Rules Hearing: Newborn Screening Chapter 246-650 WAC

Adding OTCD, GAMT, and ARG1-D

Molly Dinardo, Policy Advisor, State Board of Health
Megan McCrillis, Policy Analyst, Department of Health

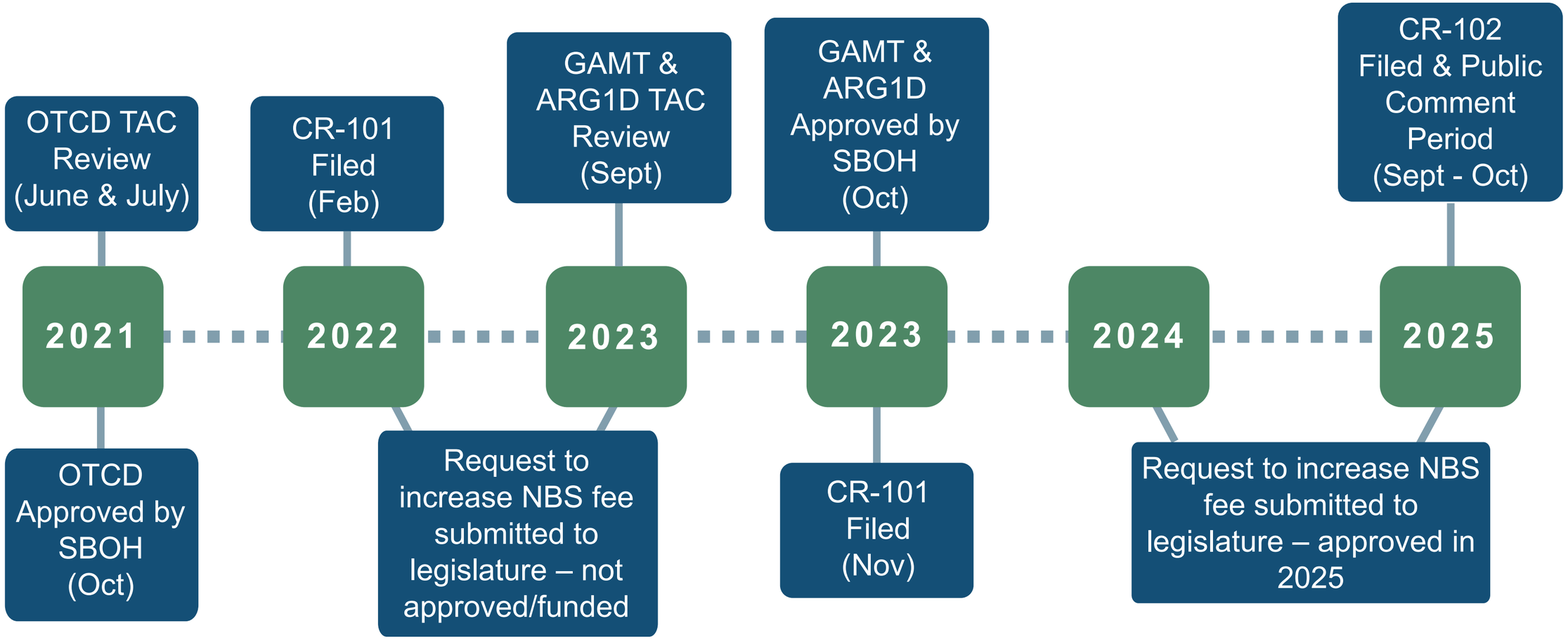
November 19, 2025

WASHINGTON STATE BOARD OF HEALTH

Overview

- Rulemaking Background
- Proposed Rule Changes
- Verbal Public Comment
- Review of Written Comments
- Board Member Discussion and Possible Action

Rulemaking Timeline



Public Health Rationale

- The Board approved the TAC recommendations to add OTCD, GAMT deficiency, and ARG1-D for the following reasons:
  - Even though these conditions are rare, early detection saves lives and prevents irreversible harm.
  - Timely screening enables effective and accessible treatment, including specialized diets, supplements, and medications to prevent neurological damage.
  - Expanding screening improves survival, reduces long-term disability, and supports better quality of life for families.
  - These conditions can be screened using existing lab technology (tandem mass spectrometry), making implementation cost-effective and feasible.

Proposed Changes

WAC 246-650-010, Definitions

- Adding a definition for GAMT.
- Adding a definition for urea cycle disorders, to include OTCD and ARG1-D.

WAC 246-650-020, Performance of Screening Tests

- Amending the list of newborn screenings to be performed from a dried blood specimen to include GAMT and urea cycle disorders (OTCD and ARG1-D).
- Renumber to retain the alphabetical nature of the list.
- Repeal subsection (3): The requirement for healthcare providers to report the date results were disclosed to parents/guardians to the Department expired January 1, 2020.

Screening Fee Increase (Jan 1, 2026)

- The Department of Health charges a one-time fee that covers all required newborn screening tests in Washington, including repeat or follow-up screens when medically necessary.
- The fee supports laboratory testing, follow-up services, and coordination with specialty care.
- When new conditions are added, the Department must seek legislative approval to adjust the fee, and the Health Care Authority (HCA) must also request legislative approval to update Medicaid managed care rates.
- During the 2025 legislative session, the Legislature approved funding for the Department and HCA.
- 2026 fee increase:
  - **Current fee**: $135.10 per baby (last updated July 1, 2023).
  - **New fee (effective Jan. 1, 2026):** +$4.02 to cover testing for OTCD, GAMT, and ARG1-D.
  - Increase supports lab and follow-up staff, testing materials (reagents), and biochemical genetics consulting for OTCD, GAMT, and ARG1-D.

Additional Consideration

- The proposed rule updates do not impose more than minor costs for businesses (SBEIS).
  - No new compliance requirements for small businesses.
  - Healthcare providers, birthing centers, midwives, and hospitals to continue existing practices.
  - Same blood samples are used for new conditions—no new equipment or procedures required.
  - No additional professional services expected for small businesses.

Verbal Public Comment Period

Summary of Written Comments

- **Public comment period:** September 30 to October 27
- We received only one comment, noted below:
  - “I personally feel all newborns should be screened with zero exceptions, though I understand the respect for freedom of religious beliefs. In cases where the parent(s) or guardian(s) refuse screening, I appreciate the requirement for a signed refusal to be completed and documented. I am a pediatrician who recently moved to the state and will soon be practicing as a pediatric hospitalist. I support the Board's proposed rule updates with the addition of the three conditions (OTCD, GMAT, ARG1-D). Though rare, early identification of these conditions is essential to optimizing lifelong care for a newborn if identified.”

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.