

# **Oregon Health Authority**

## **Northwest Regional Newborn Bloodspot Screening Advisory Board**

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### **Meeting Summary**

**November 1, 2021**

**Location:** Videoconference

### **Quorum**

Board attendees constituted a quorum.

### **Board Members**

Silke Akerson, CPM, LDM Representative of a statewide association of midwives

Anna Dennis, MS, CGC, Advocacy association regarding newborns with medical or rare disorders

Nicole Galloway, PhD, Oregon Health Authority, Oregon State Public Health Laboratory

Cheryl Hanna, MD, Representative of a statewide association of pediatricians

Marilyn Hartzell, M.Ed., Person or family member of a person affected by a disorder on the Newborn Screening Panel

Wannasiri (Awe) Lapcharoensap, MD, Representative of a statewide association of pediatricians

Jill Levy-Fisch, Advocacy association regarding newborns with medical or rare disorders

Joanne Rogovoy, Advocacy association regarding newborns with medical or rare disorders

Kara Stirling, MD, Representative of a birthing center or hospital

Cate Wilcox, MPH, Honorary representative

Amy Yang, MD, Contracted medical consultant

Collette Young, PhD, Honorary representative

### **Absent**

Philip Dauterman, MD, FCAP, Entity that contracts with NWRNBS for newborn bloodspot screening

Dana Hargunani, MD, MPH, Medicaid or insurance industry representative

### **Program Staff**

John Fontana, Oregon Health Authority, Oregon State Public Health Laboratory

Sheri Hearn, Oregon Health Authority, Oregon State Public Health Laboratory

### **Guests**

Shannon O'Fallon, Department of Justice

Diane Quiring, Oregon Health Authority, Health Systems Division

Joanna Riemenschneider, Department of Justice

Belle Shepherd, Oregon Health Authority, Government Relations

### **Members of the public**

Mary Schroth, Cure SMA  
Sarah Viall  
Cheryl Grabham  
Don Stecher  
Maynard Friesz  
Kathy Oulette  
Raffia Razzaque

### **Oregon Consensus Facilitation Team**

Robin Harkless, facilitator  
Cat McGinnis, project associate

### **ACTION ITEMS**

- Nicole will research the timing for Advisory Committee on Heritable Disorders Newborns and Infants (ACHDNC) review of a nominated condition and get back to board.
- If any board member has comments/questions they should contact Robin Harkless for process questions and Sheri Hearn for substance questions and any other board business. (Sheri is not limited by being a board member as Nicole was.)
  - **UPDATE**: Sheri Hearn has stepped in as interim Newborn Screening Program manager with Nicole providing technical and process support to the board. As such, board communications can be sent to Nicole or Robin.
- Provide slides from Sheri Hearn, and Diane Quiring along with the meeting summary.
- Form a small group to come up with a methodology and potential survey or instrument to determine (1) how many live births in Oregon are being screened? (2) Who is paying for newborn screening (Medicaid, insurance, out of pocket, etc.)? (3) How often is the fee waiver process used? The program will send questions out and invite board members to volunteer for the subcommittee.
- Nicole will share the timeline for the statute review process when known.
- Communication submitted through the advisory board's official email address will be responded to and this task is delegated to the co-chair, per the board's charter. Nicole agreed to find out if board review of a response constitutes a serial communication.
  - **Follow up**: DOJ shared back with the program that if the co-chair is delegated to respond to the public and the response doesn't include making decisions that are normally an item for board consensus making then the co-chair can ask other board members for input. However, any substantive issue that could require a board decision would be better brought to the board. They said that delegation in general is fine so long as it is not used inappropriately for continued decision making and that the delegated decision maker does exercise their authority.

## **MEETING AGENDA ITEMS**

### **1. NWRNBS program updates**

*NWRNBS hires.* The program is in the process of hiring a new manager to replace Chris Biggs, who retired. The program has hired a second follow-up coordinator. The NWRNBS program team is now working on infrastructure process improvement, including interoperability (electronic test orders and reports (ETOR); education and outreach, especially around sickle cell traits; and outreach to reduce the rate of unsatisfactory specimens.

*Improving specimen delivery.* The program received funding for looking at ways to get specimens faster (e.g., by courier or expedited shipping).

*Spinal Muscular Atrophy (SMA) update* (slides provided separately). The program received legislative funding for SMA screening.

*Program project plan 2022. (Deadlines are subject to change)*

- The program is working to implement SMA. The first step is doing a cost-benefit analysis of different SMA testing methodologies. The program will have a method evaluation plan by February 2022. The program is working on updating contracts and hopes to have them completed by June 2022. The program is working to hire a public health nurse for follow-up on SMA testing. They'll contract with a medical consultant by June 2022 and work on follow-up algorithms and education materials with an expected completion of July 2022. NWRNBS administrative rules will need to be updated to include SMA, which will take place by October 2022.
- Staff resources have been assigned for overseeing implementation of X-ALD testing. New equipment and reagents are in the process of being delivered. The method evaluation plan will be ready around February 2022. Follow-up algorithms and education materials should be complete in April 2022. Rulemaking will occur in October 2022.
- Two communications were submitted through the board's official email address related to Krabbe, and these were forwarded to the board just prior to the board meeting. One submittal was from an advocate family and one was from State Representative McLain. The board will respond immediately with an acknowledgment of receipt; and later plan to track and hear status updates on the national process of the ACHDNC review of the Krabbe nomination package for addition to the Recommended Uniform Screening Panel (RUSP).
  - ACTION. What is the timeline for review of a nominated condition to the RUSP? Nicole will research and get back to the board.
  - Comment: It will be important for the board to be prepared to conduct a review if Krabbe is added to the RUSP. The board will include a status update at their next meeting in spring 2022.
  - Could we get pre-information regarding conditions that are entering the pipeline for the RUSP?

## **2. Summary from previous meetings**

The meeting summaries from March 1, 2021, and July 12, 2021, were approved and will be posted to the NWRNBS advisory board webpage.

## **3. Board and legislature**

Question from last time: How does a board member or the board as a whole interface with the legislature? Can we comment on legislation? How do we coordinate with the program? Must it be the board as a whole? How do we comply with public meeting requirements in such cases? Belle Shepherd, OHA government relations responded:

- OHA staff must follow OHA protocols—they support OHA’s and governor’s bills and are no position on all others. A staff member can communicate with legislators or media only as a private person. OHA shares facts only, not opinions. The board is not under that guidance. The board can testify at legislative hearings, but would do so in cooperation with OHA government relations. Board members can testify alone in their professional and personal capacity, but should make clear they are not speaking on behalf of the board. Board can submit written testimony through the Legislature’s OLIS website at <https://olis.oregonlegislature.gov/liz/202111>.
- If any board member wants the full board to review and respond as a board to legislation, they can request a special board meeting.
- Any board member who is interacting with the legislature in a professional or personal capacity is invited to seek guidance from OHA government relations.
- Note that bills for the next session will drop January 14, 2022.

## **4. Public meetings laws (slides provided separately)**

Joanna Riemenschneider, Assistant Attorney General, Department of Justice, presented on public meeting laws, drawing from the Oregon Attorney General’s Public Meetings and Public Records Manual 2019 available at <https://www.doj.state.or.us/oregon-department-of-justice/public-records/attorney-generals-public-records-and-meetings-manual/>.

- When a quorum is required for public decision making, there must be public notice, documentation of the meeting, and public access.
- Serial communication between board members that constitutes a quorum, even when through an intermediary, is considered a public meeting. Polling board members would constitute a serial communication.
- Meetings of two or more board members authorized to make recommendations to the board are considered subcommittee meetings and are subject to public meeting laws.
- One way communications with the board that do not request a response are not serial communications.
- One-to-one communications between a board member and staff are not serial communications.
- An individual board member putting together an individual recommendation is not subject to the law.

- Communications between meetings that fall under the law can be accomplished quickly with internet notice and public access. A public comment period is not required.
- Things to avoid because they do not allow public access: serial email communications and serial editing of a document.
- Co-chairs can communicate with each other regarding meeting agenda items because the program manager makes the final decision on the meeting agenda.
- ACTION: Responses to board inquiries will be delegated to the co-chair. Nicole will find out if board review of a response constitutes a serial communication. (See response above.)

## 5. Midwifery

Silke Akerson, midwifery representative on the advisory board, opened this discussion suggesting that this topic related to an equity concern related to access to newborn screening. She shared information:

- There are barriers around cost and access to newborn screening for home births.
- The test kit is \$80 and if not covered by insurance, parents can be income qualified for free testing but may not utilize this reimbursement.
- The total fee for the home-delivery supply kit is \$229. A midwife can't bill separately for newborn screening.
- When considering raising the screening fee, the program needs to consider out-of-pocket screening costs.

Diane Quiring, OHA, shared a presentation on the issue (slides provided separately):

- Two OARs address the bundling of the fee for the supply kit. OHA is in the process of amending rules to carve out the newborn screening fee. There was a rule advisory committee in May 2021 and they updated provider guidance and did a fiscal analysis. They need to have leadership sign off. They're waiting for the medical services rule. The lab and radiology rule will be amended through an emergency rule and followed up with a rule advisory committee.

### Q&A:

- There was a request for data on what percent of live newborns in Oregon are being screened and who is paying for it. Nicole Galloway explained that it is hard to get the data. The program is trying to build a better link with the Center for Vital Statistics. However, NWRNBS also screens newborns from outside the state so data shows more screens than live births in Oregon.
- Hospitals are bundling the testing fee into the birthing charge. It would be hard to track if they're not billing as a separate code. Would there be value in asking hospitals to unbundle the rate? Would need to ask the hospital association. Nurses are overworked and might oppose entering yet another code. That code is unique to a home birth, not hospitals for OHP medicare births.
- Collette Young suggested that a subcommittee be formed to come up with a methodology to determine (1) screening vs. live births, (2) how much Medicaid is

reimbursing, (3) Who is paying for screening. ACTION: The program will send questions out and invite board members to volunteer for the subcommittee.

- The process to waive the newborn screening fee is in rule and the program suggests that the board consider looking at that rule.

## 6. Review of NWRNBS statute

### Overview:

- The program provided a marked up version of the statute showing potential changes. This would be a legislative concept for the 2023 legislative session. Nicole noted that statute is where authorities are granted to the program; rules are the place for the agency to describe how it will carry out its statutory authorities.
- Shannon O’Fallon, DOJ Advisor to the program, is reviewing the changes with the program.
- The program will seek input from community partners and may lean on the board to assist with connections.
- The statutes haven’t been substantively updated for decades. They include ORS 433.285, ORS 433.290, and ORS 433.295.
- Section 2 was added (moved from elsewhere and expanded to better reflect what the lab does) and calls out newborn screening. This section is also where authority is given to screen and test for other jurisdictions.
- Section 3 adds authority to have another laboratory do the screening if necessary, such as for second tier testing.
- Section 3 addresses the right to decline testing, CCO requirement to cover cost of screening, and confidentiality.
- If a revised statute is approved, rules may need to be opened up for review and possible revision to ensure alignment.

### Comments and questions:

- Need to add language back in that no one should be denied a test due to inability to pay.
- How do people know about the fee waiver? Program doesn’t know if providers are telling parents about the waiver. Collette Young felt this would be another good opportunity for a subcommittee to design methodology to survey providers and parents regarding exchange of information regarding the waiver. ACTION: The program will follow up to recruit assistance on exploring this topic.
- Should the statute require that the provider inform parents about the fee waiver? The program suggested the board look at language regarding the fee waiver in more detail.
- Section 4 ensures the program will provide education.
  - Maybe this is a place to include more about providers informing parents about the fee waiver.
- Section 5 creates immunity for NWRNBS regarding screening. What if there is gross negligence?
  - It would be a policy question for the legislature whether it wants to add an exception for gross negligence.

- Changes to ORS 433.295 establish responsibility of health care providers to report back to NWRNBS regarding confirmed conditions that were found through screening and conditions found later that weren't found through screening. This provides quality control for the program. This is not routinely done, but it will be a requirement under this amendment. The program will need to educate providers.
  - One concern: it could prove difficult to reach providers and then they will be out of compliance. There was a suggestion that this be less formal and that OHA just ask subspecialists for the information. Nicole asked for board feedback about how to get information to the providers.

Next steps: Nicole will share the timeline for public review of the statute changes.

### **7. Public comment**

Cheryl Grabham thanked the board for adding SMA to the testing panel. She and her daughter visited the board in spring 2020, and her daughter found it a very positive experience.

### **8. Board Work Plan**

Robin Harkless shared the board's work plan from 2019 to present with some outlook for 2022. The next legislative report will be due by September 2022.

The next board meeting will be held in spring 2022. The agenda will include:

- An update on disorders that have been reviewed by the board and any that have or are being reviewed by the ACHDNC .
- A 2022 short-session legislative recap
- The new permanent program manager, if hired, will guide the group on revisiting strategic directions.
- Other topics of interest to the board included timeliness of testing/results; urban/rural disparities.

### **9. Next steps**

A Doodle poll will be sent for a meeting in March or April 2022 (avoiding OR and WA spring break). A meeting evaluation and summary notes from today's meeting will be shared soon after the meeting.

**ADJOURNED**