HOUSE BILL REPORT
HB 1697

As Reported by House Committee On:
Health Care & Wellness

Title: An act relating to ensuring timely, efficient, and evidence-based additions to newborn screenings.

Brief Description: Ensuring timely, efficient, and evidence-based additions to newborn screenings.

Sponsors: Representatives Stonier, Parshley, Reed and Hill.

Brief History:
Committee Activity:
Health Care & Wellness: 2/14/25, 2/21/25 [DPS].

Brief Summary of Substitute Bill

- Modifies the newborn screening panel (panel) and the process for the State Board of Health to add new conditions to the panel.
- Establishes the Newborn Screening Revenue Account.

HOUSE COMMITTEE ON HEALTH CARE & WELLNESS

Majority Report: The substitute bill be substituted therefor and the substitute bill do pass. Signed by 18 members: Representatives Bronoske, Chair; Lekanoff, Vice Chair; Schmick, Ranking Minority Member; Caldier, Assistant Ranking Minority Member; Marshall, Assistant Ranking Minority Member; Davis, Engell, Low, Macri, Manjarrez, Obras, Parshley, Shavers, Simmons, Stonier, Stuebe, Thai and Tharinger.

Staff: Kim Weidenaar (786-7120).

Background:

This analysis was prepared by non-partisan legislative staff for the use of legislative members in their deliberations. This analysis is not part of the legislation nor does it constitute a statement of legislative intent.

Newborn Screenings.
The Department of Health's (DOH) Newborn Screening Program tests most newborn infants born in any setting in Washington for a number of rare congenital disorders. Screening tests are completed by collecting a blood sample from the infant within 48 hours of birth and again in the first few weeks after birth. Screenings are not required for newborn infants whose parents or guardians object to screening tests on the grounds of religious tenets and practices.

Newborns are screened for a variety of amino acids, endocrine, fatty acid, lysosomal storage, organic acid, and other disorders. In order to determine which conditions to include in the newborn screening panel (panel), the State Board of Health (Board) convenes an advisory committee to evaluate candidate conditions, and the Board adds tests to the panel only after a consideration of the following criteria: available technology, diagnostic testing, and treatment; prevention potential and medical rationale; public health rationale; and cost-benefit and cost-effectiveness. The panel consists of 32 conditions listed in the Board rules. The DOH charges a screening fee of $135.10 per infant.

Laboratories, attending physicians, hospital administrators, or other persons performing or requesting the performance of tests for phenylketonuria, must report to the DOH all positive tests. The Board must require, by rule, that positive tests for other heritable and metabolic disorders be reported to the DOH when it deems appropriate.

Federal Recommended Uniform Screening Panel.
The federal Recommended Uniform Screening Panel (RUSP) is a list of disorders that are supported by the Advisory Committee on Heritable Disorders in Newborns and Children and recommended by the Secretary of the Department of Health and Human Services for states to screen for as part of their state newborn screening programs. As of July 2024 there are 36 core conditions listed on the RUSP.

Disorders on the RUSP are chosen based on evidence that supports the potential net benefit of screening, the ability of states to screen for the disorder, and the availability of effective treatments.

Conditions listed on the RUSP are part of the comprehensive preventive health guidelines supported by the Health Resources and Services Administration for infants and children, which health plans must cover without cost sharing beginning on or after the date that is one year from the Secretary's adoption of the condition for screening.

Summary of Substitute Bill:

The DOH must conduct screening tests of newborn blood samples of the conditions listed in the panel determined by the Board in rule.

By January 1, 2027, the Board must reestablish the panel in rule. This initial panel must include:

- all newborn screening conditions currently required by the Board in rule as of January 1, 2025; and
- all conditions included in the existing RUSP as of January 1, 2025.

Within the first complete calendar year after the addition of a new condition to the RUSP, the Board must determine whether to add that new condition to the panel. In making its determination, the Board must avoid duplicating research and evaluation efforts, and complete and consider the findings of a feasibility review. The feasibility review must identify costs to screen for the condition, available federal funding, recommendations of changes to the fee charged for the newborn screening, and a timeline for including the new condition on the panel. In conducting the feasibility review, the Board must consult with the Health Care Authority to consider impacts on state-purchased health care programs.

If the Board determines that the condition should be included in the panel, the Board must complete rulemaking to include the condition in the panel within 12 months of the determination. The Board may add other conditions to the panel if it completes a feasibility review.

Laboratories, attending physicians, hospital administrators, or other persons performing or requesting the performance of tests for the disease and conditions included on the panel must report all positive tests to the DOH. The Board, by rule, may require that positive tests for other heritable and metabolic disorders be reported to the DOH.

The Newborn Screening Revenue Account (Account) is created in the custody of the Washington State Treasurer and all receipts collected from newborn screening fees must be deposited in the Account. Funds in the Account may only be used for newborn screening purposes and only the Secretary of Health or designee may authorize expenditures. Interest earned by this Account is retained in the account.

Substitute Bill Compared to Original Bill:

The substitute bill:

- delays the date the Board must reestablish, in rule, the panel consisting of the current newborn screening panel and all conditions included in the federal RUSP to January 1, 2027;
- removes the authorization for the public to request the Board to consider additions to the panel and the requirement for the Board to adopt standards for reviewing requests from the public;
- specifies that within the first complete calendar year after the addition of a new condition to the RUSP, the Board must determine whether to add that condition to the panel, rather than within 12 months of the addition; and
- restores current law providing that the Board may require that positive tests for

heritable and metabolic disorders be reported to the DOH.

Appropriation: None.

Fiscal Note: Available.

Effective Date of Substitute Bill: The bill contains multiple effective dates. Please see the bill.

Staff Summary of Public Testimony:

(In support) The goal with this bill is to find a way to streamline the steps to get screenings added to the panel in Washington. While Washington may have higher standards or additional considerations compared to the federal RUSP, where there are duplications in the two processes, the processes should be eliminated and streamlined.

There is an intensive amount of work at the federal level that includes a diverse group of stakeholders and experts. All families should benefit from early screenings of conditions that were fully reviewed in the federal process as early as possible. The goal of this bill is to speed up the ability to add the conditions included in the RUSP to Washington's panel. The bill maintains the Washington viewpoint, particularly about feasibility, when deciding what to add to the panel. There is also an interest in making sure that the DOH has the authority to set the fee, that there are sufficient funds to support the lab in Shoreline, and that the funds do not need to be appropriated so that the DOH does not have to keep going back to the Legislature to use the funds.

Aligning Washington's newborn screening program with the federal RUSP greatly strengthens Washington's ability to detect and address otherwise fatal diseases in newborns. This bill offers a common sense solution to remove barriers in processes. Newborn screening is one of the most important public health interventions, which saves lives, allows for more effective health care interventions, and reduces costs.

(Opposed) None.

(Other) While there is a lot of support for newborn screening and newborn screening works, there are other aspects such as time, money, and staffing to consider. Newborn screening allows babies with no symptoms to be identified and treated early. Without treatment some of these children may not survive. When a newborn tests positive, patients and their families are walked through the uncertainty of when and how these symptoms could develop, and it requires testing, monitoring, and treatment. In addition to testing, sufficient infrastructure to respond to a positive test is also necessary. The panel currently includes 27 metabolic conditions. Every child that tests positive must go through many steps to confirm that it really is a positive test and then consider the next steps. A positive screen without

follow-up care would lead to significant distress and possible medical harm.

The current clinic subsidy fee has not been changed since 2010 and needs to be updated.

This bill does not align with the Board's current process for reviewing conditions on the RUSP. The Board's multi-disciplinary advisory committee recently reviewed its process and criteria for evaluating conditions on the RUSP and deciding whether the condition should be included in the panel. The advisory committee recommended a two-year review time frame for new RUSP conditions. The bill requires the Board to do so within one year. The Board does not have dedicated full-time staff to conduct these reviews. The bill mandates that the Board adopt three conditions from the RUSP without any input from the Board's regular evaluation process. This evaluation process is specific to Washington's population, health care needs, and ensures the lab has the necessary resources to conduct screening and that the HCA can cover the costs of testing for families on Medicaid. This bill also requires the Board to create processes that limit the Board's flexibility. This bill is also not included in the Governor's budget.

Persons Testifying: (In support) Representative Monica Jurado Stonier, prime sponsor; Katherine Mahoney, Ultragenyx; and Max Brown, NW Rare Disease Coalition.

(Other) Kelly Kramer, Washington State Board of Health; and Terry Kho.

Persons Signed In To Testify But Not Testifying: None.