Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

NOTICE OF PUBLIC MEETING

Monday, October 28, 2024
9:30 a.m. – 2:30 p.m.

Note: This is a hybrid meeting held via Zoom and in-person at the Washington State Public Health Laboratory at 1610 NE 150 St, Shoreline, WA, 98155. Meeting access and instructions are provided below. Language interpretation available.

Newborn Screening Technical Advisory Committee (TAC) Agenda

Review of the Process and Criteria for Adding a Condition to the Mandatory Newborn Screening Panel

Time	Agenda Item	Speaker
9:30 a.m.	1. Welcome & Introductions	Allegra Calder, BERK Consulting Kelly Kramer, State Board of Health
10:00 a.m.	2. TAC Overview & Meeting Norms	Kelly Oshiro, TAC Co-Chair, State Board of Health Nirupama Shridhar, TAC Co-Chair, Department of Health Allegra Calder, BERK Consulting
10:10 a.m.	3. Overview of Washington State Agency Condition Review Process and Implementation Considerations and Timelines	Kelly Kramer, State Board of Health TBD, Washington State Healthcare Authority
10:30 a.m.	4. Introduction to the Recommended Uniform Screening Panel (RUSP)	Megan McCrillis, Department of Health
10:40 a.m.	Break	

10:50 a.m.	5. Overview of State Processes for Condition Review	Kelly Kramer, State Board of Health Molly Dinardo, State Board of Health
11:30 a.m.	6. Options to Consider for the WA Condition Review Process	Kelly Kramer, State Board of Health John Thompson, Department of Health
11:45 a.m.	Lunch	
12:15 p.m.	7. Voting	Kelly Oshiro, TAC Co-Chair, State Board of Health Nirupama Shridhar, TAC Co-Chair, Department of Health Allegra Calder, BERK Consulting
12:30 p.m.	8. Results and Discussion	Kelly Oshiro, TAC Co-Chair, State Board of Health Nirupama Shridhar, TAC Co-Chair, Department of Health Allegra Calder, BERK Consulting
12:50 p.m.	9. Introduction to Criteria Review	Kelly Oshiro, TAC Co-Chair, State Board of Health Nirupama Shridhar, TAC Co-Chair, Department of Health Allegra Calder, BERK Consulting
1:05 p.m.	10. Federal Criteria (RUSP) Review	Megan McCrillis, Department of Health
1:15 p.m.	11. WA Five Criteria Review and Discussion	Kelly Kramer, State Board of Health John Thompson, Department of Health
1:55 p.m.	Break	

Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

2:05 p.m.	12. Discussion and Next Steps	Kelly Oshiro, TAC Co-Chair, State Board of Health Nirupama Shridhar, TAC Co-Chair, Department of Health Allegra Calder, BERK Consulting
2:30 p.m.	Adjourn	

Zoom Meeting Information:

- **To access the meeting online and to register:**
  https://us02web.zoom.us/j/86954038444?pwd=PPT9uBEwBjIpPN1bGLsaDftIFJl4Kf.1

- **You can also dial-in using your phone for listen-only mode:**
  Call in: +1 (253) 215-8782 (not toll-free)
  Webinar ID: 869 5403 8444
  Passcode: 281973

Important Meeting Information to Know:

- This meeting is open to the public. The public can observe the meeting online.
- The Technical Advisory Committee will not take formal action or receive public comment. If you have comments or materials you would like to share with the full Board, please send them to wsboh@sboh.wa.gov.
- Times are estimates only. We reserve the right to alter the order of the agenda.
- Every effort will be made to provide Spanish interpretation, and American Sign Language (ASL). Should you need confirmation of these services, please email wsboh@sboh.wa.gov in advance of the meeting date.
- If you would like meeting materials in an alternate format or a different language, or if you are a person living with a disability and need reasonable modification, please contact the State Board of Health at (360) 236-4110 or by email wsboh@sboh.wa.gov. Please make your request as soon as possible to help us meet your needs. Some requests may take longer than two weeks to fulfill. TTY users can dial 711.

Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

AVISO DE REUNIÓN PÚBLICA

Lunes 28 de octubre de 2024
de 9:30 a. m. a 2:30 p. m.

Nota: Esta es una reunión híbrida que se realiza por Zoom y en persona en Washington State Public Health Laboratory en 1610 NE 150 St, Shoreline, WA, 98155. A continuación, le proporcionamos el acceso a la reunión y las instrucciones. Hay servicios de interpretación a otros idiomas disponibles.

TAC (por su sigla en inglés, Comité de Asesoramiento Técnico) del examen del recién nacido

Revisión del proceso y criterios para agregar una afección al panel obligatorio de examen del recién nacido

Hora	Punto del orden del día	Orador/a
9:30 a. m.	1. Bienvenida y presentaciones	Allegra Calder, BERK Consulting Kelly Kramer, Mesa Directiva de Salud del Estado
10:00 a. m.	2. Resumen y normas de la reunión del TAC	Kelly Oshiro, copresidente del TAC, Mesa Directiva de Salud del Estado Nirupama Shridhar, copresidente del TAC, Departamento de Salud Allegra Calder, BERK Consulting
10:10 a.m.	3. Resumen del proceso de revisión de afecciones, consideraciones y plazos de implementación de la Agencia del Estado de Washington	Kelly Kramer, Mesa Directiva de Salud del Estado Por determinarse, autoridad de la salud del estado de Washington
10:30 a. m.	4. Introducción al RUSP (por su sigla en inglés, Panel de evaluación uniforme recomendado)	Megan McCrillis, Departamento de Salud
10:40 a. m.	Receso	

10:50 a. m.	5. Resumen de los procesos estatales para la revisión de afecciones	Kelly Kramer, Mesa Directiva de Salud del Estado Molly Dinardo, Mesa Directiva de Salud del Estado
11:30 a. m.	6. Opciones para considerar el proceso de revisión de afecciones de WA	Kelly Kramer, Mesa Directiva de Salud del Estado John Thompson, Departamento de Salud
11:45 a. m.	Almuerzo	
12:15 p. m.	7. Votación	Kelly Oshiro, copresidente del TAC, Mesa Directiva de Salud del Estado Nirupama Shridhar, copresidente del TAC, Departamento de Salud Allegra Calder, BERK Consulting
12:30 p. m.	8. Resultados y debate	Kelly Oshiro, copresidente del TAC, Mesa Directiva de Salud del Estado Nirupama Shridhar, copresidente del TAC, Departamento de Salud Allegra Calder, BERK Consulting
12:50 p. m.	9. Introducción a la revisión de criterios	Kelly Oshiro, copresidente del TAC, Mesa Directiva de Salud del Estado Nirupama Shridhar, copresidente del TAC, Departamento de Salud Allegra Calder, BERK Consulting
1:05 p. m.	10. Revisión de criterios federales (RUSP)	Megan McCrillis, Departamento de Salud
1:15 p. m.	11. Revisión y debate de los cinco criterios de WA	Kelly Kramer, Mesa Directiva de Salud del Estado John Thompson, Departamento de Salud
1:55 p. m.	Receso	

Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

2:05 p. m.	12. Debate y próximos pasos	Kelly Oshiro, copresidente del TAC, Mesa Directiva de Salud del Estado Nirupama Shridhar, copresidente del TAC, Departamento de Salud Allegra Calder, BERK Consulting
2:30 p. m.	Cierre de la sesión	

Información sobre la reunión por Zoom:

- **Para acceder a la reunión en línea y registrarse:**
  https://us02web.zoom.us/j/86954038444?pwd=PPT9uBEwBjIpPN1bGLsaDftIFJI4Kf.1

- **También puede participar por teléfono, mediante la modalidad de solo escucha:**
  Llamada: +1 (253) 215-8782 (no es un número gratuito)
  Id. del seminario web: 869 5403 8444
  Contraseña: 281973

Información importante de la reunión que debe saber:

- Esta reunión es abierta al público. El público general puede observar la reunión en línea.
- El Comité de Asesoramiento Técnico no tomará medidas formales y no se permitirá la participación del público. Si tiene comentarios o materiales que le gustaría compartir con todos los miembros de la Mesa Directiva, envíelos a wsboh@sboh.wa.gov.
- Los horarios son estimativos. Nos reservamos el derecho de modificar el orden de los puntos que se tratarán en la reunión.
- Se hará todo lo posible para proporcionar interpretación en español y ASL (por su sigla en inglés, lenguaje de señas americano). Si necesita confirmación sobre estos servicios, envíe un correo electrónico a wsboh@sboh.wa.gov antes de la fecha de la reunión.
- Si desea acceder a los materiales de la reunión en un formato alternativo o en otro idioma, o si tiene una discapacidad y necesita una modificación razonable, comuníquese con la Mesa Directiva de Salud llamando al (360) 236-4110 o enviando un correo electrónico a wsboh@sboh.wa.gov. Le pedimos que presente su solicitud lo antes posible para ayudarnos a satisfacer sus necesidades. Es posible que algunas solicitudes tarden más de dos semanas en atenderse.
  Los usuarios de TTY pueden marcar el número 711.

Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

Newborn Screening Technical Advisory Committee (TAC) Charter

Start Date: October 28, 2024 **End Date:** June 30, 2025 (tentative)
Members: See TAC Membership Addendum A

OBJECTIVE

Serve as an expert advisory committee on newborn screening for the Washington State Board of Health (Board). Review and recommend possible updates to the Board's current newborn screening process and criteria. Additionally, evaluate several candidate conditions for potential inclusion in the Washington State mandatory newborn screening panel and provide recommendations to the Board.

BACKGROUND

The Board establishes the rules for newborn screening in Washington, including deciding which conditions all newborns must be tested for at birth. To make these decisions, the Board assembles a multidisciplinary Technical Advisory Committee (TAC) comprised of family representatives and representatives from healthcare, social services, advocacy organizations, public health, and more. Using available evidence, the TAC then assesses candidate conditions using guiding principles and five newborn screening criteria to determine which conditions should be added to the panel.

KEY ACTIVITIES

This TAC is being convened to complete the following key activities:

- Review the Board's current newborn screening candidate condition review process and criteria and identify opportunities for improvement.
- Determine whether branched-chain ketoacid dehydrogenase kinase (BCKDK) deficiency meets the Board's criteria for newborn screening panel inclusion and provide a recommendation to the Board. This is a requirement of Senate Bill 6234 (Chapter 105, Laws of 2024).
- Determine whether congenital cytomegalovirus (cCMV) meets the Board's criteria for newborn screening and provide a recommendation to the Board. This is a requirement of Senate Bill 5829 (Chapter 96, Laws of 2024).
- Review other possible candidate conditions recently brought in front of the Board between 2024 and 2025.

TAC TIMELINES (Tentative)

- Meeting 1, Process and Criteria Review – Monday, October 28, 2024
- Meeting 2, BCKDK Deficiency Review – January 2025
- Meeting 3, cCMV Review – February 2025

COMMITTEE NORMS AND EXPECTATIONS

- Be here now and stay purpose-oriented
- Listen for understanding; seek clarification and resist assumptions
- Appreciate the strength of diverse cultures and perspectives
- Engage respectfully; see with new eyes and hear with new ears
- Move up into a speaking role; move into a listening role
- Stay on topic and mind the time
- Assume positive intent; acknowledge and repair harms
- Try to avoid speaking with someone else is speaking
- Commit to using inclusive language in committee discussions and if possible, try to avoid using idioms or slang terms
- State your name each time you begin talking, and speak at a moderate pace to ensure language interpreters can appropriately translate what is being said
- Use acronyms where possible after introducing technical terms or proper nouns and encourage other committee members to do the same.

Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

Newborn Screening Technical Advisory Committee (TAC) Charter

DECISION MAKING

- Proposed voting methods: This committee will use anonymous voting via Microsoft Forms and open discussion of results to inform committee decisions and recommendations.
- Proposed Primary or Alternative Member voting: Both primary and alternative TAC Members may attend these meetings, however, if both are in attendance the primary TAC member will be responsible for speaking and voting during the meeting. The alternative member only speaks and votes when the primary is not in attendance.

INFORMATION SHARING

The Newborn Screening TAC planning team will:

- Email and post meeting materials at least 48 hours before the scheduled meeting.
- Email updates and notices to TAC members and designated alternatives.
- Post information on the Newborn Screening Criteria Review Project webpage.

RESOURCES/REFERENCE MATERIALS

- Chapter 246-650 WAC – Newborn Screening.
- Washington State Board of Health Process to Evaluate Conditions for Inclusion in the Required Newborn Screening Panel.
- Washington Department of Health Newborn Screening Webpage

Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

Newborn Screening Process and Criteria Review Technical Advisory Committee (TAC) Problem Statement:

KEY POINTS:

- Newborn screening programs across the U.S. are struggling to keep pace with rapid advancements in technology and treatments, compounded by inadequate resources and infrastructure.
- Washington, like many other states, is facing challenges with the growing number of requests to add new conditions to its required newborn screening panel. Evaluating these conditions takes a lot of time and resources.
- To address this issue, the Washington State Board of Health and the Department of Health are forming a TAC. The TAC will help to identify strategies to streamline the condition review request process, modernize the evaluation criteria, and strengthen the overall process to address current demands better.

OVERVIEW:

Over the last 60 years, newborn screening has emerged as a major public health achievement in the United States (CDC, 2011). Rapid advancements in screening technology and treatments for rare diseases pose a challenge for newborn screening programs nationwide, which struggle to keep up with these developments (Watson et.al, 2022). Many state programs face significant obstacles, including inadequate resources, limited funding, and insufficient infrastructure for equipment, staffing, and follow-up services necessary to test for new conditions.

In Washington State, the Newborn Screening Program, managed by the Department of Health, utilizes dried blood spot samples to identify rare but treatable health conditions in newborns. Annually, the program conducts approximately 12 million tests on over 172,000 specimens from about 84,000 births, identifying about 200 cases of the 32 conditions currently on the state's screening panel (DOH, n.d.). Early detection through this screening saves lives and improves health outcomes.

Washington law (RCW 70.83.050) requires that the Washington State Board of Health (Board) establish rules for newborn screening, detailed in Chapter 246-650 WAC. This includes WAC 246-650-020, which specifies the conditions for which all newborns must be screened.

The public, Legislature, Department staff, or Board members can request the Board to review potential new conditions for inclusion in the screening panel. The Board may convene an advisory committee to evaluate these conditions based on three guiding principles and an established set of five newborn screening criteria. The process and criteria were last reviewed in 2015.

Since 2023, the Board has received four petitions for new conditions to be considered for the screening panel. These conditions were: Mucopolysaccharidoses II (MPS II), Guanidinoacetate methyltransferase (GAMT) deficiency, Arginase 1 deficiency (ARG1-D), and Wilson's Disease. Additionally, by 2025, at the Legislature's direction, the Board must review two other conditions: branched-chain ketoacid dehydrogenase kinase (BCKDK) deficiency and congenital cytomegalovirus (cCMV). The Department is also monitoring 5-7 other potential conditions that may soon be proposed for review.

Given the increased volume of requests and anticipated workload, the Board and Department recognize the need to review and update the current process. The purpose of convening this Technical Advisory Committee (TAC) is to identify strategies to streamline the condition review request process, modernize the evaluation criteria, and strengthen the overall process to address current demands better.

Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

NBS TAC Membership

MEMBER	ALTERNATE	REPRESENTING
Kelly Oshiro, JD WSBOH Co-Chair Assistant Attorney General		Washington State Board of Health (WSBOH)
Nirupama Shridhar, MPH, PhD DOH Co-Chair State Genetics Coordinator		Department of Health (DOH)
Joan Chappel, RN, MSN Nursing Consultant Advisor/Supervisor	**Melissa Kundur, RN** Occupational Nurse Consultant	Washington Health Care Authority (HCA)
Byron Raynz Parent Advocate		Parent/Child Advocacy
Emily Shelkowitz, MD Pediatrics, Medical Genetics		Pediatric Specialty Care, Seattle Children's Hospital Biochemical Genetics
Eric Leung, MD Neonatologist		Neonatology and Washington Chapter of the American Academy of Pediatrics (WCAAP)
Heather Hinton, MS Certified Genetic Counselor		Genetic Counseling, MultiCare Yakima Memorial
Joon-Ho Yu, MPH, PhD Pediatrics/Public Health Bioethicist		Bioethics, Department of Epidemiology, University of Washington Bioethics, Treuman Katz Center for Pediatric Bioethics and Palliative Care
Kristine Alexander Senior Medical Policy Research Analyst		Private Insurers, Regence Health Plans
Krystal Plonski, LAc EAMP, ND, FABNP Naturopathic Pediatrics and Acupuncturist		Naturopaths, Seattle Children's Hospital, and Washington Association of Naturopathic Physicians (WANP)

Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

NBS TAC Membership

MEMBER	ALTERNATE	REPRESENTING
Lisa McGill Vargas, MD Neonatologist	**Rucha Shukla, MD** Neonatologist	Pediatrics, Neonatal-Perinatal Medicine, Sacred Heart Medical Center Neonatology Intensive Care Unit (NICU)
Peggy Harris Public Health and Children's Health Advocate		Parent/Child Advocacy, Save Babies Through Screening Foundation
Priyanka Raut, DNP, MHS, RN Senior Director of Nursing		Pediatrics, Yakima Valley Farmworkers Clinic
Roberta (Bobbie) Salveson, ARNP, PhD Pediatric Nurse Practitioner, Medical Genetics		Pediatric Specialty Care, Mary Bridge Children's Hospital Biochemical Genetics
Taylor Kaminski, Community Doula		Perinatal and Postpartum Care, Global Perinatal Services
María Sigüenza Executive Director		State Commissions, Commission on Hispanic Affairs

NBS TAC Staff Support

Kelly Kramer
WSBOH Newborn Screening Policy Advisor

John Thompson
DOH Director of Newborn Screening

Megan McCrillis
DOH Newborn Screening Policy Advisor

Molly Dinardo
WSBOH Policy Advisor

Crystal Ogle
WSBOH Administrative Assistant

Michelle Larson
WSBOH Communications Manager

Anna Burns
WSBOH Communications Consultant

Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

Key Terms and Abbreviations

- Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC)
- Branched-Chain Keto Acid Dehydrogenase Kinase (BCKDK) Deficiency
- Congenital Cytomegalovirus (cCMV)
- Decision Packages (DPs)
- Department of Health and Human Services (HHS)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Mucopolysaccharidosis type II (MPS II, or "Hunter Syndrome")
- Newborn Screening (NBS)
- Office of Financial Management (OFM)
- Office of Health and Science (OHS)
- Public Health Lab (PHL)
- Qualifying Assumption (QA)
- Revised Code of Washington (RCW)
- Recommended Uniform Screening Panel (RUSP)
- Technical Advisory Committee (TAC)
- Washington Administrative Code (WAC)
- Washington State Board of Health (WSBOH, or "Board")
- Washington State Department of Health (DOH, or "Department")
- Washington State Health Care Authority (HCA)

GUIDANCE FOR SPEAKING WITH LANGUAGE INTERPRETATION

The Washington State Board of Health (Board) offers American Sign Language and Spanish interpretation during our regular public meetings. We do this as a part of our work towards increasing language access.

We ask all speakers at Board meetings to follow this guidance to create an accessible meeting environment. If you have any questions or need guidance for presenting, please contact Board staff for support.

WHAT TO EXPECT DURING A BOARD MEETING

- You will receive a simplified version of this document at your seat on the day of the Board meeting.
- Board staff or interpreters may give you cues to slow down your pace. The cues may include:
  - Raising a paddle sign to signal you to slow down.
  - Making a brief verbal interruption asking you to slow down.

TIPS FOR SPEAKING AND PRESENTING DURING THE MEETING

We ask that you help us mitigate the need for interruptions by speaking at a comfortable pace. Our ASL and Spanish interpreters cannot deliver your message accurately if you speak too quickly.

- Take a breath after each sentence to give the interpreter time to deliver your message.
- If you are reading from a script, please be aware that you may read faster than you speak.
- To help the interpreters and audience identify you, state your name each time you begin talking.
- Wait until someone else finishes speaking before you speak. Interpreters can only choose one person to interpret at a time.
- Pause after introducing technical terms, proper nouns, dates, numbers, or figures to allow for interpretation.

TIPS FOR TECHNICAL TERMS

- We recommend including a pause after introducing technical terms, proper nouns, dates, numbers, or figures.
  - Example: *"This briefing will discuss rulemaking around newborn screening for Ornithine Transcarbamylase Deficiency (OTCD) [pause for interpretation, wait for cue from interpreter to continue], Chapter 246-650 WAC [pause for interpretation, wait for cue from interpreter to continue]."*
- After you introduce technical terms or proper nouns use their acronyms for the remainder of the introduction.
  - Example: *"For the remainder of this discussion, I will refer to this condition as OTCD."*
- If you are using visual materials (e.g., tables), incorporate descriptive language of the visual material.
  - Example: *"This is a table showing XXXX. And now, we'll look at this part of the table…"*

Washington State Board of Health

PROCESS TO EVALUATE CONDITIONS FOR INCLUSION IN THE REQUIRED NEWBORN SCREENING PANEL

The Washington State Board of Health has the duty under RCW 70.83.050 to define and adopt rules for screening Washington-born infants for heritable conditions. Chapter 246-650-020 WAC lists conditions for which all newborns must be screened. Members of the public, staff at Department of Health, and/or Board members can request that the Board review a particular condition for possible inclusion in the NBS panel. In order to determine which conditions to include in the newborn screening panel, the Board convenes an advisory committee to evaluate candidate conditions using guiding principles and an established set of criteria.

The following is a description of the Qualifying Assumption, Guiding Principles, and Criteria which the Board has approved in order to evaluate conditions for possible inclusion in the newborn screening panel. The Washington State Board of Health and Department of Health apply the qualifying assumption. The Board appointed Advisory Committee applies the following three guiding principles and evaluates the five criteria in order to make recommendations to the Board on which condition(s) to include in the state's required NBS panel.

QUALIFYING ASSUMPTION

Before an advisory committee is convened to review a candidate condition against the Board's five newborn screening requirements, a preliminary review should be done to determine whether there is sufficient scientific evidence available to apply the criteria for inclusion.

THREE GUIDING PRINCIPLES

Three guiding principles govern all aspects of the evaluation of a candidate condition for possible inclusion in the NBS panel.

- Decision to add a screening test should be driven by evidence. For example, test reliability and available treatment have been scientifically evaluated, and those treatments can improve health outcomes for affected children.
- All children who screen positive should have reasonable access to diagnostic and treatment services.
- Benefits of screening for the disease/condition should outweigh harm to families, children and society.

CRITERIA

1. **Available Screening Technology:** Sensitive, specific and timely tests are available that can be adapted to mass screening.
2. **Diagnostic Testing and Treatment Available:** Accurate diagnostic tests, medical expertise, and effective treatment are available for evaluation and care of all infants identified with the condition.
3. **Prevention Potential and Medical Rationale:** The newborn identification of the condition allows early diagnosis and intervention. Important considerations:
    - There is sufficient time between birth and onset of irreversible harm to allow for diagnosis and intervention.
    - The benefits of detecting and treating early onset forms of the condition (within one year of life) balance the impact of detecting late onset forms of the condition.
    - Newborn screening is not appropriate for conditions that only present in adulthood.
4. **Public Health Rationale:** Nature of the condition justifies population-based screening rather than risk-based screening or other approaches.
5. **Cost-benefit/Cost-effectiveness:** The outcomes outweigh the costs of screening. All outcomes, both positive and negative, need to be considered in the analysis. Important considerations to be included in economic analyses include:
    - The prevalence of the condition among newborns.
    - The positive and negative predictive values of the screening and diagnostic tests.
    - Variability of clinical presentation by those who have the condition.
    - The impact of ambiguous results. For example the emotional and economic impact on the family and medical system.
    - Adverse effects or unintended consequences of screening.

WASHINGTON STATE
BOARD OF HEALTH

Review of Timeline

January 2026

January 2028

A condition review request is made to the Board through a petition for rulemaking[1] or legislative action.

The Board decides whether there is enough information about the condition to form a TAC.

If there is enough information on the condition (it meets the Board's qualifying assumption), the Board will direct staff to convene a TAC.

The TAC evaluates the condition against the Board's criteria using available information, research, and consultations with subject matter experts. Then, they recommend to the Board whether to add the condition.

The Board reviews the TAC's recommendation. If they approve the recommendation, the Board initiates rulemaking to begin adding the condition to chapter 245-650 WAC.

The Board coordinates with the DOH and HCA to determine the resources[2] needed to add the new screening test.[3]

If necessary, the DOH will request funding from the Governor's Office and Legislature through the agency DP process[4] to increase the newborn screening fee. HCA will also request funding for additional Medicaid spending. DPs are due internally in **May 2026.**

All state agency DP requests must be sent to the OFM **by September 2026.**

The Governor's proposed budget with approved agency DP requests is released in **December 2026.**

The Legislative session starts **January 2027**. If the Legislature approves the funding request, the updated budget will go into effect **July 1, 2027**.

Once agencies secure the appropriate funding, the Board works with these agencies to determine a rulemaking and screening implementation timeline.

If the DOH wants to start screening in January of 2028, the Board must hold a public comment period and public hearing **by October 2027** to formally add the condition to the rule by the end of the year.

Updated HCA MCO[5] rates go into effect on **January 1, 2028.**

January 1, 2028, updated rules are in effect, and screening can begin (or at a date otherwise specified by the DOH).

NOTE: Annotations 1-5 on next slide

Timeline Annotations 1-5

1. If a condition review request is made through a petition, the Board has 60 days to review and respond to the petition.

2. Adding a new condition may require the DOH and HCA to request an increase to the newborn screening fee. An increase may cover the cost of the new test(s), staff time, follow-up services for babies with positive screens, and other programmatic and administrative expenses.

3. If there is an FDA-cleared kit for the new test(s), the time to implementation can follow the above schedule. If not, implementation will take longer. The FDA modified LDT oversight in May 2024. The WA PHL can perform LDTs already in effect when the rule change was made. Any modification or new LDT must be approved through the FDA.

4. Agency division concept papers for DP budget requests must be submitted in the spring (May), after the most recent Legislative session, for agency review and consideration. Once the agency has approved the request, formal DP development occurs through the end of July/early August. Agency DP approvals depend on the state budget. If OFM is cautioning agencies that there's a tight budget, getting new DP requests approved can be challenging.

5. Each year, January 1 and July 1, updated MCO rates typically go into effect.

List of Abbreviations/Acronyms

- Decision Package (DP)
- Food and Drug Administration (FDA)
- Laboratory-Developed Test (LDT)
- Managed Care Organization (MCO)
- Office of Financial Management and Budget (OFM)
- Public Health Lab (PHL)
- Technical Advisory Committee (TAC)
- Washington Administrative Code (WAC)
- Washington State Board of Health (Board)
- Washington State Department of Health (DOH)
- Washington State Health Care Authority (HCA)

Washington State Department of HEALTH

INTRODUCTION TO THE RECOMMENDED UNIFORM SCREENING PANEL (RUSP)

Megan McCrillis, MPH

Policy Analyst, WA State Newborn Screening Program

What is the Recommended Uniform Screening Panel? (RUSP)

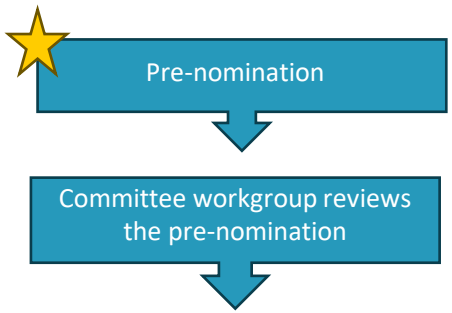
Recommended Uniform Screening Panel (RUSP)

- A national guideline for newborn screening
- Provides standardized list of conditions that states should consider screening for
  - Promotes consistency across the country
  - Maximizes chances of early detection to improve infant health outcomes
- List of core and secondary conditions
  - About 38 core conditions
- Secretary of Health and Human Services adds conditions to the RUSP, but is guided by the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC)

Nominating a Condition to be Considered for the RUSP

Process for Adding a Condition to the RUSP

- The federal nomination process also recently underwent a review and revision
- New Step 1: Pre-Nomination
  - Online form with 4 basic questions
  - 1-3 peer-reviewed references per question

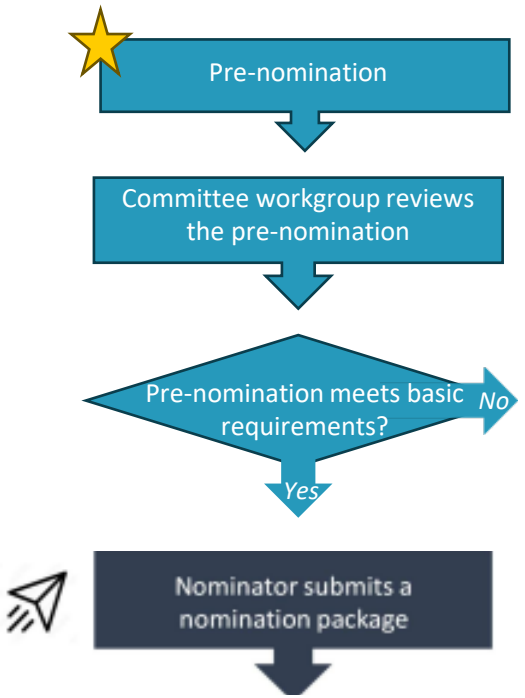


Process for Adding a Condition to the RUSP, cont.

- Next, designated workgroup verifies the pre-nomination meets the basic requirements

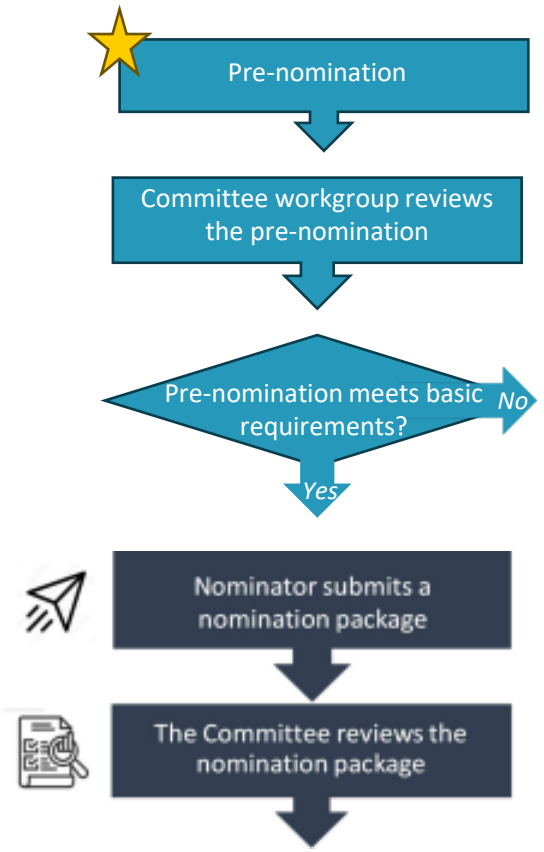
Process for Adding a Condition to the RUSP, cont.

- If the pre-nomination meets the requirements, the next step is to submit the full nomination package
  - Lots of detailed data
  - Letters of support
  - References



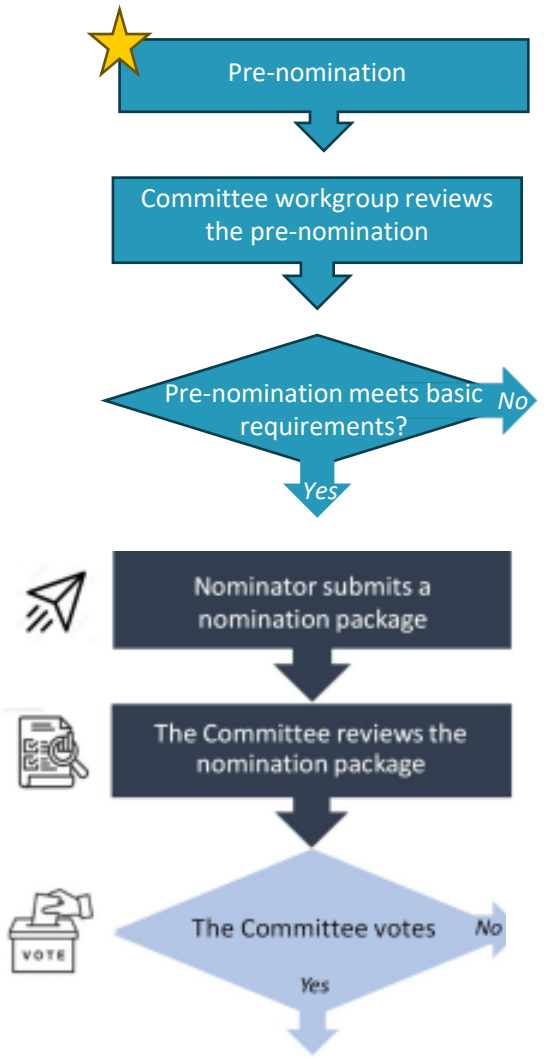
Process for Adding a Condition to the RUSP, cont.

- Dedicated workgroup then reviews the nomination package and creates a summary for the full Committee



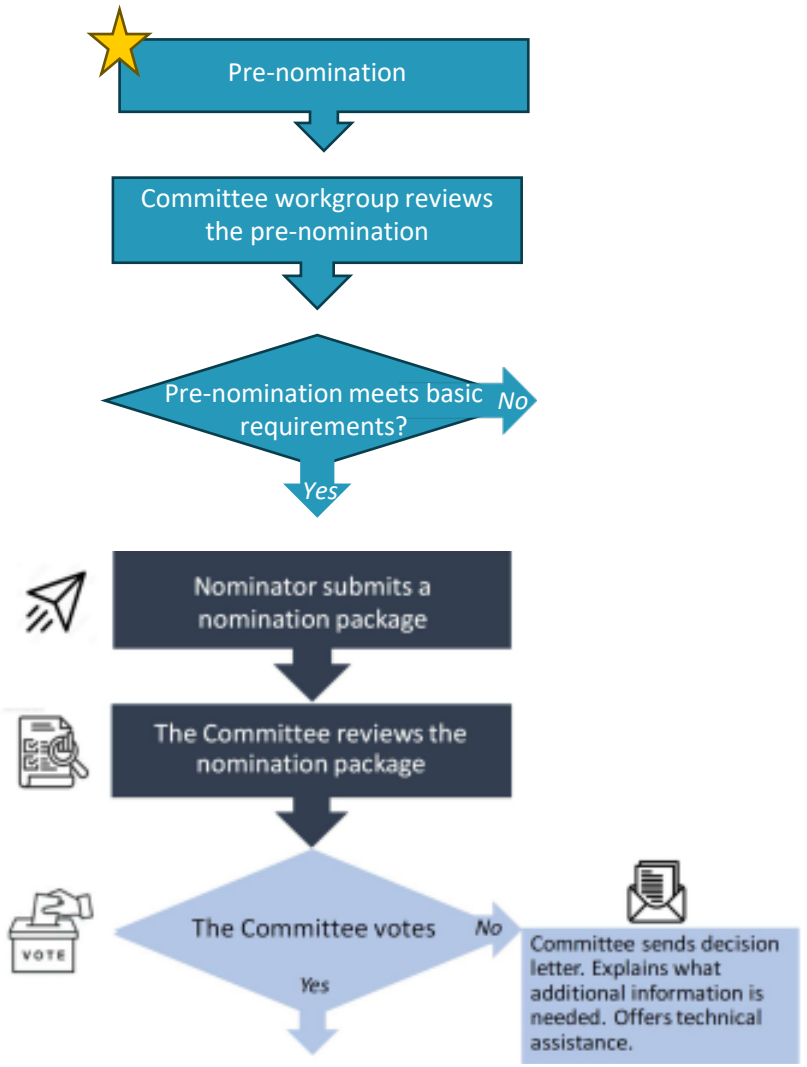
Process for Adding a Condition to the RUSP, cont.

- The Committee votes whether to move the condition forward to the full evidence review



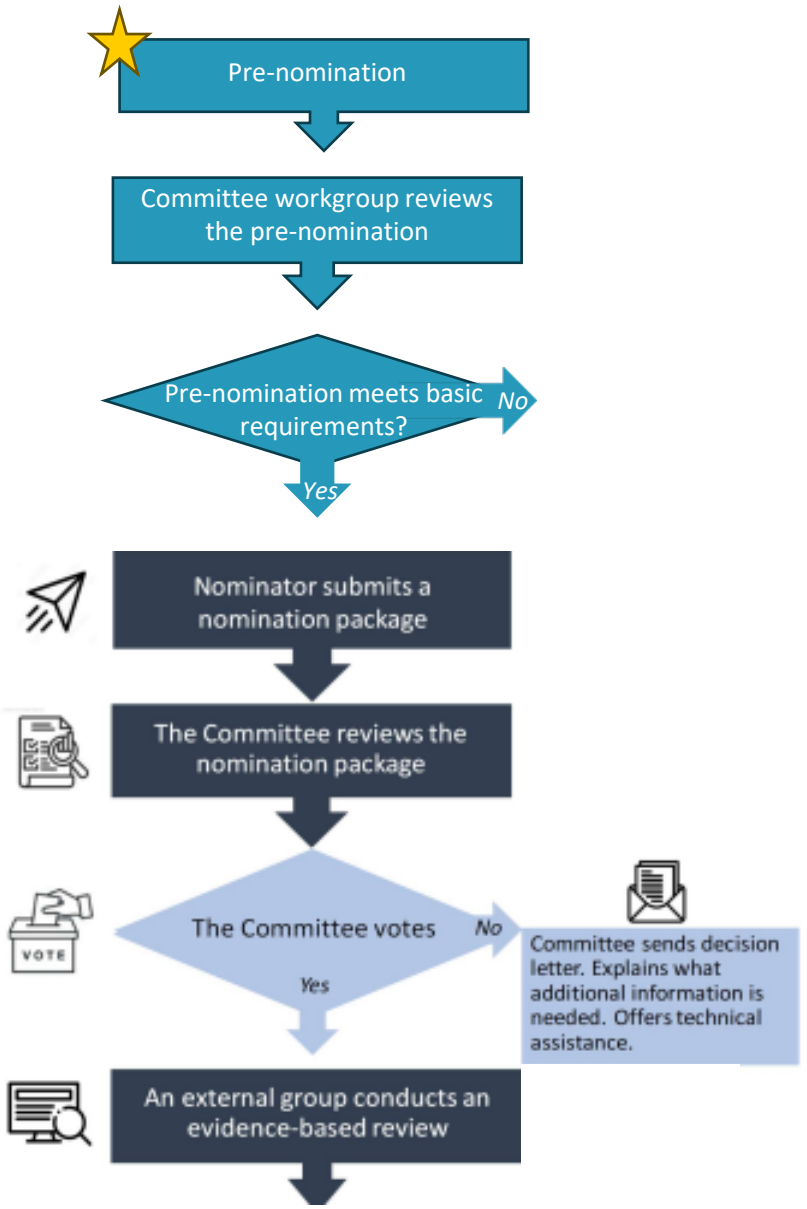
Process for Adding a Condition to the RUSP, cont.

- If the Committee votes "no", a letter is sent to the nominator explaining why



Process for Adding a Condition to the RUSP, cont.

- If the Committee votes “yes”, an external Evidence-Based Review Group will collect additional data, create final report for Committee
- At this point, the process is like that of WA State – the Committee will review the evidence and vote to either recommend screening or not



Questions?

Washington State Department of HEALTH

FEDERAL CRITERIA (RUSP) REVIEW

Megan McCrillis, MPH

Policy Analyst, WA State Newborn Screening Program

How does the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) Evaluate a Condition?

ACHDNC Approach to Evaluating Evidence

- The Committee will review and discuss the evidence-based report completed by the external and independent team of partners
- The report consists of three main sections that include a guiding question, main aims of the question, and a method to arrive to that answer

Guiding Questions of Evidence-Based Review

Guiding Question	Main Content	Methods
What are the clinical effects of early detection and treatment for the condition?	**Benefits for newborns and families** Answers to this question consider reported outcomes (both benefits and harms) of early detection and treatment for newborns, caregivers, and families.	**Systematic evidence review** This method involves review of published and unpublished reports.

Guiding Questions of Evidence-Based Review

Guiding Question	Main Content	Methods
What are the clinical effects of early detection and treatment for the condition?	**Benefits for newborns and families** Answers to this question consider reported outcomes (both benefits and harms) of early detection and treatment for newborns, caregivers, and families.	**Systematic evidence review** This method involves review of published and unpublished reports.
How would newborn screening for the condition affect the population?	**Benefit for the U.S. population** Answers to this question predict how many newborns with the condition screening would find in the U.S. and how many of those newborns would have better outcomes because of screening.	**Decision analysis modeling** This method uses data to predict how adding screening would affect the U.S. population of newborns.

Guiding Questions of Evidence-Based Review

Guiding Question	Main Content	Methods
What are the clinical effects of early detection and treatment for the condition?	**Benefits for newborns and families** Answers to this question consider reported outcomes (both benefits and harms) of early detection and treatment for newborns, caregivers, and families.	**Systematic evidence review** This method involves review of published and unpublished reports.
How would newborn screening for the condition affect the population?	**Benefit for the U.S. population** Answers to this question predict how many newborns with the condition screening would find in the U.S. and how many of those newborns would have better outcomes because of screening.	**Decision analysis modeling** This method uses data to predict how adding screening would affect the U.S. population of newborns.
How would adding newborn screening services for the condition affect the public health system?	**Public health system readiness** Answers to this question assess: • How feasible it is for state programs to expand screening to include the condition. • How ready and prepared states are to expand screening. • The projected costs of expanding screening.	**Public health system impact assessment** This method involves gathering information from state newborn screening programs about adding screening for the condition.

ACHDNC Approach to Evaluating Evidence, cont.

- Committee evaluation of the evidence-based review focuses on the overall benefit and harms of screening for nominated condition
- Following the Committee discussion, members use a rating system to assess evidence on:
  - Net benefit to the newborn
  - Feasibility of state programs to expand screening for the condition

Assessing net benefit

- Decision matrix to assess:
  - Net benefit of screening all newborns
  - Certainty of the evidence regarding the net benefit
  - Assign a letter (A-C, I)

ACHDNC
Advisory Committee on Heritable Disorders in Newborns and Children

Recommended Uniform Screening Panel Decision Matrix

	Magnitude of Net Benefit		
Certainty of Net Benefit	**Substantial**	**Moderate**	**Zero, Small or Negative**
High	A	B	C
Moderate	B	B	C
Low	I (Insufficient)		

Letter Grade	Description	Action
A	High certainty of substantial net benefit	Recommend addition to the RUSP
B	At least moderate certainty of at least moderate net benefit	Discuss and vote on recommending addition to the RUSP
C	At least moderate certainty of less than moderate net benefit	Do not recommend addition to the RUSP; Identify evidence gaps
I	Low certainty of net benefit	Do not recommended addition to the RUSP; Identify evidence gaps

Assessing feasibility

- Feasibility of implementing a comprehensive screening program is assigned into one of two categories:

a. High to Moderate Feasibility - Screening program is possible within the financial constraints of most state public health departments and the cost of screening is well balanced against the other obligations of public health programs.

b. Low Feasibility - The resources for screening are not available and the cost is not balanced against the other obligations most state health departments.

- Readiness of public health programs to implement expanded screening is assigned into one of three categories:

- Ready - Most public health departments could implement screening within one year if resources were available.
- Developmental - Most public health departments would require one to three years to implement screening, even if resources were available. Potential barriers include:
  - Need to develop high-throughput screening
  - Equipment, supplies, or training material have been developed but require refinement before full-scale implementation could occur
  - Expansions are needed in systems for diagnostic testing, treatment, or follow-up
- Unprepared - Most public health programs would not be able to implement screening in fewer than three years, even if resources were made available.

Assessing feasibility, cont.

- Once each of the feasibility and readiness ratings have been assigned, the below decision matrix is used to assign a number (1-4)

Feasibility	Readiness		
	Ready	**Developmental**	**Unprepared**
High to Moderate	**1** Most state public health departments are ready to begin comprehensive screening and screening has high to moderate feasibility.	**2** Most state public health departments have developmental readiness and screening has high to moderate feasibility.	**3** Most state public health departments are unprepared to begin comprehensive screening and screening has high to moderate feasibility.
Low	**4** Implementation of screening for the targeted condition has low feasibility.		

1. Most state public health departments are ready to begin comprehensive screening and screening has high to moderate feasibility.
2. Most state public health departments have developmental readiness and screening has high to moderate feasibility.
3. Most state public health departments are unprepared to begin comprehensive screening and screening has high to moderate feasibility.
4. Implementation of screening for the targeted condition has low feasibility.

Assessing feasibility, cont.

- The full decision matrix incorporates the net benefit (letter) rating and feasibility (number) rating
- The full matrix is intended to provide guidance, but is not intended to be prescriptive
- Those conditions coded A1 or A2 are the strongest RUSP candidates

Net Benefit	Certainty	Readiness			Feasibility
		Ready	Developmental	Unprepared	
Significant Benefit	**High**	**A1** Screening for the condition has a high certainty of significant net benefits, screening has high or moderate feasibility, and most public health departments are ready to screen.	**A2** Screening for the condition has a high certainty of significant net benefits and screening has high or moderate feasibility. However, public health departments have developmental readiness.	**A3** Screening for the condition has a high certainty of significant net benefits and screening has high or moderate feasibility. However, public health departments are unprepared for screening.	High or Moderate Feasibility
		A4 There is high certainty that screening would have a significant benefit; however, most health departments have low feasibility of implementing population screening.			Low Feasibility
	Moderate Certainty	**B 1-3** There is only moderate certainty that screening would have a significant benefit.			
Small to Zero Benefit	**High or Moderate Certainty**	**C** There is high or moderate certainty that adoption of screening for the targeted condition would have a small to zero net benefit.			
Negative Benefit		**D** There is high or moderate certainty that adoption of screening for the targeted condition would have a negative net benefit.			
	Low Certainty	**L** There is low certainty regarding the potential net benefit from screening.			

Questions?

Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

Newborn Screening (NBS) Technical Advisory Committee (TAC) Voting Instructions

Please use the Microsoft Forms ballot provided by staff during the meeting to vote on which of the condition review process option you recommend to the Board.

All votes are anonymous. Your votes will be collected and presented by the TAC facilitator and Co-Chairs for further discussion by the group.

Instructions:

- Only TAC members may vote.
- Do not forward or share the form/ballot.
- If you are unsure of not comfortable voting on these options, please indicate so in the form.

If you encounter any technical issues or difficulties accessing the form, please let staff know as soon as possible.

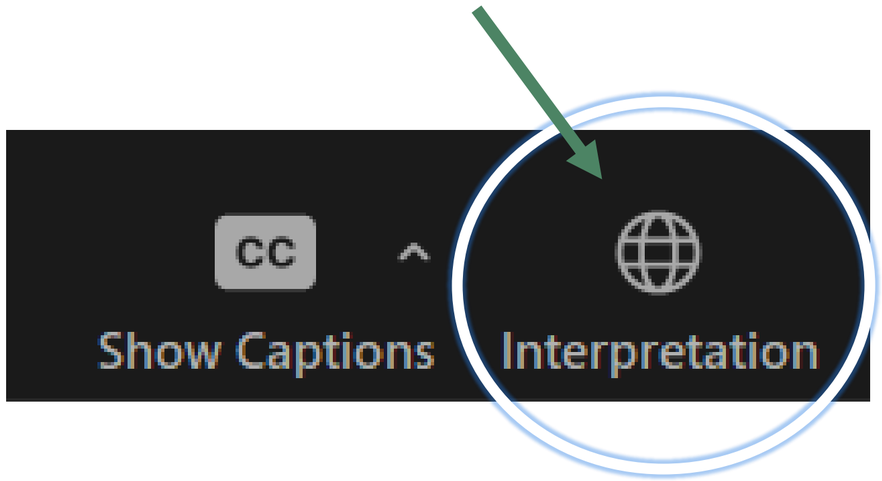
Process and Criteria for Evaluating Conditions for Newborn Screening

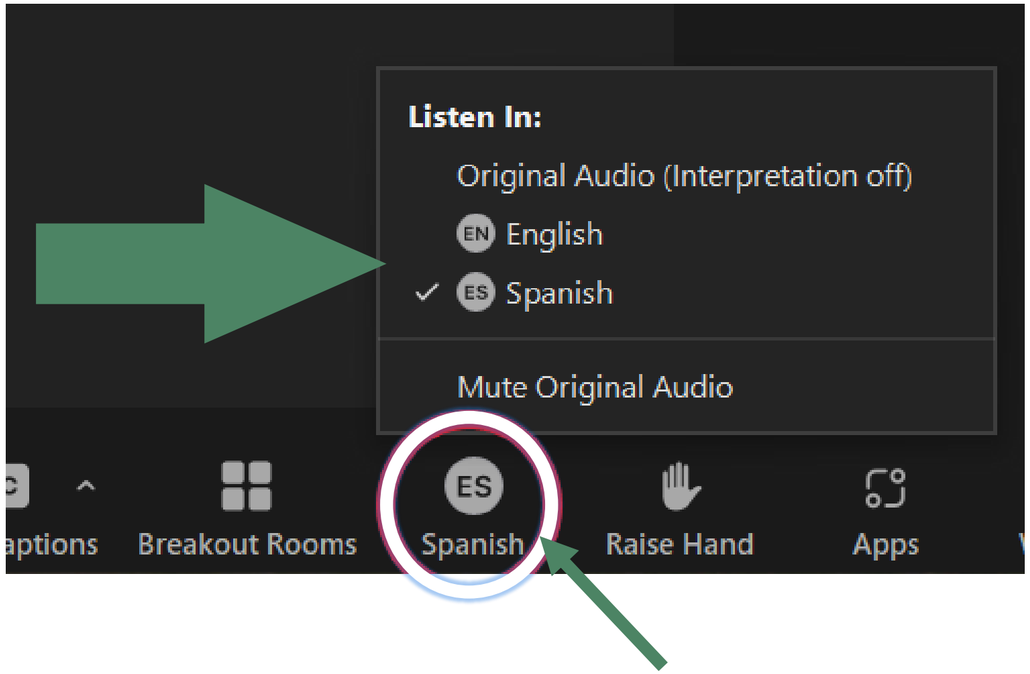
Technical Advisory Committee
October 28, 2024

WASHINGTON STATE BOARD OF HEALTH

Canales de Idioma de Zoom
Zoom Language Channels

Canales de idioma
Language channels





Elige un idioma
Choose a language

Zoom Webinar Functions

Mute/ unmute mic

View participants, change your name

Closed Captioning/Live Transcription

Turn webcam on/off

Raise hand feature

Leave meeting

Note: Depending on your role, you may not have access to all functions identified on this slide.

Introductions

Today’s Plan

- Meeting Introduction and Overview

- Part 1: Washington State Condition Review Process
  - Review the current WA condition review process and timeline for screening test implementation
  - Learn about the process at the federal level and in other states
  - Discuss options for WA to consider adjusting its process
  - Vote on options

- Part 2: State Board of Health Newborn Screening Criteria
  - Introduce the proposed plan for the criteria review
  - Learn about the criteria used at the federal level
  - Review and discuss the criteria

- Identify the Committee’s Next Steps and Recommendations for the Board

Meeting Norms

- Be here now and stay purpose-oriented
- Listen for understanding; seek clarification and resist assumptions
- Appreciate the strength of diverse cultures and perspectives
- Engage respectfully; see with new eyes and hear with new ears
- Move up into a speaking role; move up into a listening role
- Stay on topic and mind the time
- Assume positive intent; acknowledge and repair harms

TAC Overview and Purpose

Overview

First of a series of meetings

- January 2025- BCKDK
- February 2025- cCMV
- Spring/summer: Wilson’s Disease, possibly MPS-II

Purpose

- Address rapid advancements in newborn screening and the growing number of condition review requests
- Streamline the condition review process and create more certainty for requestors (families/parent/advocacy organizations)
- Modernize the five evaluation criteria
- Strengthen the overall process

Overview of Washington State Agency Condition Review Process

WA Agencies and their Roles

- The Board has rulemaking authority for newborn screening (RCW 70.83.050).
- The Department of Health (DOH) implements the WA newborn screening program (RCW 70.83.020).
- The Washington Health Care Authority's (HCA's) Medicaid Program covers 40% of births in Washington.

Current Condition Review Process

- Conditions are nominated to the panel through petitions or legislation.
- The Board reviews the condition using its qualifying assumption (QA).
- If it meets the Board's QA, the Board directs staff to convene a TAC.
- The TAC uses the three guiding principles and five criteria to make a recommendation to the Board.
- The Board reviews the recommendation and decides to approve or deny.

Implementation Considerations and Timelines

- Adding conditions to the newborn screening panel often requires increasing the newborn screening fee and adjusting HCA MCO rates.

- The DOH and HCA must submit budget changes or requests to the Office of Financial Management (OFM) through its decision package (DP) process.
  - Requests may be approved, denied, or partially approved.

- These budget requests then must be approved by the Legislature.

Review of Timeline

January 2026

January 2028

A condition review request is made to the Board through a petition for rulemaking[1] or legislative action.

The Board decides whether there is enough information about the condition to form a TAC.

If there is enough information on the condition (it meets the Board's qualifying assumption), the Board will direct staff to convene a TAC.

The TAC evaluates the condition against the Board's criteria using available information, research, and consultations with subject matter experts. Then, they recommend to the Board whether to add the condition.

The Board reviews the TAC's recommendation. If they approve the recommendation, the Board initiates rulemaking to begin adding the condition to chapter 245-650 WAC.

The Board coordinates with the DOH and HCA to determine the resources[2] needed to add the new screening test.[3]

If necessary, the DOH will request funding from the Governor's Office and Legislature through the agency DP process[4] to increase the newborn screening fee. HCA will also request funding for additional Medicaid spending. DPs are due internally in **May 2026.**

All state agency DP requests must be sent to the OFM **by September 2026.**

The Governor's proposed budget with approved agency DP requests is released in **December 2026.**

The Legislative session starts **January 2027**. If the Legislature approves the funding request, the updated budget will go into effect **July 1, 2027.**

Once agencies secure the appropriate funding, the Board works with these agencies to determine a rulemaking and screening implementation timeline.

If the DOH wants to start screening in January of 2028, the Board must hold a public comment period and public hearing **by October 2027** to formally add the condition to the rule by the end of the year.

Updated HCA MCO[5] rates go into effect on **January 1, 2028.**

January 1, 2028, updated rules are in effect, and screening can begin (or at a date otherwise specified by the DOH).

NOTE: Annotations 1-5 on next slide

Timeline Annotations 1-5

1. If a condition review request is made through a petition, the Board has 60 days to review and respond to the petition.

2. Adding a new condition may require the DOH and HCA to request an increase to the newborn screening fee. An increase may cover the cost of the new test(s), staff time, follow-up services for babies with positive screens, and other programmatic and administrative expenses.

3. If there is an FDA-cleared kit for the new test(s), the time to implementation can follow the above schedule. If not, implementation will take longer. The FDA modified LDT oversight in May 2024. The WA PHL can perform LDTs already in effect when the rule change was made. Any modification or new LDT must be approved through the FDA.

4. Agency division concept papers for DP budget requests must be submitted in the spring (May), after the most recent Legislative session, for agency review and consideration. Once the agency has approved the request, formal DP development occurs through the end of July/early August. Agency DP approvals depend on the state budget. If OFM is cautioning agencies that there's a tight budget, getting new DP requests approved can be challenging.

5. Each year, January 1 and July 1, updated MCO rates typically go into effect.

List of Abbreviations/Acronyms

- Decision Package (DP)
- Food and Drug Administration (FDA)
- Laboratory-Developed Test (LDT)
- Managed Care Organization (MCO)
- Office of Financial Management and Budget (OFM)
- Public Health Lab (PHL)
- Technical Advisory Committee (TAC)
- Washington Administrative Code (WAC)
- Washington State Board of Health (Board)
- Washington State Department of Health (DOH)
- Washington State Health Care Authority (HCA)

Introduction to the Recommended Uniform Screening Panel (RUSP)

BREAK

Overview of State Processes for Condition Review

In this section:

- Compare WA to other states
- Review different options for WA
- Vote on options

Crosswalk: State Processes

State	Washington	California	Iowa	Minnesota	Pennsylvania
Annual Births	~81,000	~400,000	~36,000	~62,000	~126,757
Process to Review	Ad hoc	RUSP-aligned	RUSP-aligned*	RUSP-aligned*	RUSP-aligned
Timeframe	N/A	2 years	Review within 12 months	N/A	2 years
Non-RUSP on Panel	Yes			Yes	Not yet
Standing Advisory Committee	No	No	Yes	Yes	Yes
Number Core Conditions	35 out of 38	37 out of 38	35 out of 38	36 out of 38	38 out of 38

Options for Condition Review

Three options to consider today

1. Ad Hoc only (status quo)
2. RUSP Alignment + ad hoc
3. RUSP meets qualifying assumption + ad hoc

For future consideration

- Biennial NBS Advisory Committee
  - To be voted on later in the year

Options for Condition Review

Ad Hoc Only

- Status quo
  - WA's current process

How conditions are added with this option:

- Petition submitted or legislature directed
  - Anyone can submit conditions for review
- The Board must review all conditions
  - Determine if they meet Qualifying Assumption
  - Will determine if TAC can be convened

Considerations for this option:

- Volume of petitions
  - Increasing number of petitions
- Not RUSP-aligned
  - Inconsistencies across states
  - Not keeping up with federal recommendations
- Challenges with funding
  - No guarantee that legislature will approve fee increase

Options for Condition Review

RUSP Alignment

How conditions are added with this option:

- All RUSP conditions added to WA panel
- All future conditions added to the RUSP will also be added to WA panel
- Conditions can still be nominated to be included on WA's mandatory panel by petition or legislature

Considerations for this option:

- Washington screens 35/38 RUSP conditions
  - Missing Krabbe and MPS-II
  - GAMT pending addition
- What is the best timeframe to add conditions to WA panel?
- What if RUSP recommendations aren’t best for WA?
- Funding resources
  - Will still need legislative approval for fee increases as conditions are added

Options for Condition Review

RUSP Meets Qualifying Assumption (QA)

- Qualifying assumption means that there is enough evidence to conduct a review of a condition and convene a TAC

How conditions are added with this option:

- All conditions on the RUSP would assume QA met
- RUSP conditions will be reviewed by a TAC
- Does not need prior review of the SBOH
- Conditions can still be nominated to be included on WA's mandatory panel
  - By petition or legislature

Considerations for this option:

- May help WA keep up with federal recommendations
- TAC can ensure that the condition is appropriate for WA babies before being added to the mandatory panel
    - Can determine if WA has the resources for each condition
      - Using WA condition criteria

Lunch

Voting

Results

Introduction to Criteria Review

- Refresher on the Board's five newborn screening criteria

- Review and discuss each criterion and explore potential options for updates. Some options could include:
  - Including updated language where applicable
  - Adding definitions for terms
  - Adding criteria "benchmarks"
  - Other items?

RUSP Criteria

Newborn Screening Criteria

1) Available Screening Technology

2) Diagnostic Testing and Treatment Available

3) Prevention Potential and Medical Rationale

4) Public Health Rationale

5) Cost-Benefit and Cost Effectiveness

1. Available Screening Technology

Sensitive, specific, and timely tests are available for the condition that can be adapted to mass screening.

2. Diagnostic Testing and Available Treatment

Accurate diagnostic tests, medical expertise, and effective treatment are available for evaluation and care of all infants identified with the condition.

3. Prevention Potential and Medical Rationale

The newborn identification of the condition allows early diagnosis and intervention. Important considerations include:

- There is sufficient time between birth and onset of irreversible harm to allow for diagnosis and intervention.
- The benefits of detecting and treating early onset forms of the condition (within one year of life) balance the impact of detecting late onset forms of the condition.
- Newborn screening is not appropriate for conditions that only present in adulthood.

4. Public Health Rationale

The nature of the condition justifies population-based screening rather than risk-based screening or other approaches.

5. Cost-benefit and Cost-effectiveness

The outcomes outweigh the costs of screening. All outcomes, both positive and negative, need to be considered in the analysis. Important considerations to be included in economic analyses include:

- The prevalence of the condition among newborns.
- The positive and negative predictive values of the screening and diagnostic tests.
- Variability of clinical presentation by those who have the condition.
- The impact of ambiguous results. For example, the emotional and economic impact on the family and medical system.
- Adverse effects or unintended consequences of screening.

Next Steps

November 13, 2024, State Board of Health Meeting

- Share updates on committee discussions and recommendations to date

Next meeting

- January 2025
- Doodle poll to be sent out to coordinate scheduling

WASHINGTON STATE BOARD OF HEALTH

THANK YOU

To request this document in an alternate format, please contact the Washington State Board of Health at 360-236-4110, or by email at **wsboh@sboh.wa.gov** | TTY users can dial 711

ACCESSIBILITY AND THE AMERICANS WITH DISABILITIES ACT (ADA)

- The Washington State Board of Health (Board) is committed to providing information and services that are accessible to people with disabilities. We provide reasonable accommodations, and strive to make all our meetings, programs, and activities accessible to all persons, regardless of ability, in accordance with all relevant state and federal laws.
- Our agency, website, and online services follow the Americans with Disabilities (ADA) standards, Section 508 of the Rehabilitation Act of 1973, Washington State Policy 188, and Web Content Accessibility Guidelines (WCAG) 2.0, level AA. We regularly monitor for compliance and invite our users to submit a request if they need additional assistance or would like to notify us of issues to improve accessibility.
- We are committed to providing access to all individuals visiting our agency website, including persons with disabilities. If you cannot access content on our website because of a disability, have questions about content accessibility or would like to report problems accessing information on our website, please call (360) 236-4110 or email wsboh@sboh.wa.gov and describe the following details in your message:
    - The nature of the accessibility needs
    - The URL (web address) of the content you would like to access
    - Your contact information

We will make every effort to provide you the information requested and correct any compliance issues on our website.