DRAFT

Oregon Health Authority
Northwest Regional Newborn Bloodspot Screening Advisory Board

Meeting Summary **May 27, 2026**

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
Marilyn Hartzell, M.Ed. Family Representative
Andrea Keating, LDM, CPM, Representative of a statewide association of midwives
Sheevaun Khaki, MD, Representative of a statewide association of pediatricians
Sherly Paul, Representative of a statewide association of nurses
Kara Stirling, MD, Representative of a birthing center or hospital
Amy Yang, MD, Contracted medical consultant

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

NBS Program Staff

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

Members of the Public

Katherine Anderson
Amanda Bain
Lesa Brackbill
Rocky Dallum
Grace Didway
Natasha Hale
Susheela Jayaraman

Corrine McKenzie
Kate Segal
Dean Suhr- MLD Foundation
Teryn Suhr- MLD Foundation

Jensen Strategies Facilitation Team
Erik Jensen, Facilitator
Emily Rehder, Operations Manager

ACTION ITEMS
The Board took the following actions:

- Approved meeting summary for the March 3, 2026, meeting.
- The Board decided to waive the provision on the disorder review protocol requiring ACHDNC recommendation to the RUSP, and allow the review of DMD and MLD to move to Step 2 of the Board's current review process.
- The Board approved the outline for the 2026 Legislative Report and directed Program staff, consultants, Board chair, and vice-chair to move forward with finalizing the Report and submitting it to the Legislature.

MEETING AGENDA ITEMS

1. **Welcome / Introductions**

   Chair Dr. Elizabeth Powers opened the meeting. Dr. Powers asked for the Board members, OHA staff, and facilitators to introduce themselves. She reminded the Board that there is an 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. For anyone interested in the position, contact Patrice Held.

2. **Meeting Overview**

   Erik Jensen, Board Facilitator, reviewed the agenda for the meeting. Erik informed the Board of the meeting schedule for the next year:

   2026-27 Advisory Board meeting dates – all are on second Monday of the designated month from 1-4pm:

   - September 14, 2026
   - December 14, 2026
   - March 8, 2027
   - June 14, 2027

   Erik reviewed the meeting agenda and recapped the protocol for Board decisions and discussions.

3. Approval of Meeting Summary

Chair Dr. Elizabeth Powers called for the approval of the March 3, 2026, Advisory Board meeting summary and asked for a formal vote.

Decision: The March 3, 2026, NWRNBS Advisory Board meeting summary was approved unanimously except for one abstention by Dr. Amy Yang because she had not attended the March 3rd meeting.

4. Public Comment

Katherine Anderson Community Research Manager from Parent Project Muscular Dystrophy. Katherine presented background information regarding Duchenne Muscular Dystrophy (DMD). She asked the Board to consider reviewing and adding the condition to the Oregon Newborn Screening Panel.

She noted that DMD is progressive and systemic with no cure, but it is treatable with FDA approved therapies. Muscle damage starts in utero, but children don't start seeing damage till age two. The average age of a DMD diagnosis is five, after which irreversible damage has already occurred. She shared that in September 2025, Every Life Foundation hosted an evidence review workshop. After the workshop, the U.S. Department of Health and Human Services (HHS) accepted the Health Resources and Services Administration (HRSA) recommendation to add it to the Recommended Uniform Screening Panel (RUSP) in December 2025.

She said the cost benefit to adding DMD would only add $3.50 per screen in comparison to the hundreds of thousands of dollars lost with diagnosis testing. Oregon already has the Genetic Screening Processor (GSP) machine for the assay for testing and has the infrastructure, evidence, and opportunity to add DMD. She encouraged the Board to add DMD to Oregon's newborn screening panel.

Amanda Bain, Parent of child with DMD who received a delayed diagnosis. Ms. Bain presented personal testimony on her experience with DMD and requested the Board's support in adding DMD to the screening panel.

Corrine McKenzie- Parent of a child who died from MLD. Ms. McKenzie said if there is an opportunity to provide treatment and giving these kids a chance, she encouraged the Board to do what they can to allow that to happen by adding DMD to the Oregon screening panel.

Dean Suhr- Co-founder of MLD Foundation and father of two children diagnosed with MLD. Mr. Suhr presented a summary of the review of MLD which is treatable but only if detected early. He said there is strong evidence to support newborn screening for this condition. Gene therapy outcomes have been showing success, but timing is critical. A half a dozen states have started implementing newborn screening for MLD, since the condition was added to the RUSP. Newborn screening is effective and he doesn't think it is appropriate to wait for uncertainty. He strongly encouraged the Board to move forward with adding MLD to the Oregon Newborn Screening Panel.

Teryn Suhr- Co-founder of MLD Foundation and mother of two children diagnosed with MLD. Ms. Suhr shared her experience with her children being diagnosed with MLD. She provided information regarding the lifesaving treatment and encouraged the Board to

consider adding MLD to the Oregon newborn screening panel to ensure all children have the ability to receive treatment.

5. Request to Review DMD and MLD

Patrice Held noted the Board received a request from State Reps. McLain and Owens, as well as advocates for DMD and MLD screening, to consider inclusion on the Oregon screening panel using the Board's current disorder review protocol. The conditions were added to the RUSP in December 2025 but without the recommendation of the ACHDNC because it had been dissolved last year.

Dr. Powers said the question is whether these two conditions should be recommended for review and, if so, if the Board wants to waive the requirement of ACHDNC review presently in Step 1 of the current review protocol.

Questions from the Board included:
Q: Are there other entities that would do the same review process as the ACHDNC?
A: The American College of Medical Genetics is putting together a committee of scientific experts to review and make recommendations for conditions to be added to state panels. Their process is delayed, with the first meeting in July, but no timeline has been set for reviewing conditions. Right now, there are no other entities that could be an alternate to the ACHDNC.

Q: Does this exception set a precedent that the Board will be expected to step outside the current review protocol for other conditions?
A: If the Board agrees to review DMD and MLD and waives the ACHDNC review requirement, there is a potential to set a precedent however, once the Board adopts a new protocol, that should not be an issue.

A motion was made by Dr. Elizabeth Powers and seconded by Marilyn Hartzell for the Program to review DMD and MLD, waiving the protocol provision in Step 1 for ACHDNC review, and moving to Step 2 of the current disorder review protocol. No discussion was offered.

Decision: The motion was approved unanimously by the Advisory Board.

Patrice noted the Oregon scientific review will take a couple of months so the conditions' review will probably not be ready December 2026 or possibly March 2027. Dr. Powers asked Patrice to relay to the scientific experts that there is a sense of urgency to complete this review.

6. Legislative Report

Patrice presented the draft outline of the 2026 legislative report. The Board is required to submit a report on its findings and any legislative recommendations by September 15th of every even numbered year. The Board had been provided with a draft outline for their review. Patrice asked the Board for approval, allowing staff, Board leadership, and consultants to prepare final text, inclusive of decisions from this meeting, and ensuring report submission by the statutory deadline.

The report will include the following items:

- Summary of 2025 / 2026 Board Meetings
- Legislative Session 2025: HB 3192 and HB 2741
- Oregon Administrative Rule Updates
- NWRNBS Advisory Board Charter Amendments
- Disorders considered for addition to the screening panel
    - Infantile Krabbe Disease
    - Update on GAMT Deficiency Implementation and MPSII Implementation
- Updates to Disorder Review Protocol
- Modernization of NBS Programs – BEACONS
- Health Equity Assessments – Screened and Unscreened Populations
- Future Direction of the NWRNBS Advisory Board

A motion was made by Marilyn Hartzell and seconded by Dr. Amy Yang for the Board to approve the outline for legislative report and directing Program staff, consultants, Board Chair, and Vice-Chair to finalize the report and submit it to the Legislature.

Decision: The motion was approved unanimously.

7. Discussion: Draft Condition Review Protocol

Patrice presented a proposed update of the Board's condition review protocol. The purpose for the revision was to:

1. Mitigate impacts to current review protocol resulting from ACHDNC dissolution.
2. Create a nomination process for a disorder review by the NWRNBS advisory board, that is not restricted to RUSP, yet sets the same standards, criteria and rigor for nominators to meet.
3. Adds an assessment of clinical evidence and screening
4. Ensure independent and comprehensive scientific review
5. Clarify evaluation criteria
6. Maintain transparency and meaningful public input opportunities

The table below compares the current and the proposed condition processes.

Current Procedure	Proposed Procedure
Step 1: Addition to the RUSP	**Step 1: Disorder Nomination**
Step 2: NWRNBS Program Evaluation	**Step 2: Initial Review Committee**
Step 3: Public Input on Disorder Review	**Step 3: NWRNBS Program Evaluation**
Step 4: NWRNBS Advisory Board Evaluation and Recommendation using Input from Steps 1-3	**Step 4: TAC Recommendations to the NWRNBS Advisory Board**
	Step 5: Public Input on Disorder Review
	Step 6: NWRNBS Advisory Board Evaluation and Recommendation

Detail of the proposed protocol included:

Step 1: Disorder Nomination
Any organization, group, or individual may submit a nomination form for a disorder to be considered by the NWRNBS Advisory Board for addition to the NWRNBS screening panel. The nominator must address all questions in the nomination form, which will inform the initial review process.

Step 2: Initial Review Committee
The NWRNBS Program will convene a Review Committee of three medical consultants who do not provide clinical care for individuals affected with the disorder. The Review Committee must include Oregon medical specialists but may also include providers from other states. The Review Committee members will individually review the disorder nomination form and accompanying information. The Review Committee members will advise the NWRNBS Program whether there is a screening test available for the condition and sufficient clinical evidence demonstrating improved outcomes with early detection and treatment for individuals affected with the disorder; thereby warranting further review of the disorder by the Advisory Board and Program. At least two Committee members must conclude there is sufficient clinical evidence demonstrating improved outcomes for the disorder to be reviewed by the Advisory Board.

Step 3: NWRNBS Program Evaluation

The NWRNBS Program will work with an outside consultant to conduct a thorough literature review of the disorder and provide a written evidence report with an executive summary addressing the disorder criteria to the Advisory Board. The consultant will also prepare a presentation summarizing their report at a Board meeting, to assist in its deliberations.

Step 4: TAC Recommendations to the NWRNBS Advisory Board
The NWRNBS program will convene a Technical Advisory Committee (TAC) of at least three medical consultants, who provide clinical care for individuals affected with the disorder. These medical consultants should be affiliated with the Program's contracted entities (e.g., Oregon Health & Science University) for newborn screening follow-up care. The TAC will review the consultant's report (step 3) and make a recommendation to the Advisory Board on whether the condition should be included on the NWRNBS panel. The recommendation will be shared by OHSU medical consultants on behalf of the TAC, at a Board meeting.

Step 5: Public Input on Disorder Review
The Advisory Board will invite input from the public to inform deliberations and recommendation on the disorder to the Program. This public engagement process will be transparent and provide clear opportunities for participation with timely notices and using multiple communication venues. At least one Advisory Board meeting will dedicate time for public input on the disorder.

Step 6: NWRNBS Advisory Board Evaluation and Recommendation
The NWRNBS Advisory Board will evaluate disorders based on the criteria, informed by all the information from Steps 1 through 5, including the consultant's report, public input, and the TAC recommendation. A consensus tool (see below) will be used to gauge the Board's level of agreement or support for recommending the Program add a disorder to the panel.

Patrice asked the Board:

- Does the draft disorder protocol process resonate with you overall? If not, what aspects would you like to discuss further?
- Do the revised protocol criteria make sense? If not, what would you change?
- Are you prepared to adopt the new protocol? If not, what needs further discussion?

Board members shared appreciation for the additional scientific reporting from the medical field. Concern was raised if the State had the resources to support its own vigorous review process and ability to fund it.

Board members wondered if the proposed review process would take longer. Patrice noted the new process will take longer but it will give advocacy groups the opportunity to present

to the Board more directly than going through the RUSP approval process. Without the RUSP review process, Oregon will need to do a more thorough review of the conditions. However, it allows the Board to make decisions with more confidence and review conditions that may have updated treatments available.

More specific questions from the Board regarding the proposed protocol included:

Q: Is there a time frame we should add to the language on which people should get a response to have appropriate expectations?
A: Patrice has seen the nomination process in another state, and she doesn't anticipate too many nominations being submitted all at once. Patrice noted that even if a condition is recommended for addition to the panel, actual implementation may take years, and the newborn screening program can't always move forward as quickly as we would like.

Q: Will we be able to review the nomination form before it is finalized?
A: Yes, the board can review the nomination form before it is adopted. However, the form specifics will not be included in the protocol language, to give flexibility for the Board to make edits at any time. Patrice has examples of other states' nomination forms and can work with others on the Board to create a form.

Q: A coordinator for the review process will be needed to track progress and move things forward. Would this be different from our current process? Is there someone in the lab who could do that?
A: Yes, there are OSPHL staff people that could coordinate and shepherd a condition nomination form through the process. This individual would not be a decision maker.

Q: Who will be doing the initial review process?
A: It would be sent to three people to answer the questions identified by the Board. These people would not be medical consultants who care for the babies with the condition to remove any bias. It wouldn't be contracted work and would be voluntarily. We have funds set aside for review of the condition but not for the proposed first step.

Q: Could the reviewers be non-medical consultants?
A: No, they would need to be medical. Perhaps, OSPHL could build it into their contract with OHSU for medical consultation.

Q: Are those three people you said are independent, are they independent from each other or are they a committee that discusses their thoughts?
A: There would be three separate opinions without any knowledge of the other reviewer's recommendations.

Board Members shared the following suggestions related to the proposed disorder review protocol:

- Add a pediatrician or family physician to Steps 2 and/or 4. It would be beneficial and informative to have their involvement.
- The nomination form and associated literature should be representative of all the literature out there.
- Modify Step 2 to include one person who cares for the babies affected by the condition but still have two people who don't to remove any bias.

Patrice said the Board does not need to decide immediately about the proposed protocol. With the course of action for DMD and MLD identified, she can work on a nomination form and do some polling with some of the independent consultants to see how they would feel about reviewing conditions not in their specialty, inquire how much additional cost would be needed to the contracts to support that activity.

The Board generally agreed that the process that has been laid out is something they can support. There were caveats noted with the number of nomination forms that will be submitted, the funding that is available for the review and management, and the timeline for the process.

Erik recommended another draft be developed and brought back to the Board in September. Patrice will also work on the nomination form and a timeline and would like to work with a small group to go over the materials. If a Board member is interested in assisting in the drafting of the nomination form, they were asked to please reach out to Patrice.

8. Program Updates

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

<u>Screening Updates</u>

Infantile Krabbe Screening:

Infantile Krabbe screening has been live for six months. They have tested ~30,619 babies. 21 babies had GALC activity less than 12% MoM (ranging from 6.4% to 11.76%). Psychosine was normal in all babies, except for one. Baby was referred to medical specialists for evaluation (8.55% GALC, 2.2 nmol/L psychosine). Presumptive late-onset Krabbe Disease.

GAMT Deficiency

Laboratory is in the process of validating an assay to combine GAMT deficiency with XALD screening using LC-MSMS. On a side note, analytes for MLD will also be incorporated for future implementation. Tentative implementation on November 1, 2026. Following the next advisory board meeting (September 2026), OHA will hold a RAC to obtain comments on the inclusion of GAMT deficiency to the panel.

MPS II

Treatment has been officially FDA approved and is showing excellent results. It has taken a bit of time to get the condition implemented due to the delay in testing kits being FDA approved. Implementation is tentatively scheduled for 2027.

<u>BEACONS Study</u>

Patrice provided an update on the BEACONS Study. The national feasibility study for whole genome sequencing. Oregon was chosen as one of the seven states to participate.

There have been numerous events over the last couple of months including:

Focus Groups

- Provider focus group was held on Wednesday May 13, 2026
- Plan to offer a parent focus group, but no date has been set

Provider Education

- Providers in all participating states are invited to join upcoming webinars about the BEACONS project. May 18 and June 3.
- *Additional Oregon specific provider education opportunities will be needed*

IRB protocol review, including consent forms

- OHA has nearly completed its review of the protocol
- OHSU and PeaceHealth are also reviewing the protocols and forms

Contracts

- OHA contract with BEACONS/APHL has been signed
- Contracts are still in review by OHSU and PeaceHealth

Questions from the Board regarding the BEACONS study included:

Q: Were emails for the events sent through the Board or OHSU?

A: The Provider group was by invitation because they wanted a small group. OHA/OSPHL will create more opportunities for feedback from Providers.

Q: Is there genetic counseling for those families who test positive?

A: Yes, GeneDx will send their reports to the lab to reach out if an abnormal result occurs, and then the lab will reach out to the proper specialists for the condition.

Q: Will the lab be releasing the report that you receive from BEACONS?

A: Yes, the report received from GeneDx will be released by newborn screening program? However, if specialists have questions or PCPs have questions, there is a BEACONS hotline to call for genetic consults.

9. Wrap-up

Dr. Powers thanked everyone for a great meeting. She appreciated that the Board made some progress on what was thought to be a hard to accomplish agenda and had an effective meeting. She is looking forward to the next steps and complimented Patrice in spearheading the BEACONS study. The next meeting will be on September 14th from 1pm to 4pm. The meeting was adjourned.