Oregon Health Authority
Northwest Regional Newborn Bloodspot Screening Advisory Board

Meeting Summary **December 3, 2025**

Location

Videoconference

Quorum

Board attendees constituted a quorum for the meeting.

Board Members Attending

Elizabeth Powers, MD, FAAFP, Board 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
Sherly Paul, Representative of a statewide association of nurses
Marilyn Hartzell, M.Ed. Family Representative
Amy Yang, MD, Contracted medical consultant
Sheevaun Khaki, MD, Representative of a statewide association of pediatricians

Board Members Absent

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

NBS Program Staff

Patrice Held, PhD, Newborn Screening Program Manager
Kasfian Khan, OSPHL Legislative and Community Engagement Coordinator
Sarah King, OSPHL Client Services Coordinator
Sarah Viall, OHSU Nurse Practitioner and health educator for the Newborn Screening Program

Guests

No guests attended

Members of the Public

Marian Johnson

Natasha Hale

M Russell

SM Smith

Jensen Strategies Facilitation Team

Erik Jensen, Facilitator
Emily Rehder, Operations Manager

ACTION ITEMS

The Board took the following actions:

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

MEETING AGENDA ITEMS

1. Welcome / Introductions

Chair Dr. Elizabeth Powers opened the meeting and asked for the Board members, OHA staff, and facilitators to introduce themselves.

2. Meeting Overview

Erik Jensen, Board Facilitator, reviewed the agenda for the meeting. Erik reminded everyone of the dates for the upcoming Board meetings noting varying times:

- Tuesday, March 3, 2026, 9:00am – Noon
- Wednesday, May 27, 2026, 1:00pm – 4:00pm

Erik noted the project team is considering 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.

3. Approval of Meeting Summary

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

Decision: The September 3, 2025, NWRNBS Advisory Board meeting summary was approved unanimously by all members present except Dr. Sheevaun Khaki who abstained because she had not been at the meeting.

4. Program Updates

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

Final Rule Making: Patrice reviewed amendments to the Oregon Administrative Rules (OAR) 333-024 that will go into effect on January 1, 2026. Public comment on the amendments can be submitted to OHA until December 16, 2025.

The specific rule amendments included:

- Adding the ability of parents or legal guardians to opt out of screening because of their religious or philosophical beliefs.
- Incorporating more inclusive language with the addition of legal guardians or parents.
- Requiring blood cards be submitted for all babies born in Oregon. If no blood is collected, a card must still be submitted. For refusals, there is a form to sign stating parents/guardians received education about screening.

- Methods of testing for each listed disorder is being removed to allow the laboratory to update methods as needed to ensure accuracy of results and alignment with best practices.

Infantile Krabbe Disease Screening: Patrice reviewed the results from the first month of screening (implemented November 1, 2025). In November, over 5,000 babies were screened for IKD. Four babies had GALC activity of <12%. Those four samples were sent to Mayo for second-tier psychosine testing. Psychosine values in all four babies were in the normal range and the IKD results were reported as normal.

Oregon has a high cutoff of 12% while other states have thresholds closer to 9% or 10%. Patrice noted that they were happy they detected a few false positives and confident they can further refine the cut off percentage to minimize the number of second-tier tests.

BEACONS (NBS x WGS): Patrice discussed the Newborn Screening by Whole Genome Sequencing (NBS x WGS) Collaboratory initiative which is administered by the National Institute of Health (NIH). The purpose of the research is to assess the feasibility of a collaborative, multi-state model for newborn screening (NBS). It will use a whole genome sequencing as a first-tier assay for analysis of a select group of genetic conditions that are actionable in the first year of life. The link to the project is: https://www.beaconsnbs.org/project

Oregon was selected to be one of the seven participating states with the study's aim is to consent about 4600 families in Oregon over two years with a predicted positivity rate of 2%, which translates to approximately one baby per week. The primary study team would be responsible for consenting families. Once routine screening was completed, the state laboratory would send a portion of the remaining NBS samples (for consented individuals) to the sequencing center.

All abnormal results would be returned by the NBS program to the baby's provider. A referral will be made to the appropriate specialist. A support call center will be set up to handle provider/parent questions.

State Public Health Laboratories (PHLs) were asked to:

- Initiate conversations with hospitals to evaluate their willingness to engage. OHSU, Salem Health, Sacred Heart PeaceHealth and Kaiser have been contacted, and all have expressed interest but have requested more information. OHA will be reaching back out to them to confirm their interest in participating.
- Provide estimated timelines for consent review by the Institutional Review Board (IRB) and whether the board would cede oversight to primary research team.
- Provide estimated timelines for contracting with the state.

A potential list of genes and a determination of which variants to report is under curation. About 400 conditions that will be evaluated and all of them will have actionable steps to take in the first year of life. Only pathogenic or likely pathogenic variants will be reported, variants of unknown significance will not be reported.

Questions and comments from the Board included:

Q: What ethical guidelines, treatment access, and the decision-making processes they are using to choose the genes they are evaluating and how does that compare and contrast to what NWRNBS is currently doing?
A: Patrice will send the Board the list of criteria used to develop the list. It was a collaborative approach, and they did seek input from multiple experts in the field. It is a research project from the standpoint of consenting and gathering information about not only the feasibility but the interest amongst families.

Comment: Dr. Amy Yang noted the information was given to her group of geneticists first and it included a draft list of genes that were treatable conditions with an onset in the first year of life, which was the major criteria they were choosing from.
Response: Patrice shared there will be recruiters placed at only two of the hospitals, because that is all that the funds afford. The consenting of families will be in person, and an exchange of information, education, and consent will take place. The study will also offer passive consent through virtual means, but it isn't clear what that will look like. Eventually opportunities should be offered to people outside of the two selected hospital systems.

Q: Are they putting any mechanisms in place to report problems or questions? Are there any unintended consequences or burdens to the system such as other family member testing and genetic counseling support?
A: NWRNBS will bring those questions to the kickoff meeting with the recognition that there might need to be something specific for Oregon since providers are not going to know who to contact.

Comment: After having a few conversations with the community birth providers, they will want a lot of comprehensive information on how the genetic information is processed, shared, and stored as well as for how long. They are very interested in privacy and want to avoid sharing information about themselves outside what they've agreed to share.
Response: The website (https://www.beaconsnbs.org/project) does address data storage and who owns the data but it isn't completely clear so it is understandable why there would be questions. The sequencing will be done at a center called Genedx and the results will be returned to the state lab. At this point, it is unclear how the sequencing data will be stored and who would have access. NWRNBS program will bring these questions to the study team.

Q: What is the timeline for when the initial steps, evaluation, and refinement would be happening? Also identifying the next steps on expanding the list and getting supportive programs for family members of the newborn?
A: They would like to enroll consenting families by the summer of 2026. The contracting process and IRB review will probably consume most of the early part of 2026. Study refinement will take place over the next two years. The study team will learn more over the two years about the ethical and social implications of early diagnosis and treatment.

Q: Do you know what the cost of the genome sequencing for a newborn might be and do they estimate it to be comparable or very different, and in what direction?
A: The study is funded through NIH and would cover the costs for any consenting parents. Not aware if a real cost estimate has been done as to what it would cost to implement sequencing statewide through the screening programs.

ACHDNC Dissolution and ACMG Next Steps: The American College of Medical Genetics and Genomics (ACMG) Board of Directors has approved establishment of a Newborn Screening Coalition. It's charge is to advise the public and NBS programs about potential conditions for inclusion on the RUSP, develop and conduct evidence-based reviews of nominated conditions, seek public input prior to Coalition vote, publish and disseminate recommendations, including rationale for both affirmative and negative votes, and foster collaboration across medical, laboratory, and public health communities to ensure equity and readiness in state NBS programs.

They intend to launch the Coalition in the first quarter of 2026, and this will be a new version of the secretary's advisory committee. It will be a guide available for Oregon to consider new conditions.

Screening for GAMT Deficiency and MPS2: Patrice explained they initially planned to incorporate GUAC and CRE (markers for GAMT deficiency) into the assay for amino acids and acylcarnitines using MSMS. Development of this assay was unsuccessful, so the laboratory needed to pivot. Instead, the laboratory developed an assay to combine GAMT deficiency with XALD using LC-MSMS. Validation has begun with a tentative implementation in May 2026.

NWRNBS has not worked on MPSII, as they are waiting to see about the availability of FDA-approved kits.

Billing for Newborn Bloodspot Screening: Patrice shared highlights from a webinar, "Navigating Billing Complexities Webinar: Insight from Newborn Screening Programs," presented by the Association of Public Health Laboratories (APHL). The webinar explored the diverse billing practices used across NBS programs. Presenters shared their experiences and challenges, highlighting strategies for managing insurance billing, repeat specimens and various billing-related considerations. The link to the webinar: https://www.newsteps.org/resource-library/webinars-events/navigating-billing-complexities-insight-newborn-screening-programs

OSPHL has posted an RFP to solicit a new vendor for billing. In the past, the vendor has primarily supported communicable disease testing. For this RFP, NBS support was included. This provides NBS with an opportunity to consider other billing models.

Models presented from other states include:

- Prepaid cards (purchase of cards in advance of testing)
- Fee for service (billing submitters after testing is completed)
- Fee for service (billing insurance/Medicaid after testing is completed)

Patrice is gathering information from NWRNBS partners for ideas on how to improve billing in the future.

Questions and comments from the Board included:

> **Q:** Could there be a listening session with the community birth providers on how billing has impacted them and what these options are and why?
> **A:** NWRNBS could have a listening session, but should it be before or after a potential model is developed or both?

Follow-up Comment: Most people have limited knowledge of how the lab works, its functions, and why a model might be more desirable over another. Providing an outline of the options could be helpful upfront and then circle back once you have more information.

Q: Is there a direction that Patrice is leaning in terms of keeping the current billing approach versus a fee-for-service?
A: There are many problems with the current model – both for users and internally. It is exciting to consider the fee for service model. It is a struggle with the expectation of families having to carry a second card to their doctor's office and get them to collect the second screen.

Q: Is there a high cost associated with the filter paper or is it okay that people have a stash of them, and when NWRNBS gets them, to bill then? There could be benefits of lowering access barriers which could create more equity.
A: The filter paper is not expensive – less than 30 cents - since the NWRNBS program orders thousands in bulk. It isn't an issue to give stacks of cards to a clinic or hospital.
Follow-up Comment: Everything we do in medicine is an invoice and not prepaid and it is kind of funny that we do this one thing differently where access is a concern.

Q: Regarding, the equity issue, are you referring to patients who have potentially lower health literacy or mental health barriers to accessing care or what are the terms that may be appropriate to use?
A: I would include language barrier, mental health, social resources, geography, race, ethnicity, and health literacy as equity concerns related to the current billing approach.

5. Public Comment

No comments were presented.

6. General Discussion

Erik led the Board in an open discussion providing an opportunity to ask questions about the NWRNBS Program, seek input from fellow Board members on issues related to NBS, identify potential topics for future Board discussions, share information related to NBS (e.g., events, programs, research), and/or recognize something that is going well.

Comment: Shout out to the extension of the subsidized card program. The funding got extended to June of 2026. An estimate of 400 plus families have been able to use the program, and it is a great benefit.

Comment: Regarding the new policy for families who chose not to do the newborn screen having to report back to the state their declination, we have received feedback from practitioners concerned about the information being shared and maintaining privacy.

Q: Does the program require patient information to be shared across program components? Do they have the right to say no to the sharing?

A: It is a rule that will go into effect January 1, 2026, and there is an opportunity to make public comment until December 16, 2025. The purpose of this new policy is to create a link between the birth record and a newborn screening record. It is important to confirm that all families received the option to have their baby screened, even if they decline.
Follow-up Comment: The concern is about information being shared that the parents or newborn would not want to be shared.
A: The results would be part of the medical record and if they test positive that condition would be added to their record. NWRNBS receives cards noting no collection was done due to personal reasons, transfer, or death. The program seeks to understand why babies are not screened, identify any potential barriers, so that we can improve our outreach and education.

Q: Is there information being shared among Western states with the changes that have occurred at the federal level?
A: The Western States Collaborative no longer exists. There are efforts to build harmonization among the programs regarding program metrics, screening algorithms, or conditions screened. There might be an opportunity to share best practices forward in future meetings.

Q: I heard recently that Washington state is screening for diseases not on the RUSP. Should we become more aware of the actions of our neighboring states such as Washington and California?
A: We have talked in previous meetings about what the Board wants to do regarding NWRNBS disorder review process since the dissolution of ACHDNC. The approach has been to wait and see what ACMG was doing and catch up on implementing some of the previously approved disorders for the screening panel.

Q: Regarding staying in harmony with other states, what can we do with other states to bring greater harmony between states. This issue comes up with babies that are coming from other states.
A: We can work with our neighbor states on harmonizing, but at times a state may take on research initiatives to expand their panel that may not be appropriate for Oregon.

Q: Is it possible or legal to meet with other state advisory boards?
A: They do have an advisory board in Washington. It would be good to know what topics or conditions they are considering. California is very RUSP aligned, and Patrice will look into what they are doing.

Q: It is hard to find patient-friendly resources or handouts for parents about conditions that is not from other states. The Oregon Newborn Screening website doesn't have a lot of that kind of information. Are there resources that are from our state?
A: We will be adding links to the website for advocacy groups for each condition. Right now, we have letters for providers, but they are not really patient centered and is a project that they would like to develop.
Follow-up Comment: The program should consider outreach to the organizations listed on the website, if see if they have handouts for families of newly diagnosed babies.

7. **Wrap-up**

Dr. Powers commented that she appreciated the extra time for discussion and excited that Oregon is taking the lead in the genome research. Wanted to express appreciation to Patrice for all that she has done with moving forward the GAMT testing. The next meeting will be on March 3rd from 9am to 12pm. The meeting was adjourned.