2019

Northwest Regional Newborn Bloodspot Screening

Advisory Board Report to the Legislature







Oregon Health Authority
PUBLIC HEALTH DIVISION

Acknowledgments

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The Northwest Regional Newborn Bloodspot Screening Advisory Board

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Executive summary

About the Northwest Regional Newborn Bloodspot Screening Program

Newborn bloodspot screening is a coordinated *public health system* that relies on providers, parents and the public health laboratory. The Oregon Health Authority's Northwest Regional Newborn Bloodspot Screening Program (Newborn Bloodspot Screening Program) tests for certain disorders that may lead to disability or death without early detection and intervention. The program sends test results to medical providers who set up treatment plans where needed. The program also provides education and works with providers to continually improve the quality of screening.

Newborn bloodspot screening is mandated in statute (ORS 433.285 through ORS 433.295) for every infant born in the state, except for those infants whose parents adhere to a religion that is opposed to it. The program is authorized under ORS 433.295 to collect fees and is entirely fee-funded.

History of newborn bloodspot screening

Newborn bloodspot screening began in the early 1960s. Oregon was one of the first states to adopt screening and has always had a regional program. In 2005, the federal government adopted a Recommended Uniform Screening Panel (RUSP) that included 29 conditions. This panel is considered the national standard. Additional disorders have since been added to the RUSP, with 35 core disorders currently recommended for screening, including two that are point-of-care tests and not part of newborn bloodspot screening.

Summary of the advisory board meetings to date

The Northwest Regional Newborn Bloodspot Screening Advisory Board (the board) was formed in 2019 under HB 2563. This report reflects the board's work to date. The board has:

- Adopted a charter, including a commitment to consensus-based decision making
- Approved a protocol and criteria for recommending the addition of disorders to Oregon's screening test panel (Appendix C), and
- Agreed on findings and recommendations for changes to improve the timeliness of newborn screening.

Timeliness of the Newborn Bloodspot Screening Program

A primary concern the advisory board learned about from the Newborn Bloodspot Screening Program is timeliness of the screening process. In December 2016, the U.S. Government Accountability Office (GAO) set national goals for newborn screening timeliness (GAO-17-196). The overall timeliness goal is for non-time critical results to be reported within seven days of birth and time-critical results to be reported within five days of birth. Based on data from Jan. 1, 2019, through June 30, 2019, the Newborn Bloodspot Screening Program reported 90 percent of all results within seven days of birth and 38 percent of time-critical results within five days of birth.

Recommendations to the Legislature

The board recommends (with strong consensus) that, for the Newborn Bloodspot Screening Program to meet national timeliness goals, the following priorities must be addressed:

- Increase the number of satisfactory newborn bloodspot specimens to reduce delays due to re-collecting specimens.
- Reduce specimen shipping time by exploring the costs and benefits of providing courier service or expedited shipping.
- Reduce test result reporting time by implementing electronic ordering and reporting.
- Update the statute to reflect current best practices.

Conclusion

The board established its role of providing guidance to the Newborn Bloodspot Screening Program. It approved a protocol and criteria for evaluating disorders for recommendation to the screening panel. In upcoming meetings, the board will use the protocol and criteria to evaluate two disorders as well as establish a protocol and criteria to recommend removal of disorders.

For the full report, see https://www.oregon.gov/oha/ERD/Pages/Government-Relations.aspx or contact:

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Introduction

As mandated by HB 2563, this is the first report of the Northwest Regional Newborn Bloodspot Screening Advisory Board (the board), which was formed in 2019 under HB 2563. The board's purpose is to assist the Northwest Regional Newborn Bloodspot Screening Program (Newborn Bloodspot Screening Program) by providing advocacy, advice, recommendations and technical information based on members' respective areas of expertise. The board assists the Newborn Bloodspot Screening Program with strategic planning and the development of policies, priorities and services related to the newborn bloodspot screening system. Their goal is to improve health outcomes for all infants and their families.

The board meets at least every six months to engage in strategic planning, review developments in newborn bloodspot screening technology and practices, and create a shared vision for the future of the program.

This report is designed to provide the legislature with:

- Background on the Oregon Health Authority's (OHA) Newborn Bloodspot Screening Program
- Context for newborn bloodspot screening in Oregon and across the nation
- The board's progress in creating a protocol and criteria for recommending the addition of conditions to the newborn bloodspot screening panel
- Findings and recommendations for advancing the work of the Newborn Bloodspot Screening Program
- Plans for the board's future work.

The report reflects the work of the board at its first two meetings July 18, 2019, and Oct. 4, 2019.

Newborn bloodspot screening is more than a test

Screening is a coordinated *public health system* that relies on providers, parents and the public health laboratory. The Northwest Regional Bloodspot Screening Program sells test kits to medical providers. The provider takes a small blood sample from the newborn's heel and sends the specimen to the program. The laboratory conducts over 40 tests for heritable disorders that may not be clinically apparent in the first weeks after birth, but may lead to early disability or death if not detected early. The program sends the test results to providers who discuss any abnormal results with parents and set up treatment plans. Parents follow through with childhood health care. The program provides ongoing education and works with providers to continually improve the quality of screening.

By identifying infants early and referring them to care, lifelong outcomes are improved, children who would have been affected lead healthier and more productive lives, families receive critical support and health care costs are reduced. Newborn bloodspot screening saves lives.

Background

Guiding legislation and rules

The Newborn Bloodspot Screening Program's authority is set out in the following statutes:

- ORS 433.285, 433.290 and 433.295, which were established in 1963
- ORS 431A.750 (originally enacted as ORS 431.310 in 1919 and renumbered in 2015)

Excluding housekeeping amendments, ORS 433.285 was last revised in 1983 and ORS 433.295 has not been revised since its creation. ORS 433.290 was revised in 2017 to add "naturopathic physicians."

The Newborn Bloodspot Screening Program describes how to carry out the statutory authority in OAR 333-024-1000 to 333-024-1110.

HB 2563, passed into law in the 2019 regular session (see HB 2563 in Appendix A), sets up the board, specifies board member representation categories, establishes the board's governance framework and prescribes the frequency of meetings and reports to the legislature. The board has adopted a charter that conforms to this legislation.

Inception and standardization of newborn bloodspot screening

Inception of newborn bloodspot screening

The push for newborn bloodspot screening nationally happened in response to incidences of intellectual disability in children in the 1960s. Phenylketonuria, a condition in which the body cannot break down phenylalanine, was found to be the cause of many of these cases and a test was developed to allow widespread screening for phenylketonuria using dried bloodspots from infants. In 1963, the first states legislated newborn bloodspot screening for the disorder. Oregon was among these states. Newborn bloodspot screening became a rapidly changing field as researchers developed tests for other conditions that could cause death or severe impairment in the newborn period.

Standardization of screening

In 2002, the American College of Medical Genetics was asked by the federal government to create standard guidelines for screening. This was due to differences in states' approaches and the number and type of conditions screened for. They established the following minimum criteria for conditions to be screened:

- The condition could be detected within 24 to 48 hours after birth, when it could not be detected by a medical exam.
- There was a test that had sufficient sensitivity and specificity for the condition.
- Early detection, timely intervention and effective treatment existed and offered a proven benefit.

The college reviewed many conditions and placed 29 on a core screening panel and an additional 25 on a secondary screening panel because they lacked an effective treatment or the disease was not well understood. The core screening panel of 29 conditions would become the first Recommended Uniform Screening Panel (RUSP). In 2003, the United States Health and Human Services Advisory Committee on Heritable Disorders in Newborns and Children was formed to advise the U.S. Secretary of Health and Human Services about whether the RUSP could become the national standard; the panel was approved in 2005. The RUSP is now the national standard and is used by newborn screening programs to help determine which conditions to add to their state screening panels. Today's panel covers 35 core conditions and 26 secondary conditions. Two of the core conditions, critical congenital heart disease and hearing screening, are point of care tests and are not performed by newborn bloodspot screening programs.

Process for adding conditions to the RUSP

Anyone can submit a nomination package to the Advisory Committee on Heritable Disorders in Newborns and Children asking the committee to consider adding a condition to the RUSP. A work group of national experts conducts an evidence-based review and presents a final report to the Advisory Committee on Heritable Disorders within nine months. The Advisory Committee on Heritable Disorders decides whether to recommend the condition to the Secretary of Health and Human Services, who makes the final decision about whether to add the condition to the RUSP.

Current trends and influences in newborn bloodspot screening

Timeliness of process

The U.S. Government Accountability Office (GAO) established standards for timeliness of the screening process. The overall goals set by the GAO are that time-critical disorders will be reported within five days of birth and all newborn screening results will be reported within seven days of birth. The screening process is divided into three stages with a benchmark of 95 percent for each:

1. Birth to collection of specimen — 48 hours
2. Collection to receipt of specimen in the lab — 24 hours
3. Laboratory testing and reporting — not specified

The GAO conducted an audit in early 2014. In 2016, they reported that no states met the benchmark for receiving specimens in the laboratory within 24 hours, and few states met the benchmarks for the other two goals.

From the report, barriers to newborn screening programs' ability to meet the goals included the following:

- Stakeholders' lack of understanding of the importance of timely screening
- Lack of standardization in laboratory information systems that hindered feedback and slowed reporting
- Lack of courier or expedited shipping methods used to transport specimens
- Limited laboratory operating hours
- Lack of feedback for specimen submitters to provide information for improvement

Testing technology

The types of tests used to screen for conditions are rapidly evolving. These changes require that screening programs respond quickly to add new expertise to perform and interpret the tests. With the addition of severe combined immunodeficiency in 2010, programs needed to add molecular testing expertise. Because of disorders that have been added recently, programs must now consider adding expertise in bioinformatics and genetic counseling as well as in genetic sequencing technology. Additionally, newer disorders have complex considerations, such as carrier status or the discovery of mutations of unknown significance. These complexities pose new questions to newborn screening programs on how to interpret, report and follow up on these results.

New disorders changing the paradigm

As with the pace of technology, the frequency of disorders being added to the RUSP has accelerated. Complexity of the conditions and their treatment has increased as well. Long-term follow-up is now needed for some disorders to determine the impact on patients and to gather more information on treatments.

The digital age of information

It is now possible to use electronic communication of screening orders and results to improve timeliness and flow of information. New ways to access and analyze data, so that it is more accessible to those who need it, are becoming more common. Overall, new technologies are presenting opportunities for programs to improve and expedite screening and expand knowledge in the field.

Northwest Regional Newborn Bloodspot Screening Program

The Northwest Regional Newborn Bloodspot Screening Program (Newborn Bloodspot Screening Program) was one of the first programs in the United States and has been in operation since the early 1960s. It provides testing regionally for Oregon, Idaho, New Mexico, Guam, Saipan, parts of the Navajo Nation and several military bases around the world. The program conducts two screens per infant — one at 24 hours after birth and another at 10–14 days after birth. It screens nearly 100,000 infants each year, which requires approximately 10,000,000 tests. The program screens for more than 40 disorders. This includes all conditions on the RUSP that are tested using a dried bloodspot specimen except two: X-linked adrenoleukodystrophy (X-ALD) and spinal muscular atrophy (SMA). The Newborn Bloodspot Screening Program has 13 testing personnel and five personnel who follow up with parents about results and with test submitters about specimen quality and patient information. The program is entirely funded by fees paid by payers, providers and parents.

Adding conditions to Oregon's screening panel

Historically, it has taken two to four years for Oregon to add a condition to its panel once the condition has been added to the RUSP. For the Newborn Bloodspot Screening Program to add a condition to the state's screening panel, the following are some of the activities required:

- Determine if there are enough staff and experts in the laboratory and follow-up unit.
- Locate an effective test.

- Procure testing equipment.
- Revise the program's governing rules.
- Seek position authority from the legislature, if necessary.
- Validate that the testing method works and how the test results will appear on the report.
- Determine the follow-up flow process.
- Update the laboratory information system.
- Create and disseminate educational materials for parents and providers.
- Update the state's *Oregon Newborn Bloodspot Screening Practitioner's Manual.*
- Notify providers of the coming change.

Timeliness of the Newborn Bloodspot Screening Program

The overall timeliness goals set by the GAO are for non-time-critical results to be reported within seven days of birth and time-critical results to be reported within five days of birth. Overall, Oregon currently reports 90 percent of results within seven days of birth and 38 percent of time-critical results within five days of birth.

Based on data from Jan. 1, 2019, through June 30, 2019, the timeliness of the Newborn Bloodspot Screening Program's process was as follows, based on a benchmark of 95 percent achievement of the GAO timeliness goals:

- Birth to collection within 48 hours — 95 percent
- Collection to receipt at the laboratory within 24 hours — 30 percent
- Receipt in the laboratory to reporting of results — 71 percent of results within three days of receipt and 96 percent within six days of receipt.

Continuous quality improvement of the Newborn Bloodspot Screening Program

The program has a culture of continuous quality improvement.
Current projects include:

- Decrease the rate of unsatisfactory specimens that must be re-collected.
- Improve the practice profile, a "report card" sent to providers monthly that has key indicators of performance.
- Improve website information for providers and parents.
- Use data more effectively. The availability of better analytic software provides more opportunities.

In addition, the Newborn Bloodspot Screening Program recently added a partial Saturday shift to improve the timeliness of results.

Advisory board information and meeting

Content of the advisory board meeting

At its first meeting, the board heard background about the national and Oregon context of newborn screening. They approved their charter and began to look at establishing a process and criteria for adding conditions to the screening panel. They discussed recommendations for the legislature. They also served as a rules advisory committee to review and provide input to the agency on a number of proposed rule changes.

A quorum of the board members attended the first meeting in person and by phone. (For a full list of advisory board members, see Appendix B.) The meeting was facilitated by Portland State University's Oregon Consensus program. The board held a second meeting Oct. 4, 2019, to continue work on criteria for adding conditions to the screening panel. A quorum was met and the board approved the protocol and criteria for adding conditions to the screening panel (see Appendix C).

Board charter and consensus decision making

The board adopted a charter that reflects requirements in HB 2563. It also addresses governance issues such as decision making and board values. The board will use a consensus-seeking decision-making process for all recommendations. All findings or recommendations will be captured as "strong," "weak" or "no consensus." When the board indicates no consensus or weak consensus on a given issue, the points of divergence will be submitted in writing for inclusion in legislative reports. There was strong consensus in support of the board values included in the draft charter. The charter was adopted in total with strong consensus. The charter as adopted is included in Appendix D.

Disorder evaluation criteria

The board approved, with strong consensus, a process and criteria for evaluating the addition of disorders to the newborn screening panel. They identified key values for disorder evaluation as *efficiency, timeliness and transparency.* To support their work, the board requested that information about the disorders be provided before deliberation on a condition and that subject matter experts are available to assist in board discussions.

Recommendations to legislature regarding timely screening

The board recommends (with strong consensus) the following priority needs be addressed to help meet timeliness goals:

- Increase the number of satisfactory newborn bloodspot specimens to reduce delays due to re-collecting specimens. Set a standard of excellence. (Currently, 4 percent of specimens sent to the Newborn Bloodspot Screening Program are unsatisfactory, compared to a national average of 2 percent.)
- Explore the cost and benefit of providing courier service or expedited shipping to get specimens from the provider to the laboratory within the GAO timeline.
- Implement electronic ordering and reporting; this is a high need for the Newborn Bloodspot Screening Program and should be a priority.
- Update the statute to reflect current best practices.

Future advisory board work

The board's upcoming goals are to do the following:

- Review X-ALD and SMA for addition to the newborn screening panel.
- Establish a process and criteria for removing conditions from the newborn screening panel.
- Discuss recommendations for statute updates.
- Discuss the costs and benefits of a courier service or paid expedited shipping for specimen delivery to the laboratory.
- Discuss opportunities for educational activities for parents and providers and their effectiveness.
- Conduct strategic visioning and planning for the Newborn Bloodspot Screening Program.

Conclusion

The board has successfully begun providing guidance to the Newborn Bloodspot Screening Program. This report reflects the group's initial work of:

- Establishing a charter
- Approving the protocol and criteria for recommending the addition of conditions to the newborn screening panel, and
- Providing recommendations to the Oregon Legislature to improve the timeliness of the screening process — a key need identified by the program and board.

In coming months, the board will begin applying its criteria to recommend adding conditions to the screening panel, establish a protocol and criteria for removal of conditions, and work with the program to apply improvements that will meet new standards of excellence in the timeliness of newborn screening in Oregon.

Appendix A: HB 2563 enrolled

80th OREGON LEGISLATIVE ASSEMBLY--2019 Regular Session

Enrolled

House Bill 2563

Sponsored by Representatives MCLAIN, SOLLMAN, SCHOUTEN, HAYDEN; Representatives ALONSO LEON, KENY-GUYER, NOBLE, NOSSE, PRUSAK, SALINAS, SMITH WARNER, WILLIAMS, WITT, Senator HANSELL (Presession filed.)

CHAPTER .....

AN ACT

Relating to screening newborns for diseases; and declaring an emergency.

Be It Enacted by the People of the State of Oregon:

SECTION 1. (1) The Newborn Bloodspot Screening Advisory Board is established in the Oregon Health Authority.

(2) The board consists of 13 voting members appointed by the Director of the Oregon Health Authority as follows:

(a) One member who is a person affected by a disorder included in the newborn screening panel or a family member of a person affected by a disorder included in the newborn screening panel;

(b) One member who is a licensed physician who by contract provides expert medical advice and consulting services to the Northwest Regional Newborn Bloodspot Screening Program;

(c) One member who is a representative of Medicaid or the insurance industry;

(d) Two members who are representatives of birthing centers or hospitals;

(e) One member who is a representative of an entity that contracts with the Northwest Regional Newborn Bloodspot Screening Program for newborn bloodspot screening services;

(f) Three members who are representatives of advocacy associations regarding newborns with medical conditions or rare disorders;

(g) One member who is a representative of a statewide association of nurses;

(h) One member who is a representative of a statewide association of midwives; and

(i) Two members who are representatives of a statewide association of pediatricians.

(3) In addition the requirements provided in subsection (2) of this section, one or more of the following professions must be represented as a voting member of the board:

(a) Neonatal intensive care specialist;

(b) Licensed physician or nurse practitioner who is board certified in obstetrics, pediatrics or neonatology;

(c) Obstetrician or gynecologist;

(d) Nurse;

(e) Ethicist;

(f) Geneticist;

(g) Dietician; and

(h) Educator.

(4) To the greatest extent practicable, the director shall appoint members from a diverse range of socioeconomic, racial and ethnic backgrounds.

(5) In addition to the 13 voting members provided for in subsection (2) of this section, members of the Legislative Assembly or employees of the Oregon Health Authority may serve as nonvoting members.

(6) The term of office of each voting member of the board is four years, but a member serves at the pleasure of the director. Before the expiration of the term of a member, the director shall appoint a successor whose term begins on July 1 next following. A member is eligible for reappointment. If there is a vacancy for any cause, the director shall make an appointment to become immediately effective for the unexpired term.

(7) A voting member of the board is entitled to compensation and expenses as provided in ORS 292.495.

(8) The board shall select two of its members to jointly serve as chairpersons and another as vice chairperson, for terms and with duties and powers necessary for the performance of the functions of the offices as the board determines. One chairperson must be a voting member and the other chairperson must be the manager of the Northwest Regional Newborn Bloodspot Screening Program or the manager's designee. The manager or manager's designee must be a nonvoting member.

(9) A majority of the voting members of the board constitutes a quorum for the transaction of business.

(10) The board shall meet at least once every six months at a time and place determined by the board. The board also may meet at other times and places specified by the call of one or both chairpersons or of a majority of the voting members of the board.

(11) The board shall report its findings and recommendations for legislative changes to the committees or interim committees of the Legislative Assembly related to health in the manner provided under ORS 192.245 no later than September 15 of each even numbered year.

SECTION 2. Notwithstanding the term of office specified by section 1 of this 2019 Act, of the members first appointed to the Newborn Bloodspot Screening Advisory Board:

(1) Three shall serve for a term ending July 1, 2020.

(2) Three shall serve for a term ending July 1, 2021.

(3) Three shall serve for a term ending July 1, 2022.

(4) Four shall serve for a term ending July 1, 2023.

SECTION 3. No later than December 15, 2019, the Newborn Bloodspot Screening Advisory Board shall conduct its first meeting and report its findings, which may include recommendations for legislative changes, to the committees or interim committees of the Legislative Assembly related to health.

SECTION 4. This 2019 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2019 Act takes effect on its passage.

Passed by House March 28, 2019

.....
Timothy G. Sekerak, Chief Clerk of House

.....
Tina Kotek, Speaker of House

Passed by Senate May 2, 2019

.....
Peter Courtney, President of Senate

Received by Governor:

.....M.,....., 2019

Approved:

.....M.,....., 2019

.....
Kate Brown, Governor

Filed in Office of Secretary of State:

.....M.,....., 2019

.....
Bev Clarno, Secretary of State

Appendix B: NWRNBS Advisory Board members and representation

Silke Akerson, representative of a statewide association of midwives

Philip Dauterman, representative of an entity that contracts with the Northwest Regional Newborn Bloodspot Screening Program for newborn bloodspot screening services

Anna Dennis, representative of an advocacy association regarding newborns with medical or rare disorders

Cheryl Hanna, representative of a statewide association of pediatricians

Dana Hargunani, representative of Medicaid or the insurance industry

Marilyn Hartzell, person or family member of a person affected by a disorder on the newborn screening panel

Wannasiri (Awe) Lapcharoensap, representative of a statewide association of pediatricians

Jill Levy-Fisch, representative of an advocacy association regarding newborns with medical or rare disorders

Joanne Rogovoy, representative of an advocacy association regarding newborns with medical or rare disorders

Kara Stirling, representative of a birthing center or hospital

Deb Wetherelt, representative of a birthing center or hospital

Cate Wilcox, honorary non-voting representative

Amy Yang, contracted medical consultant

Collette Young, honorary non-voting representative

Vacant, representative of a statewide association of nurses

Appendix C: Disorder Evaluation for Addition to the Northwest Regional Newborn Bloodspot Screening Testing Panel

Procedure for Disorder Addition Evaluation

Stage 1: Addition to the RUSP

Disorders that have been reviewed by the ACHDNC and have been added to the RUSP will be raised for further evaluation.

Stage 2: NWRNBS Program Evaluation using Category One Criteria

After a disorder has been added to the RUSP, the NWRNBS Program will evaluate the disorder using the criteria in "Category One Criteria" *(Please see below)*. This initial set of criteria will be answered using yes or no. The NWRNBS Program will share the evaluation of the Category One Criteria with the NWRNBS Advisory Board. If all criteria are answered yes, the disorder will be moved to Stage 3.

Stage 3: NWRNBS Advisory Board Evaluation and Recommendation using Category Two Criteria

Disorders that have met Category One Criteria will be brought to the NWRNBS Advisory Board for evaluation using Category Two Criteria. These criteria will be evaluated using the consensus tool (see below). The results of this evaluation will inform the recommendations to the NWRNBS Program.

Criteria for Disorder Addition Evaluation

Category One Criteria *(Evaluated as Yes or No)*

1. The condition is well-defined in newborns.
2. Earlier intervention results in improved outcomes compared to later identification.
3. The population level incidence and prevalence are known.
4. There is a Federal Drug Administration (FDA) approved testing method available using dried blood spots or an accurate testing method is available that meets clinical laboratory requirements for validation and testing by the laboratory using dried blood spots.

5. Diagnostic and specialty testing is available.
6. A treatment is available.
7. The contracted NWRNBS medical consultants have been consulted and appropriate specialized medical consultation is available or can be obtained by the Program.
8. The specific condition appears in the funded region of the Prioritized List as determined by the Oregon Health Evidence Review Commission.
9. The NWRNBS Program has sufficient information to perform a fiscal analysis.
10. The impact to the NWRNBS contracted partners has been assessed.

Category Two Criteria *(Evaluated using the Consensus Method)*

1. The population level public health benefits of screening outweigh the risks and harms.
2. There is adequate capacity and expertise in the NWRNBS program to implement and maintain testing and reporting.
3. There is adequate capacity and expertise in the NWRNBS program to implement and maintain follow-up and education for providers and parents.
4. The NWRNBS Program has adequate fiscal resources for implementing the test, performing the test and conducting follow-up and education.
5. The population level incidence, prevalence and disease burden are significant enough to merit screening.
6. Diagnostic and specialty testing is available and accessible that allows a definitive diagnosis to be made.
7. An effective treatment that is proven to result in clinically significant benefits is available and accessible.
8. There is equitable care and treatment for the disorder.
9. Addition of the disorder is not prohibitive to NWRNBS contracted partners.

Appendix D: NWRNBS Advisory Board charter

Purpose and Scope of Authority

I. The purpose of the Northwest Regional Newborn Bloodspot Screening (NWRNBS) Advisory Board (the Board) is to provide advocacy, advice, recommendations, and technical information based on members' respective areas of expertise. The Board shall assist NWRNBS Program with strategic planning and the development of policies, priorities, and services related to newborn screening including the addition or removal of tests; while considering the newborn screening system as a whole, to improve health outcomes for all infants and their families.

Sponsor

I. Executive Sponsor: The executive sponsor of the Board shall be the Center Administrator for the Center for Public Health Practice, in the Public Health Division of the Oregon Health Authority.

Membership, Appointment and Service Terms:

I. Membership:

a. *Voting Members:*

i. *Board Representation:* The Board shall be composed of 13 voting members from the following:

1. One member who is a person affected by a disorder included in the newborn screening panel or a family member of a person affected by a disorder included in the newborn screening panel;
2. One member who is a licensed physician who by contract provides expert medical advice and consulting serves to the Northwest regional Newborn Bloodspot Screening Program;
3. One member who is a representative of Medicaid or the insurance industry;
4. Two members who are representatives of birthing centers or hospitals;
5. One member who is a representative of an entity that contracts with the Northwest Regional Newborn Bloodspot Screening Program for newborn bloodspot screening services;

6. Three members who are representatives of advocacy associations regarding newborns with medical conditions or rare disorders;
7. One member who is a representative of a statewide association of nurses;
8. One member who is a representative of a statewide association of midwives; and
9. Two members who are representatives of a statewide association of pediatricians.

ii. *Discipline Representation:* One or more of the following professions must be represented as a voting member of the Board:

1. Neonatal intensive care specialist;
2. Licensed physician or nurse practitioner who is board certified in obstetrics, pediatrics or neonatology;
3. Obstetrician or gynecologist;
4. Nurse;
5. Ethicist;
6. Geneticist;
7. Dietician; and
8. Educator.

iii. *Inclusive Representation:*

1. Newborn Screening touches all infants equally and is a system that requires representation from a diverse set of stakeholders to provide the best outcomes for infants and families. As much as possible, Board representation is intended to capture the diversity of the system to bring a balanced and inclusive view to inform the policies and priorities of the NWRNBS.
2. To the greatest extent practicable, the Board shall have representation from a diverse range of socioeconomic, racial and ethnic backgrounds.

b. *Non-voting members:* Members of the Legislature or employees of the Oregon Health Authority may serve as honorary and non-voting members of the Board.

c. *Subject matter experts:* Subject matter or technical experts may be invited as guests to provide pertinent information for board consideration and contribute their expertise to specific topics of discussion. These subject matter experts shall not vote on board items unless they are already a voting member of the Board.

d. *Board Chairs and Vice Chairs:* The Board will have two Board chairs and one vice chair. One chair will be a voting Board member, the other chair will be the NWRNBS Manager or Manager designee and the vice chair will be a voting Board member. The NWRNBS Manager or Manager designee must be a nonvoting member.

II. Appointment and Service Terms:

a. Appointment:

i. *Appointment:* Board members shall be appointed by the Director of the Oregon Health Authority and serve at the pleasure of the director. Before the expiration of the term of a board member, the director shall appoint a successor whose term begins July 1st next following.

ii. *Vacancies:* If there is a vacancy, the director shall make an appointment to become effective immediately for the unexpired term.

b. *Service Terms:*

i. *Board Membership terms:*

1. *Initial Board terms:*

a. Three members shall serve for a term ending July 1, 2020

b. Three members shall serve for a term ending in July 1, 2021

c. Three members shall serve for a term ending in July 1, 2022

d. Four members shall serve for a term ending in July 1, 2023.

2. *Routine Board membership:* After initial membership, voting members of the Board shall serve four-year terms. Members are eligible for reappointment.

ii. *Voting Board chair and vice chair terms:* The initial term for the chair and vice chair will be one year. After the initial term, the chair and vice-chair selected by the Board will serve a two-year term. Term lengths can be reviewed at the will of the Board.

c. *Resignation:* Board members can resign their membership by notifying the Director of the Oregon Health Authority and the NWRNBS Manager in writing that they wish to resign their position and the date their resignation will be official.

d. *Absences:* Board members must inform the co-chairs in advance of a Board meeting if they will be unable to attend. A Board member who is absent for two consecutive Board meetings will be considered to have resigned unless there are exceptional circumstances which have been conveyed to the co-chairs prior to their absence from the second meeting.

Sub-committees

I. *Formation of Sub-committees:* Sub-committees with a defined purpose can be formed as necessary by the co-chairs.

II. *Appointment:* The NWRNBS Manager shall appoint members and chairs of sub-committees. These appointments shall be reviewed by the Board chairs.

III. *Operating Procedures:* Sub-committees will follow the same operating procedures as the Board. Sub-committee chairs shall provide feedback to the Board, as well as sub-committee meeting minutes and necessary reports.

IV. D*issolution of Sub-committees:* If it is determined that a sub-committee has fulfilled its purpose, it can be dissolved by the NWRNBS Manager upon recommendation of the Board.

Roles and Responsibilities

Board members bring their expertise from many parts of the newborn screening system including, but not limited to, clinical care, patient/family experience, and public health. Together members can provide a more holistic view of the newborn screening system and are expected to share information gained as a member of the Board with their represented organization, stakeholders, and others in their field.

I. *All Board Members:* Board members shall:

   a. Bring an open mind and be prepared to work collaboratively with others.

   b. Review and agree to the Board charter and operations.

   c. Sign a Conflict of Interest Disclosure form yearly.

   d. Attend Board meetings either in person or by teleconference.

   e. Inform the NWRNBS Manager of Board meeting absences in advance.

   f. Review Board meeting materials and participate in Board meetings in representation of their expertise to provide advice and recommendations.

   g. Participate in Rule Advisory Committees (RACs) for Newborn Screening rule changes.

II. *Board Chairs and Vice Chair:* Board chairs and vice-chair shall:

   a. Ensure a respectful, professional, and welcoming environment to encourage participation and collaboration.

   b. Assist in the creation of meeting agendas and meeting materials when appropriate.

   c. Confirm sub-committee members.

Meeting Logistics and Operating Procedures:

I. Meetings

a. *Frequency:* The Board shall meet at least once every six months. The Board may hold additional meetings by the call of one or both of the chairpersons or of a majority of the voting members of the Board.

b. *Location:* The Board shall meet at a time and location determined by the Board. One meeting each year shall be an in-person meeting where all Board members shall attend in-person except for exceptional circumstances or as otherwise determined by the Board. All other meetings shall be attended remotely unless otherwise determined by the Board.

c. *Absences:* Board members must inform the co-chairs in advance of a Board meeting if they will be unable to attend. If a Board member knows they will be absent, they can submit written comments to the NWRNBS Manager in advance of the Board meeting.

d. *Open to Public:* Board meetings shall be open to the public and adhere to public meeting requirements.

e. *Compensation:* Voting board members are entitled to compensation and expenses as provided in ORS 292.495.

II. Operating Procedures

a. *Voting on Board items:*

i. *Quorum:* A majority of the voting members of the board constitutes a quorum for the transaction of business. Each Board member has one vote and cannot vote in absentia.

ii. *Consensus:* The Board will strive for consensus on recommendations provided to the NWRNBS Program and the Legislature.

Consensus is defined as "all group members can live with the recommendation or decision." Instead of simply voting for an item and having the majority of the group getting their way, a group using consensus is committed to finding solutions that everyone actively supports, or at least can live with.

A consensus tool using a range of 1-5 will be used to signify whether the group has reached agreement and the level of agreement on a given proposal which can inform the group, and the agency, whether more work is needed to refine the proposal toward a stronger agreement.

Given the scale below:

- A **strong** consensus is one in which all or most Board members show 1's and 2's on a given proposal.
- A **weak** consensus is one in which some or several Board members show 3's and 4's.
- If anyone in the group shows a "5", the group **does not have consensus**.
- For weak or no consensus, the Board will frame up the points of divergence or minority perspectives on a given proposal.

The levels are:

"1" I enthusiastically agree with the proposal/recommendation.

"2" I agree with the proposal/recommendation.

"3" I am on the fence, have questions, or am neutral but can live with the proposal.

"4" I have serious questions or concerns, but am not willing to block the proposal.

"5" I object and will block the proposal.

b. *Open comment period:* During every Board meeting there shall be a period for open public comments. The length shall be determined by the Board chairs.

c. *Onboarding of new Board members:* New Board members shall review the Board charter and sign a conflict of interest form.

Reports

I. Reports

a. *Initial Report:* No later than December 15, 2019, the Board shall conduct its first meeting and report its findings, which may include recommendations for legislative changes, to the committees or interim committees of the Legislative Assembly related to health.

b. *Subsequent Reports:* The Board shall report its findings and recommendations for legislative changes to the committees or interim committees of the Legislative Assembly related to health no later than September 15th of each even numbered year.

Values

I. Respect — we value all members and welcome the uniqueness and diversity of their experience and viewpoints because it allows us to consider all sides of an issue.

II. Inclusivity — we actively search for partners that will help represent diverse communities and viewpoints so that we can work for all infants and their families.

III. Candor — honesty and willingness to share information are essential to the communication that will allow us to build a system that works to ensure the health of all infants and their families.

IV. Collaboration — working collaboratively allows us to leverage each person's strengths and brings balance to our discussions and recommendations.

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