

Washington State Board of Health

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

Last updated November 13, 2024

Amended Section (Approved November 2024)

The Washington State Board of Health (Board) 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 (Department), and/or Board members can request that the Board review a particular condition for possible inclusion in the newborn screening (NBS) panel. ~~In order to~~ To determine which conditions to include in the ~~newborn screening~~ NBS panel, the Board convenes an newborn screening technical advisory committee (TAC) to evaluate candidate conditions using guiding principles and an established set of criteria.

~~The following is a description of~~ This document describes 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~~ Board and Department ~~of Health~~ apply the qualifying assumption. The Board-appointed ~~Newborn Screening Advisory Committee~~ TAC 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

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Before ~~an advisory committee is convened~~ the Board convenes a TAC to review a candidate condition against the ~~Board's~~ five newborn screening ~~requirements~~ criteria, staff should complete a preliminary review ~~should be done~~ to determine ~~there is whether~~ sufficient scientific evidence is available to apply the criteria for inclusion. If the candidate condition is on the Health Resources and Services Administration (HRSA) Recommended Uniform Screening Panel (RUSP), the Board and Department will consider the qualifying assumption met and convene a TAC.

New Section (Approved November 2024)

A note on the RUSP: The RUSP is a list of conditions that the Secretary of the Department of Health and Human Services (HHS) recommends states screen for as part of their newborn screening programs. Once the HHS Secretary recommends a new condition, the Board and Department will review it for possible inclusion in the Washington NBS panel within two years of the recommendation.

New Section (Pending Board Approval)

Conditions pending RUSP Review or Previously Denied for the RUSP: RCW 34.05.330 of the Administrative Procedures Act (APA) allows any person to petition a state agency to adopt, repeal, or amend any rule within its authority. Agencies must respond to the petitioner within 60 days. If the agency accepts the petition, it must initiate rulemaking. An agency can deny the request for rulemaking, and in doing so, it must explain its reasons and, if appropriate, describe alternative steps it is prepared to take.

If the Board receives a petition for rulemaking regarding a candidate condition currently under review for the RUSP, the Board will wait until the federal committee finishes its review and the HHS Secretary makes a final decision before convening a TAC. For petitions involving conditions that have already been reviewed and denied inclusion on the RUSP, the Board will instruct staff to work with the petitioner to determine if concerns raised during the federal review have been addressed before recommending the Board convene a TAC to review the condition.

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.