

Oregon Health Authority
Northwest Regional Newborn Bloodspot Screening Advisory Board

Meeting Summary

April 27, 2022

Location

Videoconference

Quorum

Board attendees constituted a quorum for the duration of the meeting.

Board Members Attending

Cheryl Hanna, MD, Representative of a statewide association of pediatricians
Marilyn Hartzell, M.Ed., (board chair) Person or family member of a person affected by a disorder on the Newborn Screening Panel
Andrea Keating, LDM, CPM, Representative of a statewide association of midwives
Jill Levy-Fisch, Advocacy association regarding newborns with medical or rare disorders
Dawn Mautner, MD, MS, Representative of Medicaid or insurance industry
Elizabeth Powers, MD, FAAFP, Representative of birthing center or hospital
Joanne Rogovoy, Advocacy association regarding newborns with medical or rare disorders
Kara Stirling, MD, Representative of a birthing center or hospital
Amy Yang, MD, Contracted medical consultant

Board Members Absent

Philip Dauterman, MD, FCAP, Entity that contracts with NWRNBS for newborn bloodspot screening
Wannasiri (Awe) Lapcharoensap, MD, Representative of a statewide association of pediatricians

Program Staff

Oregon Health Authority, Oregon State Public Health Laboratory:

- Sara Etienne
- John Fontana
- Sheri Hearn
- Patrice Held (Board Chair)
- Sarah Humphrey King
- Kristi Murphy

Diane Quiring, Oregon Health Authority, Health Systems Division

Collette Young, Oregon Health Authority, Center for Public Health Practice

Guests

Additional Members of Rules Advisory Committee (in addition to board members)

Attending for agenda item #5 only

Jenny Cavarno, Family Advocacy and Support Network

Antoinette Awuakye, Cambia Health Solutions

Members of the Public

Jenny Cavarno

Shane Ersland

Elsa Johnson

Carolyn Lee

Representative Susan McLain

Sarah Viall

Leah Wessenberg

Oregon Consensus Facilitation Team

Robin Harkless, facilitator

Cat McGinnis, project associate

ACTION ITEMS

- Items identified for long-term funding subcommittee to address: 1) direct and review research regarding other NBS programs' funding models; 2) consider criteria for qualifying for fee waiver, as some applicants do not qualify; 3) consider format of fee waiver form and ways for program to help people fill out form; 4) look at fee waiver and other materials through a disability lens.
- Consider whether board needs to go back and review/reconsider its criteria for adding/removing disorders from the screening panel.
- Consider whether to hear directly from family advocates about the difficulties of the process for getting a disorder on the panel.
- Advisory board members to provide final feedback on the 2022 report to the legislature.

MEETING AGENDA ITEMS

1. Program updates

- June 1, 2022, SMA testing will start. The program is doing outreach to educate provider communities.
- The Practitioner Manual has been updated and will be available June 1, 2022.
- May 15, 2022, a revised version of the NWRNBS interface that is compatible with Chrome and Firefox will go live. The timeline is set by the program's data system vendor.
- Legislative report timeline and next steps
 - By 5/6—Cat will incorporate additional information from this meeting.
 - By 5/13—advisory board members provide final feedback and edits to Cat.
 - After 5/13, program will route the report through OHA's manuscript approval and report clearance processes, and work with DHS/OHA publications office to format the report.
 - Due to legislature September 2022

2. Review of meeting summaries

The January 21, 2022, and February 23, 2022, meeting summaries were adopted without changes.

3. Advisory Board Membership

The advisory board welcomed three new members to the board with terms effective April 11, 2022.

- Dr. Dawn Mautner, Medicaid Medical Director in the Health Systems Division of the Oregon Health Authority, representing Medicaid
- Dr. Elizabeth (Liz) Powers, Chief Medical Officer at Wallowa Memorial Hospital, representing a birthing center or hospital
- Andrea Keating, Certified Professional Midwife at Corvallis Birth & Women's Health Center, representing a statewide association of midwives (Oregon Midwifery Council)

4. Long-term funding subcommittee forming

The program asked the advisory board whether they would be interested in a subcommittee of the board to look at options for long-term funding of the NWRNBS program. All subcommittee meetings will be public meetings. The first meeting (for scoping) will be in summer or early fall. Interested members should complete the doodle poll that Cat will be sending.

5. Rules advisory committee—proposed NWRNBS fee increase

- See appendix A for slide presentation regarding fee increase.
- With the fee increase, the program plans to:
 - Expand specimen transport and follow-up services,
 - Add SMA and X-ALD to the screening panel and respond to national screening recommendations,
 - Develop electronic reporting to comply with federal and state requirements,

- Appropriately screen for complex disorders (e.g., gene sequencing), and
 - Improve the lab's continuity of operations plan.
- Rulemaking timeline: Rule will be filed by the end of May, including OAR changes that the board received previously. In June there will be a public hearing and written comment period as well as a budget review. All final paperwork will be filed in July. The goal is for fees to be effective August 1, 2022. Provider outreach will be concurrent with the rulemaking timeline.

Board discussion:

- Fiscal impact statement says 960 small businesses in Oregon will be impacted by the fee increase. The demographic that midwives serve will be disproportionately impacted. Providers operating small businesses who buy in bulk will experience a significant difference in upfront costs. Clients who pay out of pocket (no coverage) may not be able to pay. The fiscal impact statement needs to address the impact on midwives and their clients in detail. Response: The program will add more detail to the fiscal impact statement.
- Fee waiver requires client to pay up front for screening then fill out paperwork to see if they qualify for waiver. Some will not be able to pay up front or fill out complex paperwork. System is not user-friendly. Program response: The program may pursue a rule change to serve families better. In addition, the board has expressed an interest in discussing fee waivers with the formed subcommittee.
- Program to Rep McLain. Legislative funding for SMA marks the first time the program has received funding for adding a disorder. Would it be possible to get funding to support fee waivers? Rep. McLain response: Will begin conversations about this in legislature. Will need to know how many families can't pay the fee. Some states use general funds. She offered to send some research her office has conducted to the advisory board.
- On the website it's hard to find the fee waiver in parent-facing materials. It's in the Practitioner Manual. Program response: The program is revising the brochure and website layout. There will be a link in the resources section of the website. Also, the program is finding that many who apply for the waiver don't qualify. The program needs to look at criteria for qualifying. This would be something for the long-term funding subcommittee to address.
- We shouldn't assume families seeking a waiver can access a computer. The application needs to be on paper and the program needs to be able to help people fill it out.
- Program needs to connect with CCO care coordinators regarding fee increase and waivers.
- Need to also look at fee waiver materials through a disability lens. Need to use plain language and be accessible for the vision impaired.
- Program: We need to do user testing of website, etc. We're finding we need to use more videos.

6. Pathways for Oregon Family Advocates

- See appendix B for slides from this presentation.
- The program presented a discussion of creating pathways for parents who wish to recommend a disorder for the Oregon screening panel, including disorders that have not been added to the RUSP.
- The program asked the board: If a disease is on the RUSP does the board want to add it to the Oregon panel without further review? Does the board want to create a mechanism for parents to recommend disorders that are not on the RUSP?

Board discussion:

- What are the program costs of a review of a proposed disorder that is already on the RUSP? Program response: Needed to hire a contractor to get data—\$15,000, plus program time to review, and board in-kind costs.
- How many free screenings would that pay for?
- Program shared that in WI a program advocate helps a parent submit a disease nomination packet to the program. The nomination packet would include responses to the criteria proposed by the board for adding a new condition. The advisory board reviews the nomination packet and gets public input. Could the board pass that pre-work on to a parent advocate? Board member response: There is a high cost to scientific review—much more than \$15,000. Not every scientific evaluation gets published. Would need to network with researchers in the field to access all relevant data. The national RUSP review is much more in-depth than a parent advocate could do.
- Robin pointed out that considerations coming to the surface are: 1) cost; 2) need for a robust science review; 3) parents want a voice in the process.
- The RUSP meets ethical criteria. Is there a benefit that parents get if RUSP items are added to the Oregon panel without further review? RUSP approved disorder might not meet Oregon's needs.
- We don't know the impact if we're not screening for the disorder. Could we create equities with the money Oregon would spend on reviews?
- The RUSP process is lengthy but effective. We can't skip that process, but we should provide an avenue for families to advocate to us. Parents should be helped to get to their goal of a RUSP nomination. Funding is needed for pilot studies with consent at a few select hospitals. Other states have done this. It requires money and effort to do those studies.
- How do our criteria differ from the RUSP? What are the costs for adding RUSP disorders to our list?
- There is not really a desire to reject RUSP disorders for the Oregon panel, but the board needs to do its due diligence regarding availability of follow-up and treatment in Oregon.
- Our first child has cystic fibrosis. They were not identified at birth because the disease wasn't on the panel. Cystic fibrosis wasn't on the panel because there wasn't a definitive treatment at the time.

- SMA testing is starting. There is only one pediatric muscular specialist in Oregon. Fortunately there is a low incidence of SMA. If the incidence were higher, more providers might need to be available to provide a treatment.
- Robin: Maybe the board needs to go back and visit its criteria.
- Program: Should Oregon add disorders that are on the RUSP to its panel without further review? We can be faster about this—know what’s in the pipeline with the RUSP and we could add before RUSP finishes.
- Program: Where should this conversation go next?
- The question sounds complex and I don’t have enough information. Perhaps the board could have some materials and time to consider.
- We need more time to consider, but a voice for families is a critical element in equity.
- What is the likely volume of family nominations?
- Proposal to discuss it at the next meeting.
- Not all conditions that effect newborns are equally resourced. We have to be careful about groups with resources taking over our attention. The RUSP is an equalizer.
- Robin: Should we hear directly from family advocates about the difficulties of the process for getting a disorder on the panel?

7. Public comment period

There was no public comment

8. Looking ahead

The board will meet in late summer/early fall. This will give the subcommittee an opportunity for a scoping meeting that will get them going. We will poll regarding whether the next board meeting should be hybrid or in-person only.

Adjourned

Appendix A: Proposed Fee Increase Presentation

Oregon Newborn Bloodspot Screening

Proposed Fee Increase



Rules Advisory Committee
April 27, 2022



Prepared by: John Fontana, Sheri Hearn, Patrice Held, Nicole Galloway,
Andy Barrett, and Sarah H. King



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Newborn Bloodspot Screening (NBS) is:

- A coordinated system that tests infants for genetic and inherited disorders that result in death or severe impairment if untreated.
- A statutorily mandated, population-wide, fee for service public program that **improves the quality of life** of impacted Oregon infants and their families.
- Administered by the Northwest Regional Newborn Bloodspot Screening Program at the OSPHL.
- A regional program
 - Including New Mexico, Tribal Nations, Guam, Saipan, and others.
- 2 screens for 42 disorders.
 - Including PKU, Sickle Cell Disease, Severe Combined Immunodeficiency, Cystic Fibrosis, Congenital Hypothyroidism, and many others.



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NBS helps improve infant health outcomes



NBS is a Public Health Achievement

- More than 1 in 500 babies have abnormal results reported.
- Over 100 Oregon babies a year are referred to medical services to prevent life-altering complications.
- Early detection and treatment can prevent need for expensive, life-long care.

NBS is Equity Focused

- Population-wide, mandatory screening promotes equitable health outcomes.
- Screens for Sickle Cell Anemia and other disorders that impact minority communities.
- Provides additional testing, when practical, to help preserve maternal-child bond.

NBS is Modernizing to Increase Equity

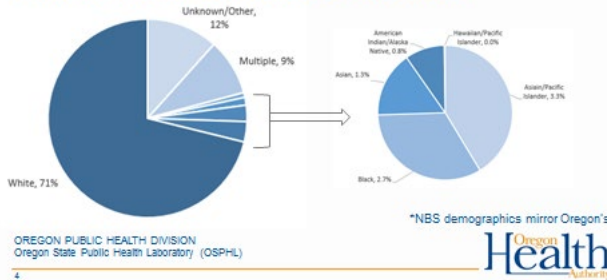
- Enhance NBS Follow-up services for carriers with health impacts (sickle cell trait).
- Upgrade the NBS lab information system.
- Improve courier services.
- Broaden education and translation services.

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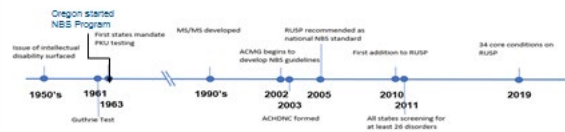
Demographics served by NBS*

- Mandated for all births in Oregon.
- Oregon has >40,000 births per year.
- In 2020, 74 Oregon babies were diagnosed with a disorder by the newborn bloodspot screening system.
- 8,857 (22%) of babies screened were identified as Hispanic.



NBS follows a national standard of care.

- Newborn Bloodspot Screening started in 1963 with 3 tests: PKU, MSUD, and Galactosemia.
- Federal recommendations were established in 2005.
- Current HHS Recommended Uniform Screening Panel includes 36 core* and 26 secondary disorders.
- US States and Territories and Tribal Nations administer NBS for their citizens.



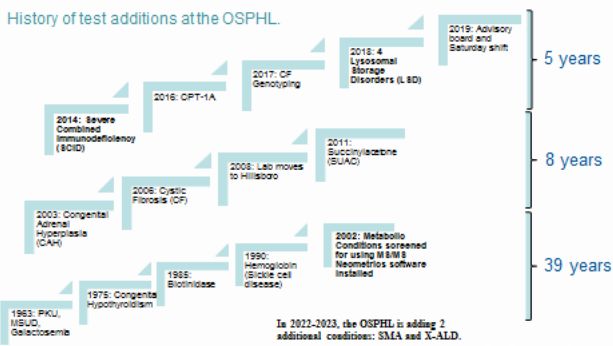
* Hearing screening and critical congenital heart disease are not performed by Public Health Laboratories.

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The rate of progress is increasing rapidly.

History of test additions at the OSPHL.



A fee increase is needed to ensure timely, quality, equitable services to promote the health of Oregon infants

- Current biennial shortfall is projected at \$4 Million.
- A fee increase from \$80 to \$175 would provide resources needed to ensure program sustainability and to advance improvement initiatives.
- For the United States, fees for Newborn Screening programs range from \$75 to \$220.*



* Programs with grant funding and consistent alternative sources of funding are excluded.

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NBS Improvement Initiatives

With this fee increase, the NBS Program will:

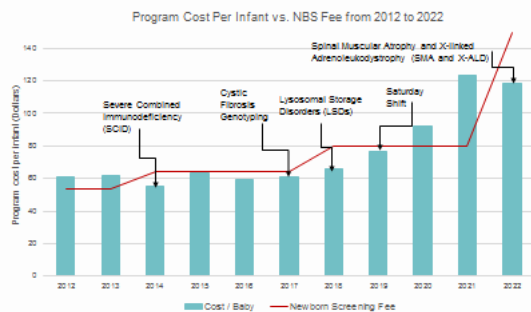
- Expand courier and follow up services.
- Add additional disorders:
 - SMA and X-ALD
 - Respond to national recommendations
- Develop electronic reporting to comply with the 21st Century CURES Act and align with REAL-D requirements.
- Appropriately screen for complex disorders (Gene Sequencing).
- Improved Continuity of Operations Plan.

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Projected budget deficit and fee increase



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How are NBS fees paid? By whom?

- NBS collection kits are purchased by medical practitioners as single, double or triple kits.
- Single kits = \$59.00
- Double / Triple kits = \$80.00
- Practitioners are reimbursed by insurance plans.
 - Global package payment for inpatient birthing services.
 - Community birth providers are reimbursed for a supply bundle.
- Some parents self-pay for NBS kits
 - Fee waiver available for qualifying families



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Future Funding Planning

- NWRNBS Advisory Board
 - Advised that fees are not a sustainable long-term funding model for the program
 - Program investigating alternative funding models used by other states
 - Program proposing subcommittee of board members to support long-term planning
- Medicaid (OHP) Reimbursement for Community Birth Providers
 - Reimburse NBS collection kit separate from supply bundle
 - Match collection kit reimbursement with NBS kit fees
- Department of Consumer and Business Services (DCBS)
 - Learning from their connections about how NBS is paid for in insurance carrier networks

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Proposed Timeline

October 2021

- Present proposed fee increase to Oregon Health Authority (OHA) leadership.
- Initial planning discussion with OHA Budget team.

January-March 2022

- Community Engagement
 - Contracted medical consultants
 - Oregon Maternal and Child Health Program
 - NWRNBS Advisory Board
 - Parent-focused and community-based organizations
- DCBS & HSD

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Proposed Timeline

April 2022

- Rules Advisory Committee
- Community Engagement

May-July 2022

- Rules filed with Secretary of State
- Public Hearing; Public comment period
- OHA Budget Office review
- Department of Administrative Services review

August 1, 2022 – Fees Effective

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Rules Advisory Committee Feedback

- Do you have any questions about why this fee change is important for the NBS Program?
- How do you see this fee change affecting the community or group you represent?
- Do you have any additional input about racial equity related to this rulemaking?

Documents to review:

- Oregon Administrative Rule Language
- Statement of Need and Fiscal Impact
 - Racial equity statement
 - Impact for small businesses

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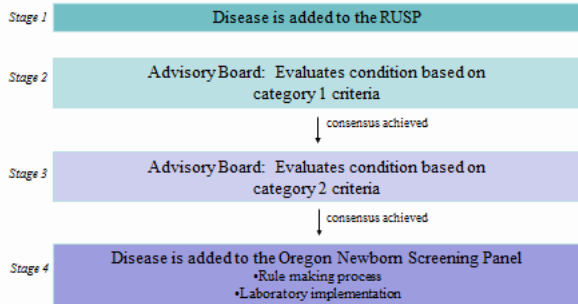
Appendix B: Pathways for Oregon Family Advocates

NBS Advisory Board

Pathways for Oregon Family
Advocates
April 27, 2022



Oregon Disease Review Process



HB4109-Lessons Learned

Advisory Board

- Scientific evidence should drive the evaluation process of new diseases to be added to state screening panels
- The HRSA sponsored committee (SACHDNC) allows for this robust scientific evaluation of new diseases to be added to the Recommended Uniform Screening Panel (RUSP).

Family Advocates

- Strong desire amongst Oregon families/advocates to bring their voices into the process for disease nomination and review



Consideration and Discussion

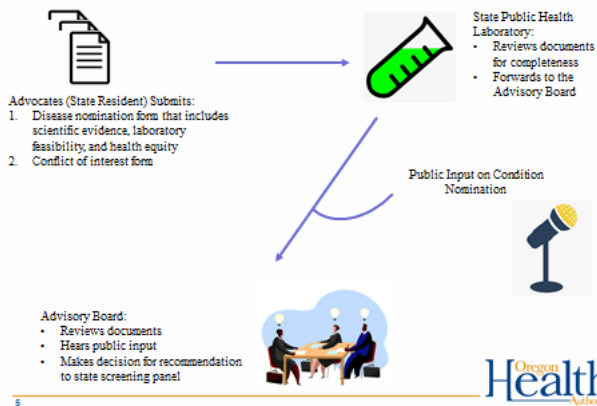
Is the advisory board interested in...

- *Automatically adding diseases on the RUSP to the Oregon panel, without additional review?*
- *Creating a mechanism for Oregon parents/advocates to submit a condition for review?*



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Example Process



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