen, Facilitator
Emily Rehder, Operations Manager

ACTION ITEMS

The Board took the following action:

- Approved meeting summary for the December 3, 2025, meeting.

MEETING AGENDA ITEMS

1. Welcome / Introductions

Vice Chair Dr. Angela Douglas opened the meeting. She reminded the Board about the open Board position for a representative of advocacy association regarding newborns with medical or rare disorders that can include a parent, physician, or other individuals who represent an advocacy organization. Dr. Douglas asked Board members, OHA staff, and facilitators to introduce themselves. She reminded the Board of the absence policy that missing two consecutive meetings without communication prior to the second meeting is considered a resignation unless there are exceptional circumstances conveyed to the Chairs in advance.

2. Meeting Overview

Erik Jensen, Board Facilitator, reviewed the agenda for the meeting. Erik reminded everyone of the date for the upcoming Board meeting noting the time:

- Wednesday, May 27, 2026, 1:00pm – 4:00pm

Erik noted the project team is returning to a rule-based calendar (e.g., "4th Wednesday of the month) for the 2026 – 2027 Board meetings to bring more consistency and predictability to meeting dates/times. The Board will be receiving a survey after the meeting to obtain what days and times of the week works best. Aiming to schedule the meetings on the first weeks of September, December, March, and June.

3. Approval of Meeting Summary

Chair Dr. Elizabeth Powers called for the approval of the December 3, 2025, Advisory Board meeting summary and asked for a formal vote.

Decision: The December 3, 2025, NWRNBS Advisory Board meeting summary was approved unanimously.

4. Program Updates

Patrice Held, NWRNBS Program Manager, provided updates on the Program.

Screening Updates

Infantile Krabbe Screening:

Infantile Krabbe screening has been live for four months. They have tested ~20,000 babies. 15 babies had GALC activity less than 12% MoM (ranging from 6.4% to 11.76%). Psychosine was normal in all babies, no referrals were made to medical specialists.

GAMT Deficiency Screening:

The laboratory is in the process of validating an assay to combine guanidinoacetate methyltransferase (GAMT) deficiency with XALD screening using LC-MSMS. Analytes for MLD will also be incorporated to prepare for future implementation, but will not be actived. Tentative implementation of the GAMT deficiency screening is Summer 2026.

MPSII Screening:

Mucopolysaccharidosis Type II (MPSII) implementation is waiting for FDA approval for testing kits. Screening for this condition may not be added until 2027.

New Laboratory Information Systems (LIMS):

The lab has switched to a new information management system with the selected vendor, Lab Vantage. The project will combine four separate LIMS of OSPHL into one with embedded analytical tools. The pilot project for the LIMS is being conducted from February 2026 through July 2026. Full implementation is “tentatively” planned for July 2027. This will be a substantial change when it goes live because the reports and how submitters interact with the system will be different.

BEACONS Study:

The BEACONS study is a three-year research initiative funded by the NIH Common Fund Venture Program.The aim is to investigate if whole genome sequencing (WGS) can be responsibly and ethically integrated into existing public health newborn screening programs. Oregon was chosen to be one of the participating public health programs along with Iowa, Texas, Minnesota, South Carolina, New York, and Puerto Rico.

The study is not intended to replace the current newborn screening process. The process will include families who have consented to participate. Only one blood sample will be collected for both the routine newborn screening and the sequencing study (for those families who have consented). Once the sequencing is completed the results will be sent back to the existing public laboratories and the lab will be delivering the results using current mechanisms for communication. If the baby has a positive screening result, then the lab will inform the primary care provider and associated specialists.

The genomic sequencing will be looking at over 700 conditions in comparison to the 46 currently on the newborn screening panel. All of the conditions in the panel have actions that can be taken within the first year of life to prevent morbidity and mortality associated with the conditions. Study will report only pathogenic/likely pathogenic variants.

The goal is to enroll and sequence 30,000 babies across all seven programs, with roughly 4,500 from Oregon over a two-year period. A 2% hit rate of positive results is anticipated coming out of the sequencing.

The study is currently in the implementation and design phase including working on some of the ethical and legal elements. Subsequently it will move into the preparation stage and then full-scale recruitment. At the end there will be interviews and structured program assessments.

There will be both active and passive recruitment of study participants. The Program is working to identify the two hospital systems with active recruiters and are currently in discussion with Peace Health and OHSU. Passive recruitment will be done through social media, targeted campaigns, and parent groups to reach people statewide and direct them to website information and instructions.

GeneDx will be doing the sequencing and will be holding the data for up to five years at which time it will be destroyed. Families have the opportunity to voluntarily opt to share their babies DNA analysis to public databases. Parents may request destruction of stored sample and data at any time.

More information can be found on the study website: www.beaconsnbs.org.

Questions and comments from the Board included:

Q: With the passive recruitment, will there be geographic limitations for accessibility specifically for those in remote or rural areas?
A: The passive recruitment would be open to anybody who delivers their baby in Oregon regardless of geographic region. Information will be shared directly with all submitters, both at hospitals and community birth providers, as well as primary care providers and pediatricians throughout the state.

Q: Is there going to be funding available to a family who has a baby with a positive result? Is there a plan for logistics around accessibility for families who might be rural or low income?
A: Unfortunately, they have not set aside funding for families, but Patrice will bring that concern back to the study team.

5. Billing Process Update

Patrice provided an update on the consideration of billing models for the screening kits.

The Program is currently funded through a pre-pay billing model with fees costing $175 for two screens. There are two options for submitters to pay - either an online order form or by sending a completed hard copy form with a paper check. The pros of the pre-pay system include the ease of using the online form, in which payment is always accurate, and no need to bill or do collections. The cons include: the manual processing time for hard copy orders; delays in getting cards when providers run out of cards; hard copy checks getting lost, bouncing, or having incorrect payment amounts; and the fiscal burden on submitters having to pay “up front” before they can be reimbursed by insurance/Medicaid.

The fee for service model under consideration would provide cards ahead of time to all facilities. Facilities would use the cards and then at the end of the month the Program would send a bill to

the submitters. A question being considered is whether to charge per baby or per specimen. If billed by specimen, there is a question about the logistics of billing clinics in addition to hospitals and midwives. Clinics may not be set-up to cover invoices from OSPHL.

The pros of the fee for service model are hospitals, clinics, and midwives always have access to cards and submitters can follow routine billing practices similar to laboratory testing. The cons are bills are not always paid in a timely manner and it can be a struggle to get payment from some submitters necessitating a collections program.

Questions and comments from the Board included:

Q: Are there other states where the lab bills insurance carriers directly and is it a legislatively mandated thing to cover?

A: Yes, there are other states that use a fee for service model. Washington for example sends a monthly invoice to hospitals and it is a smooth process. However, for community birth providers the Washington lab has elected to bill insurance directly (on behalf of the community birth provider). However, they frequently do not receive reimbursement by either private insurance or Medicaid, resulting in a loss for the program.

Comment: It seems there has been a lot of legislative interest in this topic. Oregon has a history with the mandate for Family Connect Oregon of telling insurers they have to pay for things which is to the benefit of the public. The Legislature seems to support two things: newborn screening is important and mandating insurers to cover birth related services.

Comment: Regarding separate billing to insurance, the potential impact of 39,000 Oregon births on OSPHL and having them deal with registrations, data collection, and insurance coordination is not within their current capacity. Also, even if the coverage is mandated, insurance companies require a lot of back and forth with records that would still cause an impact on OSPHL capacity to do billing.

Q: Are you leaning towards the pathway of billing at the hospital level rather than the clinic level?

A: Yes, that is what OSPHL would be leaning toward. Essentially, they are considering billing the per baby based on the first screen, as opposed to billing each sample submitted.

The Program is looking at forming a small work group to assist in navigating this billing model change. They are looking for partners who understand the billing operations in the facilities and specifically accounts payable departments. If anyone is interested in participating in the work group, contact Patrice.

6. Newborn Screening Data and Birth Records Comparison

Alyssa Rapp, Newborn Screening Program Data Analyst, presented results of birth records comparison from the OSPHL data collections during 2021-2024. Oregon's unscreened babies count has been around 1% for a couple years. The data is being used to create a health equity analysis using two cohorts for comparison: screened and unscreened population. Exclusion factors for both cohorts include deceased, out-of-state resident hospital transfers and adoption/legal proceedings. The factors found to be statistically significant were birthplace type, birth provider, payor, rurality, Kotelchuk Index, and WIC.

There have been some key findings to date. Looking at the comparison for birthplace, birth centers and home births have a much larger percentage of unscreened babies. The majority of screened babies are born at hospitals versus those birthed at home or in a birth center. The birth provider data shows the majority of screening happened with doctors/nurse practitioners whereas it was less likely with a midwife (licensed or unlicensed) or a non-medical person.

The predominant payment methods for the screened population is split between public options and private insurance, while the unscreened population has 50% of families paying out of pocket. Over the four-year period, the payment method for unscreened babies shifted in 2024 with more having private insurance.

Looking at the equity analysis of rurality, families who reside in frontier areas have twice as many unscreened babies versus screened. The percentage of unscreened babies is also higher in rural areas, as compared to urban areas. This data suggests a need to focus on rural healthcare access.

A new factor, the Kotelchuk Index, is a measure of the adequacy of prenatal care utilized by families. It takes into account gestational age and the number of prenatal visits. The data shows that 37% of unscreened babies are receiving prenatal care considered inadequate or below.

OSPHL received a budget allocation in the 2024 legislative session to subsidize cards for those paying out of pocket. As of the end of 2025, there were 476 subsidized cards from 72 community birth providers.

OSPHL will be reviewing the subsidized cards against the birth records to see if the subsidized funds have closed the gap of screened versus unscreened babies.

Questions and comments from the Board included:

Q: Will gathering and presenting this data will be easier once you implement your new LIMS system?

A: Yes. But another beneficial change was the implementation of new screening cards that allow providers to indicate why a baby was not screened (ie…parent refusal).

7. Discussion: Interim Condition Review Protocol

Given recent developments related to the dissolution of the ACHDNC, Erik led the Board in an open discussion about changing the condition review protocol. He noted no decisions would be made at this meeting but feedback from the Board will inform next steps and future discussion or decision-making.

As background, Patrice shared some current developments that relate to the Board's current disorder review protocol. The ACHDNC dissolution in April 2025 nullifies Step 1 of the Oregon Board's disorder review protocol. Over the past year, the Board had decided to focus on the implementation of the two conditions while things are sorted out on the national level. However, at the end of 2025, Duchenne and Metachromatic Leukodystrophy were added to the RUSP by the U.S. Secretary of Health and Human Services without the scientific review previously conducted by ACHDNC. Since then, the Board has had inquiries about when the

Board will review Duchenne and Metachromatic Leukodystrophy for the Oregon panel.

Erik facilitated a discussion, given this background information, about what potential actions the Board may want to take related to their current disorder review protocol.

Erik asked the question on whether or not the Board should continue to use the RUSP as a requirement for Oregon NBS review and what other interim measures or directions would the Board consider.

Feedback from the Board included using the RUSP but changing the wording in the disorder review protocol to remove it as a requirement but keep it as a consideration. Due to lack of information regarding how or what scientific review of disorders may be available or required by either the American College of Medical Genetics and Genomics or the U.S. Health and Human Services Department, the Board recommended researching what other states are using as criteria to review conditions as well as potentially partnering with other states. It was also suggested utilizing specialists within Oregon and other states could help inform the review process.

NWRNBS staff, in consultation with the Board Chairs, will work to synthesize the feedback received from the meeting and propose revised protocol language and structural options for further consideration.

8. Public Comment

No comments were presented.

9. Wrap-up

Dr. Powers commented that she appreciated the thoughtful and respectful conversation. The next meeting will be on May 27th from 1pm to 4pm. The meeting was adjourned.