

Notice of Public Meeting

Wednesday, October 8, 2025, 9:00 a.m. – 4:15 p.m.
 Physical meeting location:
 Washington State Department of Health
 111 Israel Road S.E.
 Tumwater, WA 98501
 Building: Town Center Two (TC2, Rooms 166 & 167)
 Virtual meeting: ZOOM Webinar
 (hyperlink provided below)
 Language interpretation available

Final Agenda

Time	Agenda Item	Speaker
9:00 a.m.	Call to Order & Introductions	Patty Hayes, Board Chair
9:15 a.m.	1. Approval of Agenda—Possible Action	Patty Hayes, Board Chair
9:20 a.m.	2. Approval of August 20, 2025, Minutes – Possible Action	Patty Hayes, Board Chair
9:25 a.m.	3. Board Meeting Protocol Discussion	Patty Hayes, Board Chair
9:35 a.m.	4. Public Comment	Please note: Verbal public comment may be limited so that the Board can consider all agenda items. The Chair may limit each speaker's time based on the number of people signed up to comment.
10:05 a.m.	5. Announcements and Board Business	Michelle Davis, Board Executive Director
10:15 a.m.	6. Department of Health Update	Tao Sheng Kwan-Gett, Department of Health, Secretary's Designee
10:45 a.m.	Break	
11:00 a.m.	7. Petition for Rulemaking WAC 246-290-220 , Drinking Water Materials and Additives – Possible Action	Paj Nandi, Board Member Shay Bauman, Board Staff
11:30 a.m.	8. Per- and Polyfluoroalkyl Substances (PFAS) Emergency Rule, Chapter 246-290-315 WAC – Possible Action	Paj Nandi, Board Member Shay Bauman, Board Staff Mike Means, DOH Staff
11:50 a.m.	9. School Rules Project Update	Patty Hayes, Board Chair Ash Noble, Board Staff

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Time	Agenda Item	Speaker
12:00 p.m.	10. Local Health and Community Focus	Hannah Haag, Board Staff David Windom, Director, Mason County Public Health and Human Services
12:40 p.m.	Lunch	
1:30 p.m.	11. Health Impact Review (HIR) Records Retention Policy - Possible Action	Michelle Davis, Executive Director Lindsay Herenden, Board Staff
1:40 p.m.	12. Rules Briefing Sanitary Control of Shellfish <u>Chapter 246-282 WAC</u>	Paj Nandi, Board Member Shay Bauman, Board Staff
2:25 p.m.	13. Rules Briefing – Newborn Screening to add Ornithine Transcarbamylase Deficiency (OTCD), Guanidinoacetate Methyltransferase Deficiency (GAMT) and Arginase 1 Deficiency (ARG1-D) to <u>Chapter 246-650 WAC</u>	Kelly Oshiro, Board Vice Chair Molly Dinardo, Board Staff Megan McCrillis, Department Staff
2:50 p.m.	Break	
3:00 p.m.	14. Per- and Polyfluoroalkyl Substances (PFAS) Rules Briefing – Permanent PFAS Rulemaking <u>Chapter 246-290 WAC</u>	Paj Nandi, Board Member Shay Bauman, Board Staff Mike Means, DOH Staff
3:45 p.m.	15. 2026 Legislative Statement	Michelle Davis, Board Executive Director
4:00 p.m.	16. Board Member Comments and Updates	
4:15 p.m.	Adjournment	

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- **To access the meeting online and to register:**
https://us02web.zoom.us/webinar/register/WN_tKH31e4S1CMQr6iNwN9tA
- **You can also dial in using your phone for listen-only mode:**
Call in: +1 (253) 215-8782 (not toll-free)
Webinar ID: 848 3553 4095
Passcode: 682856

Important Meeting Information to Know:

- Times are estimates only. We reserve the right to alter the order of the agenda.
- Every effort will be made to provide Spanish interpretation, American Sign Language (ASL), and/or Communication Access Real-time Transcription (CART) services. 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.

Information About Giving Verbal Public Comment at Hybrid Meetings:

- Individuals may give verbal public comments at the meeting, in-person or virtually, during the public comment period.
- The amount of time allotted to each person will depend on the number of speakers present (typically 1 to 3 minutes per person). We will first call on those who have signed up in advance.
- Sign up **by 12:00 Noon the day before a meeting** to participate in the public comment period:
 - [Email the Board](#) or
 - Register through the **Zoom webinar link. The Zoom webinar link is in the meeting agenda located on the [Meeting Information webpage](#).**
 - If you are **attending the meeting in person** and did not sign up in advance, you may write your name on the sign-in sheet to provide comments if time allows.

Information About Giving Written Public Comment:

- Please visit the Board's [Public Comment webpage](#) for details.

PO Box 47990, Olympia, WA 98504-7990
(360) 236-4110 • wsboh@sboh.wa.gov • www.sboh.wa.gov

Orden del día final

Hora	Punto del orden del día	Orador/a
9:00 a.m.	Apertura y presentaciones	Patty Hayes, presidenta de la Mesa Directiva
9:15 a.m.	1. Aprobación del orden del día – Posible acción	Patty Hayes, presidenta de la Mesa Directiva
9:20 a.m.	2. Aprobación del acta de la reunión del 20 de agosto de 2025 – Posible acción	Patty Hayes, presidenta de la Mesa Directiva
9:25 a.m.	3. Debate sobre el protocolo de la Mesa Directiva	Patty Hayes, presidenta de la Mesa Directiva
9:35 a.m.	4. Comentarios públicos	Aclaración: es posible que los comentarios verbales del público se limiten para que la Mesa Directiva pueda abordar todos los puntos del orden del día. La presidenta podrá limitar el tiempo de cada orador en función de la cantidad de personas que se hayan inscrito para hacer comentarios.
10:05 a.m.	5. Anuncios y asuntos de la Mesa Directiva	Michelle Davis, directora ejecutiva de la Mesa Directiva
10:15 a.m.	6. Actualización del Departamento de Salud	Tao Sheng Kwan-Gett, Departamento de Salud, delegado de la Secretaría
10:45 a.m.	Receso	
11:00 a.m.	7. Solicitud de creación de reglas sobre Materiales y Aditivos en el Agua Potable del WAC (por su sigla en inglés, Código Administrativo de Washington) 246-290-220 – Posible acción	Paj Nandi, miembro de la Mesa Directiva Shay Bauman, miembro del personal de la Mesa Directiva
11:30 a.m.	8. Normativa de emergencia sobre PFAS (por su sigla en inglés, sustancias perfluoroalquiladas y polifluoroalquiladas),	Paj Nandi, miembro de la Mesa Directiva

Hora	Punto del orden del día	Orador/a
	Capítulo 246-290-315 del WAC (por su sigla en inglés, Código Administrativo de Washington) – Posible acción	Shay Bauman, miembro del personal de la Mesa Directiva Mike Means, personal del DOH (por su sigla en inglés, Departamento de Salud)
11:50 a.m.	9. Actualización del proyecto sobre las normas escolares	Patty Hayes, presidenta de la Mesa Directiva Ash Noble, miembro del personal de la Mesa Directiva
12:00 p.m.	10. Salud local y enfoque comunitario	Hannah Haag, personal de la Mesa Directiva David Windom, director, Departamento de Salud Pública y Servicios Humanos del Condado de Mason
12:40 p.m.	Almuerzo	
1:30 p.m.	11. Política de retención de registros de la HIR (por su sigla en inglés, Revisión del Impacto en la Salud) – Posible acción	Michelle Davis, directora ejecutiva Lindsay Herendeen, miembro del personal de la Mesa Directiva
1:40 p.m.	12. Informe sobre las normativas de control sanitario de los mariscos,	Paj Nandi, miembro de la Mesa Directiva Shay Bauman, miembro del personal de la Mesa Directiva
2:25 p.m.	13. Informe de normas: adición de OTCD (por su sigla en inglés, deficiencia de ornitina transcarbamilasa), la deficiencia de GAMT (por su sigla en inglés, guanidinoacetato metiltransferasa) y la deficiencia de ARG1-D (por su sigla en inglés, arginasa 1), capítulo 246-650 del WAC (en inglés) a la evaluación del recién nacido.	Kelly Oshiro, vicepresidenta de la Mesa Directiva Molly Dinardo, miembro del personal de la Mesa Directiva Megan McCrillis, personal del Departamento
2:50 p.m.	Receso	

Hora	Punto del orden del día	Orador/a
3:00 p.m.	14. Sesión informativa sobre la normativa permanente de PFAS capítulo 246-290 del WAC	Paj Nandi, miembro de la Mesa Directiva Shay Bauman, miembro del personal de la Mesa Directiva Mike Means, personal del DOH
3:45 p.m.	15. Declaración legislativa para 2026	Michelle Davis, directora ejecutiva de la Mesa Directiva
4:00 p.m.	16. Comentarios y actualizaciones de los miembros de la Mesa Directiva	
4:15 p.m.	Levantamiento de la sesión	

- **Para acceder a la reunión en línea y registrarse:**
https://us02web.zoom.us/webinar/register/WN_tKH31e4S1CMQr6iNwN9tA
- **También puede participar por teléfono, mediante la modalidad de solo escucha:**
Llamada: +1 (253) 215-8782 (not toll-free)
Id. del seminario web: 848 3553 4095
Contraseña: 682856

Información importante de la reunión que debe saber:

- 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 por brindar servicios de interpretación al español, ASL (por su sigla en inglés, lenguaje de señas americano) o CART (por su sigla en inglés, servicios de transcripción simultánea). Si necesita la confirmación de 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.

Información para hacer comentarios públicos verbales en las reuniones híbridas:

- Las personas pueden hacer comentarios públicos verbales en la reunión, en persona o de forma virtual, durante el período de comentarios públicos.
- La cantidad de tiempo otorgada a cada persona dependerá de la cantidad de personas presentes que deseen hablar (suelen ser de 1 a 3 minutos por persona). Primero llamaremos a quienes se hayan anotado con anticipación.
- Regístrese **antes de las 12:00 del mediodía el día anterior a la reunión** para participar en el período de comentarios públicos:
 - [Envíe un correo electrónico a la Mesa Directiva](#) o
 - Regístrese a través del **enlace al seminario web por Zoom. El enlace al seminario web por Zoom está en el orden del día que figura en la [página web de información de la reunión](#).**
 - Si va a **asistir a la reunión en persona** y no se registra con anticipación, puede escribir su nombre en la hoja de inscripción para poder hacer comentarios si el tiempo lo permite.

Información para hacer comentarios públicos escritos:

- Visite la [página web de comentarios públicos](#) de la Mesa Directiva para obtener detalles.

WASHINGTON STATE BOARD OF HEALTH

Draft Minutes of the State Board of Health

August 20, 2025

Hybrid Meeting

ASL and Spanish interpretation available

WA Department of Labor & Industries (Auditorium)

7273 Linderson Way SW

Tumwater, WA 98501-5414

Virtual meeting: ZOOM Webinar

State Board of Health Members present:

Patty Hayes, RN, MSN, Chair

Kelly Oshiro, JD, Vice Chair

Stephen Kutz, BSN, MPH

Tao Sheng Kwan-Gett, MD, MPH, Secretary's Designee

Paj Nandi, MPH

Peter Browning, MA

Mindy Flores, MHCM

Socia Love, MD

State Board of Health Members absent:

State Board of Health staff present:

Michelle Davis, Executive Director

Melanie Hisaw, Executive Assistant

Lilia Lopez, Assistant Attorney General

Ashley Bell, Equity and Engagement
Manager

Crystal Ogle, Administrative Assistant

Hannah Haag, Community Engagement
Coordinator

Michelle Larson, Communications
Manager

Anna Burns, Communications Consultant

Marcus Dehart, Communications
Consultant

Molly Dinardo, Health Policy Advisor

Ash Noble, Health Policy Advisor

Lindsay Herendeen, Health Policy Analyst

Cait Lang-Perez, Health Policy Analyst

Guests and other participants:

Lauren Jenks, Department of Health

Michael Ellsworth, Department of Health

Kelly Cooper, Department of Health

Patty Hayes, Board Chair, called the public meeting to order at 9:05 a.m. and read from a prepared statement (on file). Michelle Davis, Board Executive Director, welcomed the Board and provided a Land Acknowledgement.

1. APPROVAL OF AGENDA

Motion: Approve August 20, 2025 agenda

Motion/Second: Member Kutz/Member Kwan-Gett. Approved unanimously

2. ADOPTION OF APRIL 9, 2025 MEETING MINUTES

Motion: Approve the June 4, 2025 minutes

Motion/Second: Member Flores/Member Browning. Approved unanimously

3. PUBLIC COMMENT

Patty Hayes, Board Chair, opened the meeting for public comment and read from a prepared statement (on file).

Gerald Braude recapped the past testimony from Natalie Chavez and shared concerns regarding the characterization of children's deaths. G. Braude talked about the Department of Health (Department) retention of vaccine fact sheets on the website and criticized their credibility. G. Braude referenced a report from 11 months ago on those who lost jobs and licenses due to the mandates.

Bob Runnells expressed gratitude to the Board and the Department for engaging in the Fluoride Science Review. B. Runnells said the National Toxicology Program (NTP) deserves unbiased attention, cited family efforts to avoid fluoride for 50 years, and raised concerns about community water fluoridation (CWF) and informed consent. B. Runnells noted three Clark County jurisdictions requesting fluoride removal and called for stronger science-based education and respectful language.

Bill Osmunson said the law is clear, the Board is like a jury and must ensure safe water for the public. B. Osmunson recently gave a presentation in Washington, D.C. B. Osmunson said the Food and Drug Administration, the Centers for Disease Control and Prevention, and others do not have any safety studies on fluoride in drinking water. B. Osmunson asked the Board to stay focused on safety.

Mariah Kunz urged the Board not to initiate rulemaking on fluoride. M. Kunz is grateful for the Department and Board support of CWF and said the science doesn't call for action. M. Kunz discussed the federal changes and urged caution against changing the current fluoridation messaging and recommendations based on studies lacking scientific standards.

Russell Maier works for Pacific Northwest University and is intimately involved in the fluoride campaign. R. Maier said the risk should be weighed against the benefits. In their community, CWF is a proven method of reducing oral health problems, infections, and health conditions that impact overall systemic health and morbidity.

Natalie Chavez said fear-based information on measles and limited vaccine data is disheartening. N. Chavez discussed preventative measures, including natural immunity, nutrition, supplements, and sanitation, and inquired why public health doesn't address

these topics. N. Chavez said this is another example of why trust in public health is lacking and declining.

Mary Long spoke against promoting or adding CWF. M. Long said fluoride is a chemical and studies show that fluoride leads to dental fluorosis, thyroid suppression, and lower IQ. M. Long raised ethical concerns about mass medication without informed consent and urged the Board to ban fluoride in Washington.

Derek Kemppainen said cavities can be reversed, but IQ loss is permanent. D. Kemppainen said 56 percent of children in fluoridated areas lose IQ points. D. Kemppainen said fluoridation poses an unreasonable risk, causing IQ loss, and an economic loss of \$556 per person per year.

Jonathon Henry said 0.7 parts of fluoride is safe and doesn't cause brain damage. J. Henry emphasized public policy should be based on evidence, not fear. J. Henry said tooth decay harms lives and leads to emergency room visits. J. Henry expressed willingness to debate this issue and urged the Board to support CWF.

Beth Ottmon said the Board must assure safe drinking water, especially for the most vulnerable. B. Ottmon said no modern safety studies prove the 0.7 parts per million optimal is safe. B. Ottmon urged opposition to CWF and to put the health of families first.

4. BOARD ANNOUNCEMENTS AND OTHER BUSINESS

Michelle Davis, Executive Director, provided updates on staff and Board Member activities. Executive Director Davis announced Dennis Worsham as the new Secretary of Health. Although Secretary Worsham was unable to attend the meeting, the Board extended a warm welcome. Executive Director Davis also introduced Yen Baynes as the new Community Engagement Coordinator for the Governor's Interagency Council on Health Disparities (HDC).

Executive Director Davis noted a complaint submitted to the Attorney General's Office. Executive Director Davis provided updates on ongoing rulemaking projects and recent legislative reports for the Newborn Screening Project and the School Environmental Health and Safety Rule Project. Executive Director Davis also highlighted two video communication projects on school hearing screenings and the Board's Environmental Health and Safety Technical Advisory Committee (TAC). These projects were made possible through Foundational Public Health Services (FPHS) funding.

Executive Director Davis discussed new legislation requiring the Board to revise its rules regarding local board of health composition. Staff have started outreach with Tribes and local health jurisdictions (LHJs). Board Member Steve Kutz will serve as Board sponsor for this rulemaking. Staff anticipate filing the CR-101 in September to initiate the rulemaking process formally.

Executive Director Davis concluded the update by noting that a copy of the FPHS concurrence letter on funding allocations was included in the meeting materials. Executive Director Davis also stated that the team is currently preparing updates for the upcoming FPHS annual reporting.

Patty Hayes, Board Chair, emphasized the Board's unique opportunity to communicate the impact of FPHS funding. Chair Hayes shared that, unlike LHJs and the Department of Health (Department), whose stories often focus on direct programmatic impacts, the Board's narrative centers on its broader work and community benefits. Chair Hayes encouraged the group to reflect on how the Board's investments, spanning language access, community engagement, and staffing, translate into real community benefits. Chair Hayes invited Board Members to provide feedback on this approach and noted ongoing discussions to better frame these stories for audiences closer to the community level.

Executive Director Davis added that many of the Board's staff positions are funded by FPHS, including both of the Board's communication consultants who have been working on video and storytelling communications. Executive Director Davis expressed appreciation for their expertise in technical production and story development.

Peter Browning, Board Member, noted collaboration with the Washington State Association of Local Public Health Officials (WSALPHO) and suggested that the Board clarify its role at the local level. Member Browning emphasized the value of connecting these efforts to the community's safety and well-being, which helps tell a more compelling and relatable story.

5. DEPARTMENT OF HEALTH UPDATE

Tao Sheng Kwan-Gett, Secretary's Designee, shared updates from the Department of Health (Department) and federal developments affecting public health. Member Kwan-Gett noted Dennis Worsham's appointment as the new Secretary of Health.

Member Kwan-Gett discussed the passage of H.R. 1, which includes drastic cuts to the Supplemental Nutrition Assistance Program (SNAP) and the elimination of the SNAP-Ed program. In Washington, 130,000 individuals are projected to lose their SNAP benefits by 2026. Member Kwan-Gett added that Washington will lose \$31-\$51 billion in federal Medicaid funding over the next decade. This could result in 250,000 Washingtonians losing Medicaid coverage and will affect rural communities where a high percentage of children rely on Medicaid. Member Kwan-Gett noted Washington is pursuing the \$50 billion Rural Health Transformation Fund. Member Kwan-Gett said H.R. 1 could impact student loans and Medicaid reimbursements for Planned Parenthood centers. The Washington Attorney General joined a multi-state lawsuit to block its enforcement.

Member Kwan-Gett also discussed that the current Health and Human Services (HHS) Secretary removed all Advisory Committee on Immunization Practices (ACIP) members and appointed new members who lack public health and science backgrounds. Additionally, the LGBTQI+ youth subnetwork of the 988 Suicide and Crisis Lifeline was shut down nationwide. However, the Department of Health (Department) is actively working to ensure that Washington's 988 crisis counselors are trained to support these youth.

Member Kwan-Gett said the Department will focus on mitigating federal impacts this 2026 legislative session. Member Kwan-Gett also discussed a locally acquired case of malaria in Pierce County.

Member Kwan-Gett concluded by reflecting on the tragic events at the Centers for Disease Control and Prevention (CDC) Atlanta offices on August 8. Member Kwan-Gett emphasized the importance of restoring public trust in public health systems.

Steve Kutz, Board Member, shared concerns about access to care in Washington State, particularly regarding uninsured people who visit emergency rooms, receive large medical bills, and face legal action to pay them. Member Kutz highlighted the difficulty people already face in accessing primary and specialty care, especially with Medicaid. Member Kutz emphasized the responsibility of the healthcare system to address these challenges, which are likely to worsen.

Member Kwan-Gett responded by acknowledging the significance of Critical Access Hospitals (CAH) in rural communities and agreed that healthcare access will continue to be a significant challenge. Member Kwan-Gett also noted that the State Health Improvement Plan (SHIP) had identified two priorities: healthcare access and mental/behavioral health. These priorities reflect the ongoing concern over access to care in Washington.

Peter Browning, Board Member, raised concerns about the impact of recent changes on smaller hospital districts in Washington. Member Browning emphasized that many districts may struggle to survive, with increasing charity-care costs being passed on to residents. Member Browning also highlighted the challenges smaller hospitals face in cutting back essential services that are not profitable, forcing patients to travel to larger cities for care. This could lead to serious access issues for those unable to travel, exacerbating healthcare disparities.

Member Kwan-Gett acknowledged Member Browning's concerns, agreeing that the changes would not only impact Medicaid recipients but also have broader ripple effects on the health of all Washingtonians.

Member Browning asked whether there had been discussions with the Insurance Commissioner about potential rate increases in the health insurance exchange and the impact this could have on medical debt and family bankruptcies. Member Browning emphasized that healthcare access is a complex issue that requires collaboration across multiple sectors.

Member Kwan-Gett noted that, while not directly involved with the Insurance Commissioner, the Department works closely with healthcare partners. Member Kwan-Gett assured the group that an update on these discussions could be provided at a future meeting.

Mindy Flores, Board Member, commended Member Kwan-Gett's reflection on public health challenges and expressed concern about the future of the healthcare workforce. Member Flores pointed out that many healthcare professionals, particularly in nursing, are expected to retire or leave the profession in the next few years due to burnout and other factors. Member Flores urged the Department to consider the impact on the workforce and to explore ways to support and train the next generation of healthcare providers.

Patty Hayes, Board Chair, acknowledged Member Flores' concerns, sharing statistics from the University of Washington Tacoma campus indicating that 30-50% of nursing graduates leave the profession within three years. Chair Hayes emphasized the role of the Washington Center for Nursing and the potential for innovation in workforce training, particularly with the use of AI and evolving licensure models. Chair Hayes suggested that the issue of workforce sustainability could be further explored in the next year as more data on these impacts emerges. Chair Hayes also looked to Member Kwan-Gett to signal when to dive deeper into these workforce topics.

The Board took a break at 10:45 a.m. and reconvened at 11:00 a.m.

6. DEPARTMENT OF HEALTH FLUORIDE SCIENCE REVIEW UPDATE

Tao Sheng Kwan-Gett, Secretary's Designee, and Lauren Jenks, Department of Health, provided an overview of the Fluoride Science Review Panel (Panel). The Department convened the Panel in response to petitions that the Board had received related to fluoride, citing evidence from the National Toxicology Program (NTP). Member Kwan-Gett and Lauren discussed oral health, the use of fluoride and community water fluoridation (CWF), the Department's role, and the Board's authority (see presentation on file).

Member Kwan-Gett and Lauren summarized the Panels process, findings, and consensus statements. Member Kwan-Gett and Lauren reviewed the Panel's three recommendations. The Panel recommended maintaining the current optimal level of fluoride concentration, beginning rulemaking to consider adopting a state action level of 1.5 mg/L for fluoride, and coordinating with public health partners to update messaging on fluoride.

Member Kwan-Gett noted that local health officers have raised concerns about the Panel's report, and there will be ongoing discussions about this topic. Lauren stated that there will be an ethics review of the Panel's consensus statements and recommendations. Lauren said we need to prepare for possible federal changes from the Environmental Protection Agency (EPA) and the Department of Health and Human Services (HHS). Lauren emphasized the need to plan for how to maintain oral health if CWF becomes unavailable.

Patty Hayes, Board Chair, opened it up for questions and discussion.

Steve Kutz, Board Member, asked for clarification on the current EPA fluoride levels. Lauren explained there is a primary action level at 4 mg/L and a secondary level at 2 mg/L, with required action at 4mg/L. Member Kutz asked about naturally occurring fluoride above 4 mg/L. Lauren stated that communities must remove fluoride and may add it back at the optimal level of 0.7 mg/L.

Member Kutz asked about fluoride levels in bottled water. Lauren stated that the Food and Drug Administration (FDA) regulates bottled water. Shay Bauman, Board staff, clarified that the FDA requires fluoride levels in bottled water to be below 0.7 mg/L, and if the water used is naturally occurring fluoride, between 1.4 and 2.4 mg/L.

Chair Hayes asked the Department and staff to be clear when they discuss action levels versus the optimal fluoridation level.

Member Kutz stated that there is a recommendation to use bottled water instead of tap water to prepare infant formula. However, if you are buying water, you may not know if bottled water has higher levels of fluoride than tap water.

Chair Hayes stated that this is an important issue to flag for the future because it pertains to labelling.

Member Kutz said that if we are recommending parents to use bottled water, then we are not accomplishing the goal. Lauren and Chair Hayes clarified that this was not part of the Panel's recommendation. Lauren added that some places recommend non-fluoridated sources, such as distilled water.

Member Kwan-Gett stated that updating fluoride messaging will require significant discussion and effort to translate the science into community guidance.

Peter Browning, Board Member, inquired about the monitoring of fluoride to address concerns from communities regarding fluctuations in fluoride levels. Lauren stated that water systems are required to continually monitor and shared an example that King County tests hourly.

Paj Nandi, Board Member, inquired about the possibility of the state examining oral health outcomes for communities exposed to naturally occurring fluoride versus those that are fluoridated in Washington State. Lauren responded that it would be difficult since oral health is also impacted by socioeconomic status, and this would not be an easy study to plan and to control for all possible variables.

Member Nandi asked whether there will be monitoring in Florida and Utah about the impacts of stopping community water fluoridation.

Kelly Oshiro, Vice Chair, commended the staff and the Science Review Panel. Member Oshiro asked about the one-third of Washingtonians not on fluoridated water. Lauren noted that some are on well water systems and that water fluoridation is a community decision. The Department has data for each water system.

Member Oshiro asked if the Panel had heard from communities that currently fluoridate their water. Lauren explained the Panel heard from partners, primarily doctors and dentists, but no broad community outreach was done.

Member Oshiro expressed that opposition to fluoride may stem more from social views than the science. Lauren stated this is a "lightning rod" issue among public health and the community.

Member Kutz asked if every water system that is regulated has fluoride levels in their annual report. Lauren stated that fluoride levels are required in communications from water systems.

Chair Hayes stated that people on well water would not get this communication.

Member Kutz asked whether there was future work that needed to be done related to action levels. Lauren responded that the Panel recommended not adjusting the current optimal level of fluoridation and considering adopting a lower state action level.

Shay Bauman, Board staff, reviewed the Board's authority related to community water fluoridation and its alignment with federal guidelines.

Molly Dinardo, Board staff, highlighted past Board recommendations from 2015 on maintaining and expanding CWF. Molly stated that staff would like to review and update these recommendations as they have not been revisited since 2015.

Shay stated that the Panel recommends that the Board consider rulemaking to adopt a SAL of 1.5 mg/L. Timing is affected by ongoing PFAS rulemaking. The Board could decide to initiate rulemaking for fluoride in early 2026. Shay stated that staff could come back later in 2025 to propose possible rulemaking scenarios.

Chair Hayes stated that staff recommend removing the document from the Board's website and returning at a future meeting to discuss potential rulemaking to consider adoption at SAL or state MCL for fluoride.

Member Kutz asked whether we would leave the recommendations on the website while we review and work on an update. Molly responded that the intent is to remove the recommendations while staff work to update them based on the Panel and other work in Washington State.

Member Nandi asked if we have web data about whether those recommendations have been accessed. Michelle Larson, Board staff, stated that the Communications team can obtain more comprehensive data on the document's use, but there has been minimal use over the past five years. Member Nandi questioned whether if it is worth staff time and capacity to update the recommendations since the Board is not legally required to do so.

Member Flores asked if we should wait for future rulemaking, depending on EPA guidance, or if we should move forward. Shay said federal actions are uncertain and staff would propose rulemaking scenarios for the Board to act independently. Member Flores stated that it sounds like we are trying to be proactive.

Chair Hayes clarified that the Panel recommended that the Board not change the 0.7 mg/L optimal fluoridation level, but to consider the action levels of 4 mg/L and 2 mg/L. That is where the discussion of rulemaking is based. The Board could consider changing those MCLs or adopting a SAL.

Member Oshiro noted that other states may consider a SAL or revise their MCL. Lauren stated that the question is out to associations, and the Department has not yet heard of other states making these considerations.

Member Kwan-Gett noted that removing the recommendations before posting an updated document could create a gap. This could be seen as a lack of support for CWF and could lead to miscommunication.

Chair Hayes suggested noting on the website that the document is under review. Chair Hayes emphasized that, whether the document is removed, left unchanged, or marked as under review, the public should know it is being updated. Molly stated these are all options we could use, and the Board could help decide the wording or leave it to the staff.

Member Kutz stated that the absence of a document would be a vacuum and would support leaving it on the website and indicating it is under review.

Motion: Direct Staff to [1] review the Recommended Strategies to Improve the Oral Health of Washington Residents (2015) document and accompanying webpage on the Board's website, indicate on the Board's website that these are under review, and work with the Department of Health to review and update the document's content and messaging; and [2] brief the Board at a future meeting regarding a potential rulemaking to consider adopting a State Advisory Level (SAL) or State Maximum Contaminant Level (MCL) for fluoride.

Member Oshiro suggested adding the second motion before the Board to the first (see above).

Motion/Second: [1] Member Kutz & [2] Member Oshiro/Member Browning. Approved unanimously

Molly asked if the Board could discuss whether they would like to have Oral Health Recommendations.

Chair Hayes suggested moving the motions and then having a conversation about intent.

Member Kutz stated the Board needs additional conversation and that potential actions could significantly impact this work. Member Kutz added that federal government decisions could extend the timeline for state decisions.

Member Flores asked whether we are asking staff to review the entire document or just the sections related to community water fluoridation.

Chair Hayes asked the Department to share the findings of the ethics review at a future meeting.

Member Nandi returned to Molly's point and asked if the Board could continue the conversation about whether we want to have policy recommendations as a Board and what role the Department could play in developing policy and programmatic recommendations. Member Nandi also stated that posting information on the Board's website may not be the best way to communicate policy recommendations.

Chair Hayes suggested future work may need to occur with the Board's partners to understand this.

The Board broke for lunch at 12:54 p.m. and reconvened at 1:30 p.m.

7. FEDERAL CHANGES IN NEWBORN SCREENING AND PROPOSED UPDATES TO WASHINGTON STATE'S CANDIDATE CONDITION REVIEW PROCESS

Kelly Oshiro, Board Vice Chair, reviewed the Board's authority and noted federal changes may affect how new conditions are reviewed.

Molly Dinardo, Board staff, and Megan McCrillis, Department of Health staff, provided updates on federal developments, including the termination of the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) and potential impacts of HR. 1 on Medicaid funding for newborn screening. The termination of the federal ACHDNC disrupted reviews for Duchenne's Muscular Dystrophy and Metachromatic leukodystrophy (MLD). The Health Resources and Services Administration (HRSA) is seeking public comment on these conditions but is not accepting new Recommended Uniform Screening Panel (RUSP) nominations.

Molly then shared insights from the newborn screening policy team regarding the candidate condition reviews and technical advisory committee (TAC) meetings over the past fiscal year. Molly highlighted that in the spring, the TAC reviewed congenital cytomegalovirus (cCMV) and evaluated three specimen types: dried blood spot, saliva swab, and dried urine filter paper. The TAC ultimately recommended dried urine filter paper as the optimal specimen, as both blood spot and saliva swab failed to meet the Board's sensitivity criteria (below 95%). However, the Board's current authority permits screening only using dried blood spot specimens. Expanding this authority would require further policy development, resources, and funding. Molly recommended that the Board focus on conditions that can be screened using dried blood spot specimens for the time being.

Molly also proposed minor updates to the Board's process and criteria for newborn screening to clarify authority and allow flexibility for changes in federal review processes. These changes are not to the rule itself but guide how the Board reviews conditions (see presentation on file).

Steve Kutz, Board Member, noted that the Board has traditionally considered evaluating conditions even if they were not on the RUSP. Member Kutz suggested that this may need to be the default approach in the future. Molly agreed, stating that Washington may need to rely more on its own process if future conditions are not reviewed nationally.

Member Kutz raised concerns about funding availability, particularly if federal or Medicaid funding for testing or follow-up is not available. Member Kutz suggested that the Board could take action on conditions but defer implementation depending on budget.

Molly explained that newborn screening is funded through legislative authority to increase the newborn screening fee and through the Health Care Authority (HCA)

negotiating fees with managed care organizations (MCOs). However, the impact of future MCO negotiations is uncertain, especially given the potential decrease in federal funding for Medicaid. This could reduce insurance coverage for many people in Washington State.

Member Kutz expressed concerns about the implications of reduced federal funding that could negatively affect health insurance coverage and rural hospitals.

Patty Hayes, Board Chair, expressed concern if many children lose Medicaid coverage, parents may be billed directly for newborn screening, and the Department may not receive reimbursement. Chair Hayes asked how the Board and Department would track these impacts. Megan said they can follow up with the Board on this. Megan added that the Department does sometimes bill people directly, such as for home births.

Chair Hayes acknowledged that while this issue is not directly related to the proposed changes, it is an essential consideration for future discussions about these tests. Molly agreed, emphasizing that ongoing conversations are necessary, as both federal and state budgets will influence the Board's decisions about recommending conditions for screening.

Tao Sheng Kwan-Gett, Secretary's Designee, asked about the impacts of the ACHDNC's discontinuation and whether a national association might fill the gap. Megan responded that the American College of Medical Genetics and Genomics (ACMG) has initiated discussions on what a new national recommended list might look like. Megan noted criticisms of the federal process, but that the RUSP list is still being maintained, and advocates continue to work toward aligning states with it.

Member Kwan-Gett stated that having more flexibility at the state level would be beneficial with the federal uncertainty.

Member Oshiro asked Molly to discuss the proposed change regarding dried blood spots.

Molly reminded the Board that four conditions on the RUSP, but not yet on Washington's panel, are scheduled for review by 2026. Three of these conditions can be tested using dried blood spots, while the fourth, congenital hearing loss, requires a point-of-care test (audiology). Molly noted that, given the recent cCMV TAC outcomes, it seems premature to convene a TAC for congenital hearing loss, especially since the Board does not have the explicit authority to mandate testing for conditions that cannot be detected via dried blood spot. Molly stated that the Board may need to revisit congenital hearing loss in the future.

Motion: The Board accepts the proposed updates clarifying authority and addressing federal uncertainty to the candidate condition review process and qualifying assumption, as presented by Board and Department staff, for the purpose of evaluating conditions for inclusion in Washington's mandatory newborn screening panel.

Motion/Second: Member Kwan-Gett/Member Nandi. Approved unanimously

Member Oshiro noted that the Board's newborn screening TAC has not reviewed the proposed changes this year. However, staff made these changes in response to the dynamic landscape and their role as stewards of the Board's resources.

Member Kutz emphasized that the newborn screening infrastructure must ensure access to services for affected babies and their families. Member Kutz expressed concern that identifying conditions without available services would be harmful and suggested that the Board might need to delay implementing screening until sufficient funding is available.

8. NEWBORN SCREENING, WILSON'S DISEASE TECHNICAL ADVISORY COMMITTEE (TAC) RECOMMENDATIONS

Kelly Oshiro, Vice Chair, introduced staff and reminded the Board of the August 2024 petition on Wilson Disease. In response to the petition, the Board and the Department of Health (Department) convened a technical advisory committee (TAC) in June to evaluate Wilson Disease using the Board's newborn screening criteria.

Molly Dinardo, Board staff, presented background on Wilson Disease and its petition for inclusion on Washington's newborn screening panel. Wilson Disease is a rare inherited metabolic disorder that prevents the elimination of excess copper, potentially leading to life-threatening health issues. It is not currently screened for in any U.S. state and has not been reviewed for inclusion on the federal Recommended Uniform Screening Panel (RUSP).

Megan McCrillis, Department of Health staff, presented on the screening technology, diagnosis and treatment, and cost-benefit analysis for Wilson Disease. Megan also outlined the infrastructure needs for screening.

Molly then presented the TAC's recommendation. 14 of 16 members voted in favor of adding Wilson Disease to the newborn screening panel. No members opposed.

Tao Sheng Kwan-Gett, Secretary's Designee, asked the presenters to discuss the content of slide six regarding the shifts in deaths and neurological cases. What does that mean for Washingtonians?

Megan explained that Washington has about 80,000 births annually, with an estimated two babies born with Wilson's Disease each year. Approximately 6% of patients may require a liver transplant, with a 13% mortality rate within a year of the procedure. Late identification carries a 3% mortality rate, but early intervention can enable a normal lifespan.

Member Kwan-Gett asked if screening would reduce neurological cases over 10 years.

Megan confirmed this is plausible. About 32% of babies with Wilson Disease may develop neurological symptoms, which are harder to treat and impact quality of life. Early intervention can prevent these systems entirely.

Steve Kutz, Board Member, noted that saving even one or two liver transplants could potentially offset the cost of early testing and care.

Member Kwan-Gett expressed appreciation for the scientific and public health reasoning behind the TAC's recommendation but raised concerns about the financial burden of adding the condition to the screening panel without clear funding.

Member Oshiro shared these concerns and worried that future generations might lack access to specialized care. Member Oshiro emphasized that Washington would be a pioneer in screening for Wilson Disease, as the RUSP has not reviewed it. Member Oshiro acknowledged the impact of powerful parent testimony and the challenges such petitions present.

Peter Browning, Board Member, asked if Wilson Disease can be predicted using family history.

Megan clarified that Wilson Disease is genetic, and without screening, family history is the primary method for early identification.

Member Browning suggested focusing on patients with a family history of Wilson Disease.

Molly explained that genetic screening access in Washington State is inconsistent, and adding Wilson Disease to the panel would make Washington a leader in this area. Molly noted that achieving RUSP inclusion is difficult, and states must first screen for a condition to generate the data necessary for RUSP consideration.

Member Browning noted that some individuals who test positive may never show symptoms, potentially revealing the true prevalence of Wilson's Disease. Member Browning recalled that the cost per test was higher than discussed in the presentation.

Member Kutz explained that rulemaking depends on legislative funding, so this wouldn't be added right away. Member Kutz suggested that early detection could save costs by preventing later-onset conditions could save costs.

Molly added that Wilson Disease is an autosomal recessive disease, so family history isn't a great way to identify potential patients.

Patty Hayes, Board Chair, asked if there was a motion. After a brief pause, Chair Hayes suggested tabling the matter.

Member Kutz then moved the Board begin rulemaking and add this project to the queue.

Member Kwan-Gett noted that rulemaking would not proceed until funding is available, addressing concerns about potential harm.

Motion: The Board directs staff to file a CR-101 to initiate rulemaking for chapter 246-650 WAC to consider adding Wilson Disease to the Washington State newborn screening panel.

Motion/Second: Member Steve Kutz/Vice Chair Kelly Oshiro. Members Browning, Nandi, and Oshiro abstained from voting. No Board Members voted against the motion. All remaining Board Members voted to approve the motion.

9. HEALTH IMPACT REVIEW FISCAL YEAR 2025 UPDATE

Cait Lang-Perez, Lindsay Herendeen, and Miranda Calmjoy, Board staff, provided an overview of Health Impact Reviews (HIR). HIR's are objective, nonpartisan analyses to determine the impacts of legislation on health equity in the state. HIR's analyses provide legislators with information for their decision making and don't make recommendations. The HIR team highlighted fiscal year 2025 HIR requests, staff engagement with key informants, feedback from legislators and participants, and opportunities for national presentations and interagency collaboration (see presentation on file).

Patty Hayes, Board Chair, expressed appreciation for the HIR team's work.

Paj Nandi, Board Member, stated that they use HIRs as part of their curriculum at the University of Washington. Students appreciate how practical, relevant, and impactful this work is. Member Nandi expressed gratitude for the HIR team's work.

Tao Sheng Kwan-Gett, Secretary's Designee, thanked the HIR team for their presentation and complimented the team for another year of great work. Member Kwan-Gett suggested using the HIR team's successes as a Foundational Public Health Systems (FPHS) story.

Michelle Davis, Executive Director, said FPHS funding funds two of three HIR analysts and their travel. The funds also support community compensation for eligible key informants. Executive Director Davis mentioned that Washington State is unique in conducting HIRs on legislative and budgetary proposals and expressed pride in the HIR team.

Chair Hayes stated that a story that reflects something FPHS does for legislators is likely to be persuasive.

Steve Kutz, Board Member, stated that although it is difficult to measure, HIRs are likely to inform and perhaps change legislative proposals. Member Kutz suggested that HIRs might be helpful to assess the impacts of Medicaid funding cuts.

10. CHAPTER 246-260 WAC AND CHAPTER 246-262 WAC WATER RECREATION RULEMAKING UPDATE

Patty Hayes, Board Chair, introduced the water recreation rulemaking update.

Joe Graham, Department of Health staff, provided an overview of Washington's 4,800 Water Recreational Facilities, key safety concerns, and two petitions related to ADA and lifeguard allowances. Joe reviewed the rulemaking timeline, responsibilities of the Department and local health jurisdictions, and next steps for rulemaking (see presentation on file).

Paj Nandi, Board Member, asked about lifeguards and costs in schools. Joe said they will follow up after asking technical experts.

Kelly Oshiro, Board Vice Chair, asked if lifeguard is a technical term and if they are accredited. Joe said yes, there are qualifications to be a lifeguard.

Tao Sheng Kwan-Gett, Secretary's Designee, thanked Joe for the work on water safety and prevention, and commented on the impact of safety in water recreation.

Peter Browning, Board Member, said that drinks in a pool can be disastrous and is sure that research supports this.

Patty Hayes, Board Chair, talked about the intersection of the School Environmental Health and Safety Rules and the need to collaborate.

Kelly Oshiro, Vice Chair, said that a list of schools with pools should be compiled.

The Board took a break at 3:20 p.m. and reconvened at 3:30 p.m.

11. STATE BOARD OF HEALTH BUDGET OVERVIEW

Ashley Bell, Board staff, and Michelle Davis, Executive Director, reviewed the Board's funding and the fiscal year 2026 budget outlook, including a \$750 million¹ shortfall and a \$22 million reduction in foundational public health services (FPHS) funding.

Executive Director Davis introduced Board Members to the concept of zero-based budgeting (ZBB), which requires every expense to be justified for each new period, starting with a zero base. Ashley discussed the implications and benefits of ZBB.

Executive Director Davis reviewed current budget cuts, salary and COLA gaps, and challenges from historical underspending. Executive Director Davis explained that the Board will need additional policy development capacity and operations support to maintain current operations and respond to a rapidly changing future. Executive Director Davis explained next steps to control spending and plans for a 2026 decision package (see presentation on file).

Kelly Oshiro, Vice Chair, asked about the policy director position. Executive Director Davis explained the position would coordinate policy work, improve agency engagement, support legislative presence, and manage bill tracking during sessions.

Steve Kutz, Board Member, noted the Board is doing well considering the circumstances, but we need to do better with community engagement, and asked if a policy director could help with that. Executive Director Davis noted the concern.

Mindy Flores, Board Member, asked if Members could do anything to further advocate for the Board. Executive Director Davis responded that Board Members could share current events with the community and help us think about how our work touches the community more broadly.

¹ Executive Director Davis inadvertently shared an incorrect forecast amount. The correct amount is \$720 million. See [here](#) for Governor Ferguson's statement on revenue forecast.

Perer Browning, Board Member, commented that the reality at local government is widespread budget shortfall, beyond even the state level, which affects the ability to provide direct services to the community. Executive Director Davis agreed.

Patty Hayes, Board Chair, commented that we need these exercises to keep grounded and that a decision package is an important step to be able to talk about our needs.

Member Kutz noted the increased presence and relevance of the Board in the public sector. Chair Hayes agreed.

12. SCHOOL RULE PROJECT UPDATE

Patty Hayes, Board Chair, explained the need for ongoing School Rule Project (SRP) updates because the Board continues to engage the technical advisory committee (TAC). Chair Hayes noted continued engagement with local health and partners and that the team is developing a communication plan that includes regular updates to the TAC (see materials on file).

13. BOARD MEMBER COMMENTS AND UPDATES

Patty Hayes, Board Chair, informed Board Members that the Board has received a rulemaking petition around osteoporosis, but that is not under the Board's rulemaking authority.

Michelle Davis, Executive Director, explained that the petition is to require insurance carriers to include bone density testing in their coverage. The Board has no authority over insurance coverage so staff are reaching out to the Health Care Authority (HCA) and the Office of the Insurance Commissioner (OIC) to determine the correct agency to handle this petition.

Executive Director Davis recognized Shay Bauman for their five years of state service.

ADJOURNMENT

Patty Hayes, Board Chair, adjourned the meeting at 4:23 p.m.

WASHINGTON STATE BOARD OF HEALTH

Patty Hayes, Chair

To request this document in an alternate format or a different language, 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.

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WASHINGTON STATE BOARD OF HEALTH BYLAWS

Updated March 14, 2018
Updated October 11, 2017
Revised October 12, 2005
Adopted May 11, 2005

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ARTICLE I: MEMBERSHIP

Members

- The Governor appoints nine members of the Washington State Board of Health (the Board) as described in RCW 43.20.030.
- The Secretary of Health or a designee is the tenth member of the Board.

Terms of Office

- A term of office is three years. The Governor may re-appoint members to additional terms.
- A member whose term has expired may continue to serve until the Governor appoints his or her successor.
- A Board member may resign if he or she is no longer able to participate in Board meetings or complete his or her term, the member must submit a letter of resignation to the Board Chair, and complete the Governor's on-line resignation form.
- As vacancies occur on the Board by resignation, death, incapacity, etc., the vacancy shall be filled by appointment by the Governor for the remainder of the term.

Reimbursement for Expenses

- Board members appointed by the Governor may receive \$50 for each day they attend official Board or committee meetings, or participate in other Board-approved activities. This will be done in accordance with RCW 43.03.240.
- A Board member who works full-time for any federal, state, or local government agency may not be paid for a day of service if they are also paid by their employer for working that day. Appointed

Board members may be reimbursed for expenses associated with Board-approved meetings or activities. Reimbursements will be made consistent with RCW 43.03.050 and 43.03.060.

- As resources allow, meetings or activities for which members may be paid include participation in ad hoc committees; meetings with other government agencies, stakeholders and community groups; or testifying or presenting on behalf of the Board, at legislative meetings or professional conferences.

ARTICLE II: BOARD OFFICERS

Officers

- The officers of the Board consist of the Chair, Vice Chair, and the Chair Pro-Tem.

Elections/Terms of Office

- The Governor will appoint the Chair from among the nine appointed members consistent with RCW 43.20.030.
- The Chair shall serve for the duration of his or her appointment, or until the Governor appoints a successor.
- The Board shall elect a Vice Chair from the remaining eight appointed members. The election shall take place at a Board meeting, by a vote of the Board, preceding the end of the term or resignation of the sitting Vice Chair.
- The Vice Chair's term starts upon election and continues until the end of his or her appointment, until the Vice Chair resigns, or upon the request for replacement by the Chair that receives the concurrence of a majority of the Board.
- If both the Chair and Vice Chair are absent or have recused themselves from a meeting or agenda item, Board members shall elect one of the remaining members present to serve as Chair Pro-Tem.
- The Chair Pro-Tem shall serve for the duration of the absence or recusal.

correspondence that reflects the Board's position on matters that aren't purely administrative in nature. This includes correspondence with the Legislature and other government agencies on matters of policy. The Chair may ask the Executive Director to sign correspondence as appropriate.

- The Vice Chair acts in the capacity of the Chair when the Chair is absent or recused because of a conflict of interest, or is otherwise unable to serve.
- The Chair Pro-Tem presides during Board meetings when the Chair and Vice Chair are absent or are otherwise unable to preside.

Duties of Officers

- The Chair provides overall leadership to the Board, presides at all meetings and has all powers and duties conferred by law and these bylaws. The Chair or a designee shall represent the Board at official functions. The Chair shall approve and sign

ARTICLE III: MEETINGS OF THE BOARD

Regular Board Meetings

- All Board meetings are subject to the Open Public Meetings Act Chapter 42.30 RCW.
- The Board shall adopt an annual schedule of dates and locations for regular meetings for each calendar year, and shall file it for publication with the Code Reviser. Agendas for regular meetings shall be posted to the Board's website 24 hours in advance, as required by RCW 42.30.077
- Regular meetings will generally take place on the second Wednesday of the month. As resources allow, meetings will occur at locations across the state.
- Any changes to the annual schedule shall be made at the discretion of the Board Chair, with the approval of the Board.
- The Chair or Executive Director may cancel a regular Board meeting for justifiable reasons, including the lack of sufficient agenda items.
- If the Board is unable to meet at a meeting location due to natural disaster including but not limited to fire, flood, earthquake, or other emergency, and the Board needs to meet to address the emergency, the Chair may move the meeting site to a place other than the published meeting site. Board staff will post the new meeting location to the Board's website and will send notice to interested parties at least one day before the meeting at the new site.

Special Board Meetings

- The Chair may call a special meeting of the Board at any time.
- Notice of a special meeting shall be provided in accordance with the Open Public Meetings Act, Chapter 42.30 RCW. Board staff will post the meeting announcement on the Board's website and will send notice by electronic mail to interested parties, 24 hours in advance of the meeting. The public notice will include a brief description of the meeting topics and specify the time and place.
- The Board may not take final action on any item that is not listed in the public notice.

Adjournment

- The Board may postpone a portion of any meeting already in progress and reconvene at another time and/or place by adopting a motion to adjourn. The motion must specify where and when the meeting will resume.
- A majority vote of the Board members at a meeting can approve a motion to adjourn even if there is not a quorum present. If all members are absent from a meeting, the Chair or Board staff may adjourn the meeting to a stated time and place.
- Whenever the Board adjourns a meeting, a notice of adjournment shall be conspicuously posted immediately on or near the door of the room where the meeting was held. The notice should include when and where the meeting will resume.

ARTICLE III: MEETINGS OF THE BOARD

(CONT'D)

Hearing Continuances

- The Board may continue any hearing to a subsequent meeting by adopting a motion to continue consistent with RCW 42.30.100.
- For rulemaking, the Board must specify the place and time of a continued hearing in the motion to continue consistent with RCW 34.05.325(5).
- The Board must provide notice on the subsequent meeting agenda whether it is continuing public testimony or comment, or whether there will only be Board member discussion and possible action. Based on Board discussion, the Chair may choose to take additional comment or testimony.
- The Board will provide notice of a continuance consistent with RCW 42.30.090.

Meetings to be Open and Public

- All meetings of the Board, except for executive sessions are open to the public.
- The Board may meet in executive session, and exclude the public only under special circumstances listed in RCW 42.30.110. Before convening in executive session, the Chair will publicly announce the reason for excluding the public and the time when the executive session will end. If the meeting continues beyond the stated time, the Chair must publicly announce the extension and a new ending time.
- The Board may adopt a resolution, rule, order, or directive only in an open public meeting that has been properly noticed.
- The Board shall hold all meetings in facilities that are accessible to individuals with disabilities.
- The Board may not require a member of the public to register his or her name and other information, complete a questionnaire, or perform any other action as a precondition for attending a Board meeting.

Meetings Interrupted by Group or Groups of Persons

- If the disorderly conduct of a person or group of people makes it impractical to continue a Board meeting, the Chair of the Board should first order that the individuals interrupting the meeting leave the room. If that action fails to restore order, the Chair of the Board can clear the room. It can also adjourn the meeting and reconvene at another place selected by a majority vote of the Board members.
- If the Board clears the room or adjourns to another location, it may only act (vote) on matters that appeared on the approved meeting agenda.
- Representatives of the press or other news media, except those participating in the disturbance, must be allowed to attend even if the room has been cleared or the Board has reconvened elsewhere.
- The Board may determine how it might readmit any individuals who were not disrupting the meeting.

Meeting Minutes and Agendas

- Board staff shall take written minutes of all regular and special Board meetings. Board staff shall accurately capture the action of the Board on each question, and shall prepare the minutes for Board approval at the next regularly scheduled meeting.
- Board staff shall retain meeting minutes, agendas and materials consistent with record retention schedules and shall then transfer these records to the State archives for permanent retention.
- Board staff shall post a preliminary draft of the agenda for the next regularly scheduled Board meeting on the Board's website at least 14 days prior to meeting.
- Board staff shall post the final proposed agenda for the next regularly scheduled Board meeting on the Board's website at least seven days prior to the meeting.

ARTICLE III: MEETINGS OF THE BOARD (CONT'D)

- Board staff shall post minutes for the previous Board meeting and materials for the next regular meeting to the website at least five days prior to the next regular Board meeting date.
- Board members should review all posted meeting materials prior to the meeting.
- Minutes approved by the Board shall be made available on the Board's web site and distributed on request within three business days of adoption.
- Public notices and agendas regarding Board meetings shall include a statement that accommodations may be provided with advance written notice to Board staff. The public notice shall include contact information for making such requests.

Meeting Attendance

- All Board and Committee meetings should be attended by at least one member of the Board staff.
- Board staff taking the minutes shall record member attendance.

ARTICLE IV: MEETINGS PROCEDURES

Quorum

- A quorum is six (6) members of the Board.
- The Board may discuss issues and deal with administrative matters in the absence of a quorum, but it may adopt any resolution, rule, order, or directive during a meeting only if a quorum is present.
- The Board may entertain a motion to adjourn without a quorum.
- Anyone participating in the meeting, including a member of the public in the audience, may call for a roll call at any time after a quorum has been established. If a quorum is not present at the time of the roll call, no further actions can be taken by the Board unless additional members enter the room and re-establish a quorum.

Order of Business

- The final agenda will detail the order of business. The Chair has discretion to modify the agenda during the meeting to manage time. The Chair may not eliminate items from the agenda without concurrence of the Board.

Public Comment

- The Board Chair may solicit public comment on any agenda items during regular Board meetings.
- The Chair may determine the amount of time for public comment by each speaker based on the number of speakers, time available, and topics to be addressed.
- All regular meeting agendas shall include an item allowing for public comment. During these public comment periods, speakers may address any issue related to the Board's authority or public health.

ARTICLE IV: MEETINGS PROCEDURES (CONT'D)

Motions, Resolutions, and Rules

- All Board actions must be expressed by motion.
- To be accepted (passed), a motion must receive a majority of votes of the Board members present to be valid.
- Staff shall record all motions in the minutes.
- In the event that the Board takes an action that directly impacts a specific person or organization (such as a complaint, petition for rulemaking, or request for variance), staff shall notify the person or organization impacted in writing.
- No Board member or staff may use his or her position with the Board to endorse or oppose an issue unless a majority vote of the members of the Board approve of the position on the issue.
- The Board may adopt a policy that authorizes the Chair or a designee to represent the Board on issues before the Legislature.

Manner of Voting

- All votes, including those for elections, motions, and resolutions shall be voice vote.
- In lieu of voice vote, a Board member may request a roll call or show of hands vote.

Rules of Procedure

- The procedures used to conduct Board business will be determined by these bylaws, the Administrative Procedures Act, the Open Public Meetings Act, and the Board's authorizing statute, Chapter 43.20 RCW.
- If a procedural issue arises that is not covered by these bylaws and applicable state laws, and the Board cannot reach consensus on how to proceed, the Board will follow the procedures contained in the most current version of Robert's Rules of Order.
- Board staff shall provide a copy of Robert's Rules of Order at all Board meetings.

ARTICLE V: COMMITTEES OF THE BOARD

Policy Committees

- The Board may establish policy committees to help execute its work. Committees are advisory in nature and may make recommendations to the Board for Board action.
- Policy committees may consist of up to five Board members who volunteer to serve on the committee. Standing committees do not include members of the public as members.
- Each policy committee must select a Committee Chair.
- The Executive Director shall identify a lead staff person to support each policy committee.
- Board staff shall create a written summary of each policy committee meeting, and shall prepare the summary for policy committee approval at the next committee meeting.
- Board staff shall retain the summary and agendas consistent with record retention schedules, and shall then transfer these records to the State archives for permanent retention.

Ad Hoc Committees

- The Board may establish Ad-Hoc Committees to fulfill specific tasks.
- Ad-Hoc Committees shall be comprised of members recommended by Board members or staff.
- The committee must disband when it completes its assigned task(s).
- Each Ad-Hoc Committee shall select a Committee Chair unless one is selected by the Board.
- Ad-Hoc Committees may include subject matter experts or members of the public.
- All committee meetings are open and will be conducted as special meetings under the Open Public Meetings Act in accordance with RCW 42.30.080.

ARTICLE VI: AMENDMENTS

Amendment to the Bylaws

- Board Bylaws may be amended upon a two-thirds majority vote of the Board.

ARTICLE VII: CONSTRUCTION

Liberal Construction of Rules

- The Board will interpret these bylaws in a manner that best protects the public's health and furthers the intents of Chapter 43.20 RCW.



Public Comment

*The following comments were received by noon on Friday,
October 3, 2025*

From: Marcy Bowers <marcy@povertyaction.org>
Sent: Friday, October 3, 2025 8:00 AM
To: DOH WSBOH
Subject: Public Comment
Attachments: WSOHC SBOH Letter_10.3.25.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

External Email

Good morning,

On behalf of the Washington State Oral Health Coalition, we are writing in strong support of community water fluoridation.

Please find attached a letter from our board of directors urging the Board of Health to protect water fluoridation practices in our state.

Thank you for your thoughtful consideration.

Warmly,
Marcy Bowers, Board Chair
Washington State Oral Health Coalition

Marcy Bowers | Executive Director, she/her | Statewide Poverty Action Network
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October 3, 2025



Dear Chair Hayes and members of the Board:

The Washington State Oral Health Coalition is a volunteer-led, broad-based partnership dedicated to improving oral health for all Washington residents through community engagement, advocacy and working with state and local leaders to support health policies that expand access to preventive health measures and accessible care. Members consist of health professionals, academic institutions, state and local agencies, and advocacy organizations working toward improving oral health care access for children, adults and senior citizens.

On behalf of the Washington State Oral Health Coalition board of directors, I urge you to support water fluoridation in our communities.

For nearly 80 years, leading cities and water districts throughout the United States have embraced community water fluoridation as a valuable health measure that has profoundly improved the oral – and overall – health for millions of people.

Studies consistently show water fluoridation helps protect teeth against cavities regardless of age, income level and other social determinants. Community leaders, health experts and advocates stand behind water fluoridation because they recognize that preventing cavities is far preferable to treating painful tooth decay and oral disease.

Cavities, tooth loss and swollen gums affect people of all ages. For children, uncomfortable tooth decay can influence school attendance, behavior, nutrition, speech patterns, self-esteem and a child's ability to thrive. Among working adults, rotting and missing teeth can impact employment opportunities, overall health, self-esteem, nutrition and how others perceive you. And for older adults, maintaining good oral health is more important than ever with a greater number of senior citizens retaining their original teeth than prior generations thanks in large part to water fluoridation and other dental care advances.

Treating cavities also can be expensive and intensify health and societal inequities. The lifetime cost of just one cavity is \$6,160. And not everyone is able to see a dentist regularly, meaning lower-income families, older adults on fixed incomes and young adults just starting out too often forego care. Providing the right balance of fluoride in our tap water ensures everyone has a fair chance at added protection for their teeth against cavities.

Thank you for your time and what you do for our community.

Sincerely,

A handwritten signature in black ink, appearing to read "Marcy Bowers". The signature is fluid and cursive, with a large, stylized "M" and "B".

Marcy Bowers
Executive Director, Statewide Poverty Action Network
Board Chair, Washington State Oral Health Coalition

From: Gerald Braude <bumbling@olypen.com>
Sent: Thursday, October 2, 2025 8:43 PM
To: DOH WSBOH
Subject: Gerald Braude public comment for October 8 BOH Meeting

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Dear Michelle:

Please sign me up for in person public comment for the October 8 Board of Health meeting. Below are my written reference comments for the board meeting as well.

Thank you,

Gerald Braude

Port Townsend

Written reference comments for the October 8, 2025 Board of Health meeting:

Advisory Committee on Immunization Practices—ACIP—conflicts of interests revealed by HHS Secretary Robert F. Kennedy in his book *The Real Anthony Fauci: Bill Gates, Big Pharma, and the Global War on Democracy and Public Health*

[Amazon.com: The Real Anthony Fauci: Bill Gates, Big Pharma, and the Global War on Democracy and Public Health \(Audible Audio Edition\): Robert F. Kennedy Jr., Bruce Wagner, Skyhorse Publishing, Inc.: Audible Books & Originals](#)

Dr. Tony Fauci's disregard for conflicts of interests concerning the COVID-19 shots:

Dr. Tony Fauci populated the key FDA and CDC committees with NIAID, NIH, and Gates Foundation grantees and loyalists to insure rubber-stamp approvals for his mRNA vaccines, without any long-term injury studies. More than half of FDA's VRBPAC committee, which approved EUAs for Moderna, Johnson & Johnson, and Pfizer, and granted final licensure to the Pfizer vaccine, were grant recipients from NIH, NIAID, BMGF, and pharmaceutical companies. More than half the CDC's ACIP committee participants were similarly compromised.

From the footnote citations:

- [NIH Awards by Location and Organization - NIH Research Portfolio Online Reporting Tools \(RePORT\)](#)
- [Committed Grants](#)

The 2006 meeting of CDC's ACIP provides an illustrative blueprint for how Tony Fauci and his Pharma partners use their "principal investigators" to control the key FDA and CDC panels that license and "recommend" new vaccines for addition to the childhood schedule.

That 2006 ACIP panel recommended two new blockbuster Merck shots: the Gardasil HPV vaccine for all girls ages nine through twenty-six,[footnote 76] and three doses of a Merck rotavirus vaccine, Rotateq, for infants at ages two, four, and six months.[footnote 77] Both Bill Gates[footnote 78] and Tony Fauci (via NIAID)[footnote 79] had provided seed and clinical trial funding for the development of both Gardasil and the rotavirus vaccine.[80,81]

Merck maintained it had not tested either vaccine against an inert placebo in pre-approval trials, so no one could scientifically predict if the vaccines would avert more injuries or cancers than they would cause.

*Nevertheless, the sister FDA panel, VRBPAC, approved Gardasil—to prevent cervical cancer—**without requiring proof that the vaccine prevented any sort of cancer**, and despite strong evidence from Merck's clinical trial that **Gardasil could dramatically raise risks of cancer and autoimmunity** in some girls.[82] ACIP, nevertheless, effectively mandated both jabs. Gardasil would be the most expensive vaccine in history, costing patients \$420 for the three-jab series and generating revenues of over \$1 billion annually for Merck.[83] That year, nine of the thirteen ACIP panel members and their institutions collectively received over \$1.6 billion of grant money from NIH and NIAID.*

Pharma and Dr. Fauci similarly rig virtually all the critical drug approval panels using this strategy of populating them with PIs who, bound by financial fealty to Pharma and NIAID funders, reliably approve virtually every new drug upon which they deliberate—with or without safety studies. From 1999 to 2000, Government Oversight Committee (GOC) Chairman Republican Congressman Dan Burton investigated the systemic corruption of these panels during two years of intense investigations and hearings.

*According to Burton, "**CDC routinely allows scientists with blatant conflicts of interest to serve on influential advisory committees that make recommendations on new vaccines . . . while these same scientists have financial ties, academic affiliations and other . . . interests in the products and companies for which they are supposed to be providing unbiased oversight.**"*

During the 1998 ACIP session, Dr. Paul Offit sat as one of five full voting members. (There were five additional nonvoting members.) His Rotateq codeveloper, Stanley Plotkin, also sat on the committee. The ACIP Committee unanimously recommended Wyeth's RotaShield vaccine. The August 2000 Congressional investigation found that the majority of ACIP members were conflicted in that vote. That report found that seven out of ten ACIP working group committee members who voted to approve the rotavirus vaccine in June 1998 had financial ties to the pharmaceutical companies that were developing different versions of the vaccine. According to the Congressional Report:

- *The Chairman served on Merck's Immunization Advisory Board.*

- One member was under contract with the Merck vaccine division, received funds from various vaccine manufacturers, including Pasteur (now Sanofi), and was under contract as a principal investigator from SmithKline (now GSK).
- Another member (of that same ACIP panel) received a salary from Merck as well as other payments from Merck.
- Another member was participating in vaccine studies with Merck, Wyeth (now Pfizer), and SmithKline (now GSK).
- Another member received grants from Merck and SmithKline (now GSK).
- Another member shared a patent on his own rotavirus vaccine funded by a \$350,000 grant for Merck to develop this vaccine and was a paid consultant to Merck.

The last of these bullet points referred to Paul "I Have No Conflicts" Offit. Dr. Tony Fauci's and Pharma's corrupt control of those two panels allowed Wyeth to obtain both an FDA license and a CDC "recommendation" without having to genuinely safety test this product, a process that would have revealed terrible risks. Even the truncated trials of Wyeth's RotaShield, conducted with no placebo, revealed serious side effects in babies, including "failure to thrive," fevers high enough to cause brain injury, and a condition called intussusception, wherein a child's intestines telescope into themselves, causing an agonizing blockage that, in some instances, results in death.

ACIP pulled RotaShield from the market in October 1999 due to the many children who, predictably, suffered intussusception.

[Suspension of Rotavirus Vaccine After Reports of Intussusception ---United States, 1999](#) VAERS, the Vaccine Adverse Event Reporting System, contains fifty reports of vaccine-related intussusception for the year 1999.

[Search Results from the VAERS Database](#)

Paul Offit's shrewd maneuvering through this sequence of events opened an unobstructed path to approval and enormous riches for his own rotavirus vaccine, RotaTeq.

Finally, in 2010, after its introduction, NIH learned that Offit's vaccine, RotaTeq, also contained the porcine retrovirus that causes an HIV-like syndrome called "wasting disease" in pigs. Neither Dr. Fauci nor any other agency has ever funded a study to establish the safety of injecting their dangerous pig retroviruses into babies. Millions of American children have now been inoculated with the virus, thanks to Offit. In 2006, ACIP added Offit's vaccine to the schedule, allowing Offit and his business partners to sell his patent rights for the formulation to Merck for \$186 million. Offit made a declared profit of over \$20 million as a result of this series of transactions. Offit reported, in a gushing 2008 Newsweek story, that the millions he made from his rotavirus caper was "like winning the lottery."

[Dr. Paul Offit: Debunking the Vaccine-Autism Link - Newsweek](#)

In a less-adoring assessment of the scam, UPI journalist Dan Olmsted and coauthor Mark Blaxill accused Offit of "voting himself rich."

The disturbing saga of Paul Offit and his rotavirus vaccine illustrates how Tony Fauci's PIs stuff the sausages at HHS. [footnote #114: Dan Olmstead and Mark Blaxill, "Voting Himself Rich: CDC Vaccine Adviser Made \$29 Million Or More After Using Role to Create Market," Age of Autism (Feb 16, 2009)]

For good measure, here is historical evidence provided by Epidemiologist Nicolas Hulscher that Kennedy just mentioned concerning the 2000 U.S. House Committee on Government Reform's [landmark report](#).

The House committee uncovered systemic, ongoing conflicts of interest within both the ACIP and the FDA's vaccine advisory counterpart, VRBPAC:

- **7 out of 10 members** of ACIP's rotavirus working group—which drafted the recommendation for the Rotashield® vaccine—**had direct financial conflicts of interest.**
- **Every ACIP member was granted a conflict-of-interest waiver**, regardless of industry ties.
- Members were allowed to vote on vaccine recommendations while holding stock in manufacturers, receiving grants, or serving as paid consultants.
- RotaShield® was taken off U.S. market in 1999. ACIP voted on October 22, 1999 to no longer recommend use of the RotaShield® vaccine for infants because of an association between the vaccine and intussusception.

*In sworn testimony, a CDC ethics official admitted, "**We generally give [waivers] to everyone... we give them out freely.**"*

From: Bill Osmunson <billosmunson3@gmail.com>
Sent: Wednesday, October 1, 2025 9:43 AM
To: DOH WSBOH
Subject: SUGAR: public comment

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Please provide this to the Board Members in Public Comment.

https://blanphear.substack.com/p/the-fluoride-experiment?utm_campaign=post&utm_medium=email&triedRedirect=true

The Board should spend their time and focus on reducing the cause of dental caries rather than mass medicating everyone with a highly toxic unapproved drug.

Bill Osmunson DDS MPH

The Fluoride Experiment

How the Sugar Industry Used Fluoridation as a Smokescreen

[BRUCE LANPHEAR](#)

SEP 30, 2025

For decades, Americans have been told that adding fluoride to our drinking water prevents tooth decay. The Centers for Disease Control and Prevention even framed fluoridation as one of the greatest public health achievements of the 20th century. But what if there's another side to the story—one that involves corporate money, manipulated science, and a policy that may be doing more harm than good?

Fluoridation's Forgotten Backstory

In the 1940s, the sugar industry faced a crisis. Research was mounting that sugar—not a lack of fluoride—was driving the epidemic of tooth decay. Reducing sugar consumption would have been the obvious solution, but that was unthinkable for an industry built on sales. So industry leaders pulled off a sleight of hand worthy of Big Tobacco. Instead of addressing sugar, they funded conferences and research that promoted fluoridation as the magic bullet.

By shifting attention from sugar to fluoridation, the industry protected its profits while recasting itself as a public health ally. Newly uncovered documents, analyzed by researcher Chris Neurath, reveal how far this strategy went. Fluoridation, once presented as a neutral scientific discovery, was in fact pushed forward with heavy industry involvement. Gerald Cox, the chemist who first proposed adding fluoride to drinking water worked with funding from the Sugar Research Institute. Protecting kids' teeth was the public rationale. Protecting sugar sales was the hidden goal.

The Cracks in the Consensus

That history alone should give us pause. But there is also new science to consider. The benefits of drinking fluoridated water appear smaller than once claimed, while the risks—especially to the developing brain—are becoming harder to ignore. Recent prospective studies from Mexico, Canada, and Bangladesh have linked prenatal fluoride exposure to lower IQ in children. In 2025, the U.S. National Toxicology Program concluded that across dozens of studies, higher fluoride exposure was associated with reduced IQ scores in children.

Anyone who claims the evidence is settled, or that fluoridation is beyond question, simply hasn't done their homework—or is misleading the public.

Neurath's new article is a bombshell. It reveals how the sugar industry bankrolled research and conferences that convinced dentists, physicians, and public health officials that fluoridation was not only safe but essential. This deliberate manipulation of science and policy raises a stark question: if fluoridation began as a smoke screen to protect sugar, how much of our confidence in it rests on solid science?

Two Stories, One Timeline

Fluoridation is contentious, and opinions run strong. My goal in this series is not to tell you what to think but to give you access to the facts so you can make up your own mind—or at least ask sharper questions.

The first installment is a timeline tracing two parallel stories: the evolving science of fluoride and the sugar industry's role in shaping the science of fluoridation. In the coming months, I'll add commentary on what this evidence means for dentists, physicians, public health officials, and parents. For now, I'll let the facts speak.

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From: Bill Osmunson <billosmunson3@gmail.com>
Sent: Sunday, September 28, 2025 9:15 AM
To: DOH WSBOH
Subject: Public Comment October Board of Health Meeting
Attachments: Public_Comment_Fluoridation_FULL_with_Appendices.docx

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Please provide the Board members with the attached public comment.

Sincerely,
Bill Osmunson DDS MPH

Washington State Department of Health

Community Water Fluoridation Panel :

Rebuttal & Public Comment

To: Washington State Board of Health, Governor Bob Ferguson, and Attorney General Nick Brown

From: Bill Osmunson, DDS, MPH

Date: August 16, 2025

SUMMARY:

The American Dental Association requires a level of confidence of “certainty” of harm, 99+ confidence of harm.

Public Health Malpractice requires a “certainty” of harm at greater than 50/50 confidence. Malpractice does not require certainty of harm, many questions may be unanswered; however, a confidence level of 51% of harm is required for malpractice.

RCW 43.20.050(2)(a) requires to Board to “assure” safe water, in other words to have less than 1% confidence of harm.

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Recommended Actions for the Board of Health on Fluoridation

The Board of Health should suspend endorsement of community water fluoridation until safety and efficacy are affirmatively established through rigorous, modern scientific evidence. Specifically:

- **Require Safety Assurance** – Do not approve or promote systemic fluoride exposure without comprehensive toxicological and clinical safety studies, including protection for vulnerable groups such as infants, pregnant women, and those with renal or genetic susceptibilities.
- **Apply Adequate Margins of Safety** – Ensure regulations account for intraspecific variability in water consumption, cumulative fluoride exposure from multiple sources, and genetic and health-related differences in sensitivity.
- **Clarify Jurisdiction** – Acknowledge that systemic fluoride use for disease prevention constitutes drug administration and should be subject to FDA CDER standards for safety, efficacy, dosing, and labeling.
- **Adopt Precautionary Policy** – Until safety is affirmatively demonstrated, the Board should follow the precautionary principle and protect the public by not exposing entire populations to an unapproved drug through drinking water.



Pictures above are of severe skeletal and dental fluorosis. The purpose of these pictures is not to demonstrate what is happening but to demonstrate EPA's "safe" dose of fluoride. Fluoride is not considered harmful by the EPA until this type of damage is observed. Harm happens at much lower doses; however, certainty of harm decreases and the EPA requires certainty of harm. In contrast, the FDA CDER and RCW require determining safety. The EPA (and to a large extent the Fluoridation Panel) assume fluoride is safe until certainty of harm based on the EPA standard of severe dental or/and skeletal fluorosis is proven.

Introduction

I have petitioned the Washington State Board of Health and the Governor for over 15 years to protect the public from excessive fluoride exposure. The Board has failed to protect the public, failed to follow the law or science, and rather than silence in the face of harm has actively promoted community water fluoridation (CWF), claiming without quality scientific evidence or Federal regulatory approval, that CWF is safe and effective.

Rather than science, the Board has relied on endorsements. Rather than Congress and the Washington State Legislature, the Board has relied on endorsements and unauthorized agencies. Such actions undermine the credibility of public health when coercive police powers are supported by endorsements instead of legally required scientific evidence, laws and agencies. The public has and is being harmed. This is your chance to protect our most vulnerable.

Rebuttal to the Fluoridation Panel's Recommendations

(And for additional limitations, see page 10)

1. Failure to Assure Safety by Retaining Current Fluoride Levels

The Panel recommends maintaining the current “optimal” concentration of fluoride without providing a single modern, high-quality safety study demonstrating that this concentration in water along with 30%-70% more fluoride from other sources is safe for all members of the population, including the most vulnerable (pregnant women, fetuses, infants, the elderly, and individuals with renal impairment). Statutory duty under RCW 43.20.050(2)(a) requires the Board to affirmatively **assure safety**, not to balance unproven benefits against unresolved risks (Washington State Legislature, 2024). In the absence of randomized controlled trials or rigorous toxicological studies, the continuation of fluoridation policy rests on assumption rather than scientific certainty (Iheozor-Ejiofor et al., 2024; U.S. FDA, 2023).

The charge to the Fluoridation Panel was noble, to review the science. However, the Panel failed to review over 90% of the available science.

The Panel members were “cherry picked” with mostly Department of Health and government employees who have promoted fluoridation for decades and receive funding from fluoridation sources. Their bias did not permit most members to have a paradigm shift. The composition of the panel did not include published science researchers, pharmacists, ethicists, neurophysiologists, endocrinologists, or other necessary experts competent to evaluate science.

Most public health professionals have not been trained to evaluate research. In my public health master's degree program, we were firmly instructed that we were not competent to evaluate the science and we were to obey authority.

2. Abdication of State Responsibility to Local Governments

The Panel's suggestion that community water fluoridation should remain a "local decision" improperly shifts responsibility for a statewide drug exposure policy onto local jurisdictions that lack the expertise, resources, or authority to evaluate drug safety. For 80 years, federal agencies including FDA CDER and EPA scientists have struggled with unresolved questions about fluoride's pharmacokinetics, toxicity thresholds, and systemic effects (NRC, 2006; National Toxicology Program [NTP], 2022). To suggest that municipal councils or water districts—entities with no toxicological or pharmacological expertise and lacking time and resources—should resolve these scientific uncertainties is an abdication of the Panel's duty. It makes no sense and is a waste of time and money to have 100+ cities and water districts go through the complex scientific regulatory process that the Fluoridation Panel has undertaken. And it would take even more time for voters to carefully review the science and laws. This approach undermines both public confidence and the principle that statewide standards exist to protect health uniformly, not variably by zip code.

3. Inadequate Margin of Safety in Adopting a 1.5 mg/L Action Level

The proposed State Action Level of 1.5 mg/L fails to protect infants and other high-exposure groups. Formula-fed infants, who consume more water per body weight than adults, would receive doses far exceeding recognized thresholds of safety (Zohoori & Maguire, 2018). The recommendation assumes that all individuals:

- drink identical amounts of water,
- metabolize fluoride uniformly,
- receive no significant additional fluoride from food, air, dental or medical products,
- have the same genetic chemical sensitivity,
- have the same total toxic chemical burden with no synergistic effects,
- and have the same health status to handle the toxic chemical effect.

Each of these assumptions is demonstrably false. Established principles of toxicology require adequate margins of safety to account for variability in water consumption, susceptibility, and cumulative exposure (EPA, 2010). The proposed action level provides no such margin and therefore cannot be regarded as protective, positively and confidently without doubt assuring safety.

4. Reliance on Messaging Rather Than Regulation

The Panel's reliance on "updated messaging" to pregnant women, fetuses, and infants acknowledges risk but fails to provide actual protection. Advisories and voluntary guidance do not meet the statutory requirement to assure safe water. Decades of similar messaging have been buried in agency documents with no measurable reduction in systemic fluoride exposure (NRC, 2006). Public health obligations cannot be met through warnings alone; enforceable regulatory limits based on rigorous safety data are required.

Rebuttal of Panel's Conclusion

The Panel's recommendations—retaining current fluoridation, delegating decisions to local jurisdictions, adopting an unsafe action level, and substituting messaging for regulation—do not satisfy the Board's statutory duty to protect the public's health. Without demonstrable proof of safety, these recommendations perpetuate risk, defer responsibility, and prioritize political expedience over scientific and ethical accountability.

The Board should instead:

- Reject continuation of fluoridation policy until safety is affirmatively established.
- Require comprehensive toxicological and clinical safety studies before endorsing fluoride ingestion at any concentration.
- Adopt a precautionary standard that ensures protection of the most vulnerable populations, rather than deferring to local political bodies.

Only by adhering to its legal and ethical duty can the Board credibly assure the people of Washington that their drinking water is safe.

References for the Rebuttal Above

Environmental Protection Agency (EPA). (2010). Fluoride: Dose-Response Analysis for Non-Cancer Effects. Washington, DC.

Iheozor-Ejiofor, Z., et al. (2024). Water fluoridation for the prevention of dental caries. Cochrane Database of Systematic Reviews, Issue 3.

National Research Council (NRC). (2006). Fluoride in Drinking Water: A Scientific Review of EPA's Standards. National Academies Press.

National Toxicology Program (NTP). (2022). Systematic Review of Fluoride Exposure and Neurodevelopmental and Cognitive Health Effects. National Institute of Environmental Health Sciences.

U.S. Food and Drug Administration (FDA). (2023). Use of Orally Ingestible Unapproved Prescription Drug Products Containing Fluoride in the Pediatric Population: Public Listening Session.

Washington State Legislature. (2024). RCW 43.20.050(2)(a). Duty of the State Board of Health to assure safe and reliable public drinking water.

Zohoori, F. V., & Maguire, A. (2018). Infant formula and fluoride exposure: A systematic review. *Journal of Public Health Dentistry*, 78(1), 18–39.

Fluoride Classified as a Poison and Legend Drug

Fluoride is highly toxic and falls under RCW 69.38.010's definition of a poison, being lethal at doses below 3,889 mg (approximately 60 grains). Whitford (1996) estimated the probable toxic dose for adults at 5 mg/kg body weight. For a 70 Kg adult, 350 mg is significantly less than 3,889, a definite poison unless regulated under drug laws as a prescription drug. In 2009, the Washington State Board of Pharmacy determined that fluoride is to be regulated as a legend (prescription) drug. However, CWF is not regulated as a legend drug, and therefore reverts to the status of an unapproved, illegal drug or poison. Infants fed formula prepared with fluoridated tap water receive up to 175 times the fluoride dose of natural breast milk, a disproportionate and unsafe exposure given their vulnerability with developing brains, organs, systems and cells. Giving local water purveyors and voters the option of CWF at their discretion while the Board actively promotes CWF on their website based on endorsements is not assuring safety.

Failure of Federal and Washington State Agencies to Provide Safety Evidence

RCW 43.20.050(2)(a) and the FDA CDER (FDA's Center for Drug Evaluation and Research) in the FD&C Act, are on the same page requiring the assurance of safety. The Board is wise to verify the FDA CDER's safety data but must include FDA CDER guidance for safety in any review and safety claims. The FDA CDER has made mistakes on drugs and has learned from their mistakes and will continue to learn. Ignoring the FDA CDER does not assure the public of safety or efficacy. The Fluoridation Panel failed to consider the FDA CDER guidance for safety.

In sworn testimony, Federal agencies including the FDA, CDC, EPA, and NSF admitted they had no safety studies on fluoride's effects on the developing brain and could not identify a safe dose. Furthermore, FDA CDER has never approved ingestion of fluoride in any form with intent to prevent dental caries. This absence of safety data constitutes a fundamental regulatory failure by both Federal and state Public Health Authorities.

Lacking guidance by the Board on what quality of scientific evidence to accept and lacking a single quality safety study, the Board's Fluoridation Panel relied on EPA's less protective standard of certainty of harm, rather than the more protective safety requirements of the FDA CDER assuring safety with safety studies.

The Fluoridation Panel was convened by the Department of Health consisting of public health staff. Cherry picking like minded employed believers who have been paid to promote CWF all their professional lives is an extremely high bar of bias to overcome. A balanced objective review of all the science was not possible due to bias, lack of appropriate charge to the Panel, educational background and time. Not a single member was a drug regulatory expert or has to my knowledge even gone through the NDA approval process. None of them or any of us have the judgment skills and training to judge safety of a drug better than the FDA CDER.

Requirements for a Safety Study of Community Water Fluoridation (CWF) (Not considered by Panel)

The Fluoridation Panel (p.4) did not assess total fluoride exposure. In other words, the Panel did not determine or seriously weigh how much fluoride an adult, child, infant or fetus is ingesting from all sources. Safety of adding more fluoride cannot seriously be determined without knowing how much fluoride is already being dosed or exposed from other sources. 30% to 70% of exposure is from other sources.

To lawfully assure the safety of CWF, rigorous standards must be met, including preclinical GLP toxicology, developmental neurotoxicity testing, endocrine, thyroid and all potential risks evaluated, dose-response modeling, and large-scale human prospective cohorts with biomarkers, exposure diaries, and validated neurodevelopmental endpoints. None of those were provided by or to the Fluoridation Panel for consideration. These requirements are established under FDA CDER's drug framework and EPA's environmental risk assessment guidance.

A. Regulatory Frame & Governance For Safety Study (Panel did not determine)

Regulatory pathway:

1. 1. FDA:

If CWF (fluoride added to water) is treated as a drug exposure (intent to prevent disease), human studies must meet ICH Good Clinical Practice (E6[R2]) and ICH E8(R1) quality-by-design principles, with IRB approval, informed consent, DSMB, preregistration, and a public statistical analysis plan (FDA).

OR

2. 2. EPA:

If treated as an environmental exposure such as endemic fluoride in Southwest Washington State, analyses must follow EPA risk-assessment methods (hazard ID, dose-response, exposure, risk characterization), using benchmark-dose (BMD) approaches and RfD derivation that explicitly protect sensitive subgroups. EPA is protective based on certainty of harm. For example, fluoride ingestion is safe until absolute certainty of harm with severe crippling skeletal fluorosis or severe dental fluorosis. In other words, for EPA's judgment which the Panel assumed, fluoride intake is not harmful until harm is close to this.

Judgment of absolute certainty is one reason the TSCA law (Toxic Substance Control Act) was written by Congress, to judge toxins with "presumed" harm rather than "certainty" of harm. That confidence level for judgment is still lower than the FDA CDER's requirement for safety with label and doctor's prescription.

FDA CDER and EPA pathways are significantly different and a key is intent of use (FDA CDER) and difficulty in removing the toxin (EPA endemic fluoride).

We are persuaded that the addition of fluoride to water (discussed below) is with the intent to prevent dental caries and is a drug based on toxicity, Board claims of disease prevention, public perception with intent to prevent dental caries, U.S. Pharmacopeia, FDA testimony to Congress, EPA Water Law Office, and more.

Drug Studies Also Require (Not seriously discussed by the Panel)

- Ethics & transparency: Independent DSMB; conflict-of-interest disclosures; data and code sharing; protocol/SAP preregistered.
- Reporting standards: CONSORT (for RCTs) and STROBE (for observational cohorts).

B. Preclinical (GLP) Toxicology Package (Not considered by Panel)

- Developmental neurotoxicity (OECD TG 426). Extended one-generation reproductive toxicity (OECD TG 443).
- Repeated-dose, chronic toxicity, carcinogenicity, and genotoxicity as indicated.
- Toxicokinetics/PBPK modeling linking dose to biomarkers.
- Endocrine and thyroid endpoints integrated. BMD modeling with uncertainty factors per EPA guidance.
- Over 20 additional risks should also be included.

C. Human Evidence — Core Studies (Not carefully considered by Panel)

- Multi-site prospective pregnancy–birth cohort, with child follow-up, supplemented by stepped-wedge/natural experiments.
- Exposure assessment: water sampling, urinary fluoride, serum fluoride, and total intake accounting (formula reconstitution, tea, dental products).
- Endpoints: neurodevelopment, thyroid function, renal indices, bone, reproductive outcomes, dental fluorosis.
- Confounding and co-exposures measured (lead, arsenic, iodine, SES, etc.). Power sufficient to detect ≤ 2 IQ-point differences.

D. Chemical Product & Water-System Characterization (Not considered by Panel)

- Verification of additive identity/purity, contaminant profiles, process controls, distribution-system mapping.

E. Decision Framework & Stopping Rules (Not considered by Panel)

- A priori harm thresholds (e.g., ≥ 2 IQ-point reduction).
- Interim analyses with DSMB oversight.
- Risk assessment synthesis integrating animal and human data to derive RfDs.

F. Quality, Compliance & Documentation (Not considered by Panel)

- IRB approvals, GCP training logs, DSMB minutes, data integrity audits, version-controlled code, public dataset access.

G. Standards & Guidance to Cite (Not considered by Panel)

- ICH E6(R2); ICH E8(R1).
- OECD TG 426; OECD TG 443.
- CONSORT; STROBE; EQUATOR.
- EPA Benchmark Dose Guidance (2012).

The Fluoridation Panel does not report a single safety study, nor do they outline what a safety study would look like in their report. Neither did the Panel determine a safe dose of fluoride versus a toxic dose of fluoride. The direct charge of the Legislature to the Board in law was legally and scientifically largely ignored. The Board cannot assure the public the water is safe without a single safety study or even know what a safety study would include.

Absence of Randomized Controlled Trials and Requirements for FDA

Approval of Benefit (Not seriously considered by Panel)

Although the Board has attempted to claim that fluoridation benefits outweigh its risks, the law does not authorize the Board to evaluate drug benefits or conduct benefit-risk assessments. That authority belongs solely to the FDA CDER. No quality randomized controlled trials (RCTs) of community water fluoridation have ever been conducted. The 2024 Cochrane Review confirmed that the evidence for caries prevention is of low certainty, based on outdated and methodologically weak observational studies.

For FDA NDA approval of any drug, including systemic fluoride, the sponsor must provide: two adequate and well-controlled RCTs demonstrating statistically significant and clinically meaningful benefit. Endpoints would include reduced caries incidence measured with standardized DMFT/DMFS scores, tooth retention, and secondary measures such as fluorosis rates and quality-of-life indicators. Representative populations and control groups must be used, with long-term follow-up and strict adherence to CONSORT standards. No such trials exist for CWF.

Thus, the Board and its Fluoridation Panel have attempted to assure benefit without legal authority or adequate science. Without FDA NDA approval, fluoridation remains an unapproved drug practice that fails both safety and efficacy standards.

Limitations of the Washington State Fluoridation Panel

The Fluoridation Panel convened by the Department of public health employees over the last six months was composed of well-meaning public health servants who have supported fluoridation for their professional careers. However, none have conducted a safety study, none understand the regulatory requirements of drug safety evaluation, and none have

petitioned FDA CDER for drug approval. The Panel lacks training in drug regulation, toxicology, and RCT design. The Board cannot lawfully rely on untrained, unauthorized employees to substitute for FDA CDER experts.

1. Scope and Legal Authority Misstated and Illegal

Benefit–risk determinations for a substance intended to prevent disease are exclusively under the U.S. Food, Drug, and Cosmetic Act (FD&C Act) and FDA’s Center for Drug Evaluation and Research (CDER). A substance marketed with intent to prevent disease is a drug under 21 U.S.C. § 321(g)(1), and approval requires an NDA with “adequate and well-controlled investigations” (21 U.S.C. § 355; 21 C.F.R. § 314). State boards may regulate water system operations, but they cannot lawfully approve or substitute benefit–risk determinations in place of FDA. Washington’s Board’s statutory authority under RCW 43.20.050 is to assure safe drinking water, not to establish drug efficacy. RCW 57.08.012 allows local systems to decide whether to fluoridate but does not displace the duty to assure safety (RCW 43.20.050). The Panel chose endorsements of benefit rather than authorized regulatory authority, the FDA CDER.

2. Evidence Base Selectively Framed

The Cochrane Collaboration’s most recent review (Iheozor-Ejiofor et al. 2024) rated the certainty of evidence for reductions in permanent tooth decay as low because most studies were ecological, at high risk of bias, and conducted before widespread use of fluoride toothpaste. No randomized controlled trials (RCTs) of community water fluoridation (CWF) efficacy or safety exist (McDonagh et al. 2000; Iheozor-Ejiofor et al. 2024). Yet FDA requires at least two adequate and well-controlled trials to establish benefit for any NDA (21 C.F.R. § 314.126). CDC itself acknowledges that fluoride’s predominant effect is topical, not systemic (CDC 2001).

3. Risk Evidence Downplayed

The National Toxicology Program (NTP 2024) concluded with moderate confidence that increased fluoride exposure is consistently associated with lower IQ in children, even at levels overlapping U.S. drinking water concentrations. In September 2024, the U.S. District Court for the Northern District of California held under the Toxic Substances Control Act (TSCA) that fluoridation at 0.7 mg/L presents an “unreasonable risk” of neurodevelopmental harm and ordered EPA to initiate regulatory action (*Food & Water Watch v. EPA*, 2024). The panel’s suggestion to “keep the current optimal level” disregards this federal finding.

3.1 NTP did NOT Determine a Safe Dose of Fluoride

The NTP did not determine a safe water fluoride concentration. Confidence in harm increased over 1.5 mg/L, but safety was not determined at any dosage or water fluoride concentration. The Court did not report a safe water fluoride concentration. The Court correctly determined an unreasonable risk at 0.7 ppm, The Court took testimony from the best scientists money could hire and the Court did not report safety or confidently dispelling doubt, that fluoride in water at 0.7 ppm is safe.

4. “Local Decision” Argument Legally Incomplete

Saying fluoridation “should remain a local decision” omits that the Board has a non-delegable duty to assure safety under RCW 43.20.050. Delegating safety assurance to localities—especially in light of a federal “unreasonable risk” determination—does not satisfy this statutory mandate. Delegating a highly complex toxic, drug, regulatory decision to voters makes no sense and does not omit the Board’s duty and permit the Board to promote fluoridation as safe and effective.

5. State Action Level of 1.5 mg/L Inconsistent and Indefensible

The Panel’s proposed 1.5 mg/L “State Action Level” is derived from WHO’s guideline intended to prevent dental fluorosis (WHO 2017), and confidence in neurodevelopmental effects harm, not safety. It is inconsistent to set a permissive state threshold at 1.5 mg/L while the NTP and a federal court have not identified a safe dosage at 0.7 mg/L (NTP 2024; Food & Water Watch v. EPA 2024).

5.1 Safety Factors and Individual Variability

The Panel confuses individual dose with the “statistical mean,” failing to account for established toxicological principles. A margin of safety—typically a factor of 10 to 100—must be applied to protect against variability in exposure and susceptibility. Not all individuals drink the same amount of water, have the same level of exposure from other sources, or share identical genetic profiles, health status, or chemical sensitivities. For example, an individual consuming two liters of water at 0.7 ppm fluoride receives double the intake of someone consuming only one liter, even though both fall within the “average” range. Furthermore, individuals with single nucleotide polymorphisms (SNPs) or other genetic variations may be markedly more sensitive to fluoride’s effects. By failing to incorporate safety factors or address intraspecific variability, the Panel’s recommendation does not meet basic standards of public health protection.

6. Messaging to Pregnant People and Infants Inadequate

Guidance to “limit exposure” is not a substitute for source protection. Pregnant women and infants ingest more water per body weight than adults (NRC 2006). About 75% of U.S. caregivers use tap water to reconstitute infant formula, resulting in exposures during the most vulnerable developmental window (CDC 2010). In contrast, breast milk contains ~0.004 ppm fluoride (Institute of Medicine 1997). Warnings cannot replace the statutory duty to deliver safe water at the tap.

The Panel appears to expect a single parent hauling an infant and toddler with groceries and now water for the formula on public transportation is ethical and reasonable.

7. Lack of FDA Regulatory Alignment

There is no FDA approval for any ingested fluoride product to prevent caries. FDA’s OTC anticaries monograph applies only to topical products (e.g., toothpaste, rinses) (FDA 2020). Systemic ingestion through water remains unapproved. The panel’s reliance on

endorsements from health organizations cannot substitute for the FDA drug approval process.

Failure to Meet Statutory Duty

RCW 43.20.050(2)(a) mandates that the Washington State Board of Health must adopt rules necessary to assure safe drinking water. This duty requires affirmative demonstration of safety, not reliance on endorsements or assumptions. Although RCW permits local governments or voters to choose fluoridation, that option does not supersede the Board's statutory duty to assure water safety. By promoting fluoridation as safe and effective without FDA-approved safety and efficacy data, the Board is in direct violation of its statutory mandate.

Credibility of Public Health

Public health professions lose credibility on all policies and rules when unable to follow state and federal law. By promoting fluoridation as safe and effective based solely on endorsements, while ignoring FDA CDER's regulatory authority, the Board undermines public trust in health governance.

Recommended Actions for the Board of Health on Fluoridation

The Board of Health should suspend endorsement of community water fluoridation until safety and efficacy are affirmatively established through rigorous, modern scientific evidence. Specifically:

- **Require Safety Assurance** – Do not approve or promote systemic fluoride exposure without comprehensive toxicological and clinical safety studies, including protection for vulnerable groups such as infants, pregnant women, and those with renal or genetic susceptibilities.
- **Apply Adequate Margins of Safety** – Ensure regulations account for intraspecific variability in water consumption, cumulative fluoride exposure from multiple sources, and genetic and health-related differences in sensitivity.
- **Clarify Jurisdiction** – Acknowledge that systemic fluoride use for disease prevention constitutes drug administration and should be subject to FDA CDER standards for safety, efficacy, dosing, and labeling.
- **Adopt Precautionary Policy** – Until safety is affirmatively demonstrated, the Board should follow the precautionary principle and protect the public by not exposing entire populations to an unapproved drug through drinking water.

Appendices

Appendix A. Requirements for a Safety Study of Community Water Fluoridation (CWF)

To lawfully assure safety, a scientifically valid safety study must include both preclinical toxicology and human clinical investigations, consistent with FDA CDER standards for drugs and EPA guidelines for environmental exposures.

A.1 Regulatory Framework

- FDA Drug Pathway (21 U.S.C. § 355; 21 C.F.R. § 314.126): CWF is a drug (intent to prevent disease), and human trials must meet ICH Good Clinical Practice (E6[R2]) and ICH E8(R1) standards, with IRB approval, informed consent, DSMB oversight, preregistration, and a published statistical analysis plan.
- EPA Risk Assessment Pathway (EPA, 2012 Benchmark Dose Guidance): If treated as an environmental exposure, analysis must follow hazard identification, dose–response modeling, exposure assessment, and risk characterization, explicitly protecting sensitive subgroups.

A.2 Preclinical GLP Toxicology

- Developmental neurotoxicity testing (OECD TG 426).
- Extended one-generation reproductive toxicity (OECD TG 443).
- Chronic toxicity, carcinogenicity, and genotoxicity studies.
- Endocrine and thyroid endpoints.
- Toxicokinetic/PBPK modeling linking intake to biomarkers.
- Benchmark dose (BMD) modeling with safety/uncertainty factors.

A.3 Human Evidence

- Prospective multi-site pregnancy–birth cohorts, with follow-up into childhood, supplemented by stepped-wedge/natural experiments.
- Exposure assessment: water sampling, urinary/serum fluoride, diet/dental sources, and total intake accounting.
- Endpoints: neurodevelopment (IQ, cognitive tests), thyroid, renal, bone, reproductive outcomes, and dental fluorosis.
- Statistical power sufficient to detect ≤ 2 IQ-point differences, as required by FDA CDER standards.

A.4 Ethical and Reporting Standards

- Independent DSMB, conflict-of-interest disclosure, protocol preregistration.
- CONSORT (for RCTs), STROBE (for observational studies), EQUATOR network guidelines.
- Public access to datasets, code, and version-controlled statistical plans.

Appendix B. Supporting Toxicological Data

B.1 Fluoride as a Poison

RCW 69.38.010 defines a poison as “liable to be destructive to adult life in quantities of 60 grains ($\approx 3,889$ mg) or less.” Whitford (1996) estimated the probable toxic dose of fluoride at 5 mg/kg body weight. For a 70 kg adult, this is 350 mg — well below the statutory definition of a poison.

B.2 Infants and Breast Milk

Breast milk contains a mean of 0.004 ppm fluoride (Institute of Medicine, 1997). Formula prepared with fluoridated tap water (~ 0.7 ppm) delivers up to $175\times$ the natural fluoride dose found in breast milk. Infants consume more water per body weight than adults, amplifying exposure during critical neurodevelopmental windows.

B.3 Systemic Accumulation

Fluoride accumulates in bones, teeth, and soft tissues, interacting with cells, enzymes, and endocrine pathways (NRC, 2006). The National Toxicology Program (2024) found consistent associations between higher fluoride exposure and reduced IQ in children, even at levels overlapping U.S. water concentrations.

Appendix C. Legal and Regulatory Framework

C.1 FDA Jurisdiction

Under 21 U.S.C. § 321(g)(1), any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease is a drug. Adding fluoride to water with the stated purpose of preventing dental caries constitutes drug administration. FDA CDER requires two adequate and well-controlled clinical trials to demonstrate efficacy (21 U.S.C. § 355; 21 C.F.R. § 314.126). FDA’s OTC anticaries monograph (21 C.F.R. pt. 355) applies only to topical fluoride products (e.g., toothpaste, rinses), not systemic ingestion.

C.2 EPA Jurisdiction

EPA regulates contaminants under the Safe Drinking Water Act. EPA’s approach is based on certainty of harm (e.g., skeletal fluorosis) rather than assurance of safety. In *Food & Water Watch v. EPA* (2024), the U.S. District Court held that fluoridation at 0.7 ppm posed an “unreasonable risk” under TSCA, reinforcing EPA’s inability to assure safety.

C.3 Washington State Law

RCW 43.20.050(2)(a): The Board of Health must adopt rules necessary to assure safe and reliable drinking water. RCW 57.08.012: Water districts may choose to fluoridate, but this does not relieve the Board of its duty to assure safety. RCW 69.38.010: Fluoride meets the legal definition of a poison unless regulated as a prescription drug.

References

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National Toxicology Program (NTP). 2024. Systematic Review of Fluoride Exposure and Neurodevelopmental and Cognitive Health Effects. Final Monograph.

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U.S. Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(g)(1), § 355.

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World Health Organization (WHO). 2017. Guidelines for Drinking-water Quality: Fourth Edition Incorporating the First Addendum. Geneva: WHO.

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Whitford, G. M. (1996). Fluoride toxicology and health effects. In: Fejerskov O, Ekstrand J, Burt B. (Eds.), Fluoride in Dentistry (2nd ed., pp. 171–214). Munksgaard.

Washington State RCW 43.20.050(2)(a). Powers and duties of state board of health.

Washington State RCW 69.38.010. Definition of poison.

Addendum: Expanded Critique of the Panel’s Recommendations and Process

A. “Recommendations in Conflict” — Additional Grounds

- A1. The Panel assessed CWF concentration rather than total fluoride dose

The report repeatedly reasons from the water concentration of fluoride (0.7 mg/L) as if it were the exposure of interest. Risk, however, turns on dose (mg/kg-day) and aggregate exposure from *all* sources (tap water, beverages/foods, tea, formula reconstituted with tap water, dental products, workplace exposures). This is not a trivial distinction; the TSCA court specifically faulted EPA for ignoring additive exposure when judging risk. A lawful, protective assessment must start from total fluoride intake across pathways and life stages—especially pregnancy and infancy—then apply conservative uncertainty factors to protect sensitive subgroups. The Panel did neither.

- Implication: Keeping 0.7 mg/L “for now” is scientifically indefensible without an aggregate-exposure analysis that includes biomonitoring (e.g., urinary/serum fluoride), dietary diaries, and infant formula practices, followed by margins of safety (10–100×) for interindividual variability.
- A2. Misapplied regulatory standard: EPA’s “certainty of harm” vs FDA/CDER’s “assurance of safety” (and RCW’s parallel duty)
- The Panel’s posture mirrors EPA contaminant logic—seeking certainty of harm—instead of FDA/CDER’s drug standard to affirmatively assure safety before population exposure. Washington’s RCW 43.20.050(2)(a) likewise charges the Board to *assure safe* drinking water, not to presume safety until definitive harm is proven.
- Recommending continuation of systemic exposure absent FDA-quality evidence inverts these standards: it treats fluoridation like a contaminant question (wait for proof of harm) rather than a drug question (require proof of safety and benefit first).
- Implication: As long as CWF is justified by intent to prevent disease, the legally relevant benchmark is FDA/CDER’s *certainty of safety and efficacy*, not EPA’s *certainty of harm*. The Panel applied the wrong standard.
- A3. “Begin rulemaking to consider a 1.5 mg/L State Action Level” is less protective than current practice

- At 1.5 mg/L, the proposed SAL is $\sim 2.14\times$ the current CWF target of 0.7 mg/L. Positioning 1.5 mg/L as “actionable” implicitly normalizes exposures substantially higher than present targets, and does so without a demonstrated margin of safety for fetuses and infants. The Panel itself cites neurodevelopmental findings converging around, at, or below this neighborhood. Raising the ceiling while conceding uncertainty for the most vulnerable is a retrograde risk posture.
 - Implication: If anything, any interim action should move toward lower ceilings pending FDA-quality safety data, not toward a permissive action level that exceeds today’s dosing by more than twofold.
 - A4. Messaging is not protection—and it has failed for decades
 - Telling the public (particularly new parents) to “limit exposure” or avoid using fluoridated tap water to mix infant formula does not satisfy a duty to provide safe water at the tap. Practical barriers (cost, time, logistics, awareness, literacy, and trust) ensure uneven compliance, disproportionately burdening low-income families. History shows warnings do not meaningfully reduce systemic exposure when the source remains the drinking water itself.
 - Implication: Source control (policy and engineering) is the public-health solution; messaging is at best a stopgap and at worst a shifting of responsibility onto those least able to bear it.
 - A5. “Optimal” is asserted without a safety dossier
 - The report labels 0.7 mg/L “optimal” but provides no modern safety dossier demonstrating protection for pregnancy, infancy, renal impairment, or genetically susceptible groups. “Optimal” is an evidentiary conclusion, not a branding term—it requires preclinical toxicology, human biomonitoring, exposure accounting, dose–response analysis, and uncertainty factors sufficient to cover vulnerable subpopulations. Those elements are absent.
 - Implication: Dropping the word “optimal” from policy and communications is appropriate until a defensible, FDA-grade safety package exists.
-

B. Process Defects: Panel Charge, Membership, and Presupposition of Benefit

- B1. Charge failed to require high-quality evidence
- The Department did not appropriately charge the Panel to require FDA-grade evidence (adequate and well-controlled trials for efficacy; GLP preclinical plus robust human evidence for safety). Instead, the charge asked the Panel to “interpret the science” around CWF—framed as a risk-benefit question—without first demanding the threshold question: *Has safety and efficacy been affirmatively established?* That omission all but guaranteed a status-quo conclusion.
- B2. Predetermined composition and expertise gap
- Staffing the Panel with public-health employees who have promoted CWF for much of their careers predictably narrowed the range of evaluation and increased the risk of confirmation bias. The Panel lacked drug regulatory, risk-assessment, clinical trials, Pharmacology and biostatistics experts necessary to evaluate what a lawful safety dossier must contain. Unsurprisingly, the process “found” a way to maintain CWF—indicating the Panel did not learn much beyond its starting assumptions.
- B3. Presupposition of benefit guided the deliberations
- The report admits the Panel “centered around how best to get the benefits of community water fluoridation while minimizing risks to fetuses and infants.” That sentence assumes benefit at the outset and narrows the inquiry to harm minimization—without the FDA-required proving of benefit via modern trials and without a safety margin for the most vulnerable. Methodologically, this is risk management after the fact, not pre-market assurance of safety and efficacy.
- B4. No safety studies reviewed—because none exist at required quality
- By the Panel’s own scope and citations, there are no randomized controlled trials of systemic CWF for benefit or safety; high-quality developmental neurotoxicity testing and comprehensive human cohort evidence with biomarkers and exposure accounting were not provided. The Panel then implicitly reversed the burden of proof—treating CWF as safe until proven unsafe with certainty—contrary to FDA/CDER standards and RCW’s duty to assure safety.
- ---

C. Specific Omissions by the Panel that Undermine the Recommendations

1. Aggregate Exposure Accounting. No comprehensive assessment of total daily fluoride intake across sources and life stages; no scenario analysis for high-end consumers (e.g., high water intake, tea consumption, formula-fed infants).
2. Biomonitoring. No plan for population-level urinary or serum fluoride monitoring to verify dose assumptions or identify overexposed groups.
3. Uncertainty/Safety Factors. No application of 10–100× factors for interindividual variability (age, renal status, iodine status, SNPs affecting susceptibility).
4. Sensitive Subgroups First. No protective limit derived from the most sensitive group (fetuses/infants), then back-translated to a water concentration.
5. Stopping Rules. No pre-specified thresholds (e.g., IQ decrement, thyroid perturbations) that would trigger immediate reduction/suspension.
6. Alternatives and Substitution. No appraisal of topical-only strategies (toothpaste/varnish) that deliver the cited benefit without systemic dosing.
7. Regulatory Alignment. No path to reconcile CWF’s disease-prevention intent with FDA/CDER jurisdiction, despite relying on “benefit” claims.

•

D. Corrective Policy Direction (to replace the Panel’s three recommendations)

1. Suspend endorsements of systemic CWF pending FDA-grade safety and efficacy evidence, with policy aligned to RCW’s duty to assure safety.
2. Adopt a protective interim ceiling derived from fetuses/infants using aggregate exposure, biomonitoring, and conservative safety factors—not a permissive 1.5 mg/L action level.
3. Replace messaging with source control: If the water is not demonstrably safe for formula reconstitution, change the water policy rather than tasking parents with workarounds.
4. Commission an independent scientific review with experts in drug regulation (FDA/CDER), developmental toxicology, epidemiology/biostatistics, exposure science, and risk assessment; require a written protocol, transparent data, and a pre-registered analysis plan.
5. Evaluate topical-only fluoride strategies as the default alternative that preserves any local dental benefit without systemic dosing.

From: Laurie Layne <laurielayne1@gmail.com>
Sent: Wednesday, September 10, 2025 8:05 AM
To: DOH WSBOH
Subject: Standing order for Covid 19 vaccines!

Follow Up Flag: Follow up
Flag Status: Flagged

External Email

I'm against this standing order from our state department of health entirely. This covid 19 vaccine has been proven to be harmful causing such health issues as Myocarditis and cancer and has even killed individuals!. And it's being made available without a subscription! Essentially being handed out like candy to adults , children and infants! It can be handed out to children without parental permission! The only positive I see is that exemption certificates are permitted and I strongly suggest parents use these for the safety of their children!! The science is untrustworthy! Again the current HHS secretary Robert F Kennedy as of June 3rd. removed recommendation for Covid 19 vaccines for healthy children and healthy pregnant women from the CDC immunization schedule! Since this has occurred I encourage this board not recommend it either! It is unsafe for citizen use! Thank you!

From: Amber King <amberking907@gmail.com>
Sent: Thursday, August 21, 2025 3:49 PM
To: DOH WSB OH
Subject: Plea to stop water fluoridation

Follow Up Flag: Follow up
Flag Status: Flagged

External Email



Amber King <amberking907@gmail.com>

to commissioners



As a resident with autoimmune conditions in one of your water districts and mother of a child with a pineal cyst I implore you to end water fluoridation. There are zero single safety studies on water fluoridation.

However the harms and risks are apparent and well studied and negatively impacting human health. <https://fluoridealert.org/key-topics/health-effects-of-fluoride/>

<https://hsph.harvard.edu/news/fluoridated-drinking-water/>

Current levels in Washington state are dangerous and causing harm (this is irrefutable at very low levels)

https://fluoridealert.org/researchers/natural_fluoride/washington-state/

I previously worked to remove fluoride from drinking water in Juneau, AK and saw a dramatic reduction in my own personal autoimmune condition symptoms in a matter of weeks, it was stark and dramatic.

While I now take filtration into my own hands for my home's drinking water, I cannot control food products, or my children's consumption at restaurants, school and other public places. But it is impacting their health every single day. We were not told the truth when this practice was sold as a "public health improvement" in reality it saves chemical companies billions of dollars in toxic waste disposal and instead gives them a market for this toxin. I work in public drinking water systems all over the United States and our health is failing. This is one small act you can take to improve public health.

The time and place to have fluoridated water has ended in the United States, it is not improving dental care as you can see by the continued improved dental health in unfluoridated water systems globally.

<https://www.npr.org/sections/shots-health-news/2025/01/09/nx-s1-5252874/fluoride-drinking-water-iq-analysis-safe> our IQ as a country is rapidly declining and now more than ever children, infants, mothers and the public need safe water to drink.

<https://ntp.niehs.nih.gov/research/assessments/noncancer/completed/fluoride>

Thank you,

--

Amber King

Bandit Springs Botanical

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907.209.2011

MLT, WA 98043



PREPROPOSAL STATEMENT OF INQUIRY

CR-101 (October 2017)
(Implements RCW 34.05.310)

Do NOT use for expedited rule making

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OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: September 10, 2025

TIME: 8:03 AM

WSR 25-19-045

Agency: Washington State Board of Health

Subject of possible rule making: Chapter 246-90 WAC, Clarifying Tribal Representation and Timelines for Modifying Local Board of Health (LBOH) Membership. The Washington State Board of Health (Board) is considering amending its LBOH composition rules to establish timelines for modifying the membership of an LBOH.

This rulemaking aims to adopt rules as required by the legislature in Engrossed Substitute House Bill (ESHB) 1946. This law clarifies the requirements for Tribal representation on LBOHs. It also requires the Board to adopt rules to establish timelines for adjusting LBOH membership to keep a balanced mix of elected and non-elected members when Tribal representatives are added.

Once the law takes effect (in July 2025), the Board will have 12 months to establish these new requirements. The Board must ensure these changes go into effect no later than July 26, 2026.

Statutes authorizing the agency to adopt rules on this subject: RCW 43.20.300

Reasons why rules on this subject may be needed and what they might accomplish: Under RCW 43.20.300, the State Board of Health has the authority to adopt rules for appointing non-elected members to a local boards of health (LBOH). Chapter 246-90 WAC establishes the requirements for this selection and appointment process.

The Board is initiating rulemaking to implement ESHB 1946 (Chapter 260, Laws of 2025), which strengthens Tribal representation on LBOHs. Rulemaking is necessary to align existing rules with the new requirements established in the updated laws, including clarifying Tribal appointment authority and establishing timelines for when an LBOH must modify its membership to maintain a balance of elected and non-elected members.

Previously, the American Indian Health Commission (AIHC) was responsible for selecting Tribal representatives for LBOHs, when applicable. The new law shifts appointment authority from LBOHs to Tribes and Urban Indian Organizations, allowing each to choose its own representative. This change strengthens Tribal representation and affirms Tribal sovereignty and self-determination.

Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies:

The Board holds the authority to adopt rules governing the appointment of non-elected members to local boards of health (LBOHs) in Washington State. The rules provide local governments with a standard process for recruiting and ultimately appointing non-elected members of local boards of health representing public health/health systems, consumers of public health, and other community members. No other federal and state agencies regulate this specific subject; therefore, coordination with other federal and state agencies is not required.

Process for developing new rule (check all that apply):

- ☐ Negotiated rule making
- ☐ Pilot rule making
- ☐ Agency study
- ☒ Other (describe)

The Board will use a collaborative rulemaking approach. The Board will consult Tribes and Tribal organizations, organizations representing county commissioners, and LBOHs in Washington State. The Board will keep interested parties informed of the rulemaking project through email, the Board's listserv, the rule project webpage, community events, and public notices in the Washington State Register. Interested parties will have opportunities to provide comments throughout the rule-making process, including informal review of the draft rules, formal review and comment on the proposed changes to the rules, and giving testimony at the board's public hearing.

Interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication by contacting:

Name: Ashley Bell

Address: PO Box 47990, Olympia, WA 98504-7790

Phone:

Fax: 360-236-4088

TTY: 711

Email: ashley.bell@sboh.wa.govWebsite: <https://sboh.wa.gov/rulemaking/agency-rules-and-activity/lboh-tribal-membership>

Other:

(If necessary)

Name: Molly Dinardo

Address: PO Box 47990, Olympia, WA 98504-7790

Phone:

Fax: 360-236-4088

TTY: 711

Email: molly.dinardo@sboh.wa.gov

Website:

Other:

Additional comments:: To sign up fo updates on this project through an 'interested parties' list, please visit <https://airtable.com/appInSCDg3PQGijEz/pagzK7PWXOq6JRpRM/form>, or by using the contact information above.

Date: 9/8/2025**Name: Michelle A. Davis****Title: Executive Director****Signature:**



ENVIRONMENTAL HEALTH COMMITTEE SPECIAL MEETING SUMMARY NOTES

What: Environmental Health (EH) Committee

When: September 11, 2025

Attending: Board of Health (Board) Members: Paj Nandi and Steve Kutz; Board staff: Michelle Davis, Ash Noble, Molly Dinardo, Michelle Larson, Anna Burns, Crystal Ogle, Ashley Bell, and Hannah Haag; Department of Health (Department) staff: Mike Means, Lauren Jenks, Dani Toepelt, Ashlie Laydon, Brian Sayrs, Joe Laxon, Emily Sanford, Katitza Holthaus, Scott Berberills, Todd Phillips, and Nina Helpling. Approximately 12 members of the public also attended the meeting.

Summary Notes:

Preview October and November Board Meetings

- **Fluoride Science Review Panel**

- Lauren Jenks, Department staff, provided an update on the Department's ethics review process to evaluate their recent Fluoride Science Review Panel. This fall, Lauren plans to present draft methods for the ethics review, including a definition of public health ethics, examples from other health departments, and evaluation methods. This discussion will continue as the process progresses.
- Steve Kutz, Board Member, expressed interest in exploring the scientific principles behind ethical decisions and emphasized the importance of aligning ethical principles with scientific evidence.
- Paj Nandi, Board Member, raised concerns about potential questions from those unfamiliar with bioethics and ethics. There would likely be many questions once more details are available in October. Member Nandi asked if discussions with Local Health Organizations (LHOs) and Local Health Jurisdictions (LHJs) would run parallel to this ethics conversation.
- Lauren responded that the Board could discuss the ethical principles and proposed methods at the upcoming meeting and provide feedback. Lauren mentioned that Dr. Tao Sheng Kwan-Gett met with local health officers, and they agreed to compile a list of FAQs to ensure consistent responses to community inquiries about community water fluoridation.

- **Drinking Water Additives Petition**

- Molly Dinardo, Board staff, shared that the Board received a petition for drinking water additives and plans to discuss it in October.

- **School Environmental Health and Safety Rule Project (SRP)**

- Ash Noble, Board staff, provided an update on upcoming outreach efforts for the SRP. Staff will present at the Washington Association of Maintenance and

(Continued on the next page)

Operation Administrators (WAMOA) and the Washington State Public Health Association (WSPHA).

- Michelle Davis, Board Executive Director, shared that the team received a media inquiry from the Seattle Times about the project and is preparing an update for Public Health Seattle King County. Executive Director Davis said the Board will participate in a panel discussion at WSPHA with the Department, a local health representative, a WAMOA member, and potentially Senator Robinson.

- **Per- and polyfluoroalkyl substances (PFAS)**

- Mike Means, Department staff, shared an update on the PFAS emergency rule and ongoing permanent rulemaking. Mike explained that both are crucial for maintaining stricter protections for PFAS. Once the emergency rules are superseded, the permanent rules will solidify these protections. The Department is collaborating with the Board on CR-102 materials and aiming to file in late September 2025. Written comments are due before the November 19 Board public hearing. Pending approval, the CR-103 filing is expected in December or January.
- Steve Kutz, Board Member, shared thoughts on potential PFAS contamination in household items like cookware. Member Kutz suggested that it's safe to assume that items with non-stick coatings may contain PFAS unless cookware documentation is available.
- Mike responded that this issue is outside the scope of the PFAS drinking water regulation. But it may fall under the jurisdiction of the Department of Ecology (Ecology).
- Member Kutz suggested issuing warnings about possible PFAS in cookware and plastic containers.
- Executive Director Davis acknowledged the concern and mentioned that Ecology may already be addressing the issue, referring to a panel discussion from the previous year on PFAS.
- Paj Nandi, Board Member, inquired about what action items will be required of the Board in October and November.
- Mike noted that the process includes the emergency rule renewal scheduled for October, followed by the permanent rules hearing in November. Mike also mentioned that the Environmental Protection Agency is expected to eliminate some regulations and timelines. The Department is working to ensure these changes are incorporated into the rules, amid ongoing legal challenges.
- Member Nandi remarked that this situation is like other decisions the Board has faced.

- **Sanitary Control of Shellfish**

- Dani Toepelt, Department staff, provided updates on the sanitary control of shellfish rulemaking project. The CR-102 has been filed, and the public comment period for the proposed rule is open. A rules briefing is scheduled for October, and a hearing is set for November.
- Paj Nandi, Board Member, asked whether the shellfish industry is expected to raise substantial questions or comments during the formal comment period.

- Dani responded that while there will be questions, many comments can be addressed through further education from the Department.
 - Steve Kutz, Board Member, raised a broader concern about the shellfish industry, particularly regarding the tracking of shellfish safety. Member Kutz shared an experience at a restaurant in Baltimore where the shellfish tag number could not be provided and highlighted potential gaps in the system for tracking public health risks.
 - Dani agreed and emphasized the importance of connecting the commercial shellfish industry with the retail side to improve accountability. Dani mentioned previous work inspecting retail establishments and the need for better tag collection and education for local health jurisdictions and inspectors. This is not currently addressed in the existing rules, but efforts are underway to close these gaps.
 - Member Kutz noted that although food inspection rules exist, ensuring compliance remains a challenge and needs improvement.
- **Rule Reviews**
 - Ash Noble, Board staff, provided updates on two rule reviews for outdoor music festivals and camps. Both rules were last updated in the early 1990s. Policy and engagement staff are collaborating on the reviews. Staff may present updates at the Board's November meeting.

Committee Member Comments, Questions, and Next Steps

- Molly Dinardo, Board staff, reminded members that the EH Committee still needs a Chair. Chair Hayes is currently serving as the temporary Chair for the Health Promotion (HP) Committee. Molly encouraged members to reach out to staff if they are interested in chairing either committee.
- Paj Nandi, Board Member, asked to discuss the chair position at an upcoming Board meeting and suggested Member Peter Browning as a strong candidate for HP Chair given their background.
- Michelle Davis, Executive Director, thanked Member Nandi for the suggestion. The Board has several vacancies, and current members are awaiting reappointment by the Governor's Office. Executive Director Davis shared details about the new appointment process and that they will try to fit the discussion into the October or November meetings.
- Steve Kutz, Board Member, thanked staff for their thorough preparation for the meeting.
- Ash Noble, Board staff, shared that the next Board meeting is scheduled for Wednesday, October 8, in Tumwater, Washington.



STATE OF WASHINGTON
WASHINGTON STATE BOARD OF HEALTH

PO Box 47990 • Olympia, Washington 98504-7990

August 20, 2025

Dr. Sihoun Hahn, M.D, Ph.D.
Key Proteo
720 Broadway
Seattle, WA, 98122

Sent Via Email

Dear Dr. Hahn:

Thank you again for the rulemaking petition you submitted to the State Board of Health (Board) on July 26, 2024, requesting to amend chapter 246-650 WAC to add Wilson Disease as a condition for newborn screening. The purpose of this letter is to follow up on your petition and provide an update on recent Board action.

As mentioned in your August 2024 petition denial letter, the Board directed staff to collaborate with the Department of Health (Department) to convene a technical advisory committee (TAC) to evaluate Wilson Disease using the Board's process and criteria for evaluating conditions. The TAC met on June 17, 2025, and reviewed information on the condition's natural history, diagnostic and treatment options, available screening technology, cost-effectiveness, and public health system readiness. The TAC voted on each criterion and an overall recommendation to the Board. Overall, there was strong support across the evaluation criteria, and most members supported adding Wilson Disease to Washington's newborn screening panel.

The Board reviewed the TAC's findings at its August 20, 2025, meeting. During the Board's discussion of Wilson Disease, members:

- Asked for clarification on data related to liver transplants and neurologic cases.
- Noted potential cost savings from avoiding surgeries and other complications, which could help offset screening costs.
- Raised concerns about the potential burden of added testing costs on families and healthcare systems, especially given expected federal healthcare funding reductions.
- Highlighted that Washington could be a leader in screening for this condition, since Wilson Disease has not yet been reviewed by the federal Recommended Uniform Screening Panel (RUSP).
- Clarified that Wilson Disease is an autosomal recessive genetic condition, and that family health history alone is an imperfect tool for presymptomatic diagnosis.

Members also acknowledged that the implementation of screening often depends on legislative funding and that early diagnosis could result in overall system savings. However, the actual number of undiagnosed cases remains uncertain.

The Board then voted on a motion to initiate the rulemaking process to add Wilson Disease to the screening panel. Four members voted yes, three abstained, one was absent, and none opposed. Because Board bylaws require a majority of members present to approve a motion, the vote passed.

As a result, the Board directed staff to file a CR-101, Preproposal Statement of Inquiry, to begin rulemaking for chapter 246-650 WAC. This filing, which announces the Board's intent to consider adding Wilson Disease, will occur once other pending work is complete.

Currently, chapter 246-650 WAC is open to add three additional conditions: Ornithine Transcarbamylase Deficiency (OTCD), Guanidinoacetate Methyltransferase (GAMT) Deficiency, and Arginase 1 Deficiency (ARG1-D). The CR-101 for Wilson Disease cannot be filed until these are finalized. The Board expects to complete this work by the end of 2025, with notice for Wilson Disease expected in early 2026.

In addition, before any new conditions can be added, the Department must obtain legislative approval to increase its [newborn screening fee](#), which funds laboratory testing, staff time, follow-up, and administrative costs. Because the Washington State Health Care Authority (HCA) covers more than 40% of state births, it must also approve adjustments to Medicaid managed care rates. Based on cost-benefit findings for Wilson Disease, the Department and HCA will need to request a fee increase to support adding the condition. The earliest this request could be submitted is the 2027 legislative session, with agency planning beginning in spring and summer 2026.

If you have questions or require further assistance, please don't hesitate to contact Molly Dinardo, Health Policy Advisor in our office, at (564) 669-3455 or at molly.dinardo@sboh.wa.gov.

Sincerely,

A handwritten signature in black ink that reads "Patty Hayes". The signature is written in a cursive, flowing style.

Patty Hayes
Board Chair

Updated Washington State School Hearing Screening Standards

Effective August 15, 2025

What You Need to Know About Recent Changes to Chapter 246-760 WAC

The State Board of Health (Board) has modernized the annual hearing screening standards for Washington. These rules were last updated in 2002. Changes were adopted on June 4, 2025, and take effect on August 15, 2025. These updates aim to make the rules easier to understand, reflect current technology and national standards, and give schools more flexibility to meet students' needs.

Key Updates

- Provide flexible and practical screening procedures suited for school settings.
- Reflect national standards and current screening technology.
- Use more plain language to make the rule easier to understand.
- Reduce barriers for students who may struggle with traditional screening methods.
- Remove stigmatizing or deficit-based language (e.g., "hearing loss," "hearing problems," "pass/fail") and replace with more inclusive language.

At-a-Glance: What has Changed?

Area	Old Rule	Updated Rule	Intended Impact for Schools
Screening Tools and Technology	Only pure tone audiometers permitted.	Allows Otoacoustic Emission (OAE) screening as an optional screening tool for students who cannot complete pure tone audiometry (e.g., developmental delays, language barriers, age).	Provides an alternative method for students who are unable to participate in traditional screening. If schools opt to use this technology, OAE equipment, calibration, and staff training will be required.
Updated Audiology Standards	Previously referenced American National Standards Institute (ANSI) audiometer standards from 1996.	Updated to reflect current national standards (2023) from the Acoustical Society of America (ASA) and ANSI.	Ensures screening meets current national audiology standards.
Clarification of Hearing Screening Procedures	No dedicated section for hearing screening procedures; only vision screening had its own detailed procedures section.	New WAC 246-760-025 Hearing Screening includes: use of linguistically, developmentally, and age-appropriate tools; following tool-specific protocols; exemptions for students with recent audiological evaluations or documented hearing levels (with option to participate).	Provides clear, consistent guidance; reduces unnecessary screenings; supports inclusion; aligns with best practices.
Hearing Screening Environment and Best Practices	Required screenings in a noise-free environment; no specific procedural best practices for pure tone screening.	Clarifies "free of extraneous noise, to the extent possible in a school setting." Adds best practices for pure tone and OAE screenings (e.g., student positioning).	Supports accurate screenings while acknowledging school limitations and provides some procedural guidance.

Area	Old Rule	Updated Rule	Intended Impact for Schools
Referral Procedures	General rescreening requirement – to rescreen within 6 weeks; less detail on process.	Clarifies that screening staff should wait a minimum of 1-2 weeks to rescreen, if possible; flexible referral process for schools, parents, and guardians; requires documentation of screening device type.	Improves follow-up, ensures timely support, and gives schools flexibility.
Rule Alignment	Vision rules updated in 2017; hearing rules not updated since 2002. Titles phrased as questions; less detailed.	Hearing and vision rules now aligned in structure, terminology, and detail. New section WAC 246-760-025 Hearing Screening mirrors the vision screening section WAC 246-760-105	Improves ease of use.
Language	Used deficit-based terms such as “hearing loss,” “hearing problems,” and “pass/fail.”	Replaced with positive, inclusive terms while keeping the same screening standards.	Updates to forms, letters, and training materials to reflect inclusive language.
Definitions and Terminology	Limited hearing-related definitions; focused primarily on vision screening. Used terms like “visual and auditory” and “acuity” throughout.	Expanded definitions for hearing screening tools, procedures, and terms (e.g., “OAE,” “probe tip,” “tonal stimuli”). Replaced “visual and auditory” with “vision and hearing” throughout the rule.	Improves clarity and consistency for staff and training.

Preparing for Annual Hearing Screenings

Planning

- Review updated Chapter 246-760 WAC and compare with your district's current school hearing screening policies.
- Update school hearing screening protocols to include inclusive language and new procedures (as needed).

Equipment and Technology

- Ensure pure tone audiometers meet ASA/ANSI S3.6-2018 (R 2023) standards.
- Acquire OAE screening equipment if planning to offer it as an alternative screening.
- Schedule regular calibration and maintenance of equipment.

Staff Training

- Train staff in updated screening procedures and inclusive language.
- Provide training on OAE use, if applicable.
- Review best practices for minimizing environmental noise and proper student positioning.

Screening and Documentation

- Use linguistically and developmentally appropriate screening tools.
- Follow tool-specific protocols and document device type.
- Track exemptions and prior audiological evaluations, if applicable.

Communication and Forms

- Update forms, letters, and training materials to reflect inclusive, positive language.
- Inform parents/guardians of any changes and new screening options.
- Ensure clear communication about results, referrals, and next steps.



Washington State School Hearing Screening Resources

How to Use this Document

This guide is a quick reference for school staff who perform hearing screenings.

- Start with the **General Hearing Screening** section for core concepts, national guidelines, and procedures.
- Use the skill-specific sections (**Pure Tone Audiometry, OAE**) for specific training or refreshers.
- Review the **Inclusive Language & Deaf Culture** section to ensure respectful, student-centered communication.
- See the **PLOTE** section for guidance on working with students whose primary language at home is not English.
- Always check [chapter 246-760 WAC](#) for Washington State requirements.

About this Document

This resource provides supplementary materials for staff involved in school hearing screening programs. These materials are intended as a starting point for training and professional development and may not reflect Washington State-specific requirements.

Community members and subject matter experts shared many of these resources during the recent rulemaking process. Note that these resources do not represent the position or endorsement of the Washington State Board of Health.

State Board of Health rule, [chapter 246-760 WAC](#), details Washington's hearing and vision screening requirements for school districts.

Questions? Contact: healthservices@k12.wa.us

General Hearing Screening Resources

- [Selecting a Location for Hearing Screening](#)
Arizona Department of Health Services
- [Clinical Practice Guidelines: Childhood Hearing Screening](#)
American Academy of Audiology (2011)
- [Hearing Assessments in Infants, Children, and Adolescents: Recommendations Beyond Neonatal Screening](#)
American Academy of Pediatrics (2023)

Pure Tone Audiometry and Otoacoustic Emission (OAE) Screening

- [Performing a Pure Tone Hearing Screening](#)
Arizona Department of Health Services
- [Performing an OAE Screening](#)
Arizona Department of Health Services

Inclusive Language and Deaf Culture

- [Deaf Awareness 101](#)
National Deaf Center on Postsecondary Outcomes
- [Understanding Terminology in Deaf Culture](#)
Deaf Services Unlimited



Tip for Schools

Using inclusive, culturally sensitive language (e.g., "Deaf" or "hard of hearing" rather than "hearing impaired" or "hearing loss") supports student identity, fosters inclusion, and aligns with best practices in hearing screening communications.

Screening Students Who Speak a Primary Language Other Than English (PLOTE)

- [Multilingual Service Delivery in Audiology and Speech-Language Pathology](#)
American Speech-Language-Hearing Association
- [Cultural Humility, A Quick Reference Guide](#)
National Center on Advancing Person-Centered Practices and Systems

Date: October 8, 2025

To: Washington State Board of Health Members

From: Paj Nandi, Board Member

Subject: Petition for Rulemaking [WAC 246-290-220](#), Drinking Water Materials and Additives—Possible Action

Background and Summary:

The Administrative Procedure Act ([RCW 34.05.330](#)) allows any person to petition a state agency for the adoption, amendment, or repeal of any rule. Upon receipt of a petition, the agency has sixty days to either (1) deny the petition in writing, stating the reasons and, as appropriate, offer other means for addressing the concerns raised by the petitioner, or (2) accept the petition and initiate rulemaking.

On August 24, 2025, the State Board of Health (Board) received a petition from Washington Action for Safe Water and Bill Osmunson, DDS MPH. The petitioners request that the Board consider amending WAC 246-290-220, Drinking Water Materials and Additives, within the Group A Public Water Supplies rules.

The Board has the authority under [RCW 43.20.050](#) to adopt rules for Group A public water systems as defined in [RCW 70A.125.010](#). Chapter 246-290 WAC establishes the standards for these water systems related to their design, construction, sampling, management, maintenance, and operation practices. The purpose of these rules is to define basic regulatory requirements and to protect the health of consumers using public drinking water supplies.

The petitioners request that the Board amend [WAC 246-290-220](#) to include new sections related to water fluoridation that state the following:

- (1) Any substance intentionally added to public drinking water with the intent to diagnose, mitigate, prevent, or treat disease in humans shall be defined as a drug for the purposes of this chapter.
- (2) Fluoride, when intentionally added to public water supplies for the stated purpose of preventing dental caries, is a drug as defined by 21 U.S.C. § 321(g)(1) and RCW 69.04.470 and shall be treated as a drug for purposes of this chapter.
- (3) Because no fluoride drug products intended for systemic ingestion via drinking water have been approved under 21 U.S.C. § 355 (New Drug Application), no public water system may add fluoride for therapeutic or disease-prevention purposes absent FDA/CDER approval.
- (4) The Washington State Board of Health, Department of Health, and local health jurisdictions shall not promote, sponsor, advertise, or recommend the addition, dilution, formulation, or any other method of introducing fluoride, or any other unapproved drug, to public water supplies until such substance or drug has been approved by the U.S. Food and Drug Administration, Center for Drug Evaluation and Research (FDA/CDER).

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(5) Manufacturers, importers, or suppliers of raw fluoride products—such as fluorosilicic acid, sodium fluoride, and sodium fluorosilicate—bear primary responsibility under federal and state law for securing FDA/CDER approval before marketing these substances for ingestion through community water fluoridation, including all costs associated with a New Drug Application (NDA), safety testing, and efficacy trials. This responsibility and financial burden shall not be borne by Washington taxpayers or public agencies.

Shay Bauman, Board staff, will present the Board Members with information related to the petition and recommendations.

Recommended Board Actions:

The Board may wish to consider and amend, if necessary, the following motions:

The Board declines the petition for rulemaking to amend WAC 246-290-220 for the reasons articulated by Board Members. The Board directs staff to notify the petitioner of the Board's decision.

OR

The Board accepts the petition for rulemaking to explore the proposed amendment to WAC 246-290-220 to consider additional language related to water fluoridation. The Board directs staff to notify the requestor of its decision and to file a CR-101, Preproposal of Inquiry, to further evaluate the request and possible rule change.

Staff

Shay Bauman, Policy Advisor

To request this document in an alternate format or a different language, 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.

PO Box 47990 • Olympia, WA 98504-7990
360-236-4110 • wsboh@sboh.wa.gov • sboh.wa.gov

Petition #23 for Rule Change

Submitted under RCW 34.05.330 and WAC Chapter 82-05

To: Washington State Board of Health

From: Bill Osmunson, DDS, MPH billosmunson3@gmail.com

And on behalf of Washington Action for Safe Water

10300 181st Ave SE Issaquah, WA 98027

Phone: 425.466.0100

Email: billosmunson3@gmail.com Date: August 23, 2025

1. Rule to be Amended

Washington Administrative Code (WAC) 246-290-220 – Treatment Techniques – Community Water Systems.

2. Authority

This petition is filed pursuant to:

- RCW 34.05.330 – Right to petition for adoption, amendment, or repeal of a rule.
- WAC 82-05-030 – Requirements for petitions for rulemaking.
- RCW 43.20.050(2)(a) – Duty of the State Board of Health to adopt rules necessary to assure safe and reliable drinking water.

3. Proposed Rule Amendment

Amend WAC 246-290-220 by adding a new section as follows (proposed draft language):

(1) Any substance intentionally added to public drinking water with the intent to diagnose, mitigate, prevent, or treat disease in humans shall be defined as a drug for the purposes of this chapter.

(2) Fluoride, when intentionally added to public water supplies for the stated purpose of preventing dental caries, is a drug as defined by 21 U.S.C. § 321(g)(1) and RCW 69.04.470 and shall be treated as a drug for purposes of this chapter.

(3) Because no fluoride drug products intended for systemic ingestion via drinking water have been approved under 21 U.S.C. § 355 (New Drug Application), no public water system

may add fluoride for therapeutic or disease-prevention purposes absent FDA/CDER approval.

(4) The Washington State Board of Health, Department of Health, and local health jurisdictions shall not promote, sponsor, advertise, or recommend the addition, dilution, formulation, or any other method of introducing fluoride, or any other unapproved drug, to public water supplies until such substance or drug has been approved by the U.S. Food and Drug Administration, Center for Drug Evaluation and Research (FDA/CDER).

(5) Manufacturers, importers, or suppliers of raw fluoride products—such as fluorosilicic acid, sodium fluoride, and sodium fluorosilicate—bear primary responsibility under federal and state law for securing FDA/CDER approval before marketing these substances for ingestion through community water fluoridation, including all costs associated with a New Drug Application (NDA), safety testing, and efficacy trials. This responsibility and financial burden shall not be borne by Washington taxpayers or public agencies.

4. Justification for the Rule Change

A. Federal Law

- 21 U.S.C. § 355(a) prohibits marketing or introduction of any new drug into interstate commerce without FDA approval.
- 21 U.S.C. § 331(d) prohibits distribution of unapproved new drugs.
- 21 U.S.C. § 321(g)(1) defines a drug as any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
- 21 U.S.C. § 352(f) deems a drug misbranded if it lacks FDA-approved directions for use.

B. Washington State Law

- RCW 69.04.450 makes it unlawful to manufacture, sell, deliver, hold, or offer for sale any drug that is adulterated or misbranded.
- RCW 69.04.470 adopts the federal definition of 'drug.'
- RCW 69.41.010(9) defines a legend drug as any drug required by federal law to be labeled 'Caution: Federal law prohibits dispensing without prescription.'
- RCW 69.41.020 prohibits the sale or distribution of legend drugs except as authorized.

C. Washington State Board of Pharmacy Ruling

When petitioned to classify fluoride as a poison due to its toxicity, the Washington State Board of Pharmacy ruled, *"This letter is in response to your request at the May 7, 2009 meeting of the Washington Board of Pharmacy for a response to your question about designating fluoride as a poison. . . Fluoride is a legend drug regulated under chapter*

69.41RCW. RCW69.41.010 defines a “legend drug” as drugs “which require by state law or regulation of the state board of pharmacy to be dispensed on prescription only or are restricted to use by practitioners only. . . .”

This determination is legally significant: it confirms that fluoride for ingestion is not merely a water additive or nutrient, but a regulated prescription drug requiring FDA approval and prescription-based distribution. By classifying fluoride as a legend drug due to both toxicity and intent of use, the Board of Pharmacy recognized that fluoride cannot lawfully be dispensed or promoted outside approved drug channels.

4A. Exclusive FDA/CDER Authority Over Drugs

- The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), is the sole authority empowered by Congress under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) to determine:

- Whether a substance qualifies as a drug.
- Whether a drug has demonstrated benefit through adequate and well-controlled studies.
- The dosage, formulation, and route of administration at which the benefit is achieved.
- The necessary warnings, contraindications, and labeling requirements to protect vulnerable populations, including fetuses, infants, children, persons with genetic polymorphisms, and those with chemical sensitivities.

- Neither the Washington State Board of Health, the Department of Health, nor any other state agency has the drug regulatory experts, scientific infrastructure, legislative authority, or regulatory experience to substitute their judgment for that of FDA/CDER.

4B. Special Concern: Developing Fetuses, Infants, and Children

- Fluoride crosses the placenta, exposing the developing fetus to systemic fluoride before birth. Infants consuming formula mixed with fluoridated water are among the most highly exposed groups.

- Of greatest concern is protecting the fetus, infant, and child, who are uniquely vulnerable to neurological and systemic harm.

- Because fluoridated water is promoted for the prevention of dental caries without FDA approval, it constitutes an adulterated and misbranded drug under 21 U.S.C. §§ 351, 352 and RCW 69.04.450.

- An unapproved, adulterated, and misbranded drug is by definition an illegal drug under both federal and Washington State law.

- Fluoridated drinking water is therefore an illegal drug being administered without prescription, dosage control, purity, or labeling safeguards.
- Critically, fluoridated water is the only example in Washington State where an illegal drug is mass-medicated to the majority of residents through a public utility. No other unapproved drug is distributed this way — not vaccines, not supplements, not prescription drugs.

4C. Illegality of Selling and Mass-Medicating with an Unapproved Drug

It is further noted that RCW 57.08.012 specifically authorizes water-sewer district commissioners, by vote, to approve the fluoridation of public water supplies. However, this authorization is permissive and local in scope, and it does not supersede or nullify the statewide statutory duty set forth in RCW 43.20.050(2)(a), which requires the State Board of Health to adopt rules necessary to assure safe and reliable public drinking water.

Under established rules of statutory construction, Washington courts harmonize statutes whenever possible, rather than finding implied repeal or conflict. RCW 57.08.012 and RCW 43.20.050(2)(a) are not in irreconcilable conflict: one provides local governance authority to decide whether to fluoridate, while the other imposes a superior statewide obligation to assure safety. In practice, this means that a local district may only fluoridate if it can do so in full compliance with state and federal safety requirements.

RCW 43.20.050(2)(a) is a mandatory public health and safety statute, requiring safety to be affirmatively assured. This higher duty cannot be displaced by a local commissioner's vote. In effect, RCW 57.08.012 provides permission, but RCW 43.20.050(2)(a) sets the condition: water fluoridation is only lawful if safety can be demonstrated. Moreover, federal supremacy requires compliance with the Federal Food, Drug, and Cosmetic Act, which mandates FDA/CDER approval for any substance intended for disease prevention. Thus, state or local authorization does not eliminate federal drug law obligations.

The Washington State Board of Pharmacy has historically interpreted RCW provisions as permitting the practice of community water fluoridation. However, such an interpretation cannot be read as superseding or nullifying the broader framework of state and federal law.

- **No Override of Drug Laws:** Permission to fluoridate does not exempt fluoride products from the requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355), which requires New Drug Applications and FDA/CDER approval to assure both safety and efficacy.
- **No Override of Poison Statutes:** Likewise, an administrative interpretation cannot nullify statutory provisions classifying fluoride as a poison when present in toxic concentrations (e.g., RCW 69.40.030).
- **No Override of Safety Mandates:** RCW 43.20.050(2)(a) requires the Board of Health to adopt rules to “assure safe ... drinking water.” A permissive ruling by the Board of Pharmacy cannot reduce the statutory duty to assure safety with reasonable certainty. For example, the legislature may authorize a building or road construction; however, such authorization does not exempt licensed engineers and contractors from their independent statutory duty to ensure safety. Similarly, authorization to fluoridate does not negate or diminish the legal duty to assure that the water supply is safe.ⁱ

Accordingly, while the Board of Pharmacy’s ruling may have provided precedent for fluoridation practices, it does not constitute blanket authorization to bypass established drug, poison, or safety laws. These higher standards remain binding and must be satisfied independently.

- Under the Federal Food, Drug, and Cosmetic Act (FDCA):

- 21 U.S.C. § 355(a) prohibits introduction of any new drug without FDA approval.
- 21 U.S.C. § 331(a), (d), (k) makes it illegal to manufacture, sell, deliver, or distribute any drug that is adulterated, misbranded, or unapproved.
- 21 U.S.C. § 333 establishes criminal penalties, including fines and imprisonment, for violations.

- Under Washington State law:

- RCW 69.04.450 prohibits the manufacture, sale, delivery, or offer for sale of any adulterated or misbranded drug.
- RCW 69.04.470 incorporates the federal definition of 'drug.'
- RCW 69.41.020 prohibits the distribution of legend drugs except as authorized by law.

- **By definition, fluoridated water marketed as a means of preventing dental caries is:**

- An unapproved new drug (no FDA New Drug Application).
- A misbranded drug (no FDA-approved labeling, dosage, or warnings).
- An adulterated drug (not manufactured under FDA drug standards).

- Accordingly, fluoridated water is an illegal drug under both federal and Washington law. Unlike vaccines or approved medications, fluoridated water is the only unapproved drug mass-medicated to the majority of Washington residents through a public utility.

In summary, RCW 57.08.012 provides only limited local permission for water-sewer districts to consider fluoridation, whereas RCW 43.20.050(2)(a) imposes an overriding state duty to assure safe drinking water. Permission to fluoridate does not equate to proof of safety. Safety must be independently established and affirmatively assured under both state and federal law before fluoridation can be considered lawful.

****4C-1. Responsibility of Raw Fluoride Product Manufacturers****

Manufacturers of raw fluoride products such as fluorosilicic acid, sodium fluoride, and sodium fluorosilicate bear primary responsibility under federal and state law for securing FDA/CDER approval before marketing these substances for ingestion through community water fluoridation.

Under the FD&C Act (21 U.S.C. §§ 321(g)(1)(B), 351, 352, 355), any article intended for disease prevention is a drug and requires a New Drug Application (NDA) demonstrating safety and efficacy. Until such approval is obtained, these products remain unapproved, adulterated, and misbranded drugs. State authorization does not exempt manufacturers from liability, and absent FDA oversight, the products also retain their legal classification as poisons under RCW 69.40.030.

It is neither lawful nor equitable for Washington taxpayers to bear the financial burden of demonstrating safety for manufacturers who profit from these products. The duty to fund and pursue FDA/CDER approval, including the full cost of NDA submission and required safety and efficacy trials, rests with the raw product manufacturers, not the public. This ensures that the entities who benefit financially from selling fluoridation chemicals bear the responsibility for compliance with federal law, thereby protecting both public health and public resources.

The costs of conducting the required safety and efficacy studies are insignificant relative to the revenues of multinational fertilizer and chemical companies that manufacture and sell fluoride additives. These entities routinely fund regulatory submissions and compliance programs for other products; there is no rational basis to shift this burden to taxpayers.

4D. Fluoride as a Poison When Not Regulated as a Drug

This section is not intended as a threat or warning, rather an indication of the Legislature's emphasis on safety for the public.

If fluoride added to public water for caries prevention is not lawfully regulated as a drug and is deemed a "poison" under Washington law, several criminal and civil penalty provisions may be implicated:

- RCW 69.40.030 — Placing poison or other harmful substance in food, drink, medicine, or water: Class B felony; punishable by imprisonment (not less than five years) or fine (not less than \$1,000).
- RCW 70.54.010 — Polluting water supply: Gross misdemeanor for depositing any dangerous or deleterious matter into waters used for drinking or into a public water system watershed.
- 42 U.S.C. § 300i-1 — Tampering with a public water system: Federal felony; up to 20 years imprisonment or fines; civil penalties up to \$1,000,000 for tampering events.

These statutes underscore that adding a poisonous substance to public drinking water—outside lawful drug regulation and authorization—carries significant criminal penalties. Nothing in this petition seeks to penalize authorized, good-faith operators who comply with governing law; rather, it clarifies that continued addition of an unapproved drug or poison is unlawful and exposes agencies and suppliers to enforcement.

4E. Applicability of Criminal Statutes and Liability Considerations

This section's intent is not as a threat but to emphasize the seriousness, the import, the Legislature has put on protecting the public health from toxins and the urgency for due diligence to protect the public health. For 15 years and now the 23rd petition to protect the health of the public, further delay in protecting the public is unacceptable.

- State Criminal Statutes: Laws such as RCW 69.40.030 (placing poison in food, drink, or water, Class B felony) and RCW 70.54.010 (polluting water supply, gross misdemeanor) contain no explicit exemptions for state agencies.
- Federal Statutes: 42 U.S.C. § 300i-1 (tampering with a public water system) similarly establishes penalties without agency exemptions.
- Immunity and Good Faith: While public officials generally enjoy qualified immunity from personal civil liability for policy decisions made in good faith and within their official duties,

such immunity does not extend to criminal statutes if courts later determine the acts to be unlawful.

This petition does not assert that the Board or its members are criminally liable. Rather, it respectfully raises the question of whether, in the absence of FDA/CDER approval of fluoride ingestion as a drug, continued promotion or authorization of community water fluoridation could unintentionally expose agencies, water purveyors, or officials to statutory liability. For this reason, a precautionary clarification by designating FDA/CDER as the proper authority is prudent to protect both the public and those acting under color of state law.

To protect local entities and the Board from liability, the Board should have the Attorney General designate where liability for harm and lack of FDA CDER NDA rests; the Legislature, Board, Department, local authorities, and/or the drug raw product manufacturers.

References:

- RCW 69.40.030 – Placing poison in food, drink, medicine, or water.
- RCW 70.54.010 – Polluting water supply.
- 42 U.S.C. § 300i-1 – Tampering with a public water system.
- RCW 4.24.470 – Immunity for state officers acting in good faith within their official capacity.

4F. Neither starting nor stopping fluoridation has quality science and is supported only by endorsements and promotion, not quality science.

Neither benefit nor safety have a single randomized controlled trial (RCT) considered the gold standard of research, of benefit or safety. The FDA CDER requires two RCTs for approval, in part, because observational studies have significant limitations and even RCTs are in time found to be incorrect. Experience has taught the FDA CDER to require quality research and fluoridation does not have any over the last 80 years. Observational studies have numerous limitations.

The cessation of fluoridation is not well studied and has mixed evidence. Some locations such as British Columbia, Germany, Cuba and China did not report an increase in dental caries after cessation of fluoridation. Alberta and Alaska areas reported an increase in

hospitalizations with cessation and Port Angeles reported the opposite with an increase in hospitalizations after 10 years of fluoridation.

Hospitalization for dental treatment is likely more a treating clinician's choice than an increase in dental caries. From my experience, physical restraint is a bad choice and emotionally harmful to the child. Chemical sedation of a child was good in my hands for one or two short pediatric visits, but the patient was then often uncooperative and reluctant for further life-time visits. A general anesthesia prevented creating a dental phobic and was safer in the hospital with proper equipment and a trained anesthesiologist. Hospital utilization is more a clinician's choice and lack of clinician training in general anesthesia for office use than a reasonable measurement of dental caries prevalence or fluoridation's possible benefit or lack of benefit. Hospitalization is too crude of an assessment to have significance of benefit or lack of benefit of fluoridation.

4G. Industrial-Grade Fluoridation Additives and Foreign Imports (Not Pharmaceutical Grade)

- The compounds used for community water fluoridation are fluorosilicic acid (FSA), sodium fluorosilicate, and sodium fluoride. The most common is FSA.
- FSA used in drinking water is an industrial byproduct captured from wet-process phosphoric acid production; it is certified to NSF/ANSI Standard 60 for drinking water additives and seldom assayed. Fluoridation drugs are not manufactured to United States Pharmacopeia (USP) pharmaceutical-grade standards or FDA drug GMP requirements (CDC/AWWA/NSF guidance).
- EPA's Fluorosilicic Acid Supply Chain Profile notes limited domestic manufacturing capacity and a strong reliance on imports; the primary trading partner for U.S. imports for fluoride products in 2015–2020 was China.
- China's national Standards for Drinking Water Quality (GB 5749-2022) set a maximum fluoride limit of 1.0 mg/L. Pilot municipal fluoridation in Guangzhou begun in the 1960s was discontinued in 1983; artificial fluoridation is not practiced nationally. Many jurisdictions worldwide do not fluoridate water. Over 96% of Europe is fluoridation free.
- Consequently, the fluoride product added to U.S. public water is an industrial-grade chemical—often imported—and not a pharmaceutical-grade product approved by FDA/CDER.

Neither do any of the manufacturing steps for the drug abide by good drug manufacturing practices as required by the FDA CDER. Current Good Manufacturing Practices (CGMP) CGMP Regulations, authoritative sources:

- **21 CFR Parts 210 & 211** (regulatory basis)
- **2018 Q&A on CGMP for Drugs** (general interpretive guidance)
- **2024 Q&A on Production and Process Controls** (practical operations)
- **2025 Draft on § 211.110 Compliance** (for advanced manufacturing contexts)

Frequently, authorities mistakenly rely on the EPA to regulate the manufacturing of the fluoridated drug. The EPA has repeatedly clarified that they do not regulate drugs, prohibited by the Safe Drinking Water Act.

[4H. Known Risks of Harm and Alleged Benefits have been covered in detail in our previous 22 petitions for rule change and not repeated here.](#)

5. Public Health Rationale

- Fluoridation is not comparable to disinfection or corrosion control, which directly improve water quality. It delivers a compound solely for a claimed therapeutic effect.
- The Board of Pharmacy's classification of fluoride as a legend drug establishes that ingestion of fluoride for therapeutic purpose falls under prescription drug regulation.
- Community water fluoridation has never received FDA approval via New Drug Application, making its promotion an unlawful endorsement of an unapproved drug.
- Specifically, the developing fetus and infants face elevated exposure with no dose-adjusted consultation or labeling — this bypasses fundamental drug safety mechanisms.
- Preventing state agencies from promoting such unregulated drug exposures upholds both statutory standards and public health protection mandates.
- Requiring the drug manufacturers to gain FDA CDER approval with quality research on safety and efficacy, purity, dosage, and label, relieves the state and local entities from each needing to gain FDA CDER NDA, an unreasonable cost for tax payers.

6. Requested Action

The undersigned petitioner respectfully requests that the Washington State Board of Health:

1. Initiate rulemaking to amend WAC 246-290-220 as proposed above;
2. Classify fluoride added for caries prevention in drinking water as a drug;
3. Acknowledge that FDA/CDER is the only legally authorized and scientifically qualified body to determine drug benefit, dosage, and labeling;
4. Prohibit the promotion, sponsorship, advertising, or recommendation of unapproved drugs, including fluoride, through public water systems unless FDA/CDER approved;
5. Direct the Department of Health to issue written notice to all manufacturers, importers, suppliers, and water purveyors that no fluoride drug product may be marketed or supplied for systemic ingestion via drinking water absent FDA/CDER approval, and that the responsibility and financial burden of obtaining such approval rests with the manufacturers, importers, or suppliers—not Washington taxpayers or public agencies. The Department shall provide a reasonable compliance period not exceeding 12 months.

7. Petitioners Signature

Bill Osmunson, DDS, MPH

On behalf of Washington Action for Safe Water

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References

Washington State Statutes

- RCW 43.20.050(2)(a). Powers and duties of the State Board of Health—Drinking water safety.
- RCW 57.08.012. Authority of water-sewer district commissioners to fluoridate water by vote.

- RCW 69.40.030. Placing poison in food, drink, medicine, or water—Penalty.
- RCW 70.54.010. Polluting water supply—Penalty.
- RCW 4.24.470. Immunity for state officers acting in good faith within scope of duty.

Federal Law

- 21 U.S.C. § 355. New Drug Application requirement under the Federal Food, Drug, and Cosmetic Act.
- 42 U.S.C. § 300i-1. Tampering with a public water system—Criminal and civil penalties.

Regulatory and Technical Standards

- National Sanitation Foundation/American National Standards Institute (NSF/ANSI). Standard 60: Drinking Water Treatment Chemicals – Health Effects. NSF International; latest revision.
- United States Environmental Protection Agency (EPA). *Fluorosilicic Acid Supply-Chain Profile*. EPA, Office of Water, 2015.
- Chinese National Standards. GB 5749-2022. Standards for Drinking Water Quality. Ministry of Health of the People’s Republic of China.

Scientific and Historical Sources

- Whitford GM. “Fluoride Toxicology and Health Effects.” In: Fejerskov O, Ekstrand J, Burt B, eds. *Fluoride in Dentistry*. 2nd ed. Copenhagen: Munksgaard; 1996:171.
- Guangzhou Municipal Health Bureau. Historical records on discontinuation of pilot fluoridation project (1983).
- Iheozor-Ejiofor Z, et al. “Water fluoridation for the prevention of dental caries.” *Cochrane Database of Systematic Reviews*. 2024; Issue 6.

8. Board of Health Response (for agency use)

- ☐ Petition denied (written statement of reasons attached)
- ☐ Petition accepted – Rulemaking initiated under RCW 34.05.320

Date received: _____

Agency official: _____

¹ Washington law illustrates this principle in the context of building and construction. While the legislature may authorize or fund public projects, independent statutory safety obligations remain in force for professionals. For example, licensed professional engineers are required under RCW 18.43.020 to practice in a manner that safeguards life, health, and property, and contractors must comply with building safety standards established under the State Building Code Act (RCW 19.27). Legislative authorization of a project does not exempt compliance with these independent statutory duties. By analogy, statutory permission to fluoridate does not override existing drug, poison, or safe drinking water laws requiring affirmative assurance of safety.



Petition for Rulemaking

WAC 246-290-220, Drinking Water Materials and Additives

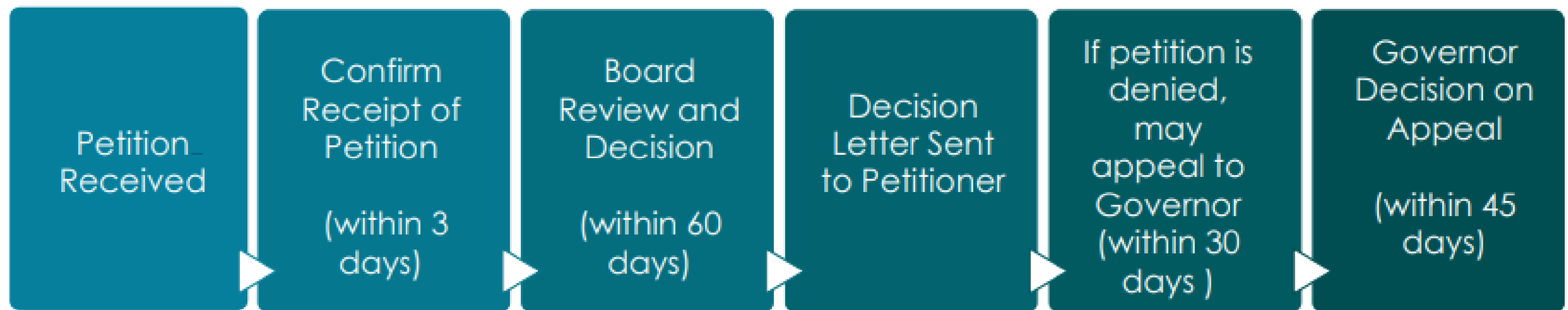
Shay Bauman, Policy Advisor
October 8, 2025

WASHINGTON STATE 
BOARD OF HEALTH

Background

Under the Administrative Procedures Act, RCW 34.05.330, any person may petition a state agency to adopt, repeal, or amend any rule within its authority.

Overview of the Board's Petition Process



RCW 43.20.050 grants the Board authority to adopt rules for Group A Public Water Systems necessary to assure safe and reliable drinking water and protect the public health. These rules are within Chapter 246-290 WAC.

Petition

The petition requests the Board add a new section to WAC 246-290-220 stating the following:

- (1) Any substance intentionally added to public drinking water with the intent to diagnose, mitigate, prevent, or treat disease in humans shall be defined as a drug for the purposes of this chapter.
- (2) Fluoride, when intentionally added to public water supplies for the stated purpose of preventing dental caries, is a drug as defined by 21 U.S.C. § 321(g)(1) and RCW 69.04.470 and shall be treated as a drug for purposes of this chapter.
- (3) Because no fluoride drug products intended for systemic ingestion via drinking water have been approved under 21 U.S.C. § 355 (New Drug Application), no public water system may add fluoride for therapeutic or disease-prevention purposes absent FDA/CDER approval.
- (4) The Washington State Board of Health, Department of Health, and local health jurisdictions shall not promote, sponsor, advertise, or recommend the addition, dilution, formulation, or any other method of introducing fluoride, or any other unapproved drug, to public water supplies until such substance or drug has been approved by the U.S. Food and Drug Administration, Center for Drug Evaluation and Research (FDA/CDER).
- (5) Manufacturers, importers, or suppliers of raw fluoride products—such as fluorosilicic acid, sodium fluoride, and sodium fluorosilicate—bear primary responsibility under federal and state law for securing FDA/CDER approval before marketing these substances for ingestion through community water fluoridation, including all costs associated with a New Drug Application (NDA), safety testing, and efficacy trials. This responsibility and financial burden shall not be borne by Washington taxpayers or public agencies.

WAC 246-290-220 – Drinking Water Materials and Additives

WAC 246-290-220 requires Group A public water systems to test and certify for conformance with NSF/ANSI Standards 60 and 61 for:

- treatment chemicals added to public drinking water supplies; and
- public water system components in substantial contact with potable water such as water pipes, tank coatings or liners, and treatment system media.



Board Discussion

- The language proposed in the petition refers to federal regulations under the United States Food and Drug Administration (FDA).
- The FDA *does not* regulate public water supplies.
 - This authority is granted to the United States Environmental Protection Agency (EPA) by the Safe Drinking Water Act.¹
- The FDA's Center for Drug Evaluation and Research (CDER) does not approve any materials or additives for the purpose of drinking water because it is not within their authority.
- The Board cannot give authority within its rules to a federal agency that is not granted that authority.
- Further, Washington case law provides that fluorides in public drinking water are not drugs.²

Staff Recommendation: Decline the petition for rulemaking.

¹ [Does FDA Regulate Fluoride in Drinking Water? | FDA](#)

² *Protect the Peninsula's Future v. City of Port Angeles*, 175 Wn. App. 201, 215 (2013)

tes government [Here's how you know](#) 

[ion logo](#)

[Drugs](#) / [Information for Consumers and Patients | Drugs](#) / [Frequently Asked Questions on Popular Topics](#) / [Does FDA Regulate Fluoride](#)

Does FDA Regulate Fluoride in Drinking Water?

The 1974 Safe Drinking Water Act gave regulatory oversight of public drinking water (tap water) to the U.S. Environmental Protection Agency (EPA). FDA has responsibility for ensuring that the quality standards for bottled water are compatible with EPA standards for tap water. According to the EPA, fluoride is voluntarily added to some drinking water systems as a public health measure to help reduce the incidence of cavities among the population. The decision to fluoridate a water supply is made by the State or local municipality, and is not mandated by EPA or any other Federal entity.

For more information, please see [EPA: Basic Information about Fluoride in Drinking Water](#).

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:
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 - 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.

Fluoridation of Public Water Systems: Federal, State, and Local Roles

Fluoride is a mineral found naturally in the environment, including in soil, rocks, and water. It can also be added to everyday products like toothpaste, mouthwash, and drinking water. Fluoride is commonly used to help prevent cavities and tooth decay.

Community Water Fluoridation is a public health practice used in many communities across the U.S. It involves adjusting the amount of fluoride in public drinking water to a level that helps reduce tooth decay. Some water systems naturally have fluoride; others may choose to add it.

Level of Government	Agency/Entity	Role in Water Fluoridation
Federal	U.S. Environmental Protection Agency (EPA)	Sets enforceable maximum contaminant levels (MCLs) for fluoride under the Safe Drinking Water Act; regulates public water systems for safety.
	U.S. Public Health Services (USPHS)	Recommends the optimal fluoride level (currently 0.7 mg/L); provides non-binding guidance for states and local governments on water fluoridation to promote oral health.
	U.S. Food and Drug Administration (FDA)	Regulates fluoride in consumer products (toothpaste, supplements, bottled water); coordinates with other agencies to ensure product safety and consumer protection.
	U.S. Department of Agriculture (USDA)	Tracks fluoride levels in food and beverages; provides dietary intake guidance.
State	Washington State Board of Health (Board)	Sets health and safety standards for Group A public water systems in Washington under chapter 246-290 WAC; establishes the optimal fluoride level for systems that practice water fluoridation; adopts federal MCL standards. The Board does not mandate or prevent community water fluoridation.
	Washington State Department of Health (Department)	Enforces the rules established in Chapter 246-290 WAC; conducted the Fluoride Science Review Panel to review the emerging science and provide recommendations to the Board for review.
Local	Public Water Systems / Local Governments	Make the final decision on whether to fluoridate water; implement fluoridation policies following state standards if chosen.

Fluoridation of Public Water Systems: Federal, State, and Local Roles

This fact sheet was developed by the State Board of Health policy staff as an educational resource for Board Members. It is intended solely for informational purposes and should not be considered or relied upon as legal advice.

Background:

Fluoride is a mineral that occurs naturally in the environment, including in soil, rocks, and water. Most drinking water sources contain some level of fluoride due to natural processes such as the breakdown of rocks and minerals.^{1,2} Fluoride may also be added to everyday products like toothpaste and to public drinking water in a controlled way to help prevent tooth decay.³

Community Water Fluoridation (CWF) is the practice of adjusting fluoride levels in public water systems to help reduce cavities.⁴ While some water systems may have naturally occurring fluoride, other systems choose to add it.⁵ Approximately 64% of the population in Washington State drinks water from a public water system that fluoridates.⁶

Decision-Making Authority for CWF:

- In the U.S., the decision to fluoridate public water systems is made at the state or local level.^{7,8}
- The federal government provides direction and guidance on the safety and effectiveness of CWF.
 - The U.S. Environmental Protection Agency (EPA) sets national safety standards for fluoride in drinking water (4.0 mg/L and 2.0 mg/L) under the [Safe Drinking Water Act](#) of 1974 (SDWA).
 - The U.S. Public Health Service (USPHS) recommends the optimal fluoride level in public water systems for systems that choose to fluoridate (currently 0.7 mg/L).
- In Washington State, decisions about whether to fluoridate public water systems are made at the local level, by public water systems or local governments.⁵
- [RCW 70.05.060 \(3\)](#) authorizes local boards of health to enact rules necessary to preserve and improve public health, including whether to require fluoridation of public water systems within their jurisdiction ([AGO 2008 No. 5](#)).
- In addition, [RCW 57.08.012](#) authorizes fluoridation of a water district's water by a majority vote of water district commissioners.
- If communities choose to fluoridate, they must follow public water system rules set by the Washington State Board of Health (Board).

State Board of Health's (Board) Role:

- State law ([RCW 43.20.050](#)) requires the Board to set health and safety standards for public water systems to ensure safe drinking water.
- Under this regulatory authority, the Board:
 - Sets the *optimal fluoride level* for large public water systems (Group A) that choose to fluoridate. This is established in state rule ([WAC 246-290-460](#)) and is currently aligned with [the U.S. Public Health Service \(USPHS\) recommendation](#) of 0.7 mg/L (last updated in 2015).

- Adopts the maximum contaminant level (MCL) for fluoride in drinking water ([WAC 246-290-310](#)), consistent with federal standards. This determines the highest allowable concentration of fluoride before a water system must take corrective action. The MCL adopted by the Board must be at least as stringent as the MCL established in the SDWA.
- These are two distinct regulatory authorities:
 - The *optimal fluoride level* supports public health benefits for systems that choose to fluoridate.
 - The *MCL* addresses potential health risks from fluoride, whether from natural sources or added sources that exceed the optimal level.
- The optimal level is based on guidance from USPHS, while the MCL is based on standards set by the U.S. Environmental Protection Agency (EPA).
- The Board does not require or ban fluoridation in its rules.

Federal Government's Role:

- The federal government's role in regulating water fluoridation is limited.⁷
- The two agencies primarily involved in CWF are: the Environmental Protection Agency (EPA) and the United States Public Health Service (USPHS).
- The federal government does not require communities to add or remove fluoride from drinking water, as long as levels stay below the EPA's Maximum Contaminant Level (MCL) of 4.0 mg/L.
- USPHS does not have the same public health authority as state or local governments to regulate water fluoridation. They only issue guidance. This guidance is not a regulation, and it is not legally binding.

Federal Agencies and their Roles:

U.S. Environmental Protection Agency (EPA)

- Regulates fluoride levels in public drinking water under the 1974 Safe Drinking Water Act (SDWA).⁹
- Sets both primary (enforceable) and secondary (non-enforceable) standards for fluoride in drinking water.⁷
 - The primary standard sets the maximum contaminant level (MCL) at 4.0 mg/L to protect against health risks.¹⁰
 - The secondary standard sets the MCL at 2.0 mg/L as a guideline, primarily to address cosmetic concerns such as tooth discoloration.¹¹
- Focuses on managing fluoride concentrations that pose health risks, whether naturally occurring or added and exceeding the optimal level.⁷

U.S. Public Health Service (USPHS)

- Part of the U.S. Department of Health and Human Services (HHS), USPHS includes the Centers for Disease Control (CDC), Food and Drug Administration (FDA), and Agency for Toxic Substances and Disease Registry (ATSDR).
- Recommends the *optimal fluoride level* in public water systems that choose to fluoridate (currently 0.7 mg/L) to prevent tooth decay while minimizing health risks.

- Provides *guidance and recommendations* to support state and local decision-making on fluoridation. These are not enforceable standards.^{4,7}

U.S. Food and Drug Administration (FDA)

- Also under HHS – oversees the safety and effectiveness of fluoride in consumer products such as toothpaste, mouthwash, and dietary supplements.¹² This authority is granted through the Food, Drug, and Cosmetic Act (FD&C Act).¹³
- Sets labeling and safety standards for fluoride-containing products sold to the public.
- Coordinates with the CDC, EPA, and USDA to ensure product safety and consumer protection under the FD&C Act.
- Regulates fluoride as an over-the-counter drug when it is intended to prevent or treat disease. In the case of fluoride, the disease is tooth decay.^{14,15}
- Regulates fluoride levels in bottled water and ensures that those standards are compatible with EPA regulations for public drinking water. When the EPA sets a new standard for a contaminant, the FDA either adopts the same standard for bottled water or determines it is not necessary.¹⁶
- Regulates fluoride levels in bottled water but does not regulate fluoride in public drinking water—that role belongs to the EPA under the SDWA.

U.S. Department of Agriculture (USDA)

- Oversees farming, food safety, and national nutrition programs.¹⁷
- Collects and shares data on fluoride levels in food and beverages.^{18,19}
- Provides dietary guidance through tools like the National Nutrient Database and the Dietary Reference Intakes (DRIs), which consider fluoride intake from food sources.
- Agency does *not* regulate fluoride in drinking water or consumer products.

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³Centers for Disease Control and Prevention. About Fluoride. Oral Health. May 23, 2024. Accessed July 22, 2025. <https://www.cdc.gov/oral-health/prevention/about-fluoride.html>

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⁷The Network for Public Health Law. Federal Regulation of Fluoride in Drinking Water. Oral Health Fact Sheet. Accessed July 22, 2025. <https://www.networkforphl.org/wp-content/uploads/2025/06/Federal-Regulation-of-Fluoride-in-Drinking-Water-1.pdf>

⁸ Michaud J, Kates J, Published NN. Water Fluoridation in the U.S.: The Federal Role in Policy and Practice. KFF. December 13, 2024. Accessed July 22, 2025. <https://www.kff.org/other/issue-brief/water-fluoridation-in-the-u-s-the-federal-role-in-policy-and-practice/>

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¹⁰ US Environmental Protection Agency O. National Primary Drinking Water Regulations. November 30, 2015. Accessed July 22, 2025. <https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations>

¹¹ US Environmental Protection Agency O. Secondary Drinking Water Standards: Guidance for Nuisance Chemicals. September 2, 2015. Accessed July 22, 2025. <https://www.epa.gov/sdwa/secondary-drinking-water-standards-guidance-nuisance-chemicals>

¹² Food and Drug Administration. What does FDA regulate? FDA. March 29, 2024. Accessed July 22, 2025. <https://www.fda.gov/about-fda/what-we-do/what-does-fda-regulate>

¹³ Library of Congress. Enforcement of the Food, Drug, and Cosmetic Act: Select Legal Issues. February 9, 2018. Accessed July 22, 2025. <https://www.congress.gov/crs-product/R43609>

¹⁴ Food and Drug Administration. Classification of Products as Drugs and Devices and Additional Product Classification Issues. May 12, 2021. Accessed July 22, 2025. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/classification-products-drugs-and-devices-and-additional-product-classification-issues>

¹⁵ Food and Drug Administration. Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?). FDA. September 11, 2024. Accessed July 22, 2025. <https://www.fda.gov/cosmetics/cosmetics-laws-regulations/it-cosmetic-drug-or-both-or-it-soap>

¹⁶ Food and Drug Administration. Bottled Water Everywhere: Keeping it Safe. Food and Drug Administration. April 22, 2022. Accessed July 22, 2025. <https://www.fda.gov/consumers/consumer-updates/bottled-water-everywhere-keeping-it-safe>

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Understanding Community Water Fluoridation (CWF): State and Federal Roles - Frequently Asked Questions

This document was prepared by the State Board of Health policy staff as a plain-language educational resource for Board Members and the general public. It is provided for informational purposes only and does not constitute legal advice.

What is fluoride?

Fluoride is a mineral found naturally in the environment, including in soil, rocks, and water. It can also be added to everyday products like toothpaste, mouthwash, and drinking water. Fluoride is commonly used to help prevent cavities and tooth decay.

What is community water fluoridation (CWF)?

CWF is a public health practice used in many communities across the U.S. It involves adjusting the amount of fluoride in public drinking water to a level that helps reduce tooth decay. Some water systems naturally have fluoride; others may choose to add it.

Who decides whether to start or stop CWF?

In the U.S., the decision to fluoridate public water systems is made at the state or local level.

In Washington State, the decision to fluoridate drinking water is made at the local level by each public water system or local government.

If a community decides to add fluoride, it must follow the rules set by the Washington State Board of Health (or “Board”). The Washington State Department of Health is responsible for enforcing these rules through its Drinking Water Program.

What is the role of the State Board of Health in CWF?

State law (RCW 43.20.050) requires the Board to set health and safety standards for public water systems to ensure safe and reliable drinking water.

Does the Board of Health require CWF?

No. The Washington State Board of Health does not require or ban water fluoridation. It is up to each public water system or local government to decide whether to fluoridate.

The Board has set an optimal fluoride concentration level of 0.7 milligrams per liter (mg/L) in state rule (WAC 246-290-460). This rule applies to large (Group A) public water systems that choose to fluoridate.

What role does the federal government play in CWF?

The federal government sets national safety standards for fluoride in drinking water under the Safe Drinking Water Act of 1974 (SDWA) through the Environmental Protection Agency (EPA).

Two federal agencies are mainly involved in CWF: the Environmental Protection Agency (EPA) and the United States Public Health Service (USPHS).

The federal government does not require communities to add or remove fluoride from drinking water if levels stay below the EPA's limit of 4.0 milligrams per liter (mg/L). This limit is also called the Maximum Contaminant Level (MCL).

The USPHS recommends a fluoridation level of 0.7 mg/L for water systems that choose to fluoridate.

Communities have made decisions about fluoridation since 1945, when Grand Rapids, Michigan, became the first U.S. city to fluoridate its water.

Other federal agencies, such as the Food and Drug Administration (FDA), regulate fluoride when it is added to consumer products like toothpaste, mouthwash, and dietary supplements.

Which federal agencies are involved in CWF and what do they do?

U.S. Environmental Protection Agency (EPA)

- Regulates fluoride levels in public drinking water under the Safe Drinking Water Act.
- Sets the enforceable safety limit at 4.0 mg/L to protect against health effects from too much fluoride, whether naturally occurring or added in excess of the optimal level.
- Focuses on the level of fluoride that presents a health risk.

U.S. Public Health Service (USPHS)

- Part of the U.S. Department of Health and Human Services (HHS), USPHS includes the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and Agency for Toxic Substances and Disease Registry (ATSDR).
- Recommends the optimal fluoride level in drinking water (0.7 mg/L) to help prevent tooth decay while minimizing health risks.
- Provides scientific guidance to support state and local public health decisions.

U.S. Food and Drug Administration (FDA)

- Part of HHS that works to ensure the safety and effectiveness of medicines, vaccines, medical devices, and other health-related products. They also oversee the safety of some food, cosmetics, dietary supplements, and more.
- Responsible for making sure fluoride is safe and effective when used in consumer products. This includes toothpaste, mouthwash, fluoride supplements, and other over-the-counter dental products.
- Sets standards for how consumer products are labeled and ensures they meet safety and quality requirements before they are sold to the public.
- Does not regulate fluoride levels in public drinking water.

U.S. Department of Agriculture (USDA)

- Oversees farming, food safety, and nutrition programs.
- Collects and shares data on fluoride levels in food and beverages.
- Supports nutrition and public health guidance that considers fluoride intake from dietary sources.
- Does not regulate fluoride levels in public drinking water or consumer products.

Why is there recent increased attention on CWF and fluoride?

There is growing national attention on fluoridation due to:

- New scientific studies
- A recent federal court ruling
- Ongoing discussions at the federal level

What's happening at the federal level regarding CWF or fluoride?

In April 2025, the EPA announced it would review new scientific data on fluoride health risks, following a court order. This ruling did not ban fluoride or require any immediate changes. As of August 2025, the EPA has not taken formal action or provided updates on this work.

In May 2025, the FDA announced it is beginning the process to possibly remove ingestible fluoride prescription drug products for children from the market. The FDA plans to finish a safety review and collect public feedback by October 31, 2025.

Is anything changing in Washington State regarding CWF?

No. CWF remains a local decision. The Board will continue monitoring federal developments in collaboration with the Department of Health. The Board will also:

- Receive updates on the latest science and evidence from the Department of Health's Fluoride Science Review Panel.
- Provide updates as new information becomes available.

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Date: October 8, 2025

To: Washington State Board of Health Members

From: Paj Nandi, Board Member

Subject: Rules Briefing—Group A Public Water Supplies, [WAC 246-290-315\(8\)](#) PFAS
Emergency Rulemaking—Possible Action

Background and Summary:

[RCW 43.20.030\(2\)\(a\)](#) grants the Washington State Board of Health (Board) authority to adopt rules for Group A public water systems that are necessary to assure safe and reliable drinking water and to protect public health.

In October 2021, the Board adopted drinking water state action levels (SALs) for per- and polyfluoroalkyl substances (PFAS) in [chapter 246-290 WAC](#), Group A Public Water Supplies and related provisions in [chapter 246-390 WAC](#), Drinking Water Laboratory Certification and Data Reporting. WAC 246-290-315 includes criteria for monitoring, reporting, follow-up actions, and public notification relevant to SALs.

On June 12, 2024, the Board adopted emergency rules to correct criteria in the rule that apply when the Environmental Protection Agency (EPA) adopts a federal maximum contaminant level (MCL) for a contaminant that has a state action level set in rule. Before the change, WAC 246-290-315(8) said that upon *adoption* of a federal MCL, the MCL will supersede a SAL, and the associated requirements, including for monitoring and public notice.

The emergency rulemaking, filed as [WSR 24-14-016](#), changed this to state that *when a federal MCL becomes effective*, the MCL will supersede a SAL and its requirements. This change ensures that the protections Washington currently has in place for the SALs remain in place until the federal MCLs become effective in April 2029. Emergency rules remain in effect for 120 days, and the emergency rule will expire before the hearing date of November 19, 2025, when the Board will decide whether to adopt permanent revisions.

Today, Shay Bauman, Board staff, will brief the Board on the impacts of the emergency rule and provide a recommendation.

Recommended Board Actions:

The Board may wish to consider and amend, if necessary, the following motions:

The Board directs staff to do the following:

- File a CR-103E to initiate rulemaking for WAC 246-290-315, to continue to clearly maintain the SALs and associated requirements until the federal standards are effective.

Staff

Shay Bauman, Policy Advisor

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WAC 246-290-315(8) – PFAS Emergency Rulemaking

Shay Bauman, Policy Advisor
October 8, 2025

WASHINGTON STATE 
BOARD OF HEALTH

Current Rule

WAC 246-290-315(8): State action levels (SALs) and state maximum contaminant levels (MCLs).

(8) Upon federal adoption of an MCL, the federal MCL will supersede a SAL or a less stringent state MCL, and the associated requirements, including for monitoring and public notice. If the federally adopted MCL is less stringent than a SAL or state MCL, the board may take one of the following actions:

- (a) Adopt the federal MCL; or
- (b) Adopt a state MCL, at least as stringent as the federal MCL, using the process in subsections (6) and (7) of this section.



Current rule will lapse before federal rules become effective.

Emergency Rules expire 120 days after they go into effect.

- Fourth emergency Rule adopted and effective on June 19, 2025
- Rule expires Friday, October 17, 2025

Recommendation:

- Initiate emergency rulemaking to continue to clearly maintain the SALs and associated requirements.
 - Anticipated effective date October 18, 2025.
 - Hearing to consider permanent revisions scheduled for November 19, 2025.

Federal Rule Provisions	Effective Date
• Analytical Requirements*	June 25, 2024
• Consumer confidence reporting* • Ongoing compliance monitoring* • Reporting and recordkeeping* • Initial monitoring results reporting • Public notification for testing and procedure violations	April 26, 2027
• PFAS MCL violations • MCL compliance requirements • 30-day Public Notification for MCL violations*	April 26, 2029

Proposed Language

~~Upon federal adoption of an MCL, the federal~~ When a federal MCL becomes effective, the MCL will supersede a SAL or a less stringent state MCL, and the associated requirements, including for monitoring and public notice. If the federally adopted MCL is less stringent than a SAL or state MCL, the board may take one of the following actions:

- (a) Adopt the federal MCL; or
- (b) Adopt a state MCL, at least as stringent as the federal MCL, using the process in subsections (6) and (7) of this section.

Action Item:
Proceed with emergency rulemaking?



Questions?

THANK YOU

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RULE-MAKING ORDER EMERGENCY RULE ONLY

CR-103E (December 2017)
(Implements RCW 34.05.350
and 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: June 18, 2025
TIME: 8:30 AM

WSR 25-13-104

Agency: State Board of Health

Effective date of rule:

Emergency Rules

- ☒ Immediately upon filing.
☐ Later (specify)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

☐ Yes ☒ No If Yes, explain:

Purpose: Testing of drinking water contaminants - State action levels (SALs) and state maximum contaminant levels (MCLs) in WAC 246-290-315.

The State Board of Health (board) has authority under RCW 43.20.050 to adopt rules for group A public water systems that are necessary to assure safe and reliable public drinking water and to protect the public health. Chapter 246-290 WAC, Group A Public Water Supplies, establishes standards and requirements for these water systems. The Department of Health (department) administers the rules.

To ensure safe drinking water, water must be tested for contaminants. The board establishes SALs and MCLs to ensure contaminate levels are below a certain threshold. The board sets criteria for the adoption of SALs and MCLs in WAC 246-290-315, and includes criteria that would apply upon federal adoption of MCLs. WAC 246-290-315(8) states that upon federal adoption of a MCL, the MCL will supersede a less stringent SAL and associated requirements, including monitoring and public notice.

The EPA published new federal standards for per- and polyfluoroalkyl substances (PFAS) on April 10, 2024, with an adoption date of June 25, 2024. These new standards include MCLs. This affects the board's rule and triggers the provision in WAC 246-290-315(8). The federal standards, however, have delayed effective dates for criteria and public health protections that are currently in place for Washington. According to the Washington state rules associated with the SALs, public water systems must notify customers of detections of PFAS above the SAL within 30 days of that detection. This is necessary to allow people the opportunity to protect themselves by using bottled water, securing a filter, or taking other measures. 30-day public notification is not effective for MCLs in the federal standard until April 2029. Without this amendment to WAC 246-290-315, customers served by group A public water systems will no longer be notified of dangerous levels of PFAS in their drinking water, which is a significant reduction in protections.

The board adopted an emergency rule on June 12, 2024, to amend WAC 246-290-315 such that the criteria would apply on the effective date of an MCL as set in the federal standard, not the adoption date, in order to maintain vital public health protections for drinking water safety. Along with the emergency rulemaking, the board initiated a permanent rulemaking to amend the rule language to align with the emergency provision and explore other protections. The CR-101, Preproposal Statement of Inquiry, for the permanent rulemaking was filed as WSR 24-20-093 on September 30, 2024. This 4th emergency rule continues the emergency rule originally filed on June 24, 2024 as WSR 24-14-016 and extended on October 22, 2024 and February 19, 2025 as WSR 24-21-138 and WSR 25-05-095, respectively, without change.

Citation of rules affected by this order:

New: None

Repealed: None

Amended: WAC 246-290-315

Suspended: None

Statutory authority for adoption: RCW 43.20.050(2)(a)**Other authority:** None**EMERGENCY RULE**

Under RCW 34.05.350 the agency for good cause finds:

- ☒ That immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.
- ☐ That state or federal law or federal rule or a federal deadline for state receipt of federal funds requires immediate adoption of a rule.

Reasons for this finding: The federal adoption date of the standards was June 25, 2024, at which point the MCLs and relative protections would have superseded the SALs. Because of the delayed effective date, currently active public health protections would have ended on that date. The Board finds that emergency adoption of this rule is necessary to preserve public health.

**Note: If any category is left blank, it will be calculated as zero.
No descriptive text.**

**Count by whole WAC sections only, from the WAC number through the history note.
A section may be counted in more than one category.**

The number of sections adopted in order to comply with:

Federal statute:	New 0	Amended 0	Repealed 0
Federal rules or standards:	New 0	Amended 0	Repealed 0
Recently enacted state statutes:	New 0	Amended 0	Repealed 0

The number of sections adopted at the request of a nongovernmental entity:

New 0	Amended 0	Repealed 0

The number of sections adopted on the agency's own initiative:

New 0	Amended 1	Repealed 0

The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New 0	Amended 0	Repealed 0

The number of sections adopted using:

Negotiated rule making:	New 0	Amended 0	Repealed 0
Pilot rule making:	New 0	Amended 0	Repealed 0
Other alternative rule making:	New 0	Amended 1	Repealed 0

Date Adopted: June 18, 2025

Name: Michelle Davis, MPA

Title: Executive Director, Washington State Board of Health

Signature:



WAC 246-290-315 State action levels (SALs) and state maximum contaminant levels (MCLs). (1) The department shall consider the following criteria to select a contaminant for developing a SAL:

(a) Drinking water contributes to human exposure to the contaminant.

(b) The contaminant is known or likely to occur in public water systems at levels of public health concern. Sources of occurrence information include, but are not limited to:

(i) Washington state department of agriculture;

(ii) Washington state department of ecology; and

(iii) Monitoring results reported in accordance with 40 C.F.R. 141.35.

(c) The contaminant has a possible adverse effect on the health of persons exposed based on peer-reviewed scientific literature or government publications, such as:

(i) An EPA health assessment such as an Integrated Risk Information System assessment;

(ii) Agency for Toxic Substances and Disease Registry toxicological profiles;

(iii) State government science assessment; and

(iv) EPA guidelines for exposure assessment such as the EPA exposure factors handbook.

(d) A certified drinking water lab can accurately and precisely measure the concentration of the contaminant in drinking water at and below the level of public health concern using EPA-approved analytical methods.

(2) After consideration of the criteria in subsection (1) of this section, the department may develop a SAL based on the following:

(a) Evaluation of available peer-reviewed scientific literature and government publications on fate, transport, exposure, toxicity and health impacts of the contaminant and relevant metabolites;

(b) An assessment based on the most sensitive adverse effect deemed relevant to humans and considering susceptibility and unique exposures of the most sensitive subgroup such as pregnant women, fetuses, young children, or overburdened and underserved communities; and

(c) Technical limitations to achieving the SAL such as insufficient analytical detection limit achievable at certified drinking water laboratories.

(3) The state board of health shall consider the department's findings under subsections (1) and (2) of this section when considering adopting a SAL under this chapter.

(4) Contaminants with a SAL.

(a) If a SAL under Table 9 of this section is exceeded, the purveyor shall take follow-up action as required under WAC 246-290-320. For contaminants where the SAL exceedance is determined based upon an RAA, the RAA will be calculated consistent with other organic contaminants per WAC 246-290-320(6) or other inorganic contaminants per WAC 246-290-320(3).

TABLE 9
STATE ACTION LEVELS

Contaminant or Group of Contaminants	SAL	SAL Exceedance Based On:
Per- and polyfluoroalkyl substances (PFAS)		
PFOA	10 ng/L	Confirmed detection
PFOS	15 ng/L	Confirmed detection
PFHxS	65 ng/L	Confirmed detection
PFNA	9 ng/L	Confirmed detection
PFBS	345 ng/L	Confirmed detection

(b) If a system fails to collect and submit a confirmation sample to a certified lab within ten business days of notification of the sample results, or as required by the department, the results of the original sample will be used to determine compliance with the SAL.

(5) The department shall consider the following when developing a state MCL:

(a) The criteria in subsection (1) of this section;

(b) Whether regulating the contaminant presents a meaningful opportunity to reduce exposures of public health concern for persons served by public water systems;

(c) The need for an enforceable limit to achieve uniform public health protection in Group A public water systems; and

(d) The need for an enforceable limit to support source water investigation and clean-up of a contaminant in drinking water supplies by responsible parties.

(6) In addition to the requirements in subsection (5) of this section, the department shall:

(a) Meet the requirements of subsection (2) of this section;

(b) Comply with the requirements in RCW 70A.130.010 to establish standards for chemical contaminants in drinking water;

(c) Consider the best available treatment technologies and affordability taking into consideration the costs to small water systems; and

(d) Determine that the probable benefits of the rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs.

(7) The state board of health shall consider the department's findings under subsections (5) and (6) of this section and follow the requirements under chapters 34.05 and 19.85 RCW when adopting a state MCL under this chapter.

(8) (~~Upon federal adoption of an MCL~~) When a federal MCL takes effect, the federal MCL will supersede a SAL or a less stringent state MCL, and the associated requirements, including for monitoring and public notice. If the federally adopted MCL is less stringent than a SAL or state MCL, the board may take one of the following actions:

(a) Adopt the federal MCL; or

(b) Adopt a state MCL, at least as stringent as the federal MCL, using the process in subsections (6) and (7) of this section.

RCW 43.20.050 Powers and duties of state board of health—Rule making—Delegation of authority—Enforcement of rules. (1) The state board of health shall provide a forum for the development of public health policy in Washington state. It is authorized to recommend to the secretary means for obtaining appropriate citizen and professional involvement in all public health policy formulation and other matters related to the powers and duties of the department. It is further empowered to hold hearings and explore ways to improve the health status of the citizenry.

In fulfilling its responsibilities under this subsection, the state board may create ad hoc committees or other such committees of limited duration as necessary.

(2) In order to protect public health, the state board of health shall:

(a) Adopt rules for group A public water systems, as defined in RCW 70A.125.010, necessary to assure safe and reliable public drinking water and to protect the public health. Such rules shall establish requirements regarding:

(i) The design and construction of public water system facilities, including proper sizing of pipes and storage for the number and type of customers;

(ii) Drinking water quality standards, monitoring requirements, and laboratory certification requirements;

(iii) Public water system management and reporting requirements;

(iv) Public water system planning and emergency response requirements;

(v) Public water system operation and maintenance requirements;

(vi) Water quality, reliability, and management of existing but inadequate public water systems; and

(vii) Quality standards for the source or supply, or both source and supply, of water for bottled water plants;

(b) Adopt rules as necessary for group B public water systems, as defined in RCW 70A.125.010. The rules shall, at a minimum, establish requirements regarding the initial design and construction of a public water system. The state board of health rules may waive some or all requirements for group B public water systems with fewer than five connections;

(c) Adopt rules and standards for prevention, control, and abatement of health hazards and nuisances related to the disposal of human and animal excreta and animal remains;

(d) Adopt rules controlling public health related to environmental conditions including but not limited to heating, lighting, ventilation, sanitary facilities, and cleanliness in public facilities including but not limited to food service establishments, schools, recreational facilities, and transient accommodations;

(e) Adopt rules for the imposition and use of isolation and quarantine;

(f) Adopt rules for the prevention and control of infectious and noninfectious diseases, including food and vector borne illness, and rules governing the receipt and conveyance of remains of deceased persons, and such other sanitary matters as may best be controlled by universal rule; and

(g) Adopt rules for accessing existing databases for the purposes of performing health related research.

(3) The state board shall adopt rules for the design, construction, installation, operation, and maintenance of those

on-site sewage systems with design flows of less than three thousand five hundred gallons per day.

(4) The state board may delegate any of its rule-adopting authority to the secretary and rescind such delegated authority.

(5) All local boards of health, health authorities and officials, officers of state institutions, police officers, sheriffs, constables, and all other officers and employees of the state, or any county, city, or township thereof, shall enforce all rules adopted by the state board of health. In the event of failure or refusal on the part of any member of such boards or any other official or person mentioned in this section to so act, he or she shall be subject to a fine of not less than fifty dollars, upon first conviction, and not less than one hundred dollars upon second conviction.

(6) The state board may advise the secretary on health policy issues pertaining to the department of health and the state. [2021 c 65 s 37; 2011 c 27 s 1; 2009 c 495 s 1; 2007 c 343 s 11; 1993 c 492 s 489; 1992 c 34 s 4. Prior: 1989 1st ex.s. c 9 s 210; 1989 c 207 s 1; 1985 c 213 s 1; 1979 c 141 s 49; 1967 ex.s. c 102 s 9; 1965 c 8 s 43.20.050; prior: (i) 1901 c 116 s 1; 1891 c 98 s 2; RRS s 6001. (ii) 1921 c 7 s 58; RRS s 10816.]

Explanatory statement—2021 c 65: See note following RCW 53.54.030.

Effective date—2009 c 495: "Except for section 9 of this act, this act is necessary for the immediate preservation of the public peace, health, or safety, or support of the state government and its existing public institutions, and takes effect immediately [May 14, 2009]." [2009 c 495 s 17.]

Findings—1993 c 492: "The legislature finds that our health and financial security are jeopardized by our ever increasing demand for health care and by current health insurance and health system practices. Current health system practices encourage public demand for unneeded, ineffective, and sometimes dangerous health treatments. These practices often result in unaffordable cost increases that far exceed ordinary inflation for essential care. Current total health care expenditure rates should be sufficient to provide access to essential health care interventions to all within a reformed, efficient system.

The legislature finds that too many of our state's residents are without health insurance, that each year many individuals and families are forced into poverty because of serious illness, and that many must leave gainful employment to be eligible for publicly funded medical services. Additionally, thousands of citizens are at risk of losing adequate health insurance, have had insurance canceled recently, or cannot afford to renew existing coverage.

The legislature finds that businesses find it difficult to pay for health insurance and remain competitive in a global economy, and that individuals, the poor, and small businesses bear an inequitable health insurance burden.

The legislature finds that persons of color have significantly higher rates of mortality and poor health outcomes, and substantially lower numbers and percentages of persons covered by health insurance than the general population. It is intended that chapter 492, Laws of

1993 make provisions to address the special health care needs of these racial and ethnic populations in order to improve their health status.

The legislature finds that uncontrolled demand and expenditures for health care are eroding the ability of families, businesses, communities, and governments to invest in other enterprises that promote health, maintain independence, and ensure continued economic welfare. Housing, nutrition, education, and the environment are all diminished as we invest ever increasing shares of wealth in health care treatments.

The legislature finds that while immediate steps must be taken, a long-term plan of reform is also needed." [1993 c 492 s 101.]

Intent—1993 c 492: "(1) The legislature intends that state government policy stabilize health services costs, assure access to essential services for all residents, actively address the health care needs of persons of color, improve the public's health, and reduce unwarranted health services costs to preserve the viability of nonhealth care businesses.

(2) The legislature intends that:

(a) Total health services costs be stabilized and kept within rates of increase similar to the rates of personal income growth within a publicly regulated, private marketplace that preserves personal choice;

(b) State residents be enrolled in the certified health plan of their choice that meets state standards regarding affordability, accessibility, cost-effectiveness, and clinical efficaciousness;

(c) State residents be able to choose health services from the full range of health care providers, as defined in RCW 43.72.010(12), in a manner consistent with good health services management, quality assurance, and cost effectiveness;

(d) Individuals and businesses have the option to purchase any health services they may choose in addition to those included in the uniform benefits package or supplemental benefits;

(e) All state residents, businesses, employees, and government participate in payment for health services, with total costs to individuals on a sliding scale based on income to encourage efficient and appropriate utilization of services;

(f) These goals be accomplished within a reformed system using private service providers and facilities in a way that allows consumers to choose among competing plans operating within budget limits and other regulations that promote the public good; and

(g) A policy of coordinating the delivery, purchase, and provision of health services among the federal, state, local, and tribal governments be encouraged and accomplished by chapter 492, Laws of 1993.

(3) Accordingly, the legislature intends that chapter 492, Laws of 1993 provide both early implementation measures and a process for overall reform of the health services system." [1993 c 492 s 102.]

Short title—Savings—Reservation of legislative power—Effective dates—1993 c 492: See RCW 43.72.910 through 43.72.915.

Severability—1992 c 34: See note following RCW 69.07.170.

Effective date—Severability—1989 1st ex.s. c 9: See RCW 43.70.910 and 43.70.920.

Savings—1985 c 213: "This act shall not be construed as affecting any existing right acquired or liability or obligation incurred under the sections amended or repealed in this act or under any rule, regulation, or order adopted under those sections, nor as affecting any proceeding instituted under those sections." [1985 c 213 s 31.]

Effective date—1985 c 213: "This act is necessary for the immediate preservation of the public peace, health, and safety, the support of the state government and its existing public institutions, and shall take effect June 30, 1985." [1985 c 213 s 33.]

Severability—1967 ex.s. c 102: See note following RCW 43.70.130.

Rules and regulations—Visual and auditory screening of pupils: RCW 28A.210.020.

School Environmental Health and Safety Rule 2024-2025

Recommended New Draft Rule Frequently Asked Questions

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The New Draft Rule

Chapter 246-370 WAC sets minimum environmental health and safety standards for schools. The new draft rule will establish modern, statewide standards for K-12 school facilities. Chapter 246-370 WAC is intended to replace the current chapter 246-366 WAC, which is over 60 years old.

Q Why is this new rule needed?

- A The current rule (chapter 246-366 WAC) is outdated and is not based on the most recent science or building and operating standards. The changes in the draft rule will help ensure that schools are healthier and safer places for children.

Q What is the phased implementation and why is the Board recommending it?

- A The State Board of Health (Board) has recommended phased implementation to balance student health and safety with cost mitigation for schools and local health jurisdictions. A phased approach will also allow the Board to review costs for each phase of rulemaking.
- Phase 1: Focuses on making plans and laying the foundation for future changes. Includes sections that do not make substantive changes to the rule, set out basic WAC structures (such as definition and applicability sections), and require the development of plans (such as the extreme temperature readiness plan).
- Phase 2: Focuses on activities that require collaboration between school officials and local health jurisdictions (such as inspections and assessments).
- Phase 3: Brings schools into full implementation, including new rule requirements such as specialized rooms.

Q Where can I read the new draft rule?

- A You can read the draft rule in the final report: [WAC 246-370 School Environmental Health and Safety Rule Report 2025-06-30 0.pdf](#). The draft rule text includes a key that identifies the implementation phase for each section.

School Environmental Health and Safety Rule 2024-2025

Q Which schools does this new rule apply to?

A This draft rule applies to all public and private school facilities that:

- Are operated for the primary purpose of providing K-12 education
- Include primary and secondary school facilities that offer preschool education or transition services

This draft rule does not apply to:

- State-Tribal education compact schools
- Facilities that are licensed and regulated by the Washington State Department of Children, Youth and Families, including preschools and daycare centers not associated with a K-12 schools
- Home-based schools

Funding

The technical advisory committee and the board identified funding as an important consideration for fully implementing the draft rule.

Q Where will funding come from to implement this rule?

A Public schools will need funding from the Legislature. Private schools rely on funding from private individuals and organizations (e.g. tuition, donations). Local health jurisdictions may be funded through federal, state, or county resources and some jurisdictions may collect fees from schools for inspections and reviews.

Q Where can I find more resources for funding?

A The [OSPI Policy & Funding](#) and [OSPI Grants](#) pages describe programs that are available to schools.

Q Which organizations may have information related to environmental health and safety?

A Organizations that may have additional resources and technical information include:

- Washington Association of Maintenance and Operation Administrators ([WAMOA](#))
- Washington Association of School Administrators ([WASA](#))
- Washington State Office of the Superintendent of Public Instruction ([OSPI](#))
- Washington State Department of Health ([DOH](#))
- U.S. Centers for Disease Control and Prevention ([CDC](#)).

School Environmental Health and Safety Rule 2024-2025**Rule Requirements**

The scope of the rule is specific to environmental health and safety within schools. In some cases, other rules address specific health and safety standards that apply to schools.

Q Is drinking water covered in this rule?

No. The quality of drinking water is not addressed in this rule. Drinking water requirements are covered by other rules and laws:

- [Chapter 246-290 WAC Group A Public Water Supplies](#)
- [Chapter 246-291 WAC Group B Drinking Water Systems](#)
- [RCW 28A.210.410 Lead contamination at drinking water outlets](#)
- [RCW 43.70.830 Lead contamination in drinking water in school buildings—Sampling and testing—Data-sharing agreement](#)

Q Does the rule address indoor air quality in schools?

A Yes. The draft rule includes a section on Indoor Air Quality and Ventilation. Phase 1 of the rule development plan requires schools to develop and implement written indoor air quality plans within five years of the effective date of the Indoor Air Quality and Ventilation rule section. Indoor air quality plans must include the identification of areas of concern, preventive measures to address those concerns, a routine inspection schedule for HVAC systems, an integrated pest management plan, a plan for ensuring health and safety when outdoor air quality is poor, and a plan to monitor and address carbon dioxide levels (CO₂), if applicable. Additional indoor air quality concerns will be addressed in Phase 3.

Q Will a school have to replace or install a new HVAC system to meet the rule requirements for indoor air quality?

Q No. A school will not have to replace or install a new HVAC under the draft rule. Schools must develop an indoor air quality plan and are encouraged to use the Department of Health guidelines to follow best practices. New construction may require an HVAC to meet temperature and indoor air quality standards.

Q What is an HVAC test and balance?

A The test and balance of an HVAC system involve measuring and balancing the heating, ventilation, and air conditioning systems. The goal is to achieve the right airflow, temperature, and humidity levels in a building or space. The process is typically done by certified professionals and requires specialized equipment to measure and adjust the HVAC systems. The draft rule requires testing and balancing every 15 years.

Q Do schools need to close when indoor temperatures are outside the ranges in the rule?

A No. The draft rule does not require schools to shut down at that point. Instead, schools must implement their extreme temperature readiness plan that they will develop with the help of the local health jurisdiction. The plan may include short-term solutions to address the temperature and additional temperature ranges that indicate when the school should close. The readiness plan is designed for the unique characteristics of each school facility.

School Environmental Health and Safety Rule 2024-2025

Q Are Corsi-Rosenthal Boxes an option to provide better indoor air quality?

- A The draft rule does not forbid or recommend Corsi-Rosenthal boxes. While these DIY filtration systems may be less expensive and more effective than retail room air filters, they are designed as a short-term solution to poor indoor air quality. Schools and local health jurisdictions should consider the following:
- Someone will need to replace the filters as frequently as every four months—replacement includes dismantling and rebuilding the box from scratch.
 - The boxes take up space in a classroom and may be an obstruction.
 - The sound from the fan can interfere with hearing—especially for those seated closest to the fan.
 - Higher-rated filters required by building code reduce the air circulation from the boxes.
 - The filters can remove particulates (such as smoke, pollen, and airborne pathogens) from the air but do not remove harmful gases (such as CO₂ or Radon).

Q Can teachers or parents bring household cleaning materials to school?

- A No. The draft rule requires that the school provide cleaning supplies that meet state and federal guidelines. Household cleaners may interact with other cleaners, causing a safety hazard, or may affect students with allergies or asthma.

Safety Concerns

The technical advisory committee identified that the effectiveness of this draft rule relies on the collaboration between schools, local health jurisdictions, teachers, parents, and students. Safety is everyone's concern.

Q What can I do if I see something that doesn't look safe or healthy?

- A Please contact your school first to see if they can resolve your concern, and then you may wish to contact the school district. Additional support may be available at your local [Educational Service District](#) or by reaching out to your local health jurisdiction. You may want to discuss your concerns with your School Board.

Q What if a school can't meet the standards?

- A The draft rule allows for variances and emergency waivers, and a process to appeal decisions of the local health officer. The phased implementation encourages collaboration between local health jurisdictions and schools to address more complex requirements.

Local Health Jurisdictions

The technical advisory committee recognized that local health jurisdictions vary in program capacity and services.

Q How do I contact my local health jurisdiction?

- A Visit [Washington State Local Health Jurisdictions](#) to find contact information by county.

School Environmental Health and Safety Rule 2024-2025

Q Where can I find fees charged by local health jurisdictions?

A Each local health jurisdiction sets their own fees. To learn more about yours, go to [Washington State Local Health Jurisdictions](#).

Q Where can schools get the forms, guidance, and training?

A The [Department of Health Schools](#) page offers guidance and key resources. Go to the [Health and Safety Guide for K-12 Schools in Washington State](#).

Related Rules

The technical advisory committee acknowledged that some considerations of health and safety are already addressed in other rules and laws.

Q What other health and safety rules have an impact on schools?

A The following rules may have an impact on school facilities:

- Chapter 246-215 WAC Food Service
- Chapter 246-217 WAC Food Worker Cards
- Chapter 246-260 WAC Water Recreation Facilities
- Chapter 246-262 WAC Recreational Water Contact Facilities
- Chapter 246-272A WAC On-site Sewage Systems
- Chapter 246-272B WAC Large On-site Sewage System Regulations
- Chapter 246-290 WAC Group A Public Water Supplies
- Chapter 246-291 WAC Group B Public Water Supplies
- RCW 43.70.830 through 43.70.845 Lead in Drinking Water in School Buildings

This is not a complete list of all rules that may affect schools. Schools are also subject to rules adopted by the Office of Superintendent of Public Instruction, and other state requirements including energy efficiency, worker safety, and state building code requirements.

Q Are there differences between this rule and to Labor & Industries (L&I) rules for protecting adults in the school?

A Yes, there are differences. L&I rules apply to all workplaces and protect employees in Washington State and fall under the Washington Industrial Safety & Health Act, chapter [49.17 RCW](#). While students may indirectly benefit from some of these requirements, L&I rules do not address their specific needs to ensure a healthy and safe learning environment. If the two rules have different requirements on the same topic, the more stringent of the two will apply.

Q How do these rules work with the Clean Building Performance Standard?

A Some of the draft rule requirements may result in increased energy use to meet the minimum health and safety standards for students. This may not meet the Clean Buildings Performance Standard. During the 2025 legislative session the Legislature amended the Clean Buildings Performance Standard to allow additional exemptions and extensions

School Environmental Health and Safety Rule 2024-2025

including financial hardship for K-12 schools and when a school is actively working to adhere to the school rules.

The Clean Buildings Performance Standard requires the Department of Commerce to establish rules for energy performance standards for covered commercial buildings, to collect data on compliance, and to report on outcomes. The standard is focused on maximizing reductions in greenhouse gas emissions from buildings and setting requirements for energy use intensity targets. Learn more about the [Clean Building Performance Standard](#) and Department of Commerce rule activities.

Q Is the K-12 Health and Safety Guide (K-12 Guide) more protective than the rule?

A The draft rule sets minimum requirements for health and safety. The K-12 Guide includes detailed best practices for how to meet or exceed those requirements. Schools that follow best practices within the guide may achieve healthier and safer school environments.

Q Can you share a list of state-approved vendors for projects related to these requirements?

A As a state agency, the Board cannot refer or recommend vendors. The Department of Enterprise Services website includes a [search for contracts](#) so you can see which vendors have an active contract with the state.



Updating School Health and Safety Standards

At the June 2025 State Board of Health meeting, the Board approved a report to the Governor and Legislature that recommends new draft rules for school environmental health and safety. The draft rule will establish updated minimum health and safety standards.



The Challenge

Since 2010, the state budget has prevented the Board from implementing updated health and safety rules for schools. Schools and local health jurisdictions remain subject to standards that are more than 60 years old. The outdated rules do not address modern environmental health concerns such as air quality.



A Collaborative Approach

In 2024, the Legislature directed the Board to review and propose updated minimum health and safety standards. The Board formed a technical advisory committee (TAC). The TAC included school representatives, the Office of the Superintendent of Public Instruction, the Department of Health, parent groups, and local health officials. Together, they drafted a legislative report with proposed rules, a fiscal analysis, and an environmental justice assessment.



Making a Difference

The new rule helps to foster partnerships between schools and local health agencies. It lets each school adjust to its own needs while keeping student safety and costs in check. For the first time, Washington will have indoor air quality requirements for schools to protect student health.

Phased Implementation

The legislative report recommends filing updated rules in phases to balance student safety and mitigate costs.

Phase 1

Modernizes safety standards by clarifying facility requirements, developing readiness plans for indoor air quality, radon testing, and extreme temperatures

Phase 2

Strengthens partnerships between schools and local health jurisdictions to better protect student health and safety

Phase 3

Includes remaining sections with new requirements such as specialized rooms and indoor air quality

Next Steps

If the Legislature lifts the proviso in 2026, we can begin the Phase 1 rulemaking as early as summer 2026.

The Board is committed to continuing conversations with interested and affected parties.





Who Does What?



Public & Private Schools

Provide and maintain clean and safe facilities



State Board of Health

Adopts environmental health and safety requirements for schools serving K-12 students



Local Health Jurisdictions

Inspect schools and respond to public health concerns

Washington Schools by the Numbers



1.2+ million

Students in Washington's public and private schools



180

Days per year students spend in school facilities

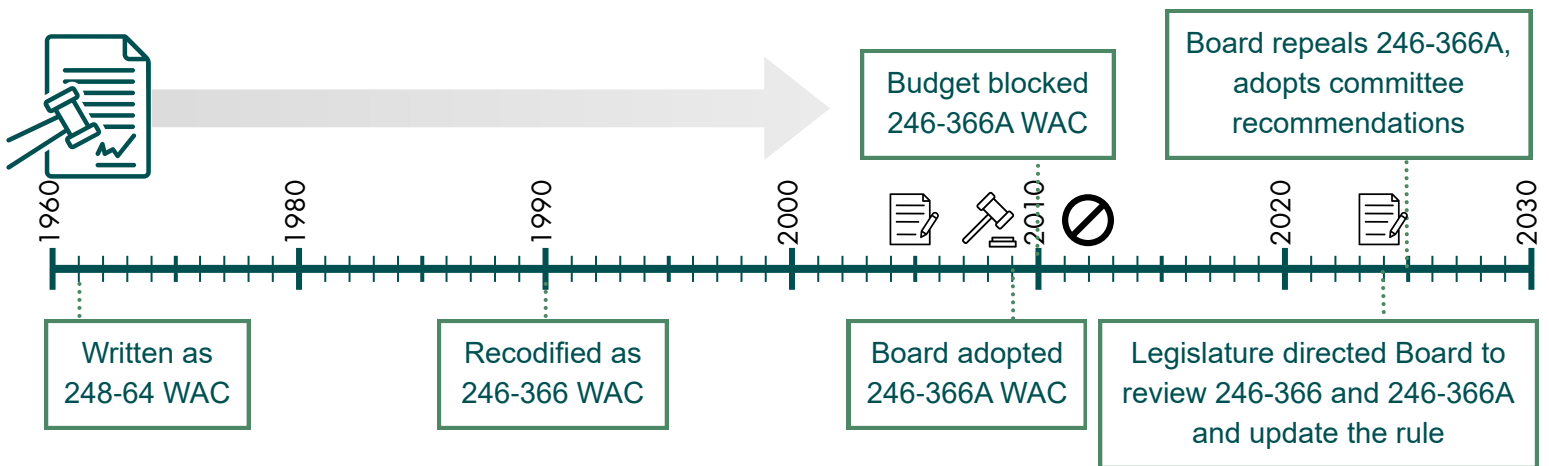


13,320

Hours students spend in schools over 13 years during their K-12 journey



Rulemaking Timeline



WASHINGTON STATE 
BOARD OF HEALTH

Contact Us: schoolehs@sboh.wa.gov

Learn More: [School Environmental Health and Safety Rule](#)

Scan QR Code



SBOH Public Meeting - October 8, 2025
Local Health and Community Focus



Dave Windom, Director

Dave brings a wide range of experience to Public Health. He worked 25 years in private business and served 27 years with the National Guard, including two tours of duty in Iraq. He initially started in environmental health in Okanogan before receiving his master's degree in health science and becoming Northeast Tri-county Health District's administrator in Colville. Dave's master's thesis examined the barriers to in-school childhood obesity interventions. Dave is now the Mason County Public Health and Human Services Director in Shelton, WA.

Dave participates in many community activities, including Mason Matters, Peninsula Community Health Services, CHOICE, his church, and the private school board. He is the current chair of the Public Health Executive Leadership Committee for Washington State and President of the Washington Rural Health Association. He has been a Rotarian for over 25 years and served as the Rotaplast photojournalist for a cleft palate and cleft lip mission to Cebu in the Philippines in 2011 and India in 2012. Dave now resides in Shelton with Brenda, his high school sweetheart and wife of 43 years.

Mason County Public Health and Human Services

VISION: A healthy Mason County

MISSION: Promote health in Mason County through education, prevention, protection and preparedness

Date: October 8, 2025

To: Washington State Board of Health Members

From: Michelle Davis, Executive Director

Subject: Health Impact Review Records Retention Policy

Background and Summary:

The Washington State Secretary of State publishes the [State Government General Records Retention Schedule](#). All state agencies are required to follow the State Government General Records Retention Schedule for the destruction/transfer of public records under [Chapter 40.14 RCW](#). The State Government General Records Retention Schedule is intended to be used with other approved schedules that relate to unique functions of a state agency.

The Washington State Board of Health (Board) follows the State Government General Records Retention Schedule and the Department of Health's (Department's) approved schedule. The Board also maintains a Records Retention Guide for records that are unique to the Board.

The Board's Health Impact Review (HIR) reports fall under the State Government General Records Retention Schedule Disposition Authority Number (DAN) GS 19004 (page 46), which is related to reporting to external agencies. The schedule for DAN GS 19004 is: retain for six years, then destroy. Based on this schedule, HIR reports would be eligible for destruction after six years.

Board staff identified the need to retain HIR reports and underlying source material (e.g., EndNote library, journal articles, strength-of-evidence ratings) beyond six years.

- The Board's website serves as the only archive for completed HIRs. Legislators, the Governor's Office, and other interested parties access previously completed HIRs on the Board's HIR webpage.
- Decision-makers reference previous HIRs when working on related proposals or policy topics.
- HIR staff refer to previously completed HIRs for reference and templates.
- Decision-makers request HIRs on proposals or policy topics related to previously completed HIRs.
- Legislative proposals may span multiple Legislative Sessions. Decision-makers request HIRs, or updates to previous HIRs, on proposals or topics that span multiple Legislative Sessions or biennia.

Based on conversations with the Department's Records and Information Officer, no other State Government General Records Retention Schedule would apply to or be appropriate for HIR reports, so it is not possible to update the DAN for HIRs. However, based on the need to retain HIR reports and underlying source material beyond 6 years, the Department's Records and Information Officer suggested the Board write a specific HIR Records Retention Policy.

Board staff are recommending the Board adopt a policy to retain HIRs and underlying source material for six years and then convert these documents to reference material to retain as convenience/reference copies.

In your materials, staff have drafted the Health Impact Review Records Retention policy (Draft Policy 2025-001) for your consideration.

Recommended Board Action:

The Board may wish to consider and amend, if necessary, the following motion:

The Board adopts Draft Policy 2025-001 specific to Health Impact Review Records Retention (*including any changes discussed today*) and directs staff to formalize the policy and incorporate the policy into the Board's Records Retention Guide.

Staff

Lindsay Herendeen, Policy Analyst

To request this document in an alternate format or a different language, 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.

PO Box 47990 • Olympia, WA 98504-7990
360-236-4110 • wsboh@sboh.wa.gov • sboh.wa.gov

Washington State Board of Health Policy & Procedure

Draft Policy Number:	Draft Policy 2025-001
Subject:	Health Impact Review Records Retention
Approved Date:	

Policy Statement

The Washington State Board of Health (Board) follows the [State Government General Records Retention Schedule](#) and the Department of Health's approved schedule. The Board also maintains a Records Retention Guide for records that are unique to the Board.

The Board's Health Impact Review (HIR) reports fall under the State Government General Records Retention Schedule Disposition Authority Number (DAN) GS 19004 (page 46), which is related to reporting to external agencies. The schedule for DAN GS 19004 is: retain for 6 years, then destroy. Based on this schedule, HIR reports would be eligible for destruction after 6 years. While it is not possible to update the DAN for HIRs, this policy is intended to clarify records retention policy and procedure for HIR reports and underlying source material (e.g., EndNote library, journal articles, strength-of-evidence ratings).

To meet the unique functions of HIRs, the Board will retain HIRs and underlying source material for 6 years and then convert these documents to reference material to retain as convenience/reference copies.

Procedure

- 1) **Maintain HIRs and underlying source material in Board files.** For 6 years, HIRs and underlying source material will be maintained in Board files (e.g., on the Board's shared drive or other platform, as appropriate).
- 2) **Convert HIRs and underlying source material to reference materials.** After 6 years, HIRs and underlying source material will be converted to reference materials and retained in Board files as convenience/reference copies. The Board's file structure will clearly label these documents as reference materials.
- 3) **Maintain all final HIR reports, beginning with reports completed in 2014, on the Board's website.** The HIR webpage on the Board's website will serve as an archive for completed HIRs reports. HIR reports completed in the past 6 years will be maintained on the HIR landing page. Reports older than 6 years will be available on the "full archive" page of the HIR webpage.

WASHINGTON STATE
BOARD OF HEALTH

Date: October 8, 2025

To: Washington State Board of Health Members

From: Patty Hayes, Board Chair

Subject: Rules Briefing—The Sanitary Control of Shellfish, chapter 246-282 WAC. This is not an action item.

Background and Summary:

The State Board of Health (Board) and the Washington Department of Health (Department) collaborate to regulate the sanitary control of molluscan shellfish. The Board serves as the rulemaking body and the Department serves as the regulatory agency. The Department also serves as the state shellfish authority administering the model ordinance of the National Shellfish Sanitation Program (NSSP).

[RCW 69.30.030](#) authorizes the Board to adopt rules governing shellfish sanitation, shellfish growing areas, and shellfish operations to protect public health and safety. Further, [RCW 43.20.050](#), establishes authority to adopt rules for the prevention and control of infectious and noninfectious disease, including food and vector borne illness.

On February 23, 2022, the Board filed a CR-101, Preproposal Statement of Inquiry, as [WSR 22-06-034](#), to initiate rulemaking to update [chapter 246-282 WAC](#), Sanitary Control of Shellfish. The rulemaking covers miscellaneous technical revisions along with updates to WAC 246-282-006, *Vibrio parahaemolyticus* (Vp) Control Plan and other parts of the rule.

Complementing this update to the chapter, on March 9, 2022, the Board delegated rulemaking authority to the Department to amend the Vp Control Plan in the event heat-wave conditions occurred early in the Vp control season and prior to completion of rulemaking on the chapter. The Department exercised this authority and adopted an emergency rule on [May 17, 2023](#) and [June 6, 2025](#), to enforce the strictest Vp time-to-cooling standards for commercial oyster harvesters and dealers.

Board staff coordinated with the Department's Office of Environmental Health and Safety to review the rule. The Board filed a formal rule proposal as WSR 25-18-076 on August 29, 2025, and opened a formal comment period to solicit feedback. The rule is scheduled for hearing at the November 19, 2025, Board meeting.

Today, Danielle Toepelt from the Department's Office of Environmental Health and Safety will present the Board with additional background on the rule and rulemaking process, engagement with the shellfish industry, and answer any questions the Board may have in preparation for the scheduled hearing at the November 19, 2025, Board meeting.

This is an informational briefing only. The Board will not take action at this meeting.

Staff

Shay Bauman, Policy Advisor

To request this document in an alternate format or a different language, 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.



SANITARY CONTROL OF SHELLFISH PRELIMINARY RULE BRIEFING

October 8, 2025

Presenters



Dani Toepelt, R.S.

Manager

Shellfish Licensing & Certification



Kseniya Efremova

Rules Coordinator

EPH Rules Team

Setting the Stage

Authority

- RCW 69.30.030: Requires the **State Board of Health** to adopt rules for sanitary shellfish in order to protect public health and carry out the provisions of the chapter.
- Chapter 246-282 WAC: Establishes minimum performance standards for shellfish intended for human consumption.
- Washington state **Department of Health** is the regulatory authority administering the shellfish program under chapters 69.30 RCW and 246-282 WAC.

Authority Cont.

- The National Shellfish Sanitation Program (NSSP) is the Federal/State cooperative program.
 - Recognized by the FDA & Interstate Shellfish Sanitation Conference (ISSC).
 - Sanitary control of bivalve shellfish intended for human consumption.
- NSSP Guide for the Control of Molluscan Shellfish (Model Ordinance).
 - Provides consistency nation wide.
- The Department of Health is the designated Shellfish Authority for the implementation of the Model Ordinance in Washington.

Rulemaking Background

- High number of *Vibriosis* cases in 2021, largely due to exceedingly high temperatures.
 - The Department of Health expects the trend of high temperatures to continue.
 - Highlighted gaps in the rule and demonstrated the need to explore additional protections.
- In 2022, Board delegated emergency rulemaking authority to the Department if heat waves conditions occur before July 1.
 - The Department filed emergency rules in May 2023 and again in June 2025.

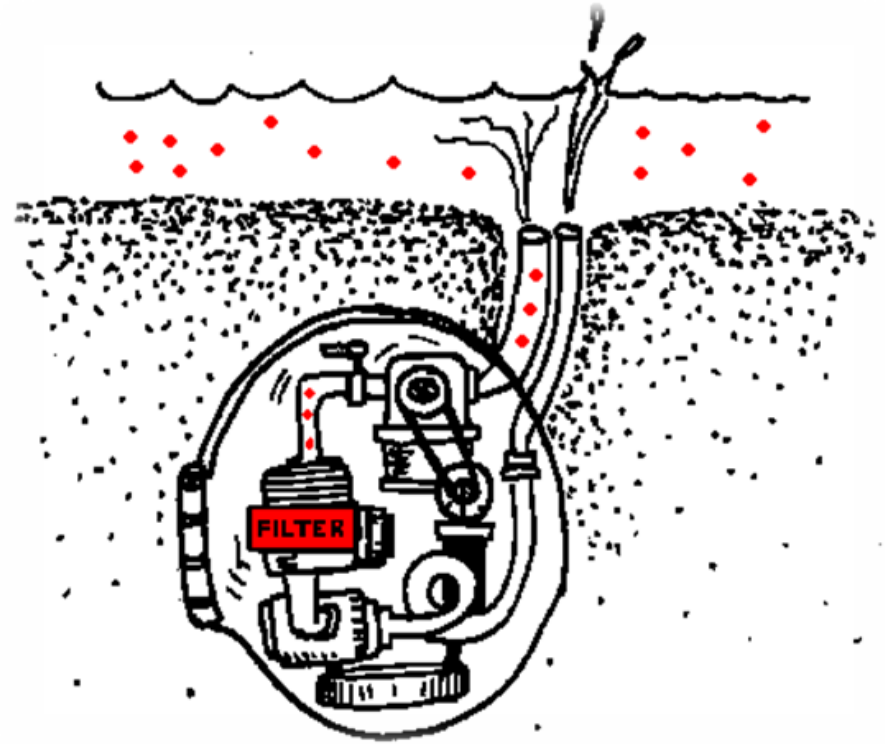
Timeline

2021	2022	2023	2024	2025
• High Vp illnesses from heat dome showed a gap in current rules	• Filed CR-101 for permanent rulemaking • SBOH delegated emergency rulemaking authority • RAC meetings begin	• Filed first emergency rule for heat wave conditions	• First informal comment period for RAC members only • Update to the Board • Scheduled four additional workshops	• Second informal comment period for all industry members and the public • Filed second emergency rule for heat wave conditions • Distributed cost-benefit survey • Filed CR-102

*Vibrio parahae*molyticus (Vp)

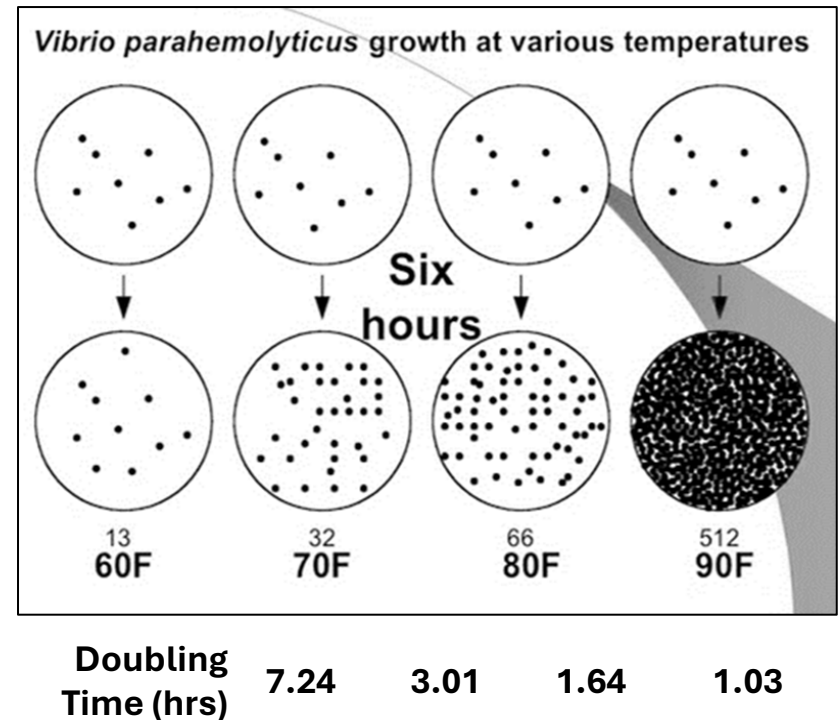
Shellfish Are Filter Feeders!

- Feed on bacteria, viruses, pollution, chemicals, and biotoxins
- Growth of bacteria slowed by proper handling practices.
- Bacteria and virus killed with cooking—toxins cannot.

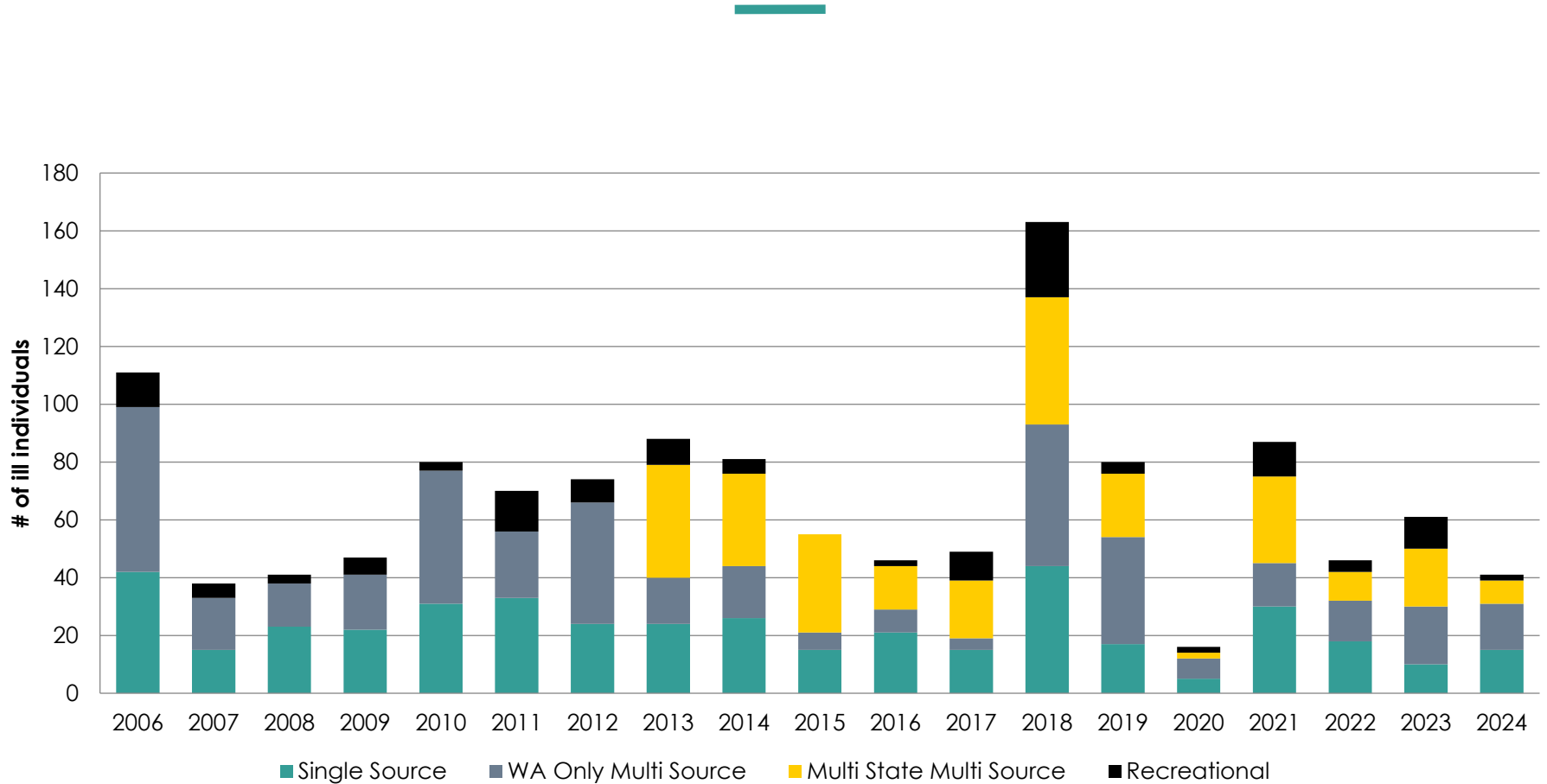


What is Vibrio?

- Naturally-occurring bacteria
- *Vibrio parahaemolyticus* & *Vibrio vulnificus*
- Common in warm marine and estuarine environments
 - Highly temperature dependent
 - Vp/Vv levels increase as air/water temps rise
- Illnesses from eating raw or undercooked shellfish



Confirmed Vp Illnesses Attributed to Oyster Shellstock from Washington from 2006 to 2024



Rulemaking Process



Rules Advisory Committee (RAC)

- Membership comprised of industry representatives and Tribes.
- Six RAC meetings were held between October 2022 and April 2023.
 - Discussion topics included the Vp control plan, seed size, growing areas, and operational provisions.
- First informal comment period with the RAC was held in April and May 2024.
- Four additional workshops were held between December 2024 and February 2025.
 - Discussion topics included harvest timing and practices, the transfer of ownership, and labeling requirements.

Tribal Engagement

- Six RAC workshops for Tribal partners were held between October 2022 and April 2023.
- A Tribal partner workshop was also held in January 2025.
- Workshop participants expressed the importance of traceability, recordkeeping, and Treaty rights.
- Workshop participants also reiterated concerns regarding the potential removal of the harvest site characteristics from the application and provided suggestions for revision.

Broader Engagement

- An informal comment period for the entire shellfish community and the public was held March - April 2025.
 - Six shellfish operations, one Tribe, and two associations provided comments.
 - Comments were largely focused on opposition to a label for shucked meats, concerns about seed size, concerns about the regulation of transplanting, and various requests for clarification throughout the rule.
- A cost-benefit survey was distributed to industry and tribal partners in June 2025.
 - 15 respondents completed the survey.
 - 12 of the 15 respondents identified as small businesses. One respondent was not sure how many employees their operation has.

Proposal



Overview of Proposed Changes

- The majority of the proposed changes are editorial in nature and provide clarification without changing the effects of the rule.
 - Conformance with the 2025 Bill Drafting Guide.
 - Incorporation of state statute or federal Model Ordinance by reference.
 - Clarification of application requirements.
 - Clarification of rules that relate only to internal governmental operations that are not subject to violation by a nongovernment party.

Key Changes

Vp control
plan

Seed size

Transplant

Key Changes



VP CONTROL PLAN

Harvest to Cooling Requirements

- **Issue:** Warmer temps prior to July and after August.
 - Ex: Heat Dome in 2021
- **Rule Change:** Removes the dates in the harvest to cooling table and specifies that the conditions listed in the table apply during all control months.
 - Control months: May 1st – September 30th.

(b) Category 2:

((Requirements)) <u>Condition at Harvest:</u>	<u>Time of Harvest to Cooling:</u>
Except as noted below, the time of harvest to cooling requirement ((from May 1st through September 30th)) is:	7 hours
When <u>ambient air temperature</u> ((at harvest is greater than 85°F, the time of harvest to cooling requirement)) is <u>85.0°F or above:</u>	5 hours
When <u>harvest temperature</u> is ((between 66°F and 68°F from July 1st through August 31st, the time of harvest to cooling requirement is)) <u>66.0°F to 68.0°F:</u>	3 hours
((<u>Harvest Control:</u> From July 1st through August 31st, harvest is not allowed for twenty-four hours)) When <u>harvest temperature</u> is above 68.0°F ((:)) :	<u>Harvest is not allowed for 24 hours</u>

Harvest to Cooling Requirements

- **Feedback:**
 - Some shellfish operations already follow the stricter temperature controls.
 - Other shellfish operations may incur a loss of sales/revenue, as they will not be able to harvest during warmer conditions, as compared to the current rule.
- **Public health benefit:** Reducing the risk of vibriosis by requiring the most stringent time-to-temperature controls at any time during the control months (May through September) when the temperatures could increase *Vibrio* growth and cause illness.
 - Continued use of emergency rulemaking confirms the need for this permanent change.

Key Changes



SEED SIZE – PROHIBITED/ UNCLASSIFIED AREAS

Seed size – Prohibited/ Unclassified Areas

- “Seed” is shellfish that is less than market size and, for the purpose of this section, relates to shellfish being moved from Prohibited or unclassified areas to Approved or Conditionally Approved areas.
- The definition of “seed” in WAC 246-282-010 establishes maximum shell lengths for mussels, scallops, Olympia oysters, Kumamoto oysters, **other oyster species**, geoducks, and other clam species.
- The Model Ordinance requires the shellfish authority to set the maximum seed size, based on current market size and a minimum of 120 days of growing outside the initial waters, for shellfish moved from unclassified or Prohibited waters to waters in other classifications.
- This is the only way to move shellfish, for human consumption, from an unclassified or Prohibited area.

Seed size – Prohibited/ Unclassified Areas

- **Issue:** The market for Pacific and other oyster species has become smaller in recent years (now ~2 inches). Seed size must be reduced to ensure that the public does not consume shellfish from a Prohibited or Unclassified area that has not been in an Approved or Conditionally Approved area for at least 120 days.
- **Rule Change:** Modifies the definition of “seed” to reduce the maximum shell length from 2 inches to 1 ½ inches, for other oyster species (including Pacific oysters).
 - This reduction is based on the evaluation of available data from growers to determine shellfish growth rates.

Seed size – Prohibited/ Unclassified Areas

- **Feedback:**
 - Some shellfish operations will not be impacted by the proposed rule, as their operations do not involve the purchase or planting of seed.
 - Other operations, including some of the largest in the state, will incur costs. Costs are attributed to increased training, increased labor to measure and to cull commercial oysters from seed/cultch, and potential mortality of seed.
- **Public health benefit:** In the current rule, maximum seed size is large enough to allow shellfish to directly enter the market without the required grow-out period. The proposed rule is necessary to meet the requirements of the Model Ordinance, ensure safe shellfish, and protect the health of shellfish consumers.

Seed Size - Waiver and Study

- **Issue:** Industry concerns with using shell length for measurement and requested other options, such as width or weight. The Department does not have the data to support other options.
- **Rule Change:** Allows a waiver to the seed length requirement provided a study is completed showing the requested option meets public health standards.
- The exact parameters of the study will be developed in guidance after rule adoption, with significant input from interested parties.

Seed Size - Waiver and Study

- **Feedback:**
 - It is unknown how many shellfish operations would apply for a waiver and want to complete the study.
 - 6/12 respondents said that they do not plan to apply for the waiver.
 - 6/12 respondents said that they do not know whether they will apply for the waiver.
 - The cost of conducting the study and completing the waiver application is indeterminate.
- **Public health benefit:** The study will determine if the requested measurement (width, weight, etc.) meets the public health standards requiring a minimum of 120 day grow out time outside of the Prohibited or unclassified area prior to achieving market size. Meeting the standards will allow the industry to move shellfish from Prohibited and unclassified areas without risk to public health.

Key Changes



TRANSPLANT

Transplant – Identification During Transport

- **Issue:** Current practices have not aligned with RCW 69.30.050(7), which addresses moving shellstock that are not meant for immediate human consumption. This change clarifies the department's authority in statute.
- **Rule Change:** Requires shellfish operations to identify shellstock during transit, by tagging or other methods approved by the department.
 - Identification must include the date the shellstock was removed from the original harvest site(s), the quantity and species of shellstock, and the original harvest site(s) and grow out site(s).

Transplant – Identification During Transport

- **Feedback:**
 - Some shellfish operations will not be impacted, since they do not transplant shellstock.
 - Other shellfish operations may incur costs associated with the time and labor it would take to fill out bag tags, as well as the cost of the tags themselves.
 - Shellfish operations have also expressed concern with the department regulating this activity.
- **Public health benefit:** The proposed rule will give the shellfish operation the flexibility to either fill out a tag or use some other method to identify shellstock while in transit. It also identifies the shellstock so the department knows where the shellstock is going to.

Additional Changes Being Proposed

Vp Control Plan	• Harvest plan submission. • Thermometer requirements. • Transfer of ownership. • Returning oysters to the same tidal level or lower than where they were collected.
Aquaculture	• Minimum grow-out period requirements. • Record keeping requirements for seed greater than 1 inch and less than 1 ½ inches from a Prohibited or unclassified area.
Relay Permit	• Reducing the grow-out period to align with Model Ordinance.
Wild Seed Permit	• Removing requirement for staking or marking the grow-out site. • Removing requirement for a lot identification number. • Reducing the grow-out period to align with Model Ordinance. • Harvesting of wild seed from Conditionally Approved or Restricted areas.
Transplant	• Maintaining accurate and detailed records for transplanted shellstock.
Export Certificates	• Issuance of export certificates to countries other than Asian countries.
Identification and Records	• Requirements for harvester and dealer tags.

Next Steps



Anticipated Timeline

- Written comments due October 27th at 11:59 pm
- Public hearing: November 19th at 1:30 pm
- Date of intended adoption: November 19th
- CR-103 filing if adopted: Late December/early January
- If adopted, rules become effective 31 days after CR-103 filing

Questions?





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PROPOSED RULE MAKING

CR-102 (June 2024)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: August 29, 2025

TIME: 9:20 AM

WSR 25-18-076

Agency: State Board of Health

☒ **Original Notice**

☐ **Supplemental Notice to WSR**

☐ **Continuance of WSR**

☒ **Preproposal Statement of Inquiry was filed as WSR 22-06-034 ; or**

☐ **Expedited Rule Making--Proposed notice was filed as WSR _____; or**

☐ **Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or**

☐ **Proposal is exempt under RCW _____.**

Title of rule and other identifying information: Chapter 246-282 WAC, Sanitary Control of Shellfish. The State Board of Health (board) is proposing to amend chapter 246-282 WAC, with the exception of WAC 246-282-990, and to create two new sections, WAC 246-282-017 and 246-282-044, to modify harvest control requirements by setting more proactive measures to prevent illnesses and protect public health. The rule proposal also updates definitions, makes changes to seed size and various tagging requirements, and makes technical and editorial changes as needed.

Hearing location(s):

Date:	Time:	Location: (be specific)	Comment:
11/19/2025	1:30 pm	Washington State Department of Health 111 Israel Road S.E. Tumwater, WA 98501 Building: Town Center Two (TC2, Rooms 166 & 167)	The rules hearing will be hybrid. Individuals may attend either virtually or in-person. Register to participate via Zoom here: https://us02web.zoom.us/webinar/register/WN_DII0Jo2yQUe1KBgX_flccw

Date of intended adoption: 11/19/2025 (Note: This is **NOT** the **effective** date)

Submit written comments to:

Name Shay Bauman
Address PO Box 47990, Olympia, WA 98504-7990
Email shellfish@sboh.wa.gov
Fax None
Other <https://fortress.wa.gov/doh/policyreview/>
Beginning (date and time) Date and time of filing
By (date and time) 10/27/2025 at 11:59 pm

Assistance for persons with disabilities:

Contact Shay Bauman
Phone 360-236-4110
Fax None
TTY 711
Email shay.bauman@sboh.wa.gov
Other wsboh@sboh.wa.gov
By (date) 11/05/2025

Purpose of the proposal and its anticipated effects, including any changes in existing rules:

The majority of chapter 246-282 WAC has not been updated since 2002 and 2015 and many of the changes proposed in this rulemaking are editorial or technical, to enhance readability and conform with the style guide used by the Office of the Code Reviser. In addition to these changes, the rule proposal amends controls found in the Washington State Vibrio parahaemolyticus (Vp) Control Plan, WAC 246-282-006, to address rising early season temperatures that can result in increased illnesses. The Department of Health (department), using delegated rulemaking authority from the board, has filed two emergency rules, once in 2023 and again in June 2025, to address this issue. The board is also proposing to make additional changes in chapter 246-282 WAC to address various gaps in the regulation of commercial shellfish and to align with federal regulations.

Reasons supporting proposal:

Vp is a naturally occurring bacteria found in marine waters. Molluscan bivalve shellfish acquire Vp through filter feeding. Humans who consume raw or undercooked shellfish containing Vp can develop an intestinal disease called vibriosis. The current Vp Control Plan, last updated in 2015, establishes a control season between May 1 and September 30. However, the

strictest time-to-cooling requirements for oysters currently begin July 1. In 2021, there were a high number of vibriosis cases involving Washington shellfish largely due to very high temperatures during the summer months. Early season high temperatures and midday low tides also occurred in May 2023 and June 2025 and as a result, the department filed emergency rules to address the need for more stringent time to cooling controls. The department expects this trend to continue. A review of rule requirements revealed gaps in the current controls and opportunities to more adequately protect consumers. The board is proposing more proactive measures to prevent illness and protect public health.

Statutory authority for adoption: RCW 69.30.030 and 43.20.050

Statute being implemented: RCW 69.30.030

Is rule necessary because of a:

Federal Law?

☐ Yes ☒ No

Federal Court Decision?

☐ Yes ☒ No

State Court Decision?

☐ Yes ☒ No

If yes, CITATION:

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None

Name of proponent: State Board of Health

Type of proponent: ☐ Private. ☐ Public. ☒ Governmental.

Name of agency personnel responsible for:

Name	Office Location	Phone
Drafting Shay Bauman	111 Israel Road SE Tumwater WA 98501	360-236-4110
Implementation Dani Toepelt	111 Israel Road SE, Tumwater, WA 98501	360-890-6054
Enforcement Dani Toepelt	111 Israel Road SE, Tumwater, WA 98501	360-890-6054

Is a school district fiscal impact statement required under [RCW 28A.305.135](#)?

☐ Yes ☒ No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:

Name

Address

Phone

Fax

TTY

Email

Other

Is a cost-benefit analysis required under [RCW 34.05.328](#)?

☒ Yes: A preliminary cost-benefit analysis may be obtained by contacting:

Name Shay Bauman

Address PO Box 47990, Olympia, WA 98504-7990

Phone 360-236-4110

Fax None

TTY 711

Email shay.bauman@sboh.wa.gov

Other N/A

☐ No: Please explain:

Regulatory Fairness Act and Small Business Economic Impact Statement

Note: The [Governor's Office for Regulatory Innovation and Assistance \(ORIA\)](#) provides support in completing this part.

(1) Identification of exemptions:

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see [chapter 19.85 RCW](#)). For additional information on exemptions, consult the [exemption guide published by ORIA](#). Please check the box for any applicable exemption(s):

☐ This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.061](#) because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.

Citation and description:

☐ This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by [RCW 34.05.313](#) before filing the notice of this proposed rule.

☐ This rule proposal, or portions of the proposal, is exempt under the provisions of [RCW 15.65.570](#)(2) because it was adopted by a referendum.

☒ This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025](#)(3). Check all that apply:

☒ [RCW 34.05.310](#) (4)(b)
(Internal government operations)

☒ [RCW 34.05.310](#) (4)(c)
(Incorporation by reference)

☒ [RCW 34.05.310](#) (4)(d)
(Correct or clarify language)

☐ [RCW 34.05.310](#) (4)(e)
(Dictated by statute)

☐ [RCW 34.05.310](#) (4)(f)
(Set or adjust fees)

☒ [RCW 34.05.310](#) (4)(g)
(i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit)

☐ This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025](#)(4). (Does not affect small businesses).

☐ This rule proposal, or portions of the proposal, is exempt under RCW _____.

Explanation of how the above exemption(s) applies to the proposed rule: WAC 246-282-001, 246-282-014, 246-282-020, 246-282-060, 246-282-070, 246-282-104, 246-282-120, and 246-282-130 are exempt under RCW 34.05.310(4)(d), as the proposed changes clarify the language in the rule without changing its effect. WAC 246-282-010 is also exempt under RCW 34.05.310(4)(d), as terms defined in this section are intended to clarify the meaning of the terms used throughout the chapter and are not intended to set standards. WAC 246-282-012, 246-282-036, and 246-282-042 are exempt under RCW 34.05.310(4)(d) and (4)(g)(ii), as the proposed changes are editorial, related to a process requirement for making an application to the agency for a license or permit, and are intended to provide clarification without changing the effects of the rule. WAC 246-282-092, 246-282-100, and 246-282-102 are exempt under RCW 34.05.310(4)(b) and (d), as the proposed changes are editorial and are intended to provide clarification without changing the effects of the rule. The proposed changes also relate only to internal governmental operations that are not subject to violation by a nongovernment party. WAC 246-282-005 and 246-282-110 are exempt under RCW 34.05.310(4)(c) and (d), as the proposed changes are editorial, incorporate federal model ordinance by reference without material change, and are intended to provide clarification without changing the effects of the rule. Finally, new WAC 246-282-017 is exempt under RCW 34.05.310(4)(b), as the proposed new section relates only to internal governmental operations that are not subject to violation by a nongovernment party.

(2) Scope of exemptions: Check one.

☐ The rule proposal: Is fully exempt. (Skip section 3.) Exemptions identified above apply to all portions of the rule proposal.

☒ The rule proposal: Is partially exempt. (Complete section 3.) The exemptions identified above apply to portions of the rule proposal, but less than the entire rule proposal. Provide details here (consider using [this template from ORIA](#)):

☐ The rule proposal: Is not exempt. (Complete section 3.) No exemptions were identified above.

(3) Small business economic impact statement: Complete this section if any portion is not exempt.

If any portion of the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

☐ No Briefly summarize the agency's minor cost analysis and how the agency determined the proposed rule did not impose more-than-minor costs.

☒ Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses and a small business economic impact statement is required. Insert the required small business economic impact statement here:

The following is a brief description of the proposed rule including the current situation/rule, followed by the history of the issue and why the proposed rule is needed. A description of the probable compliance requirements and the kinds of professional services that a small business is likely to need in order to comply with the proposed rule.

The Washington Department of Health (department) regulates the commercial shellfish industry in order to prevent illness or death from consumption of contaminated molluscan shellfish. Chapter 246-282 WAC, Sanitary Control of Shellfish, establishes standards for the growing, harvesting, processing, and marketing of molluscan shellfish for human consumption. The State Board of Health (board) serves as the rulemaking body, while the department serves as the regulatory agency. The department also serves as the state shellfish authority administering the Model Ordinance of the National Shellfish Sanitation Program (NSSP). The Model Ordinance, a consensus code, contains requirements for both the

shellfish industry and state shellfish control agencies (e.g., the department) that must be followed in order for shellfish to be shipped interstate and abroad.

Chapter 246-282 WAC is the primary mechanism used by the department for ensuring that the industry meets the requirements of NSSP and for fulfilling its statutory direction to regulate the commercial shellfish industry for the protection of public health.

Consuming raw or undercooked oysters can lead to a gastrointestinal illness called Vibriosis caused by the pathogenic form of *Vibrio parahaemolyticus* (Vp) bacteria found in oysters. Vp is a naturally occurring bacteria found in marine waters. Molluscan bivalve shellfish acquire Vp through filter feeding. Vp bacterium is active in warmer temperatures and dormant in cooler temperatures and has one of the fastest reproductive rates among human pathogens. As a result, vibriosis occurs primarily during the summer months with an increased incidence of illness during warmer years compared to cooler years.

In 2021, there were 87 confirmed Vp cases¹ involving Washington shellfish largely due to exceedingly high temperatures during the summer months. The department expects this trend to continue. Together, the board and department determined rule revisions were necessary to ensure current controls are adequate to protect consumers. They also want to consider more proactive measures to prevent illness and protect public health.

Additionally, the board is proposing to modify the definition of “seed” to reduce the maximum shell length for other oyster species from 2 inches to 1 and 1/2 inches. The reduction is based on the evaluation of available data to determine shellfish growth rates. “Seed” refers to shellfish that are less than market size for human consumption. The Model Ordinance requires each shellfish authority to set the maximum seed size (based on current market size and a minimum of 120 days of growing outside the initial waters) for shellfish moved from Unclassified or Prohibited waters to waters in other classifications. While shell length in chapter 246-282 WAC has, until now, remained unchanged, the market for Pacific and other oyster species has become smaller in recent years, with Pacific oysters now reaching the market in sizes around 2 inches. The proposed change is necessary to meet the requirements of the Model Ordinance, ensure safe shellfish, and protect the health of shellfish consumers.

To address concerns regarding the use of shell length for measurement (as opposed to width or weight), the board is proposing rule language that will allow this requirement to be waived provided a substitute measurement accurately protects public health and meets the requirements of the NSSP. To be granted a waiver, the shellfish operation would have to complete a study that determines shellfish growth in the defined time period.

Finally, the proposed rule revision includes updating definitions, tagging requirements, and other technical and editorial changes.

The board does not anticipate that compliance with the proposed rules will require small businesses to hire or engage with any professional services.

SBEIS Table 1 identifies and summarizes which businesses are required to comply with the proposed rule using the North American Industry Classification System (NAICS).

SBEIS Table 1. Summary of Businesses Required to comply to the Proposed Rule

NAICS Code (4, 5 or 6 digit)	NAICS Business Description	Number of businesses in Washington State	Minor Cost Threshold
114112	Shellfish Fishing*	64***	\$1,175.62
112512	Shellfish Farming**	34***	\$3,098.51

* The Shellfish Fishing category includes establishments primarily engaged in the commercial catching or taking of shellfish from their natural habitat.

** The Shellfish Farming category includes establishments primarily engaged in farm raising shellfish.

*** The Washington Department of Revenue reported 98 businesses categorized under either “Shellfish Fishing” or “Shellfish Farming” as of 2021. Separately, the Department of Health Shellfish Licensing and Certification Program reports the number

¹ This number includes multisource, single source, and recreational illnesses.

of license holders for harvesters as 78, shellstock shippers as 209, and shucker packers as 22. NAICS codes and Department of Health number of licenses by activity type are not intended to be comparable and each have their unique parameters for inclusion.

The board conducted an analysis of probable costs of businesses in the industry to comply with the proposed rule and includes the cost of equipment, supplies, labor, professional services, and administrative costs. The analysis considers if compliance with the proposed rule will cause businesses in the industry to lose sales or revenue.

To gather information on the costs and benefits of the proposed rule changes, the board and the department collaborated to create a cost survey that was distributed to shellfish operations and Tribal partners. This survey was distributed via email which included a SurveyMonkey link. The survey was open from June 5th through June 19th.

The cost survey was intended to serve as a snapshot of potential costs and benefits associated with complying with the proposed rule. The cost survey was not designed or analyzed with the purpose of producing cost estimates that are representative of all shellfish operations in Washington state, nor was it intended to provide inference about the costs of any Shellfish operations that did not respond to the cost survey. Throughout section 3, the cost survey presents the board and department with informed insight about the types and ranges of costs that shellfish operations could experience to comply with the proposed rule.

25 respondents started the survey, however 10 of these respondents did not answer any of the survey questions. Of the 15 respondents that provided answers, 12 identified as small businesses, meaning that they have 50 or fewer employees². One respondent said that they were not sure how many employees their operations has.

Throughout each of the WAC sections in this analysis, the board has provided the number of respondents that answered each question.

For the purposes of the analysis, increased cost was defined as the costs to adhere to the proposed rule that are in addition to what a shellfish operation already incurs, both up front and ongoing costs. Cost savings is defined as funds saved due to adherence to the proposed rule. One-time costs are defined as costs that occur only once, whereas recurring costs are costs that occur one time per year.

Portions of the proposed rule are exempt from the requirements of the Regulatory Fairness Act as identified above. The board has considered the costs for the remaining portions of the proposed rules, which are described below.

WAC 246-282-006, Washington state *Vibrio parahaemolyticus* control plan.

WAC 246-282-006(4):

Description: The current rule requires a harvester or shellfish dealer to submit new harvest plans, or changes to their current harvest plan, to the department by March 1st each year. The proposed rule requires submission of the harvest plan at least 14 calendar days before the first planned harvest.

14 shellfish operations provided an answer to this survey question.

Cost(s): Based on responses from the survey it is estimated that the one-time costs could range from neutral or insignificant to \$5,000, while the annual recurrent costs could range from neutral or insignificant to \$2,000.

One respondent (1/14) estimated a one-time cost of \$5,000 and a recurrent cost of \$2,000 but did not provide an explanation for their estimate. Five respondents (5/14) indicated that this question did not apply to their operation. One of these respondents (1/5) provided the following explanation:

- “We are a shellfish shipper always handling shellfish under temperature control during shipment and holding. We do not harvest.”

Most survey respondents (8/14) indicated that the impact would be cost neutral or insignificant. These operations made the following statements:

- “As I understand it – this doesn’t add to our expense. But I might not understand it.”
- “14 days makes more sense.”

² [RCW 19.85.020: Definitions](#). “Small business” means any business entity, including a sole proprietorship, corporation, partnership, or other legal entity, that is owned and operated independently from all other businesses, and that has fifty or fewer employees.

- “The current rule aligns with my annual license renewal, which is convenient. Our active harvest season goes through the new year, so any interruption to harvest in January, waiting on approval of harvest plans, would affect my and employee earnings.”
- “Nothing has changed on our farm so my plan doesn’t change. If the plan requirements or format change, I will have additional costs.”
- “This is helpful. Thanks!”

WAC 246-282-006(10):

Description: The current rule specifies time of harvest to cooling requirements based on certain dates (i.e. from June 1st through September 30th or from July 1st through August 31st.) The proposed rule removes these dates and specifies that the conditions listed in the table apply during all control months, which are from May 1st through September 30th.

12 shellfish operations provided an answer to this survey question.

Cost(s): Based on responses from the survey it is estimated that both the one-time and annual recurrent costs could range from neutral or insignificant to \$25,000.

One respondent (1/12) estimated a one-time cost of \$1,000 and a recurrent cost of \$2,000. This respondent did not provide an explanation for their estimate.

An additional respondent (1/12) estimated a one-time cost ranging from \$18,750 to \$25,000 and a recurrent cost of \$25,000. This respondent explained that the provided values are “based on estimated opportunity cost of removing 3 potential harvest month[s] during the year. We cannot predict the future but harvest value will increase with inflation, so [the] estimate will increase annually above \$25K eventually.”

Another respondent (1/12) estimated a recurrent cost of \$200, saying that “this was estimated as the hours needed for recording during May.”

Two respondents (2/12) indicated that this question did not apply to their operation. These operations made the following statements:

- “[We] do not transport shellfish after harvest, so this rule change does not apply. However, if transportation of shellfish to a facility was part of the business operation, then this can cause an increase[d] cost due to changes in temperature, which can change due to need to purchase ice to cool oysters, or the cancellation of orders or delayed orders, therefore the increase cost varies and depends on order size.”
- “We purchase from SP. Perhaps there are higher costs associated with more temperature control/ice costs that might impact costs. It is hard to say impact. Yet cooling is key control to health during vibrio season.”

Most survey respondents (7/12) indicated that the impact would be cost neutral or insignificant. These operations made the following statements:

- “We already follow strict temperature controls from moment of harvest to cooler with ice and document the temperature every hour. This is not only during the control period of May 1 to Sept 30, but all year long.”
- “The dates in Washington already are May 1 to September 30.”
- “This makes sense from a health perspective, although, we do not currently produce oysters in the May-Sept vibrio season.”
- “[We] operate as if the VP rule covers all control months in all growing areas already. This brings the rule up to the standard we have set internally.”

WAC 246-282-006(10)(d):

Description: The current rule specifies that when a harvester or shellfish dealer places oysters in a container or conveyance but does not remove them from the tide flat as part of their harvest and the harvest exceeds the time to cooling requirements, the oysters must be covered by the tide for a minimum of four hours before the harvest can be completed. The proposed rule keeps the four-hour resubmergence requirement but also requires the oysters to be returned to approximately the same tidal level or lower than where they were collected.

13 shellfish operations provided an answer to this survey question.

Cost(s): Based on responses from the survey it is estimated that the one-time costs could range from neutral to insignificant to \$1,600, while the annual recurrent costs could range from neutral to insignificant to \$15,000.

Three respondents (3/13) indicated that the proposed change would result in both one-time and recurrent increased costs for their operations. The respondents estimated one-time costs of \$250, \$500, and \$1,600 and recurrent costs of \$2,500, \$10,000, and \$500, respectively. These operations provided the following statements regarding costs:

- “Additional gear and labor is needed.”
- “Tides are changing every day and harvest times are always changing. Sometimes it’s best [to] place the harvest where it will be best for the next harvest.”
- “This seems a little ridiculous. If the 4 hours is important, just require that they are submerged for minimum 4 hours. Growers do not have access to all tidal elevations all the time, but they can figure out where to locate product to meet the requirement of 4 hours without returning to a specified elevation. Also, growers harvest from multiple elevations at the same time - so which elevation would be relevant with the new rule?”

One survey respondent (1/13) estimated a recurrent cost of \$15,000. This respondent provided the following comment:

- “On our Oakland Bay farm, when water temperatures are not at risk of approaching the limit (May, June, September) we will put sacks of oysters on the ramp and harvest them on the falling tide before they are uncovered. This process would no longer be permitted, so our boat will have to pick the sacks at high tide and make a special delivery to the processing plant for all control months, despite water temperature.”

Five respondents (5/13) indicated that this question did not apply to their operation. One of these respondents (1/5) said that “when oysters are harvested and bagged, they are left at the tidal level where they are harvested.” Another respondent (1/5) said that “as a dealer, this is not going to change our operation.”

Three respondents (3/13) indicated that the impact would be cost neutral or insignificant and one respondent (1/13) said that they are “unable to determine cost. It depends on the level of the tide any given day.”

WAC 246-282-006(12):

Description: The current rule specifies that harvesters and shellfish dealers shall take measurements with a thermometer that is verified weekly using manufacturer specifications or with a method approved in a harvest plan. The proposed rule requires measurements to be taken either with a thin-tip digital thermometer that is verified monthly using manufacturer specifications or with a method approved in a harvest plan, or with an NIST certified thermometer that has a manufacturer certificate that does not need to be verified monthly.

12 shellfish operations provided an answer to this survey question.

Cost(s): Based on responses from the survey it is estimated that both the one-time and annual recurrent costs could range from neutral or insignificant to \$500.

Two respondents (2/12) indicated that the proposed change would result in only a one-time increased cost for their operation. These respondents estimated one-time costs of \$55 and \$100 and said the following regarding their estimates:

- “I must purchase a new, instant read, thin tipped digital thermometer that can be verified monthly.”
- “Bought a new thermometer which can be calibrated as per our HACCP plan. Our current thermometers are tested every week during Vibrio season but can’t be calibrated. I understand the need for accurate temps so I bought a third one that can be calibrated.”

One respondent (1/12) indicated that the proposed change would result in only a recurrent increased cost of \$300 for their operation, stating that “although our digital thermometers have always matched the inspector’s temp, we need to buy new ones because we don’t have NIST certified.”

Three respondents (3/12) indicated that the proposed change would result in both a one-time and recurrent increased cost for their operation. The respondents estimated one-time costs of \$400, \$500, and \$500, and recurrent costs of \$100, \$500, and \$50, respectively. Two of these respondents (2/3) said the following about costs:

- “New digital thermometers cost. Ongoing annual replacement costs.”

- “New rule sounds fine. We would just need to source new thermometers.”

One respondent (1/12) indicated that this question did not apply to their operation.

Three respondents (3/12) indicated that the impact would be cost neutral or insignificant, with one of these respondents explaining that “we already do this.”

The cost survey revealed potential misunderstandings regarding the proposed rule change. Operations must use a thin-tip digital thermometer (as low as \$10 on Amazon³) or a NIST certified thermometer (as low as \$34⁴). Either will suffice. The department does not anticipate a reoccurring cost unless the thermometers must be replaced. However, depending on the size of the operation and how many growing areas the operation is harvesting from, multiple thermometers may need to be purchased.

WAC 246-282-006(18)

Description: The current rule outlines record-keeping requirements when ownership of oysters is transferred prior to the oysters being cooled in accordance with the time of harvest to cooling requirements. It also requires the receiving dealer to meet the time of harvest to cooling requirements for the original harvest time. The proposed rule adds a new requirement for the harvester to provide the receiving dealer with the total time of harvest to cooling for the oysters, based on the growing area risk category.

12 shellfish operations provided an answer to this survey question.

Cost(s): Based on the responses from the survey it is estimated that the one-time costs could range from cost neutral or insignificant to \$250, while the annual recurrent costs could range from cost neutral to insignificant to \$50.

Two respondents (2/12) indicated that the proposed change would result in an increased cost for the operation. One of these respondents (1/2) estimated a one-time cost of \$200 and a recurrent cost of \$50. This respondent said the following about costs:

- “Increased training of supervisors and employees; increased documentation and guide and map of growing areas, classes, and time to temperature requirements.”

The other respondent (1/2) estimated a one-time cost of \$250, stating that the “new rule requires an update to farm documentation.”

Six respondents (6/12) indicated that the question did not apply to their operation. The following are some of the reasons that were provided by these respondents:

- “Our operations do not involve transporting shellfish from [the] area after harvest; therefore, [this] change will not apply to [our] operation.”
- “In our case, ownership is never transferred prior to the oysters being cooled in accordance with the time of harvest to cooling requirements.”
- “I do not sell to a dealer or wholesale. I am strictly retail.”
- “Dealer does not have changed actions in this.”

Finally, four respondents (4/12) indicated that the impact would be cost neutral or insignificant, with three of these respondents (3/4) stating that they already do this practice.

In addition to the proposed changes described above, the board made the following changes in this section, which are exempt from analysis:

WAC 246-282-006: The proposed changes throughout the section amend language to conform with the 2025 bill drafting guide and make several editorial changes to existing language. The proposed changes are editorial only and are intended to

³ [Amazon.com: Professional Meat Thermometer Digital, ±0.5°F NIST Certified Accuracy, Instant Read Food Thermometer for Cooking Grill, 100% Waterproof, Auto-Rotate Backlit Display, Motion-Sensing On/Off, Red : Industrial & Scientific](https://www.amazon.com/Professional-Meat-Thermometer-Digital-0.5F-NIST-Certified-Accuracy-Instant-Read-Food-Thermometer-for-Cooking-Grill-100-Waterproof-Auto-Rotate-Backlit-Display-Motion-Sensing-On-Off-Red-Industrial-Scientific/dp/B07K9QZQZQ)

⁴ [McMaster-Carr](https://www.mcmaster.com/carr/)

provide clarification without changing the effects of the rule. The proposed changes are considered exempt under RCW 34.05.310(4)(d).

WAC 246-282-006(3): The proposed changes clarify the type of information that harvesters or shellfish dealers shall report to the department. The proposed changes are intended to provide clarification without changing the effects of the rule. The proposed changes are considered exempt under RCW 34.05.310(4)(d).

WAC 246-282-006(6): The proposed changes reduce the time for the department to review and either approve or deny the harvest plan from 30 days to 14 calendar days of receipt. The proposed changes relate only to internal governmental operations that are not subject to violation by a nongovernment party. The proposed changes are considered exempt under RCW 34.05.310(4)(c).

WAC 246-282-006(8): The proposed changes clarify that growing area risk categories are based on the number of single source cases that occurred during the previous consecutive five-year period that were within the control months and attributed to that growing area. The proposed changes are intended to provide clarification without changing the effects of the rule. The proposed changes are considered exempt under RCW 34.05.310(4)(d).

WAC 246-282-006(11): The proposed changes clarify the requirements for recording and maintaining a harvest temperature record. The proposed changes are intended to provide clarification without changing the effects of the rule. The proposed changes are considered exempt under RCW 34.05.310(4)(d).

WAC 246-282-006(14): The proposed changes reduce the department's review time for harvest plans from 30 days to 14 days. The proposed changes relate only to internal governmental operations that are not subject to violation by a nongovernment party. The proposed changes are considered exempt under RCW 34.05.310(4)(c).

WAC 246-282-006(16): The proposed changes clarify the requirements for the more stringent time of harvest to cooling to be used if shellstock is beach wet stored in a growing area with a different risk category than where it was harvested. The proposed changes are intended to provide clarification without changing the effects of the rule. The proposed changes are considered exempt under RCW 34.05.310(4)(d).

WAC 246-282-006(19): The proposed changes clarify that a person who trains another must have completed the department-approved training within the last 5 years. The proposed changes are intended to provide clarification without changing the effects of the rule. The proposed changes are considered exempt under RCW 34.05.310(4)(d).

WAC 246-282-006(24): The proposed changes add a new definition for 'time of harvest' and amended 'harvest temperature' and 'single source case.' Terms defined in this section are intended to provide clarification on the meaning of the term used throughout the section without changing the effects of the rule. The proposed changes are considered exempt RCW 34.05.310(4)(d).

WAC 246-282-016, Aquaculture.

WAC 246-282-016:

Description: The current rule sets a maximum shell length of fifty-one millimeters or 2 inches for other oyster species. This definition currently impacts only permits issued for wild seed. The proposed rule reduces the maximum shell length to thirty-eight millimeters or 1 and 1/2 inches for other oyster species. This will impact the permits issued for wild seed, as well as those for aquaculture activities.

12 shellfish operations provided an answer to this survey question.

Cost(s): Based on responses from the survey it is estimated that the one-time costs could range from cost neutral or insignificant to \$20,000, while the annual recurrent costs could range from neutral or insignificant to \$1,800.

Three respondents (3/12) indicated that the proposed rule would result in both one-time and recurrent costs for their operations. One of these respondents (1/3) estimated a one-time cost of \$1,800 and a recurrent cost of \$1,800. This operation provided the following explanation:

- "Increased training of supervisors and employees, increased labor to measure, increased labor to cull commercial oysters from seed and/or cultch, mortality of seed from additional required handling."

Another respondent (1/3) estimated a one-time cost of \$20,000 but did not provide an explanation for their estimate.

Finally, the third respondent (1/3) estimated a one-time cost of \$3,000,000 and a recurrent cost of \$250,000, which relate to the establishment of nurseries in Approved areas to enable the operation to grow bigger seed. Since this is not a requirement of the proposed rule, these estimates have been excluded from the summary of costs. This operation provided the following explanation and information regarding this proposed change:

- “The sections of WAC 262-282-010 and WAC 246-282-016 regarding seed size have the potential to have financial implications on the shellfish industry. [We] appreciate[s] the Department’s option for a waiver and how this may allow for seed greater than 1.5” in length. Record keeping to confirm grow out in approved waters for 120 days, regardless of seed size is a solution [we] support[s]. [We] [are] investing more than \$3,000,000 to develop infrastructure, with an annual operating cost of more than \$250,000, to grow seed larger in approved waters before planting onto the beach. Seed cost is a significant portion of a shellfish farm’s expenses and the larger the seed when out planted, the higher the survival. Our experience shows that 1.5” – 2” oysters survive 50% better than 0.5” – 0.75” oysters planted onto the farm. With threats from invasive species, such as European Green Crab, and other unknown future predators / diseases, [we] [are] concerned that the importance of planting larger oyster seed will only continue to grow. While [we] [have] the resources and scale to invest in secondary nurseries in approved waters, permitting and environmental monitoring costs, which were greater than \$500,000 for this project, are cost prohibitive for most of the industry. In the fast-growing summer months, seed that is 0.75” will pass the 1.5” size maximum in 3 weeks. In 2 weeks or less, you may find more than 5% of the fastest growing animals in that bin has passed the 1.5” mark. [We] [urge] the Department to consider increasing this allowance to 10%. These oysters are comingled with smaller oysters and will be treated as a single lot, so risk to human health is insignificant compared to the cost of depletion. The cost of depletion on oysters within a single nursery bin in our flupsy is more than \$8,000. [We] [urge] the Department to consider increasing the seed size exceedance allowance to 10% and consider how waivers could be utilized to grant shellfish farms the flexibility to grow seed to the size that best fits their farm’s needs while ensuring 120 days of grow out in approved waters.

The majority of respondents (8/12) indicated that the question did not apply to their operation. The following are the explanations provided by these operations:

- “We don’t buy large seed.”
- “Small business operations do not involve seed purchase or planting.”
- “This rule is based on no science and should not be adopted. As a dealer, it does not change anything for me.”

Finally, one respondent (1/12) indicated that the impact would be cost neutral or insignificant, with this respondent stating that this was “not applicable to my operation.”

WAC 246-282-016(3)(a):

Description: The proposed rule adds new language to clarify the requirements for aquaculture operations harvesting oyster seed, other than Kumamoto and Olympia, that have a seed size greater than one (1) inch and less than one and one half (1½) inches. One of these requirements is starting the minimum grow-out period the moment when the entire lot is added to the grow-out site.

11 shellfish operations provided an answer to this survey question.

Cost(s): The majority of respondents (9/11) indicated that this question did not apply to their operation. One respondent (1/11) indicated that the impact would be cost neutral or insignificant. Another respondent (1/11) indicated that the impact would be cost neutral or insignificant and also stated that this was “not applicable to my operation.”

WAC 246-282-016(3)(b):

Description: The proposed rule adds new language to clarify the requirements for aquaculture operations harvesting oyster seed, other than Kumamoto and Olympia, that have a seed size greater than one (1) inch and less than one and one half (1½) inches. One of these requirements is to keep records for each lot of shellfish that show the species, location, date, and quantity moved from the initial site, the grow-out location, and the date of first harvest of any of those shellfish from the grow-out site.

12 shellfish operations provided an answer to this survey question.

Cost(s): One respondent (1/12) indicated that the proposed rule would result in a recurrent cost of \$15,000 for their operation, but did not provide an explanation.

The majority of respondents (10/12) indicated that this question did not apply to their operation.

One respondent (1/12) indicated that the impact would be cost neutral or insignificant, stating that “[we] already collect this information.”

WAC 246-282-016(4):

Description: The proposed rule provides shellfish operations with the ability to apply for a seed size waiver if it is consistent with the applicable standards and intent of the definition, as related to market size and the 120-day grow-out time. As part of this process, the shellfish operation will have to complete a study that determines shellfish growth in the defined time period.

Survey Respondents: 12 shellfish operations provided an answer to this survey question.

Cost(s): When asked whether they plan to apply for a seed size waiver, half of the respondents who answered this question (6/12) said that they do not plan to apply for a waiver, and half (6/12) said that they do not know at this time.

Shellfish operations who answered either “no” or “I don’t know at this time” to the question of whether they plan to apply for a waiver, were subsequently asked why they responded that way. The following were some of their responses:

- “Unsure of grow out calculation, seed size per species, seed size availability, ability to source cultch, etc.”
- “I buy seed oysters from Taylor Shellfish to grow out to a size I can sell retail. That usually takes 360 days or more.”
- “I don’t anticipate being in this situation.”
- “I don’t capture natural set seed. I don’t sell seed.”
- “We don’t want to waste time and money completing a study.”
- “Because I don’t understand.”
- “I’m a dealer in this case.”
- “[We] have invested in nursery infrastructure in approved waters.”
- “This is not applicable to my operation.”
- “[My] business operations do not involve seed purchase or planting.”

The board acknowledges that there will be a cost for those shellfish operations that decide to apply for a seed size waiver and have to complete the associated study. If the proposed rules are adopted, the department will work with shellfish operations on a guidance document establishing the parameters of the study. Since these parameters have not yet been established, the cost for this portion of the proposed rule language is indeterminate at this time.

In addition to the proposed changes described above, the board made the following changes in this section, which are exempt from analysis:

WAC 246-282-016(1): The proposed changes amend language to conform with the 2025 bill drafting guide. The proposed changes are editorial only and are intended to provide clarification without changing the effects of the rule. The proposed changes are considered exempt under RCW 34.05.310(4)(d).

WAC 246-282-016(2): The proposed changes add new language to clarify a complete application for getting an aquaculture permit from the department. The proposed changes are related to a process requirement for making an application to the agency for a license or permit and are intended to provide clarification without changing the effects of the rule. The proposed changes are considered exempt under RCW 34.05.310(4)(g)(ii).

WAC 246-282-016(2): The proposed changes add new language to outline and clarify aquaculture activities that may be approved in Prohibited and unclassified areas. The proposed changes are intended to provide clarification without changing the effects of the rule. The proposed changes are considered exempt under RCW 34.05.310(4)(d).

WAC 246-282-032, Relay permit.

WAC 246-282-032(8):

Description: The current rule exempts growers from the validation study requirement if relaying shellfish to an approved grow-out site for a minimum of six months (180 days). The proposed rule reduces the grow-out period from six months (180 days) to greater than 60 days, to align with the NSSP Model Ordinance.

12 shellfish operations responded to this survey question. Shellfish operations were asked whether this proposed rule will result in cost savings for their operation, with the following answer options: “Yes”, “No” and “Neutral (\$0).”

Cost(s): Three respondents (3/12) indicated no cost savings resulting from this proposed change and eight respondents (8/12) selected the neutral (\$0) option. One of the respondents (1/3) who indicated that there would be no cost savings provided the following explanation:

- “When a validation study is done, we are doing so to get quick turnaround on market ready products. While we appreciate the move towards alignment with the NSSP, the difference will not change the instances a validation study is required.”

Shellfish operations who indicated a neutral (\$0) impact chose this option because they are dealers, they do not relay, or their business operations do not involve growing of shellfish.

In addition to the proposed change described above, the board made the following changes in this section, which are exempt from analysis:

WAC 246-282-032: The proposed changes throughout the section amend language to conform with the 2025 bill drafting guide and make several editorial changes to existing language. The proposed changes are editorial only and are intended to provide clarification without changing the effects of the rule. The proposed changes are considered exempt under RCW 34.05.310(4)(d).

WAC 246-282-032(2): The proposed changes clarify application requirements for getting a relay permit from the department. The proposed changes are related to a process requirement for making an application to the agency for a license or permit and are intended to provide clarification without changing the effects of the rule. The proposed changes are considered exempt under RCW 34.05.310(4)(g)(ii).

WAC 246-282-032(8): The proposed changes clarify that only microbiological contaminants need to be reduced, to ensure consistency with the NSSP Model Ordinance. The proposed changes are intended to provide clarification without changing the effects of the rule. The proposed changes are considered exempt under RCW 34.05.310(4)(d).

WAC 246-282-034, Wild Seed Permit.

WAC 246-282-034:

Description: The current rule sets a maximum shell length of fifty-one millimeters or 2 inches for other oyster species. This definition currently impacts only permits issued for wild seed. The proposed rule reduces the maximum shell length to thirty-eight millimeters or 1 and 1/2 inches for other oyster species. This will impact the permits issued for wild seed, as well as those for aquaculture activities.

The costs of this proposed rule change are captured under the Aquaculture section, WAC 246-282-016.

WAC 246-282-034(3)(g):

Description: The current rule requires a person operating under a wild seed permit to stake or mark the grow-out site. The proposed rule removes the requirement for staking or marking, but a person operating a wild seed permit must still keep records that identify the grow-out site.

12 shellfish operations responded to this survey question. Shellfish operations were asked whether this proposed rule will result in cost savings for their operation, with the following answer options: “Yes”, “No” and “Neutral (\$0).”

Cost(s): Three respondents (3/12) indicated no cost savings resulting from this proposed change and nine respondents (9/12) selected the neutral (\$0) option. One of the respondents (1/3) who indicated that there would be no cost savings stated that “we don’t use wild seed.”

Similarly to the responses provided in the relay permit section, shellfish operations who indicated a neutral (\$0) impact chose this option because they do not anticipate needing this, they are dealers, or because their business operations do not involve purchasing, planting, or processing seed. Additionally, one operation stated that “this is appreciated, but not necessarily cost saving.”

WAC 246-282-034(3)(h):

Description: The current rule requires a person operating under a wild seed permit to keep records for each lot of seed harvested that show a lot identification number. The proposed rule removes the requirement for a lot identification number as part of recordkeeping.

12 shellfish operations responded to this survey question. Shellfish operations were asked whether this proposed rule will result in cost savings for their operation, with the following answer options: “Yes”, “No” and “Neutral (\$0).”

Cost(s): Five respondents (5/12) indicated no cost savings resulting from this proposed change and six respondents (6/12) selected the neutral (\$0) option. One of the respondents (1/5) who indicated that there would be no cost savings stated that “we don’t use wild seed.”

The explanations given by the shellfish operations who indicated a neutral (\$0) impact were nearly identical to those described for WAC 246-282-034(3)(g) above. These operations stated that they are dealers, that their business operations do not involve seed purchase, planting, or processing, or that this was simply not applicable to them. Again, one operation stated that “this is appreciated, but not necessarily cost saving.”

WAC 246-282-034(3) and (5):

Description: The current rule requires seed to be left in a grow-out site for a minimum of six months before final harvest. The proposed rule reduces the grow out period from six months (180 days) to 120 days, to align with the NSSP Model Ordinance.

12 shellfish operations responded to this survey question. Shellfish operations were asked whether this proposed rule will result in cost savings for their operation, with the following answer options: “Yes”, “No” and “Neutral (\$0).”

Cost(s): Six respondents (6/12) indicated no cost savings resulting from this proposed change and five respondents (5/12) selected the neutral (\$0) option. One of the respondents (1/6) who indicated that there would be no cost savings stated that “we don’t use wild seed.”

The three explanations given by the shellfish operations who indicated a neutral (\$0) impact were identical to those described for WAC 246-282-034(3)(h) above. In addition, one operation stated that “wild seed normally requires more time than this to mature anyway.”

WAC 246-282-034(6):

Description: The current rule allows the harvesting of wild seed from a Conditionally Approved area in closed status or from a Restricted area, as long as live shellfish larger than seed size is limited to less than 5% and the shellfish are moved to a grow out site for a minimum of six months. The proposed rule allows the harvesting of wild seed from these areas as long as the relay standards in WAC 246-282-032 are followed. Shellfish can be moved to a grow out site for seven to greater than 60 days.

12 shellfish operations responded to this survey question.

Cost(s): The majority of respondents (11/12) indicated that this question did not apply to their operation because they don’t plan to harvest wild seed and one respondent (1/12) indicated that the impact was cost neutral or insignificant.

In addition to the proposed change described above, the board made the following changes in this section, which are exempt from analysis:

WAC 246-282-034: The proposed changes throughout the section amend language to conform with the 2025 bill drafting guide and made several editorial changes to existing language. The proposed changes are editorial only and are intended to provide clarification without changing the effects of the rule. The proposed changes are considered exempt under RCW 34.05.310(4)(d).

WAC 246-282-034(2): The proposed changes clarify application requirements for getting a wild seed permit from the department. The proposed changes are related to a process requirement for making an application to the agency for a license or permit and are intended to provide clarification without changing the effects of the rule. The proposed changes are considered exempt under RCW 34.05.310(4)(g)(ii).

NEW WAC 246-282-044, Transplant.

WAC 246-282-044(1)(d):

Description: The proposed rule adds new requirements for transplanting shellstock to another harvest site. One of these new requirements is to identify the shellstock during transit, by tagging or other methods approved by the department. This identification must include the date the shellstock was removed from the original harvest site(s), the quantity and species of shellstock, and the original harvest site(s) and grow out site(s).

12 shellfish operations responded to this survey question.

Cost(s): Based on responses from the survey it is estimated that the one-time costs could range from neutral or insignificant to \$4,500, while the annual recurrent costs could range from neutral or insignificant to \$5,000.

Three respondents (3/12) indicated that the proposed change would result in increased costs for their operation. One respondent (1/3) estimated a one-time cost of \$500 and a recurrent cost of \$250. This operation indicated that the proposed change “would require an update to harvest bag tags for the purpose of transferring seed.” Another respondent (1/3) estimated a one-time cost of \$4,500 and a recurrent cost of \$5,000. This respondent explained that “with this requirement each time product is moved for any reason (husbandry, farming, thinning, finishing, etc) from harvest site to harvest site, tagging, records, labor to fill out forms, etc. is necessary.” Finally, one respondent (1/3) estimated a \$4,000 recurrent cost, which encompasses the “cost of tags and time to fill out tags.”

The majority of respondents (8/12) indicated that this question did not apply to their operation. The following are some of the reasons provided by this category of respondents:

- “We don’t transplant.”
- “Dealer.”
- “We are given transfer paperwork from Taylor Shellfish, which delineates how many baby oysters we are transporting to our site, which has a San Juan County parcel number on this paperwork.”
- “Shellfish are not moved or transplanted, they remain at [the] harvest site.”

One respondent (1/12) indicated that the impact was cost neutral or insignificant.

WAC 246-282-044(1)(e):

Description: The proposed rule adds new requirements for transplanting shellstock to another harvest site. One of these new requirements is to keep and maintain accurate and detailed records of the original harvest site, transplant method, and destination of transplanted shellstock for one year.

12 shellfish operations responded to this survey question.

Cost(s): Based on responses from the survey it is estimated that the one-time costs could range from neutral or insignificant to \$12,000, while the annual recurrent costs could range from neutral or insignificant to \$25,000.

Two respondents (2/12) indicated that the proposed change would result in increased costs for their operation. One respondent (1/2) estimated a one-time cost of \$1,000 and a recurrent cost of \$600. Another respondent (1/2) estimated a one-time cost of \$12,000 and a recurrent cost of \$25,000. This respondent explained that “one-time costs include adjusting current inventory tracking software to track transplant method, which in our opinion is unnecessary information to track. Ongoing costs is the additional time managers will spend inputting data entries for every lot of transplant instead of monthly entries as is our current practice.”

Half of the respondents (6/12) indicated that this question did not apply to their operation, with similar reasons provided as in the previous question.

Four respondents (4/12) indicated that the impact was cost neutral or insignificant. The following were some of the reasons provided by this category of respondents:

- “We already do this so there is no extra cost.”
- “Cannot determine the cost at this time. Likely minimal.”
- “We do this already.”

In addition to the proposed new rules described above, the board is proposing the following rule in this section, which is exempt from analysis:

WAC 246-282-044(2): The proposed rule clarifies that after 14 days, the shellstock will take on the characteristics and properties of the transplant site. The proposed changes are intended to provide clarification without changing the effects of the rule. The proposed changes are considered exempt under RCW 34.05.310(4)(d).

WAC 246-282-080, Identification and records.

WAC 246-282-080(3) and (4):

Description: The proposed rule adds a new requirement for harvester tags to have the department harvest site application number, harvest ID, parcel number, or other approved harvest site identifier. This information must be listed on the harvester tag, harvest record, and harvest site certificate. The proposed rule also requires the dealer tag to have the exact harvest site information as provided on the original harvest tag, when shellstock is retagged.

12 shellfish operations responded to this survey question.

Cost(s): Based on responses from the survey it is estimated that the one-time costs could range from cost neutral or insignificant to \$40,000, while the annual recurrent costs could range from cost neutral or insignificant to \$2,000.

The majority of shellfish operations that responded to this question (7/12) indicated that the proposed change would result in increased costs for their operation. One-time costs estimated by the respondents were as follows: \$40 - \$1,000; \$250; \$500; \$500; \$2,000, \$6,000, and \$40,000. Only four of those respondents (4/7) indicated that the proposed change would result in recurrent costs. The estimated recurrent costs were \$100, \$100, \$1,000, and \$2,000.

Respondents provided the following information regarding costs:

- “Adding harvest identifier or parcel number would take additional employee time and would vary depending on the quantity of orders at value of \$800-\$9,000 per order. The number of orders determines the amount of tags and time to add department harvest site number (or parcel number).”
- “Tag editing, printing and labor to make changes.”
- “This would require an upgrade to harvest bag tags.”
- “I will have to replace all of the tags I just purchased and reprogram the app we use to include the new requirements.”
- “We will have to figure out how we will do this. Some farms have the same code for different beaches.”
- “Initial costs include updating tag formatting, developing a database that connects internal tracking codes to a parcel ID/HSC and the labor it will take to do the data entry to develop the records in accordance with the new rule. Ongoing costs include maintaining this database as it needs updating.”

One respondent (1/12) indicated that this question did not apply to their operation, explaining that “we already include our harvest site ID on the tag.”

Four respondents (4/12) indicated that the impact was cost neutral or insignificant. The following were some of the reasons provided by this category of respondents:

- “We seldom retag our shellfish and keep the original information as required from the SP we purchase from. If we retag we would provide this harvest site information.”
- “Any extra information I may need on the ticket I will write on it until I run out of stock. I already have most of the info on my tags.”
- “Just starting to get my first tags printed so this shouldn’t increase costs.”

The cost survey revealed potential misunderstandings regarding the proposed rule change. The proposed rule allows for flexibility with what is on the tag itself. It does not have to be the parcel number, but some other approved identifier that can be linked to a harvest site. The department anticipates that the majority of shellfish operations are already doing this or a portion of this, and that complex changes such as those to databases will not be required. Furthermore, shellfish operations will not be required to immediately replace all of their tags or purchase new tags once the rule goes into effect. They will be able to use up existing inventory first.

In addition to the proposed change described above, the board made the following change in this section, which is exempt from analysis:

WAC 246-282-080: The proposed changes throughout the section amend language to conform with the 2025 bill drafting guide and made several editorial changes to existing language. The proposed changes are editorial only and are intended to provide clarification without changing the effects of the rule. The proposed changes are considered exempt under RCW 34.05.310(4)(d).

WAC 246-282-082, Export certificate.

WAC 246-282-082(2)(a):

Description: The current rule specifies that the department will issue an export certificate to a shellfish dealer for a specific lot if the dealer is “exporting the lot to an Asian country that requires a production certificate from a governmental health authority.” The proposed rule removes the language “an Asian country” to expand export certificates to be approved to any country that requires a production certificate from a governmental health authority.

12 shellfish operations responded to this survey question.

Cost(s): None of the respondents (0/12) estimated increased costs as a result of this proposed change.

The majority of respondents (8/12) indicated that this question did not apply to their operation. The following were some of the reasons provided by this category of respondents:

- “This does not apply to business operations so cost will not be impacted.”
- “Our market is local, Lopez Island. We are too small to export anything.”

Four respondents (4/12) indicated that the impact was cost neutral or insignificant. One of these respondents (1/4) explained that “we are already paying for our exports”, while another (1/4) said that “we use this service weekly for our exports to Asia so this change won’t impact this program. However, perhaps countries outside of Asia will accept them as Health Certs instead of NOAA.”

In addition to the proposed change described above, the board made the following changes in this section, which are exempt from analysis:

WAC 246-282-082: The proposed changes throughout the section amend language to conform with the 2025 bill drafting guide. The proposed changes are editorial only and are intended to provide clarification without changing the effects of the rule. The proposed changes are considered exempt under RCW 34.05.310(4)(d).

WAC 246-282-082(2): The proposed changes clarify application requirements for getting an export certificate from the department. The proposed changes are related to a process requirement for making an application to the agency for a license or permit and are intended to provide clarification without changing the effects of the rule. The proposed changes are considered exempt under RCW 34.05.310(4)(g)(ii).

All WAC Sections: Operation documentation.

Description: Operation documentation is required to align with the most current WAC language. This rulemaking amends nearly every WAC section within the chapter and will most likely require shellfish operations to update plans of operations, harvest and sales logs, etc.

14 shellfish operations responded to this survey question.

Cost(s): Based on responses from the survey it is estimated that the one-time costs could range from cost neutral or insignificant to \$10,000, while the annual recurrent costs could range from cost neutral or insignificant to \$2,500.

The majority of respondents (9/14) estimated increased costs associated with updating their documentation. Five of these respondents (5/9) indicated that updating their documentation would result in only one-time costs for their operation. The one-time costs estimated by these operations were \$30, \$250, \$500, \$500, and \$5,000. The following were some of the explanations provided by these operations:

- “Employee time paid to make updates.”
- “Estimated administrative time.”
- “My harvest area is not yet fully approved so we are somewhat inactive and we are updating documents in an ongoing basis.”
- “Updating all required documents will take a significant number of hours to complete. The plan of operations and all harvest and sales documents will need to be updated. Hopefully that will be a one time requirement.”

One respondent (1/9) indicated that updating their documentation would result in only recurrent costs for their operation. This respondent estimated recurrent costs of \$2,235 but did not provide an explanation.

Three respondents (3/9) indicated that updating their documentation would result in both one-time and recurrent costs. These respondents estimated one-time costs of \$415, \$1,500, and \$10,000, as well as recurrent costs of \$515-750, \$250, and \$2,500 respectively. These operations provided the following explanations regarding their estimates:

- “Form editing & modification; printing expenses; management; supervisory and employee (harvester) training time; follow-up check of employee understanding; repeat of training for new hires.”
- “This question is so general that answering correctly is nearly impossible. Also, what cost, direct costs, new system costs, new data management costs?”
- “Administrative time is the primary cost driver. Also, I may need to re-print an inventory of harvest tags.”

One shellfish operation (1/14) stated that they are “unable to estimate additional cost until an inspector visits to tell me I need to adjust the record keeping.”

Two shellfish operations (2/14) indicated that this question did not apply to their operation.

Finally, two shellfish operations (2/14) indicated that the impact was cost neutral or insignificant, with one of these operations (1/2) stating that “[they] don’t see it increasing any time or cost for [their] small farm.”

SBEIS Table 2. Summary of Section 3 probable cost(s)

WAC Citation and Description	Probable Cost(s)
WAC 246-282-006(4): Harvest plans.	Cost neutral or insignificant up to \$5,000 in one-time costs and \$2,000 in recurrent costs.
WAC 246-282-006(10): Harvest to cooling requirements.	Cost neutral or insignificant up to \$25,000 in one-time costs and \$25,000 in recurrent costs.
WAC 246-282-006(10)(d): Returning oysters to the same tidal level or lower.	Cost neutral or insignificant up to \$1,600 in one-time costs and \$15,000 in recurrent costs.
WAC 246-282-006(12): Thermometers.	Cost neutral or insignificant up to \$500 in one-time costs and \$500 in recurrent costs.
WAC 246-282-006(18): Transfer of ownership documentation.	Cost neutral or insignificant up to \$250 in one-time costs and \$50 in recurrent costs.
WAC 246-282-016: Reducing the maximum shell length for seed.	Cost neutral or insignificant up to \$20,000 in one-time costs and \$1,800 in recurrent costs.
WAC 246-282-016(3)(a): Minimum grow-out period start time.	Cost neutral or insignificant.
WAC 246-282-016(3)(b): Record keeping for aquaculture operations harvest oyster seed with a seed size greater than 1 inch and less than 1 1/2 inches.	Cost neutral or insignificant up to \$15,000 in recurrent costs.
WAC 246-282-016(4): Seed size waiver and study.	Indeterminate at this time.
WAC 246-282-032(8): Reducing the grow-out period from 180 days to greater than 60 days.	Cost neutral (\$0).
WAC 246-282-034(3)(g): Removing the requirement for staking or marking the grow-out site.	Cost neutral (\$0).
WAC 246-282-034(3)(h): Removing the lot identification number as part of record keeping.	Cost neutral (\$0).
WAC 246-282-034(3) and (5): Reducing the grow-out period from 180 days to 120 days.	Cost neutral (\$0).
WAC 246-282-034(6): Harvest of wild seed and relay standards.	Cost neutral or insignificant.
WAC 246-282-044(1)(d): Identifying shellstock during transit.	Cost neutral or insignificant up to \$4,500 in one-time costs and \$5,000 in recurrent costs.
WAC 246-282-044(1)(e): Record keeping requirements for transplant.	Cost neutral or insignificant up to \$12,000 in one-time costs and \$25,000 in recurrent costs.

WAC 246-282-080(3) and (4): Requirements for harvester and dealer tags.	Cost neutral or insignificant up to \$40,000 in one-time costs and \$2,000 in recurrent costs.
WAC 246-282-082(2)(a): Expanding export certificates.	Cost neutral or insignificant.
All sections: Operation documentation.	Cost neutral or insignificant up to \$10,000 in one-time costs and \$2,500 in recurrent costs.

The board anticipates that compliance with one of the proposed rules may cause businesses in the industry to lose sales or revenue. This pertains to the expansion of the most strict time-to-cooling months in WAC 246-282-006. This change may result in growers not being able to harvest during warmer conditions, compared to the current rule. While this may cause growers to lose sales, it is most protective of public health. Additionally, the majority of survey respondents indicated that this change would result in a cost neutral or insignificant impact, with some of the respondents already operating under the most strict controls.

The following is an analysis on if the proposed rule may impose more than minor costs for businesses in the industry. It includes a summary of how the costs were calculated.

Yes, the costs of the proposed rule are greater than the minor cost threshold.

Summary of how the costs were calculated.

The minor cost threshold for Shellfish Fishing as of 2021 is \$1,175.62, based on 0.3% of Average Annual Gross Business Income as calculated by data collected by the Washington Department of Revenue (SBEIS Table 1).

Of the 19 portions of rule analyzed in Section 3 (SBEIS Table 2), 9 portions have probable costs that exceed the minor cost threshold of \$1,175.62. Additionally, while the costs for the seed size waiver and study are indeterminate at this time, it is very likely that they will exceed the minor cost threshold.

Determination on if the proposed rule may have a disproportionate impact on small businesses as compared to the 10 percent of businesses that are the largest businesses required to comply with the proposed rule.

The board estimates that the proposed rule may have a disproportionate impact on small businesses as compared to the 10 percent of businesses that are the largest businesses required to comply with the proposed rule.

Explanation of the determination

Of the 15 respondents that provided answers to the survey questions, 12 identified as small businesses, meaning that they have 50 or fewer employees. One respondent said that they were not sure how many employees their operations has. Based on what the department knows about this shellfish operation, they were categorized as a small business for the purpose of this analysis. Two survey respondents categorized themselves as large businesses, meaning that they have 51 or more employees. This breakdown is representative of the shellfish industry in the state of Washington.

Of the two large businesses that participated in the survey, only one completed the survey in its entirety, with the other large business providing a response to only the first question in the survey.

The summary of costs from the cost survey by business size is presented below in SBEIS Table 3.

SBEIS Table 3. Summary of probable cost(s) for small businesses and large businesses*

WAC Citation and Description	Probable Cost(s), Small Businesses	Probable Cost(s), Large Businesses
WAC 246-282-006(4): Harvest plans.	Cost neutral or insignificant up to \$5,000 in one-time costs and \$2,000 in recurrent costs.	Cost neutral or insignificant.
WAC 246-282-006(10): Harvest to cooling requirements.	Cost neutral or insignificant up to \$25,000 in one-time costs and \$25,000 in recurrent costs.	Cost neutral or insignificant.
WAC 246-282-006(10)(d): Returning oysters to the same tidal level or lower.	Cost neutral or insignificant up to \$1,600 in one-time costs and \$10,000 in recurrent costs.	\$15,000 in recurrent costs.

WAC 246-282-006(12): Thermometers.	Cost neutral or insignificant up to \$500 in one-time costs and \$500 in recurrent costs.	No costs indicated.
WAC 246-282-006(18): Transfer of ownership documentation.	Cost neutral or insignificant up to \$250 in one-time costs and \$50 in recurrent costs.	Not applicable.
WAC 246-282-016: Reducing the maximum shell length for seed.	Cost neutral or insignificant up to \$20,000 in one-time costs and \$1,800 in recurrent costs.	Cost estimate outside of scope.**
WAC 246-282-016(3)(a): Minimum grow-out period start time.	Cost neutral or insignificant.	Cost neutral or insignificant.
WAC 246-282-016(3)(b): Record keeping for aquaculture operations harvest oyster seed with a seed size greater than 1 inch and less than 1 1/2 inches.	Cost neutral or insignificant up to \$15,000 in recurrent costs.	Cost neutral or insignificant.
WAC 246-282-016(4): Seed size waiver and study.	Indeterminate at this time.	Indeterminate at this time.
WAC 246-282-032(8): Reducing the grow-out period from 180 days to greater than 60 days.	Cost neutral (\$0).	No cost savings indicated.
WAC 246-282-034(3)(g): Removing the requirement for staking or marking the grow-out site.	Cost neutral (\$0).	Cost neutral (\$0).
WAC 246-282-034(3)(h): Removing the lot identification number as part of record keeping.	Cost neutral (\$0).	No cost savings indicated.
WAC 246-282-034(3) and (5): Reducing the grow-out period from 180 days to 120 days.	Cost neutral (\$0).	No cost savings indicated.
WAC 246-282-034(6): Harvest of wild seed and relay standards.	Cost neutral or insignificant.	Not applicable.
WAC 246-282-044(1)(d): Identifying shellstock during transit.	Cost neutral or insignificant up to \$4,500 in one-time costs and \$5,000 in recurrent costs.	\$4,000 in recurrent costs.
WAC 246-282-044(1)(e): Record keeping requirements for transplant.	Cost neutral or insignificant up to \$1,000 in one-time costs and \$600 in recurrent costs.	\$12,000 in one-time costs and \$25,000 in recurrent costs.
WAC 246-282-080(3) and (4): Requirements for harvester and dealer tags.	Cost neutral or insignificant up to \$6,000 in one-time costs and \$1,000 in recurrent costs.	\$40,000 in one-time costs and \$1,000 in recurrent costs.
WAC 246-282-082(2)(a): Expanding export certificates.	Cost neutral or insignificant.	Cost neutral or insignificant.
All sections: Operation documentation.	Cost neutral or insignificant up to \$10,000 in one-time costs and \$2,500 in recurrent costs.	\$2,235 in recurrent costs.

* For some of the survey questions, shellfish operations were asked whether this proposed rule will result in cost savings for their operation, with the following response options: "Yes", "No" and "Neutral (\$0)." If the respondent selected "no", this was reported as "no cost savings indicated" in Table 3. For other survey questions, shellfish operations were able to enter both one-time and annual recurrent costs, as well as select whether the impact of the proposed rule is cost neutral (\$0) or insignificant, or the question did not apply to their operation. If the respondent did not enter any costs nor select the cost neutral option, this was reported as "no costs indicated" in Table 3. If the respondent indicated that the question did not apply to their operation, this was reported as "not applicable" in Table 3.

** One large shellfish operation provided a one-time cost of \$3,000,000 and an annual recurrent cost of \$250,000, which relate to the establishment of nurseries in Approved areas to enable the operation to grow bigger seed. Since this is not a requirement of the proposed rule, these estimates have been excluded from the summary of costs.

The following steps have been identified and taken to reduce the costs of the rule on small businesses.

- 1. **Reducing, modifying, or eliminating substantive regulatory requirements.**
The proposed rule reduces how often thermometers need to be verified.
- 2. **Simplifying, reducing, or eliminating recordkeeping and reporting requirements.**
The proposed rule eliminates the requirement for lot identification numbers.
- 3. **Delaying compliance timetables.**
The department will allow shellfish operations to utilize their inventory of existing tags before ordering new ones.
- 4. **Any other mitigation techniques including those suggested by small businesses or small business advocates.**
The proposed rules add the ability for shellfish operations to apply for a waiver to the seed size to allow the operations another way to measure their seed.

While the steps identified above are applicable to all shellfish operations, they will ease the burden on small businesses, which are the majority of operations in the state of Washington.

Description of how small businesses were involved in the development of the proposed rule.

Small businesses comprised the majority of the shellfish operations participating in the Rules Advisory Committee (RAC) meetings that the board and department have been holding as part of this rulemaking project. An additional strategy that was utilized to provide space for small growers/operations to voice their unique concerns or suggestions was the separation of those RAC meetings held in winter 2024 into small and large operations.

The estimated number of jobs that will be created or lost as a result of the compliance with the proposed rule.

The board does not anticipate that there will be any jobs created or lost as a result of compliance with the proposed rule.

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name Shay Bauman
Address PO Box 47990, Olympia, WA 98504-7990
Phone 360-236-4110
Fax None
TTY 711
Email shay.bauman@sboh.wa.gov
Other N/A

Date: 8/29/2025 Name: Michelle Davis, MPA Title: Executive Director, Washington State Board of Health	Signature: 

AMENDATORY SECTION (Amending WSR 01-04-054, filed 2/5/01, effective 3/8/01)

WAC 246-282-001 Scope and purpose. These requirements, as authorized under chapter 69.30 RCW, establish minimum performance standards for the growing, harvesting, processing, packing, storage, transporting, and selling of shellfish for human consumption or bait. These requirements do not apply to persons who conduct activities limited to:

- (1) Retail food service, in compliance with the requirements of chapter 246-215 WAC, Food service;
- (2) Personal use, in compliance with requirements of chapters 77.32 RCW, Licenses, and 77.15 RCW, Fish and wildlife enforcement code; and
- (3) Transporting as a common carrier of freight.

AMENDATORY SECTION (Amending WSR 25-06-081, filed 3/4/25, effective 4/4/25)

WAC 246-282-005 Minimum performance standards. (1) ~~((Any))~~ A person engaged in a shellfish operation ~~((or))~~, possessing a commercial quantity of shellfish, or possessing any quantity of shellfish for sale for human consumption or bait, must comply with and is subject to:

(a) The requirements of the U.S. Food and Drug Administration National Shellfish Sanitation Program (NSSP), Guide for the Control of Molluscan Shellfish (2023) (copies available through the U.S. Food and Drug Administration, Shellfish Sanitation Branch, and the Washington state department of health, office of ~~((shellfish and water protection))~~ environmental health and safety);

(b) The provisions of 21 Code of Federal Regulations (C.F.R.), Part 123 - Fish and Fishery Products, adopted December 18, 1995, by the United States Food and Drug Administration, regarding Hazard Analysis Critical Control Point (HACCP) plans (copies available through the U.S. Food and Drug Administration, Office of Seafood, and the Washington state department of health, office of ~~((food safety and shellfish programs))~~ environmental health and safety); ~~((and))~~

(c) Chapter 69.30 RCW; and

(d) All other provisions of this chapter.

(2) If a requirement of the NSSP Model Ordinance or a provision of 21 C.F.R., Part 123, is inconsistent with a provision otherwise established under this chapter or other state law or rule, then the more stringent provision, as determined by the department, will apply.

AMENDATORY SECTION (Amending WSR 15-08-083, filed 3/31/15, effective 5/1/15)

WAC 246-282-006 Washington state *Vibrio parahaemolyticus* control plan. (1) This section establishes the ~~((Washington state))~~ *Vibrio parahaemolyticus* (Vp) control plan (control plan) for the months of

May 1st through September 30th (control months). The requirements of this section are an extension of the NSSP Model Ordinance.

(2) ~~((All))~~ A harvester(~~((s and))~~) or shellfish dealer(~~((s))~~) harvesting or delivering oysters to a certified shucker packer for shucking or postharvest processing (PHP) during the control months ~~((must))~~ shall label the oysters with a harvest tag stating "For shucking by a certified dealer" or "For PHP by a certified dealer." Oysters harvested and tagged in compliance with this subsection are exempt from subsections (3) through ~~((+20))~~ (23) of this section.

(3) ~~((The following definitions apply throughout this section:~~

~~(a) "Single-source *Vibrio parahaemolyticus* case" or "case" means a laboratory-confirmed *Vibrio parahaemolyticus*-associated illness or illnesses with a common exposure that are reported to the department. The case must:~~

~~(i) Be associated with commercially harvested shellstock;~~

~~(ii) Not involve documented postharvest abuse; and~~

~~(iii) Be traced back to a single growing area.~~

~~(b) "Control months" means May 1st through September 30th.~~

~~(c) "Cool" or "cooling" means to:~~

~~(i) Adequately ice or place in a controlled environment with a temperature of 45°F (7.2°C) or less; and~~

~~(ii) Reach and maintain an internal oyster tissue temperature of 50°F (10°C) or less.~~

~~(d) "Harvest temperature" means the water temperature or internal oyster tissue temperature at the time of harvest. The harvester or shellfish dealer shall state whether they use water temperature or internal oyster tissue temperature for harvest temperature in their harvest plan.~~

~~(4) All))~~ A harvester(~~((s and))~~) or shellfish dealer(~~((s))~~) harvesting or processing oysters during the control months shall report the volume of oysters harvested or processed. This information must be reported by month, oyster species, size class, utilization type (raw, shucked, postharvest processed), and growing area for all control months. This information must be compiled and reported to the department by December 31st ~~((each year))~~ annually. A harvester((s and)) or shellfish dealer((s)) that ((do)) does not submit this information to the department may not harvest oysters during the control months during the next calendar year.

~~((+5))~~ (4) A harvester(~~((s and))~~) or shellfish dealer(~~((s))~~) harvesting oysters during the control months shall complete, submit to the department, and keep on file a current ~~((*Vibrio parahaemolyticus*))~~ Vp harvest plan of operations (harvest plan). ~~((In order for the department to review the harvest plan prior to May 1st,))~~ The harvest plan must be submitted ((by March 1st each year)) to the department for review at least 14 calendar days before the first planned harvest within the control months unless no changes have been made to the existing harvest plan. Each harvester((s and)) or shellfish dealer((s)) shall sign and date their harvest plan each year and make it available to the department upon request.

~~((+6))~~ (5) The harvest plan must include, at a minimum:

~~((Describe))~~ The harvest, temperature collection, cooling, and conveyance methods((-));

~~((Include))~~ An example of the harvest temperature record designed to meet the requirements in subsection ((+11)) (10) of this section((-)); and

~~((Identify))~~ If water temperature or internal oyster tissue temperature ((is)) will be used as the harvest temperature to meet the

requirements in subsection ~~((11))~~ (10) of this section and specifically how this measurement will be taken.

~~((7))~~ (6) The department shall review and either approve or deny the harvest plan within ~~((thirty))~~ 14 calendar days of receipt. If the department denies approval of the harvest plan, the department shall notify the applicant of the decision in writing stating the reasons for the denial and providing the opportunity to correct the deficiencies. A harvester~~((s and))~~ or shellfish dealer~~((s))~~ may not harvest oysters during the control months unless the department has approved the plan.

(7) A harvester or shellfish dealer shall follow their approved harvest plan. Failure to follow the approved harvest plan subjects the shellfish operation to actions in WAC 246-282-110.

(8) Time of harvest to cooling requirements and harvest controls are based on a risk categorization of each growing area. The department shall assign each growing area a category of 1, 2, or 3, ~~((+))~~where 1 corresponds to the least stringent and 3 the most stringent harvest controls~~((+))~~. These categories are based on the number of single source cases that occurred during the previous consecutive five-year period that were within the control months and ~~((were))~~ attributed to that growing area.

(9) ~~((The department shall categorize coastal growing areas in Willapa Bay and Grays Harbor as Category 1 for the first year of implementation attributing no illnesses to these areas for the years 2010 to 2014. For subsequent years, the department shall categorize coastal growing areas based on the criteria in subsection (8) of this section.~~

~~((10))~~ The department shall complete risk categorization and publish a list of all growing areas by risk category ~~((no later than))~~ by February 1st annually. The department shall use a rolling five-year average number of cases to calculate risk categories as follows:

(a) Category 1: An average of 0.2 or fewer cases attributed to the growing area over a five-year period.

(b) Category 2: An average of more than 0.2, but less than 1.0 cases attributed to the growing area over a five-year period.

(c) Category 3: An average of 1.0 or more cases attributed to the growing area over a five-year period.

~~((11) Time of harvest begins after the first oysters to be harvested are exposed to the air.))~~ (10) Time of harvest to cooling requirements ((and harvest controls are as follows:)) during control months are listed in the tables in (a), (b), and (c) of this subsection. If multiple conditions apply at the time of harvest, then the most stringent time of harvest to cooling must be used.

(a) Category 1:

<u>((Requirements)) Condition at Harvest:</u>	<u>Time of Harvest to Cooling:</u>
Except as noted below, the time of harvest to cooling requirement ~~((from June 1st through September 30th))~~ is:	9 hours
When ambient air temperature ~~((at harvest is greater than 90°F, the time of harvest to cooling requirement))~~ is <u>90.0°F or above:</u>	7 hours

<u>((Requirements)) Condition at Harvest:</u>	<u>Time of Harvest to Cooling:</u>
When harvest temperature is ((between 68°F and 70°F from July 1st through August 31st, the time of harvest to cooling requirement is)) 68.0°F to 70.0°F:	5 hours
~~((Harvest Control: From July 1st through August 31st, harvest is not allowed for twenty-four hours))~~ When harvest temperature is above 70.0°F((-):	<u>Harvest is not allowed for 24 hours</u>

(b) Category 2:

<u>((Requirements)) Condition at Harvest:</u>	<u>Time of Harvest to Cooling:</u>
Except as noted below, the time of harvest to cooling requirement ((from May 1st through September 30th)) is:	7 hours
When ambient air temperature ((at harvest is greater than 85°F, the time of harvest to cooling requirement)) is 85.0°F or above:	5 hours
When harvest temperature is ((between 66°F and 68°F from July 1st through August 31st, the time of harvest to cooling requirement is)) 66.0°F to 68.0°F:	3 hours
~~((Harvest Control: From July 1st through August 31st, harvest is not allowed for twenty-four hours))~~ When harvest temperature is above 68.0°F((-):	<u>Harvest is not allowed for 24 hours</u>

(c) Category 3:

<u>((Requirements)) Condition at Harvest:</u>	<u>Time of Harvest to Cooling:</u>
Except as noted below, <u>the</u> time of harvest to cooling requirement ((from May 1st through September 30th)) is:	5 hours
When ambient air temperature ((at harvest is greater than 80°F, the time of harvest to cooling requirement)) is 80.0°F or above:	3 hours
When harvest temperature is ((between 64°F and 66°F from July 1st through August 31st, the time of harvest to cooling requirement is)) 64.0°F to 66.0°F:	1 hour
~~((Harvest Control: From July 1st through August 31st, harvest is not allowed for twenty-four hours))~~ When harvest temperature is above 66.0°F((-):	<u>Harvest is not allowed for 24 hours</u>

(d) When a harvester or shellfish dealer places oysters in a container or conveyance, but does not remove them from the ((~~tid~~ flat)) harvest site as part of their harvest ((~~and the harvest exceeds the~~

~~time to cooling requirements in subsection (11) of this section, then)), the following conditions must be met:~~

(i) The harvester or shellfish dealer shall hold a valid site certification for that site;

(ii) The oysters in the container or conveyance must be returned to approximately the same tidal level or lower than where they were collected; and

(iii) The oysters must be covered by the tide for a minimum of four hours before harvest can be completed.

~~((12) Harvesters and shellfish dealers shall take the following measurements at the times specified below and record this information in a harvest temperature record for each harvest site for all harvests occurring within the control months.))~~ (11) A harvester or shellfish dealer shall record and maintain a harvest temperature record for each harvest site for all harvests during the control months. The harvest temperature record must be maintained for three years and made available to the department upon request. The following measurements must be taken at the date, time, and location of harvest and recorded in the harvest temperature record:

(a) Air temperature; and

(b) Harvest temperature. A harvester or shellfish dealer using water temperature for the harvest temperature must take the water temperature at the depth of oysters unless another method is documented in their harvest plan.

(12) A harvester((s—and)) or shellfish dealer((s)) shall take ((these)) the measurements required by subsection (11) of this section with ((a)) either:

(a) A thin-tip digital thermometer that is verified ((weekly)) monthly using manufacturer specifications or with a method approved in a harvest plan((. Thermometer verification must be documented and maintained)); or

(b) A thermometer certified by the National Institute of Standards and Technology (NIST) with a manufacturer certificate that does not need to be verified monthly.

(13) A harvester or shellfish dealer using a thermometer according to subsection (12)(a) of this section shall document and maintain the thermometer verification with operational records. ((Harvesters and shellfish dealers shall record the following measurements and the date and time they were taken in the record, maintain the record for three years, and make the record available to the department upon request:

(a) Air temperature at time and location of harvest; and

(b) Harvest temperature at time and location of harvest. Harvesters and shellfish dealers using water temperature for harvest temperature shall take water temperature at depth of oysters unless another method is documented in their harvest plan.

~~((13)))~~ (14) A harvester or shellfish dealer using a thermometer according to subsection (12)(b) of this section shall keep the manufacturer certificate with operational records.

(15) A harvester((s—and)) or shellfish dealer((s)) shall initiate cooling as soon as practical from the time of harvest and within the time of harvest to cooling requirements for the growing area where the oysters were harvested to ensure that the Vp growth is minimized and maximum ((number of)) time of harvest to cooling hours specified in subsection (10) of this section is not exceeded.

~~((14)))~~ (16) If shellstock is beach wet stored or stored in a flow-through wet storage system in a growing area with a different

risk category than where it was harvested, the more stringent time of harvest to cooling requirement must be used.

(17) If the required time of harvest to cooling requirements are not met after removal from the ~~((tide-flat))~~ harvest site, the harvester or shellfish dealer shall dispose of the oysters using one of the methods below and record the disposition on the harvest record:

(a) Destroy the oysters;

(b) Place the oysters within the original growing area or another approved growing area and allow a minimum of ~~((fourteen))~~ 14 days before reharvesting; or

(c) Deliver the oysters to a certified shucker packer for shucking or PHP and attach a harvest tag meeting the requirements in subsection (2) of this section.

~~((15))~~ (18) If ownership of oysters is transferred ((prior to)) before the oysters ((being)) are cooled ((in accordance with the time of harvest to cooling requirements)) to an internal temperature of 50.0°F or less, the receiving dealer shall meet the time of cooling requirement outlined in subsection (10) of this section. The harvester shall ((include in the harvest record required under WAC 246-282-080 the)) provide the following information to the receiving dealer:

(a) Temperatures recorded under subsection ~~((12))~~ 11 of this section;

(b) Date, time, and name of the person or entity ((to whom the oysters were transferred)) who received the oysters; ~~((and))~~

(c) Growing area risk category for the harvested ~~((product.~~

~~((d) The receiving shellfish dealer shall meet the time of harvest to cooling requirements for the original harvest time.~~

~~((16) Vibrio parahaemolyticus training requirements are as follows:~~

~~((a))~~ oysters; and

(d) The total time of harvest to cooling for the oysters based on the growing area risk category. If shellstock is wet stored after purchase, the purchasing dealer shall comply with subsection (16) of this section.

(19) A harvester((s-and)) or shellfish dealer((s)) shall complete an initial department-approved training specific to the requirements of this section ((prior to)) before harvesting or shipping oysters during the control months.

~~((b))~~ (a) A harvester((s-and)) or shellfish dealer((s)) shall complete department-approved refresher training within one year following any revision of this ((rule)) section considered significant under RCW 34.05.328 or at least every five years.

~~((e) Those)~~ (b) A person responsible for the on-site management of harvest activities must be trained by either((+

~~((i) Harvesters and shellfish dealers at their operation who completed the department-approved training; or~~

~~((ii) The department))~~ the department or a person who completed the department approved training within the last five years.

~~((d))~~ (c) A harvester((s-and)) or shellfish dealer((s)) shall maintain a record ((those trained in their operational records)) of all persons who completed training.

~~((17))~~ (20) A harvester or shellfish dealer may request a waiver from specific requirements of this section from the department. The request must:

(a) Be in writing;

(b) Identify the requirement requested to be waived;

(c) State the reason for the waiver; and

(d) Provide supporting information.

~~((18))~~ (21) The department may grant a waiver request if it:

(a) Is consistent with the applicable standards and the intent of this section; and

(b) Provides a comparable level of public health protection to the requirement being waived.

~~((19))~~ (22) If the department approves a waiver request, the department shall notify the requestor of the decision in writing.

~~((20))~~ (23) If the department denies a waiver request, the department shall notify the requestor of the decision in writing stating the reasons for the denial. The requestor shall comply with the provision that was the subject of the waiver request.

~~((21) The department shall review this section to evaluate the effectiveness of the rules and determine areas where revisions may be necessary by November 2017.))~~ (24) For the purposes of this section:

(a) "Control months" means May 1st through September 30th.

(b) "Cool" or "cooling" means to:

(i) Adequately ice or place in a controlled environment with a temperature of 45.0°F (7.2°C) or less; and

(ii) Reach and maintain an internal oyster tissue temperature of 50.0°F (10.0°C) or less.

(c) "Harvest temperature" means the water temperature or internal oyster tissue temperature when harvested.

(d) "Single source Vp case" or "case" means a laboratory-confirmed Vp associated illness or illnesses with a common exposure that are reported to the department. The case must:

(i) Be associated with commercially harvested shellstock;

(ii) Not involve documented postharvest abuse; and

(iii) Be traced back to a single growing area.

(e) "Time of harvest" begins when the first oyster to be harvested in a lot is removed from the water or is no longer submerged by the tide.

AMENDATORY SECTION (Amending WSR 14-09-003, filed 4/3/14, effective 5/4/14)

WAC 246-282-010 Definitions. The ~~((following))~~ definitions in this section, as well as those in chapter 69.30 RCW and the NSSP Model Ordinance, apply ~~((in the interpretation and the implementation of these rules and regulations))~~ throughout chapter 246-282 WAC unless the context clearly requires otherwise. If a definition of the NSSP Model Ordinance or chapter 69.30 RCW is inconsistent with a provision otherwise established under this chapter, then the more stringent definition, as determined by the department, will apply.

(1) "Abatement" means an action or series of actions to eliminate a public health hazard or reduce it to a level acceptable to the ~~((secretary))~~ department.

(2) "Approved" means acceptable to ~~((the secretary based on the department's determination as to))~~ the department based on conformance with appropriate standards and good public health practice.

(3) "Approved laboratory" means a laboratory that is in conformance with requirements of the NSSP Model Ordinance.

(4) "Beach wet storage" or "beach wet stored" means when shellstock greater than maximum seed size is harvested from one harvest site and placed in another harvest site for less than 14 days.

(5) "Certificate of approval" means a license issued by the department.

~~((5))~~ (6) "Civil penalty" means a monetary penalty administratively issued by the ~~((secretary))~~ department. It does not include any criminal penalty; damage assessment; wages, premiums, or taxes owed; or interest or late fees on any existing obligation.

~~((6) "Commercial quantity" means any quantity exceeding:~~

~~(a) Forty pounds of mussels;~~

~~(b) One hundred oysters;~~

~~(c) Fourteen horse clams;~~

~~(d) Six geoducks; or~~

~~(e) Fifty pounds of other hard or soft shell clams; or~~

~~(f) Fifty pounds of scallops.))~~

(7) "Cultch" means any material, other than live shellfish, used for the attachment of seed shellfish.

(8) "Department" means the state department of health.

(9) "Export certificate" means a certificate issued by the department to a licensed shucker-packer or shellstock shipper for use in the foreign export of a lot or shipment of shellfish.

(10) "Harvest" means the act of removing shellstock from a harvest site and its placement on or in a container for transport.

(11) "Harvester" means a shellfish operation with activities limited to growing shellstock, placing shellstock in a container, harvesting shellstock, transporting shellstock using proper transportation conveyances within Washington state, and delivering shellstock to a shellfish dealer licensed by the department within four hours of landing it. A harvester does not process shellfish, ship shellfish outside of Washington state, sell shellfish outside of Washington state, sell shellfish to retail outlets, shuck shellfish, repack shellfish, or store shellfish in any location outside of the approved growing area from where the shellfish is harvested.

(12) "Harvest site" means an area of intertidal or subtidal property within a commercial shellfish growing area, that is described by a unique county parcel number, department of fish and wildlife tract number, department of fish and wildlife catch area number, tribal identification number, or other government identification.

(13) "Harvest site certificate" means a type of certificate of approval that designates one or more harvest sites approved for the harvesting of shellfish.

(14) "Hatchery" means an operation where shellfish larvae are produced and grown to the first sessile stage of life.

(15) "Marina" means any water area with a structure including, but not limited to, docks, basins, floating docks, or mooring buoys used for docking and constructed to provide temporary or permanent docking or buoy moorage space for more than 10 boats. This only includes boats with a marine sanitation device.

(16) "Mooring area" means any portion of a growing area that is used to provide temporary or permanent anchorage or attachment to a mooring buoy for more than 10 boats. This only includes boats with a marine sanitation device.

(17) "Mooring buoy" means a floating marker permanently secured to a waterway bed with an anchoring line that can be used by boats instead of a dock.

~~((16))~~ (18) "Notice of correction" means a document issued by the department that describes a condition or conduct that is not in compliance with chapter 69.30 RCW, this chapter, or the NSSP Model Ordinance and is not subject to civil penalties as provided for in RCW 43.05.110. It is not a formal enforcement action and is not subject to appeal. It is a public record.

~~((16))~~ (19) "NSSP Model Ordinance" means the U.S. Food and Drug Administration National Shellfish Sanitation Program (NSSP), Guide for the Control of Molluscan Shellfish, as adopted in WAC 246-282-005.

~~((17))~~ (20) "Nursery" means an operation where shellfish are grown from an early sessile stage of life up to a maximum size meeting the definition of shellfish seed.

~~((18))~~ (21) "Number of previous violations" means the number of prior violations of the same or a similar nature for which the department has taken a license action or assessed a civil penalty.

~~((19))~~ "Person" means any individual, firm, corporation, partnership, company, association, or joint stock association, and the legal successor thereof.

~~((20))~~ (22) "Person in charge" means an individual responsible for the supervision of employees and the management of any shellfish operation.

~~((21))~~ (23) "Public health threat" is either:

(a) "Low," which means a violation that poses a minor possibility of direct or indirect hazard to public health;

(b) "Intermediate," which means a violation that poses a moderate possibility of direct or indirect hazard to public health; or

(c) "High," which means a violation that poses a known significant hazard or possibility of significant direct or indirect hazard to public health.

~~((22))~~ (24) "Sale" means to sell; offer for sale; barter; trade; deliver; consign; hold for sale, consignment, barter, trade, or delivery; donate; and/or possess with intent to sell or dispose of in a commercial manner.

~~((23))~~ "Secretary" means the secretary of the department of health or the secretary's authorized representative.

~~((24))~~ (25) "Seed" means shellfish that are less than market size for human consumption and have a maximum shell length of:

(a) Thirteen millimeters (1/2 inch) for mussels;

(b) Twenty-five millimeters (1 inch) for scallops;

(c) Nineteen millimeters (3/4 inch) for Olympia oysters;

(d) Nineteen millimeters (3/4 inch) for ~~((Kumamoto))~~ Kumamoto oysters;

(e) ~~((Fifty-one))~~ Thirty-eight millimeters ~~((2))~~ 1 and 1/2 inches) for other oyster species;

(f) Thirty-eight millimeters (1 and 1/2 inch) for geoducks; and

(g) Thirteen millimeters (1/2 inch) for other clam species.

~~((25))~~ (26) "Shellfish" means all varieties of fresh or fresh-frozen oysters, clams, scallops or mussels, either shucked or in the shell, and all fresh or fresh-frozen edible products thereof.

~~((26))~~ (27) "Shellfish dealer" means a person with a shellstock shipper or shucker-packer license.

~~((27))~~ (28) "Shellfish growing area" means the classified lands and waters in and upon which shellfish ~~((are))~~ may be grown for harvesting in commercial quantities or for sale for human consumption.

~~((28))~~ (29) "Shellfish operation" means growing, placing in a container, harvesting, transporting, processing, culling, shucking,

packing, and repacking, storing, shipping, or reshipping of shellfish in commercial quantities or for sale for human consumption.

~~((+29+))~~ (30) "Shellfish operation license" means a type of certificate of approval applying to the overall activities of a shellfish operation.

~~((+30+))~~ (31) "Shellstock shipper" means a shellfish operation that does not shuck shellfish or repack shucked shellfish.

~~((+31+))~~ (32) "Shucker-packer" means a shellfish operation that may shuck and pack shellfish.

~~((+32+))~~ (33) "Technical assistance" means information provided by the department to a person regarding chapter 69.30 RCW; this chapter; technologies or other methods to achieve compliance with these rules; assistance in applying for a departmental license or permit required by these rules; or the goals and objectives of these rules. This is not intended to modify the definition of "technical assistance" as provided in RCW 43.05.010(3).

~~((+33+))~~ (34) "Transplant" means when shellstock greater than maximum seed size is moved from one harvest site and placed in another harvest site for 14 days or more.

(35) "Violation" means the commission of an act or acts prohibited by the provisions of chapter 69.30 RCW, ~~((these rules))~~ this chapter, or the NSSP Model Ordinance.

~~((+34+))~~ (36) "Wet storage" or "wet stored" means the ~~((temporary storage))~~ placement of harvested shellstock in containers or floats in natural bodies of water or in tanks containing natural or synthetic seawater. Types of wet storage include beach wet storage, flow-through wet storage, and recirculating wet storage.

~~((+35+))~~ (37) "Wild seed" means naturally set seed shellfish.

AMENDATORY SECTION (Amending WSR 11-19-011, filed 9/7/11, effective 10/8/11)

WAC 246-282-012 Certificates of approval—Operation licenses, harvest site certificates. (1) The department shall issue~~((s—two types of))~~ the following certificates of approval to a person~~((s))~~ who conducts shellfish operations~~((—They are))~~ and meets the requirements in this chapter and chapter 69.30 RCW:

(a) A shellfish operation license~~((s))~~; and

(b) A harvest site certificate~~((s))~~.

(2) ~~((Any))~~ A person ~~((who possesses a commercial quantity of shellfish or any quantity of shellfish for sale for human consumption must possess, or act on behalf of a person who possesses,))~~ engaged in the actions listed in WAC 246-282-005(1), or a person acting on behalf of them, must have a valid shellfish operation license.

~~((To obtain))~~ (3) An applicant for a shellfish operation license~~((, a person must))~~ shall:

(a) Submit to the department a ~~((completed))~~ complete application on a form ~~((developed))~~ provided by the department~~((—~~

~~((b))~~ Submit to the department an acceptable~~(())~~ and a written plan of operations that completely describes the shellfish operation;

~~((c))~~ (b) Pass a preoperational inspection demonstrating compliance with chapter 69.30 RCW, this chapter, and the NSSP Model Ordinance; and

~~((d))~~ (c) Pay the (department any shellfish operation li-
ense) applicable fee required by ((this chapter)) WAC 246-282-990.

~~((3) Any person who harvests))~~ (4) A person harvesting a commer-
cial quantity of shellfish or any quantity of shellfish for sale for
human consumption ((must possess, or act on behalf of a person who
possesses,)) or bait, or a person acting on behalf of them, shall have
a valid harvest site certificate. ((In order for a person to obtain a
harvest site certificate, all of the following requirements must be
met.))

(5) To qualify for a harvest site certificate, an applicant
shall:

(a) ((The person possesses)) Have a valid shellfish operation li-
cense((-));

(b) ((The person)) Submit((s)) to the department a completed ap-
plication ((that describes)) on a form provided by the department. The
form must require, at a minimum, the following characteristics ((of))
describing the site:

(i) Geographic location;

(ii) Map showing legal boundaries;

(iii) Unique government identification number, such as county
parcel number, department of fish and wildlife tract number, depart-
ment of fish and wildlife catch area number, or tribal identification
number; and

(iv) Documentation of legal ownership or lease for shellfish har-
vesting((-

~~(c) The harvest site is in a growing area that meets the require-~~
~~ments of chapter 69.30 RCW, this chapter, and the NSSP Model Ordinance~~
~~for a commercial shellfish growing area.~~

~~(d) The harvest site is not impacted by any actual or potential~~
~~sources of pollution.~~

~~(e) The harvest site passes a pollution assessment inspection~~
~~conducted by the department if necessary to determine if the site is~~
~~impacted by any actual or potential sources of pollution.~~

~~(f) The person signs the current conditionally approved area man-~~
~~agement plan, if applicable.~~

~~(g) The person pays the department any harvest site application~~
~~fee required by this chapter)); and~~

(c) Pay the applicable fee required by WAC 246-282-990.

~~((4) All))~~ (6) The department shall issue a harvest site certif-
icate if all of the requirements in subsection (5) of this section are
met and:

(a) The harvest site is in a growing area that meets the require-
ments of chapter 69.30 RCW, this chapter, and the NSSP Model Ordinance
for a shellfish growing area;

(b) The harvest site is not impacted by any actual or potential
sources of pollution. If necessary to determine whether the site is
impacted by any actual or potential sources of pollution, the harvest
site must pass a pollution assessment inspection conducted by the de-
partment; and

(c) The applicant signs the current conditionally approved area
management plan, if applicable.

(7) A shellfish operation license((s)) and harvest site certifi-
cate((s)) for a shellfish dealer((s)) expires on ((the thirtieth day
of June each year)) June 30th annually. ((All))

(8) A shellfish operation license((s)) and harvest site certifi-
cate((s)) for a harvester((s)) expires on ((the thirty-first day of
March each year)) March 31st annually.

WAC 246-282-014 Operating provisions. (1) ~~((Any person who possesses a commercial quantity of shellfish or any quantity of shellfish for sale for human consumption must display a photocopy or original of a valid shellfish operation license))~~ A person engaged in the actions listed in WAC 246-282-005(1), or a person acting on behalf of them, shall show a valid shellfish operation license, upon request, to ~~((any))~~ an authorized representative of the department, a fish and wildlife patrol officer, or an ex officio patrol officer. The shellfish operation license can be an electronic copy, photocopy, or the original issued by the department. Failure to do so subjects the person to the penalty provisions of this chapter, as well as immediate seizure of the shellfish by the representative or officer.

(2) ~~((Any person who harvests))~~ A person harvesting a commercial quantity of shellfish or any quantity of shellfish for sale for human consumption ~~((must display a photocopy or original of))~~ or bait, or a person acting on behalf of them, shall show a valid harvest site certificate, upon request, to ~~((any))~~ an authorized representative of the department, a fish and wildlife patrol officer, or an ex officio patrol officer. The harvest site certificate can be an electronic copy, photocopy, or the original issued by the department. Failure to do so subjects the person to the penalty provisions of this chapter, as well as immediate seizure of the shellfish by the representative or officer.

(3) ~~((Any person who places))~~ A person placing a commercial quantity of shellfish or any quantity of shellfish for sale for human consumption or bait in containers at a harvest site ~~((must do so only at a site for which the person possesses)), or a person acting on behalf of them, shall have a valid harvest site certificate.~~

(4) The owner(s) of a shellfish operation ~~((must))~~ shall designate an individual as the person in charge of the operation. The owner(s) of a shellfish operation that includes one or more harvest sites may designate a different individual as the person in charge of the operation's harvest site(s) than the individual designated as the person in charge of all other phases of the shellfish operation.

(5) The owner(s) and the designated person in charge of a shellfish operation ~~((must))~~ shall:

(a) Ensure that at least one individual harvesting shellfish on behalf of the operation at each harvest site carry a copy, either electronic or paper, of ~~((both the))~~ a valid operation license and ~~((the))~~ a valid harvest site certificate ~~((designating that the site is approved by the department for harvesting by that operation));~~

(b) Ensure the individuals harvesting on behalf of the operation furnish shellfish tags ~~((meeting))~~ that comply with the requirements of chapter 69.30 RCW, ((these rules)) this chapter, and the NSSP Model Ordinance ~~((to those individuals harvesting on behalf of the operation));~~

(c) Ensure, by supervision at harvest sites or other adequate means, that ~~((those))~~ the individuals working on behalf of the operation harvest only from harvest sites approved by the department for the operation; and

(d) Notify the department if ~~((an owner or person in charge has))~~ they have reason to believe that ~~((any))~~ an individual is using the operation's tags, shellfish operation license, or harvest site certifi-

icate for ~~((any))~~ a purpose other than ~~((one))~~ a purpose approved by the department.

(6) The designated person in charge of a shellfish operation ~~((must))~~ shall have a functioning telephone ~~((message device or service issued by a telephone service provider))~~ with voice mail capabilities and an email address belonging to the owner(s) or person in charge. The person in charge ~~((must))~~ shall:

(a) Monitor the ~~((device or service))~~ telephone, voice mail inbox, and email each day that the shellfish operation is active, regarding messages from the department about emergency closure of harvest areas or recall of shellfish products; and

(b) Notify the department whenever the telephone number or email used for this purpose changes; or

(c) Maintain another equivalent method of contact with the department approved in the plan of operations.

AMENDATORY SECTION (Amending WSR 19-14-094, filed 7/1/19, effective 8/1/19)

WAC 246-282-016 Aquaculture. ~~((Any person who conducts an aquaculture operation and is in possession of a commercial quantity of shellfish or any quantity of shellfish for sale for human consumption must meet all requirements of this chapter.))~~ (1) A person who engages in aquaculture activities must have an aquaculture permit. To qualify for an aquaculture permit approved by the department, the person shall comply with the NSSP Model Ordinance Chapter 6 - Shellfish Aquaculture.

(2) The department shall approve an operation for aquaculture activities in prohibited and unclassified areas if the following requirements are met:

(a) The person has a valid shellfish operation license;

(b) The operation has an aquaculture plan of operations and aquaculture permit approved by the department;

(c) Shellfish must not exceed the defined maximum seed size. The person shall limit the production of seed larger than maximum seed size commingled with the smaller seed to less than five percent of the total number of seed in the lot. Depletion of the shellstock above maximum seed size is required if more than five percent of the seed lot is above maximum seed size;

(d) The beginning of the minimum grow-out period for a lot is the moment when the entire lot is added to the grow-out site;

(e) Shellfish are moved to approved or conditionally approved areas for a minimum of 120 days in open status; and

(f) The initial and grow-out sites are listed on the shellfish dealer's harvest site certificate.

(3) If the person intends to harvest oyster seed, other than Kukumamoto and Olympia, that have a seed size greater than one inch and less than one and one-half inches, from a prohibited or unclassified area, the operation must:

(a) Begin the lot minimum grow-out period the moment when the entire lot is added to the grow-out site; and

(b) Keep records for each lot of shellfish that show the species, location, date, and quantity moved from the initial site; the grow-out

location; and the date of first harvest of any of those shellfish from the grow-out site.

(4) The department may grant a waiver to seed size as defined in WAC 246-282-010(25) if:

(a) It is consistent with the applicable standards and the intent of the definition, as related to market size and 120-day grow-out time;

(b) Studies are completed that determine shellfish growth in the defined time period; and

(c) It provides a comparable level of public health protection to the requirement being waived.

(5) If the department approves a waiver request, the department shall notify the requestor of the decision in writing.

(6) Waiver approval will only be granted for the growing areas evaluated in subsection (4)(b) of this section.

(7) If the department denies a waiver request, the department shall notify the requestor of the decision in writing stating the reasons for the denial.

NEW SECTION

WAC 246-282-017 Mooring areas. In a mooring area with a density of greater than one boat per acre, the department shall conduct a pollution assessment to support the classification of that portion of the growing area in accordance with the NSSP Model Ordinance. The department may amend the density requirement in this section if the mean water depth in an enclosed bay is less than 12 feet or under certain hydrographic conditions where dilution calculations show the area cannot meet 14 fecal coliform/100 ml at the sanitary line.

AMENDATORY SECTION (Amending WSR 01-04-054, filed 2/5/01, effective 3/8/01)

WAC 246-282-020 Growing areas. (1) ~~((Any person who harvests))~~ A person harvesting a commercial quantity of shellfish or any quantity of shellfish for sale, for human consumption ~~((must do so))~~ or bait, or a person acting on behalf of them, shall harvest only from a harvest site that meets one or more of the following conditions:

(a) The department has classified the shellfish growing area as ~~((("))approved((("))~~ or ~~((("))conditionally approved,((("))~~ according to provisions of the NSSP Model Ordinance and the harvest site is in open status ~~((at the time of harvest))~~ when harvested;

(b) The department has approved the harvest site according to provisions of a permit for relay, wild seed, or bait;

(c) The harvest site is used for shellfish activities limited to a hatchery or a nursery operation handling only seed obtained from a hatchery; or

(d) The harvest site is used for shellfish activities limited to the initial harvest of seed attached to containerized empty shellfish shells or other cultch material.

(2) The department classifies a shellfish growing area as ~~((("))restricted(((")) or ((("))prohibited((("))~~ according to provisions of the NSSP Model Ordinance. ~~((However, the department considers classifying a harvest site as "restricted" only when the department has received a valid application for a permit for relay or wild seed harvest from the site.))~~ A restricted classification will be considered when the department receives a complete application for a permit for relay or wild seed harvest for the site and there is no impact from a wastewater treatment plant or wastewater collection system, marina, combined sewage overflow, or other pathogens of human origin.

(3) While a harvest site is in closed status, ~~((no))~~ a person may not move shellfish ~~((from it))~~ to a location outside of the harvest site or above the mean low tide line of the harvest site, unless the department has approved:

(a) Harvesting shellfish by that person from the site according to provisions of a permit for relay, wild seed harvest, or bait harvest; or

(b) Moving shellfish by that person from the site to another site in a natural body of water within the same ~~((("))~~conditionally approved~~((("))~~ growing area under a written plan of operations.

(4) Harvesting is prohibited ~~((from))~~ in all ~~((growing areas))~~ unclassified ~~((by the department))~~ areas except for bait harvest according to WAC 246-282-036 and aquaculture according to WAC 246-282-016.

AMENDATORY SECTION (Amending WSR 11-17-104, filed 8/22/11, effective 9/22/11)

WAC 246-282-032 Relay permit. (1) The department ~~((will))~~ shall issue a relay permit ~~((to a person))~~ to move shellfish from a harvest site in a shellfish growing area classified as ~~((("))restricted(((")) or ((("))conditionally approved((("))~~ in closed status meeting the criteria for ~~((("))restricted(((")) classification((, if all of the following conditions))~~ if the requirements in this section and chapter 69.30 RCW are met.

(2) An applicant for a relay permit shall:

(a) ~~((The person possesses))~~ Have a valid shellfish operation license~~(((-)))~~;

(b) ~~((The person possesses))~~ Have a valid harvest site certificate listing both the initial harvest site and the grow-out site~~(((-)))~~;

(c) ~~((The initial harvest site and grow-out site meet the requirements for relay specified in this chapter and the NSSP Model Ordinance.~~

~~((d) The person submits a completed written))~~ Submit a complete application on a form provided by the department and a written plan of operations ((approved by the department)) that completely ((describing)) describes the procedures and conditions of the relay operation~~(((-)))~~;

~~((e) The person conducts))~~ (d) Conduct and document~~((s))~~ a separate validation study approved by the department for each of the following periods of time when shellfish will be relayed:

(i) May 1st through October 31st; and

(ii) November 1st through April 30~~(((-)))~~th; and

~~((f) The person pays the department a relay permit application fee or renewal))~~ (e) Pay the applicable fee as required by ((this chapter)) WAC 246-282-990.

~~((2) Each))~~ (3) The department shall issue a relay permit if all of the requirements in subsection (2) of this section are met and the initial harvest site and grow-out site meet the requirements for relay specified in this chapter and the NSSP Model Ordinance.

(4) A validation study for a relay permit must demonstrate that shellfish harvested from a specified initial site do not contain excessive levels of fecal coliform bacteria and when relayed to a specified grow-out site for a specified ((time)) period consistently purge themselves of bacteria to approved levels. ((Each)) The validation study must ((meet all of the following conditions.)):

(a) ((It must)) Document that the geometric mean fecal coliform bacteria level in a minimum of five 100-gram tissue samples, representative of shellfish of the same species in the entire initial harvest site, is equal to or less than 1,300, with no sample having more than 2,300((-)):

(b) ((It must)) Document that specified relay procedures, times, and environmental conditions reduce fecal coliform bacteria in a minimum of five 100-gram tissue samples, representative of the entire lot of shellfish relayed, to levels that are equal to or less than:

(i) 330, with no more than two samples having greater than 230; or

(ii) Ten percent greater than the geometric mean of a minimum of five 100-gram tissue samples representative of the same shellfish species grown continuously for a minimum of six months at the grow-out site((-)):

(c) ((It must be repeated)) Repeat a minimum of once every ((twelve)) 12 years for a continuing operation and whenever relay conditions change((-)); and

(d) Document that all samples ((must be)) are analyzed by an approved laboratory.

~~((3) A person operating under a relay permit must follow all procedures in))~~ (5) The plan of operations ((approved by the department, including)) required in subsection (2)(c) of this section must describe the following activities:

(a) How staking ((or)), marking, or documenting will be done to easily identify the grow-out site ((to be easily identified by the person)) until the minimum relay period ((of time)) is passed; and

(b) ((Considering the beginning of the minimum relay time period for a lot to be the moment that the last part of the lot is added to the grow-out site;

(c) Relaying)) How the person will relay the shellfish to a designated grow-out site for a minimum of seven days, or longer period ((of time)) as approved by the department((-); and

(d) Keeping records for each relayed lot of shellfish that show a lot identification number; the species, location, date, and quantity moved from the initial harvest site; the grow-out location; and the date of first harvest of any of those shellfish from the grow-out site.

(4)) (6) The beginning of the minimum relay period for a shellfish lot is the moment when the last part of the lot is added to the grow-out site.

(7) The operation shall keep documentation for each relayed lot, that shows:

(a) A lot identification number;

(b) The species, location, date, and quantity moved from the initial harvest site;

(c) The grow-out location; and

(d) The date of first harvest of any of those shellfish from the grow-out site.

(8) For ~~((each lot of))~~ shellfish relayed to a site for a grow-out period of less than ~~((fourteen))~~ 14 days, a person ~~((must))~~ shall:

(a) Collect at least one sample from the ~~((shellfish))~~ lot at the initial harvest site and have it analyzed by an approved laboratory to demonstrate that the lot contains no more than 2,300 fecal coliform bacteria per 100 grams of shellfish tissue; and

(b) Collect at least one sample from the ~~((shellfish))~~ lot at the grow-out site at the end of the relay period and have it analyzed by an approved laboratory to demonstrate that the lot contains fecal coliform bacteria within the maximum limits determined by a validation study, as described in subsection ~~((+2))~~ (3)(b) of this section, before releasing control of the ~~((shellfish))~~ lot.

~~((+5))~~ (9) A person is exempt from ~~((any))~~ fees required by WAC 246-282-990 for an initial application and a validation study conducted by the department for a relay permit for the purpose of relaying shellfish from a growing area that the department downgraded from a classification of ~~(("))~~ approved~~(("))~~ or ~~(("))~~ conditionally approved~~(("))~~ to ~~(("))~~ restricted~~(("))~~ within the previous ~~((twenty-four))~~ 24 months.

~~((+6))~~ (10) A ~~((person's))~~ relay permit issued under this section expires on the same date as the ~~((person's))~~ shellfish operation license.

~~((+7))~~ (11) A person is exempt from the provisions of subsection ~~((+1-e))~~ (2)(d) of this section for the purpose of relaying shellfish to an approved grow-out site for a minimum of ~~((six months))~~ 60 days. Only microbiological contaminants need to be reduced.

~~((+8))~~ (12) A person ~~((possessing))~~ must have a valid shellfish operation license ~~((may))~~ to act as an agent for another person ~~((possessing))~~ with a valid shellfish relay permit for the purpose of harvesting shellfish from the initial harvest site specified in the relay permit, ~~((provided that))~~ if the agent conducting the harvest is:

(a) Documented in the permit;

(b) In possession of a copy of the permit ~~((at the time of harvest))~~ when harvesting; and

(c) Conducting activities described in the written plan of operations approved by the department for the agent's shellfish operation.

AMENDATORY SECTION (Amending WSR 01-04-054, filed 2/5/01, effective 3/8/01)

WAC 246-282-034 Wild seed permit. (1) The department ~~((will))~~ shall issue a wild seed permit ~~((to a person))~~ to move shellfish from a harvest site in a growing area classified by the department as ~~(("conditionally approved" in closed status, "restricted," or "prohibited," if all of the following conditions are met))~~ prohibited if the requirements in this section and chapter 69.30 RCW are met.

(2) To qualify for a wild seed permit:

(a) The ~~((person possesses))~~ applicant shall:

(i) Have a valid shellfish operation license~~((-))~~; and

~~((b) The person possesses))~~ (ii) Have a harvest site certificate listing both the initial harvest site for the seed and the grow-out site((-));

~~((e))~~ (b) The original harvest site ((has)) must have acceptable levels of poisonous chemicals, is not in an area known to be a hazardous chemical disposal site, and is not in a closure zone of a wastewater treatment plant or marina((-));

~~((d))~~ (c) The grow-out site ((is)) must be in a natural body of water classified by the department as ((("))approved((")) or ((("))conditionally approved.((("))

~~((e) The person submits a completed written))~~ (3) To apply for a wild seed permit the applicant shall:

(a) Submit to the department a complete application on a form provided by the department and a written plan of operations ((approved by the department)) that completely ((describing)) describes the procedures of the wild seed operation, including the size distribution of the seed((-)); and

~~((f) The person pays the department a wild seed permit application fee or renewal))~~ (b) Pay the applicable fee as required by ((this chapter)) WAC 246-282-990.

~~((2))~~ (4) A person operating under a wild seed permit ((must)) shall:

(a) Follow all procedures in the plan of operations approved by the department;

(b) Harvest seed from an area classified as ((("))prohibited((")) only during daylight hours;

(c) Harvest seed from an area classified as ((("))prohibited((")) only under direct monitoring by a person approved by the department;

(d) Leave seed in a grow-out site for a minimum of ((six months)) 120 days before final harvest;

(e) Limit harvest of live shellfish larger than seed size attached to, or commingled with, the seed to less than five percent of the total number of the shellfish harvested from the site;

(f) Place any live shellfish larger than seed size attached to, or commingled with, the seed in the grow-out site for a minimum of ((six months)) 120 days after initial harvest; and

(g) ((Stake or mark the grow-out site to be easily identified by the person for a minimum of six months from the time of moving to the site any seed attached to, or commingled with, shellfish larger than seed size; and

(h)) Keep records for each lot of seed harvested that show ((a lot identification number;)) the species, location, date, and quantity moved from the initial harvest site; the grow-out location; and the date of first harvest of any of those shellfish from the grow-out site.

~~((3) A person's))~~ (5) A wild seed permit issued under this section expires on the same date as the ((person's)) shellfish operation license.

~~((4))~~ (6) A person is exempt from the requirements of this section for the activity of harvesting seed attached to containerized empty shellfish shells or other cultch material, provided that the person:

(a) Meets the conditions of subsection ((1)) (2)(a) through ((d)) (c) of this section;

(b) Leaves the seed in the grow-out site for a minimum of ((six months)) 120 days before final harvest; and

(c) ~~((Fully describes the seed harvest and grow-out activities in))~~ Submits a written plan of operations ~~((approved by))~~ to the department that completely describes the seed harvest and grow-out activities for the person's shellfish operation license.

(7) Wild seed harvested from a conditionally approved area in closed status or a restricted area must follow the relay standards listed in WAC 246-282-032.

AMENDATORY SECTION (Amending WSR 01-04-054, filed 2/5/01, effective 3/8/01)

WAC 246-282-036 Bait permit. (1) The department ~~((will approve and))~~ shall issue a bait permit ~~((to a person))~~ to harvest shellfish from a harvest site in a growing area classified by the department as ~~((("))prohibited, (((")) restricted, (((")) or (((")) conditionally approved(((")) in closed status ((if all of the following conditions are met.))~~ or from an unclassified area if the requirements in this section and chapter 69.30 RCW are met.

(2) To qualify for a bait permit:

(a) The ~~((person possesses))~~ applicant shall:

(i) Have a valid shellfish operation license((-)); and

~~((b) The person possesses))~~ (ii) Have a valid harvest site certificate for the site((-));

~~((e))~~ (b) The harvest site ((is not)) must not be impacted by biotoxin levels that would cause the department to close it for harvest for human consumption((-));

~~((d) The person submits a completed written))~~ (3) To apply for a bait permit the applicant shall:

(a) Submit a complete application to the department on a form provided by the department and written plan of operations ((approved by the department)) that completely ((describing)) describes the procedures of the bait operation((-)); and

~~((e) The person pays the department a bait permit application fee or renewal))~~ (b) Pay the applicable fee as required by ((this chapter)) WAC 246-282-990.

~~((2))~~ (4) A person operating under a bait permit ((must)) shall:

(a) Follow all procedures in the plan of operations approved by the department;

(b) Harvest bait from an area classified as ~~((("))prohibited(((")) or unclassified~~ only during daylight hours;

(c) Harvest bait from an area classified as ~~((("))prohibited(((")) or unclassified~~ only under direct monitoring by a person approved by the department;

(d) Completely immerse the shellfish in an approved dye that imparts an easily noticeable permanent color to the tissue immediately upon landing the shellfish;

(e) Label each container of shellfish "NOT FOR HUMAN CONSUMPTION - BAIT USE ONLY" ~~((prior to))~~ before removal from the harvest site;

(f) Store the shellfish physically separated from any shellfish intended for human consumption; and

(g) Keep records for each lot of shellfish harvested for use as bait showing a lot identification number, the species, the harvest

site, the harvest date, the quantity harvested, the names of all buyers, and the quantity sold to each buyer.

~~((3) A person's))~~ (5) A bait permit issued under this section expires on the same date as the ((person's)) shellfish operation license.

~~((4) Any))~~ (6) A person possessing a commercial quantity of bait shellfish is exempt from the requirement to obtain a bait permit ((provided)) if that ((the)) person:

- (a) Obtains the shellfish from a person with a valid bait permit;
- (b) Possesses a sales invoice for the shellfish from a person with a valid bait permit; and
- (c) Maintains each container of shellfish prominently labeled "NOT FOR HUMAN CONSUMPTION - BAIT USE ONLY."

AMENDATORY SECTION (Amending WSR 01-04-054, filed 2/5/01, effective 3/8/01)

WAC 246-282-042 Wet storage permit. ~~((1) Any person who wet stores a commercial quantity of shellfish or any quantity of shellfish for sale for human consumption must have a written plan of operations, approved by the department, completely describing the activity.~~

~~(2) A person licensed as a harvester may wet store only in a natural body of water that is part of the same growing area as the harvest site of the shellfish.~~

~~(3) Any person who operates a recirculating or flow-through wet storage system must possess a wet storage permit issued by the department. A wet storage permit will be issued to a person for a recirculating or flow-through wet storage system if the person:~~

- ~~(a) Possesses a valid shellfish operation license;~~
- ~~(b) Submits a completed written application and plan of operations to the department completely describing the procedures of the wet storage operation;~~
- ~~(c) Documents that the water used for the operation meets the requirements of the NSSP Model Ordinance;~~
- ~~(d) Passes an inspection by the department; and~~
- ~~(e) Pays the department a wet storage application fee or renewal fee as required by this chapter.~~

~~(4) If a person uses a natural body of water for a wet storage operation, the person must possess a valid harvest site certificate listing the body of water.~~

~~(5) If a person uses artificial seawater for a wet storage operation, the chemicals used to make the seawater must be approved food grade.~~

~~(6) A person operating under a wet storage permit must follow all procedures in the plan of operations approved by the department.~~

~~(7) A person's wet storage permit expires on the same date as the person's shellfish operation license.))~~ (1) The department shall issue a wet storage permit for recirculating, flow-through, or beach wet storage if the requirements in this section and chapter 69.30 RCW are met.

(2) To qualify for a wet storage permit the applicant shall:

- (a) Have a valid shellfish operation license;
- (b) Have a valid harvest site certificate for the applicable site(s);

(c) Submit to the department a complete application on a form provided by the department and a written plan of operations that completely describes the procedures of the wet storage operation;

(d) Document that the water used for the operation meets the requirements of the NSSP Model Ordinance;

(e) Pass an inspection by the department; and

(f) Pay the applicable fee required by WAC 246-282-990.

(3) If shellstock are beach or flow-through wet stored, the following requirements must be met:

(a) The person shall have a valid wet storage permit for where the shellstock are stored;

(b) Both the original harvest site and the wet storage site must be classified as approved or conditionally approved in open status;

(c) The shellstock must:

(i) Contain a tag as specified in WAC 246-282-080 when moved from one harvest site to another;

(ii) Be identified by lot, with each lot containing shellstock of the same harvest site and date. Shellstock must not be commingled with other lots;

(iii) Be held in containers and stored in a manner that ensures the free flow of water to all shellstock; and

(iv) Be tagged according to requirements listed in WAC 246-282-080 once harvested.

(4) If shellstock are wet stored in a recirculating system, the following requirements must be met:

(a) The person shall have a valid wet storage permit for where the shellstock are stored;

(b) The operation shall undergo and pass a validation study as described in the NSSP Model Ordinance;

(c) The operation shall maintain water testing requirements as described in the NSSP Model Ordinance;

(d) The shellstock must:

(i) Contain a tag as specified in WAC 246-282-080;

(ii) Be identified by lot, with each lot containing shellstock of the same harvest site and date. The shellstock must not be commingled with other lots; and

(iii) Be held in containers and stored in a manner that ensures the free flow of water to all shellstock; and

(e) If the operation uses artificial seawater for a recirculating wet storage operation, the chemicals used to make the seawater must be approved food grade.

(5) If shellstock is wet stored for less than 14 days, the shellstock will keep the characteristics and properties of the original harvest site.

(6) If shellstock is wet stored, excluding a recirculating wet storage system, on a site for 14 days or more, the shellstock will take on the characteristics and properties of that harvest site and be considered transplanted. These shellstock must meet the requirements under WAC 246-282-044.

(7) A person operating under a wet storage permit shall follow all procedures in the plan of operations approved by the department.

(8) A wet storage permit issued under this section expires on the same date as the shellfish operation license.

NEW SECTION

WAC 246-282-044 Transplant. (1) To transplant shellstock, the following requirements must be met:

- (a) The person shall have a valid shellfish operation license;
 - (b) The person shall have a valid harvest site certificate for the original harvest site(s) and the original harvest site(s) are classified as approved or conditionally approved in the open status.
 - (c) The person shall have a harvest site certificate showing grow-out site(s) as approved transplant site(s);
 - (d) During transit, the shellstock must be identified by tagging or other methods approved by the department. The identification must include:
 - (i) The date the shellstock was removed from the original harvest site(s);
 - (ii) The quantity of shellstock;
 - (iii) The species of shellstock; and
 - (iv) The original harvest site(s) and grow-out site(s); and
 - (e) The operation shall keep and maintain accurate and detailed records of the original harvest site, transplant method, and destination of transplanted shellstock for one year.
- (2) After 14 days, the shellstock will take on the characteristics and properties of the transplant site.
- (3) While in transit, shellstock under this section are exempt from the requirements in WAC 246-282-006.

AMENDATORY SECTION (Amending WSR 01-04-054, filed 2/5/01, effective 3/8/01)

WAC 246-282-050 Packing, handling, and storing of shucked shellfish. (~~((1) Any person who packs, handles, or stores shucked shellfish must maintain it at an internal product temperature of forty-five degrees Fahrenheit or less beginning within three hours after it is shucked.~~

~~(2) Any))~~ A person who packs, handles, or stores shucked shellfish or operates a shucked shellfish repacking plant ((must)) shall meet all the requirements specified in this chapter and the NSSP Model Ordinance for packing plants.

AMENDATORY SECTION (Amending WSR 01-04-054, filed 2/5/01, effective 3/8/01)

WAC 246-282-060 Personal health and cleanliness. (1) ~~((Any))~~ A person may not work in any growing area, shucking, packing, or repacking plant in any capacity when ill with or the carrier of a communicable disease which is transmissible through food and is in the infectious stage ((may not work in any growing area, shucking, packing or repacking plant in any capacity)) where that person might contaminate the shellfish or food contact surfaces with pathogenic organisms. The

owner, the person in charge, and the employee are all responsible for compliance with the requirements of this section.

(2) ~~((Any))~~ A person who is an owner, a person in charge, or an employee of a shellfish operation must practice good personal cleanliness while handling shellfish. ~~((These))~~ The person ~~((s—must))~~ shall wash their hands thoroughly with soap and water before ~~((starting to handle))~~ handling shellfish and as often as ~~((is))~~ necessary to remove filth and soil that might contaminate shellfish.

(3) If the department determines by investigation that an owner or employee of a shellfish operation might be the source of a food-borne illness transmitted through shellfish, ~~((then the secretary))~~ it may require medical examination of that person and laboratory examination of clinical specimens from that person to determine presence of infection. ~~((Any))~~ A person failing to ~~((obtain))~~ get an examination required by the ~~((secretary))~~ department may not work for a shellfish operation, for a period ~~((of time))~~ the department determines that person could be infectious, in any capacity that could result in contamination of shellfish with pathogenic organisms.

AMENDATORY SECTION (Amending WSR 01-04-054, filed 2/5/01, effective 3/8/01)

WAC 246-282-070 Construction and maintenance. (1) ~~((All owners and persons))~~ An owner or person in charge of shellfish operations ~~((must))~~ shall arrange their physical facilities to aid in the flow of shellfish products through all handling, processing, and storage areas in a manner that will minimize contamination of the shellfish.

(2) ~~((Any))~~ An owner of a shellfish operation ~~((must))~~ shall submit to the department for consultation properly prepared plans and specifications of physical facilities for shellfish processing or sanitation activities at least ~~((thirty))~~ 30 days before the facilities are:

(a) Originally constructed;

(b) Converted from another use; or

(c) Extensively remodeled to the extent that a plan for a building permit is required by the city or county where located.

(3) The department ~~((will))~~ shall review properly prepared plans and specifications of physical facilities for shellfish processing or sanitation activities required by subsection (2) of this section within ~~((thirty))~~ 30 days of receipt and provide technical assistance to the owner of the shellfish operation regarding whether the proposed physical facilities would meet the requirements of this chapter.

AMENDATORY SECTION (Amending WSR 01-04-054, filed 2/5/01, effective 3/8/01)

WAC 246-282-080 Identification and records. (1) ~~((Any))~~ A person ~~((who possesses a commercial quantity of shellfish or any quantity of shellfish for sale for human consumption must possess))~~ engaged in the actions listed in WAC 246-282-005(1), or a person acting on behalf

of them, shall have a written record documenting that the shellfish came from one or more of the following sources:

(a) A harvest ((site(s))) site or sites for which the person ~~((possesses))~~ has a valid harvest site certificate;

(b) Another shellfish operation licensed by the department; or

(c) A shellfish dealer located outside of the state who ~~((is in compliance))~~ complies with the requirements of the NSSP Model Ordinance and is eligible for inclusion on the current Interstate Certified Shellfish Shippers List, published by the U.S. Food and Drug Administration.

(2) ~~((Any person who possesses))~~ A person possessing a commercial quantity of shellstock or any quantity of shellstock for sale for human consumption ~~((must))~~ or bait shall identify the shellstock by an approved tag with permanent marking, according to requirements of the NSSP Model Ordinance, upon removal from the harvest site.

(3) ~~((Any))~~ If the person possessing shellstock in subsection (2) of this section is the harvester, the tag must include the growing area name and either the department harvest site application number (ex: 2012-23), harvest ID, parcel number, or other approved harvest site identifier. This information must be listed on the harvester tag, harvest record, and harvest site certificate.

(4) When retagging shellstock, the dealer tag must have the exact harvest site information as provided on the original harvest tag.

(5) A person ((who packs)) packing a commercial quantity of shucked shellfish or any quantity of shucked shellfish for sale for human consumption ~~((must do so))~~ or bait, shall pack the shellfish in approved containers that are legibly labeled by permanent marking, in accordance with the requirements of the NSSP Model Ordinance and with:

(a) Wording equivalent to "keep refrigerated" on containers of fresh shellfish; and

(b) Wording equivalent to "keep frozen" on containers of frozen shellfish.

~~((4))~~ (6) The owner or person in charge of a shellfish operation ~~((must))~~ shall keep accurate records of all lots of shellfish harvested, received, wet stored, shucked, packed, shipped, or sold by the shellfish operation for a minimum of three years.

~~((5) Information recorded by))~~ (7) The harvester-shipper shall ~~((include))~~ record the following:

(a) Location of harvesting area(s) by name or code ~~((r))~~ ;

(b) Name and quantity of shellfish ~~((r))~~ ;

(c) Date of harvest ~~((r))~~ ; and

(d) Date shipped.

~~((6))~~ (8) All tags for shellstock and labels for containers of shucked shellfish required by this section ~~((must be used))~~ are only for use with the original lot of shellfish for which they were intended and must not be reused.

AMENDATORY SECTION (Amending WSR 01-04-054, filed 2/5/01, effective 3/8/01)

WAC 246-282-082 Export certificate. (1) The department ~~((will))~~ shall issue an export certificate to a shellfish dealer for a specific lot of shellfish if ~~((the dealer:~~

~~(1) Is exporting))~~ all requirements are met.

(2) To qualify for an export certificate from the department, a shellfish dealer shall:

(a) Export the lot to ~~((an Asian))~~ a country that requires a production certificate from a governmental health authority;

~~((2) Possesses a))~~ (b) Have a valid shellfish operation license issued by the ~~((secretary))~~ department;

~~((3) Is in compliance))~~ (c) Comply with the requirements of chapter 69.30 RCW, this chapter, and the NSSP Model Ordinance;

~~((4) Completes an application specified))~~ (d) Submit to the department a complete application on a form provided by the department;

~~((5))~~ (e) Document~~((s))~~ use of each export certificate as specified by the department; and

~~((6) Pays the department any fee for each export certificate))~~

(f) Pay the applicable fee required by ~~((this chapter))~~ WAC 246-282-990.

AMENDATORY SECTION (Amending WSR 01-04-054, filed 2/5/01, effective 3/8/01)

WAC 246-282-092 Inspection by department. (1) The department ~~((enters and inspects any))~~ may enter or inspect a harvest site, physical facility, records, vehicle, or vessel used by a shellfish operation as often as necessary to determine compliance with chapter 69.30 RCW, this chapter, and the NSSP Model Ordinance.

(2) The department shall inspect~~((s))~~ each shellfish operation:

(a) A minimum of once per year;

(b) Before issuing a new shellfish operation license to a person;

(c) Within 30 days after issuing a new shellfish operation license;

(d) Before a shellfish operation uses any physical facility for the first time; and

~~((d))~~ (e) Before the shellfish operation uses any extensively remodeled physical facility.

(3) If the department determines by inspection or investigation that an owner, person in charge, or ~~((any))~~ a person working on behalf of the shellfish operation is in violation of any of the requirements of chapter 69.30 RCW, this chapter, or the NSSP Model Ordinance, then the department may conduct a reinspection of the shellfish operation. If the same violation is identified by the department during the reinspection, then another reinspection may be conducted by the department within one month. The department may charge the owner of a shellfish operation a fee for a second or subsequent reinspection.

(4) If necessary to conduct an inspection, ~~((then))~~ the department may apply to a court of competent jurisdiction for an administrative warrant in accordance with RCW 69.30.120.

(5) During inspections, the department ~~((has))~~ shall have free and unimpeded access to any of the following ~~((in order))~~ to determine whether the operation ~~((is in compliance))~~ complies with chapter 69.30 RCW, this chapter, and the NSSP Model Ordinance:

(a) Buildings, yards, warehouses, storage facilities, transportation facilities, vehicles, vessels and other places reasonably considered to be or to have been used in connection with the shellfish operation;

(b) Ledgers, books, accounts, memorandums, or records reasonably believed to be or to have been used in connection with the shellfish operation;

(c) Shellfish, shellfish products, components, or other materials reasonably believed to be or to have been used, processed or produced by or in connection with the shellfish operation;

(d) Copies of any documents reasonably believed to be or to have been used in connection with the shellfish operation; and

(e) Samples of shellfish to determine whether they are safe for human consumption.

(6) The department may inspect shellfish growing areas at any time of day and will inspect any other aspect of a shellfish operation:

(a) Between 8:00 a.m. and 5:00 p.m. on any weekday that is not a legal holiday;

(b) During any time the shellfish operation has established as its business hours;

(c) During any time the shellfish operation is open for business or is otherwise in operation; and

(d) During any other time with the consent of the owner or the person in charge of the shellfish operation.

AMENDATORY SECTION (Amending WSR 01-04-054, filed 2/5/01, effective 3/8/01)

WAC 246-282-100 Notice of decision—Adjudicative proceeding.

(1) ~~((The department's))~~ A notice of a denial, suspension, modification, or revocation of a license ~~((is consistent))~~ from the department must comply with RCW 43.70.115. An applicant or license holder has the right to an adjudicative proceeding to contest the decision.

(2) ~~((The department's))~~ A notice of imposition of a civil penalty ~~((is consistent))~~ from the department must comply with RCW 43.70.095. A person ~~((upon whom the department imposes))~~ who receives a civil fine from the department has the right to an adjudicative proceeding to contest the decision.

(3) A license applicant or holder or a person ~~((upon whom the department imposes a civil penalty))~~ who receives a notice as described in subsection (1) or (2) of this section from the department, may contest a department decision, within ~~((twenty-eight))~~ 28 days of receipt of the decision by filing a written application for an adjudicative proceeding by a method showing proof of receipt with the administrative hearings unit, department of health. The person ~~((must))~~ shall include the following in or with the application:

(a) A specific statement of the issue or issues and law involved;

(b) The grounds for contesting the department decision; and

(c) A copy of the contested department decision.

(4) An adjudicative proceeding is governed by the Administrative Procedure Act (chapter 34.05 RCW), this chapter, and chapter 246-08 WAC. If a provision in this chapter conflicts with chapter 246-08 WAC, the provision in this chapter governs.

AMENDATORY SECTION (Amending WSR 01-04-054, filed 2/5/01, effective 3/8/01)

WAC 246-282-102 Denial, revocation, suspension of license, certificate, or permit—Civil penalties. (1) The department may deny, revoke, or suspend a shellfish operation license, harvest site certificate, or permit and may assess a civil penalty if a person:

(a) Fails to comply with any of the provisions of chapter 69.30 RCW, ~~((these rules))~~ this chapter, and the NSSP Model Ordinance;

(b) Refuses an inspection by the department;

(c) Harvests shellfish from any harvest site for which the ~~((see-retary))~~ department has not issued a harvest site certificate to the person;

(d) Knowingly obtains shellfish from a person who is not in compliance with any requirements of chapter 69.30 RCW, this chapter, or the NSSP Model Ordinance;

(e) Makes false statements or misrepresentations to the department during any investigation, inspection, or application for a shellfish operation license or any permit required by ~~((these rules))~~ this chapter;

(f) Makes false statements or misrepresentations to the department during any investigation, inspection, or application for a shellfish harvest site certificate;

(g) Fails to cooperate with the department or the department of fish and wildlife during an inspection or investigation;

(h) Aids another person in violating any requirement of chapter 69.30 RCW, ~~((these rules))~~ this chapter, or the NSSP Model Ordinance;

(i) Provides the department with false or fraudulent records of the shellfish operation;

(j) Transfers or reassigns a shellfish operation license to another person without the written approval of the department; or

(k) Fails to comply with the terms of a conditional area management plan, shellfish operation license, harvest site certificate, or any permit required by this chapter.

(2) The department may treat violations of chapter 69.30 RCW, ~~((these rules))~~ this chapter, or the NSSP Model Ordinance committed by a person in charge, employee, or agent of a person issued a shellfish operation license ~~((may be treated by the department))~~ as a violation committed by the licensee.

AMENDATORY SECTION (Amending WSR 01-04-054, filed 2/5/01, effective 3/8/01)

WAC 246-282-104 Penalty assignment—Calculation of penalty and proportionate adjustment—Aggravating and mitigating factors. (1) The department calculates an appropriate penalty based on the following factors:

(a) The level of threat to public health;

(b) The number of previous violations attributed to the violator;
and

(c) The presence of aggravating or mitigating factors.

(2) The department determines administrative penalties from the range in the following penalty schedule. The standard penalty is assessed unless either a proportionate adjustment is warranted ~~((and/))~~ or there are aggravating or mitigating factors present or both.

Penalty Schedule

NUMBER OF PREVIOUS VIOLATIONS	ADJUSTMENT FACTORS	PUBLIC HEALTH THREAT		
		LOW License Action/ Civil Penalty	INTERMEDIATE License Action/ Civil Penalty	HIGH License Action/ Civil Penalty
0	Mitigated	0 Months/\$150	0 Months/\$300	3 Months/\$350
	Standard	0 Months/\$200	1 Month/\$350	6 Months/\$400
	Aggravated	1 Month/\$250	3 Months/\$400	9 Months/\$450
1	Mitigated	0 Months/\$200	1 Month/\$350	6 Months/\$400
	Standard	0 Months/\$250	3 Months/\$400	9 Months/\$450
	Aggravated	3 Months/\$300	6 Months/\$450	12 Months/\$500
2	Mitigated	0 Months/\$250	3 Months/\$400	12 Months/\$500
	Standard	3 Months/\$300	6 Months/\$450	18 Months/\$500
	Aggravated	6 Months/\$350	9 Months/\$500	24 Months/\$500
3 or More	Mitigated	3 Months/\$300	6 Months/\$450	18 Months/\$500
	Standard	6 Months/\$350	9 Months/\$500	24 Months/\$500
	Aggravated	9 Months/\$400	12 Months/\$500	36 Months/\$500

(3) The department reserves the right to proportionately increase the civil penalty and decrease the license action under certain circumstances. These circumstances include situations where license actions as a deterrent are ineffective and include, but are not limited to, violations by persons who are not licensed.

(4) The department reserves the right to proportionately decrease the civil penalty and increase the license action when circumstances in a particular case demonstrate the ineffectiveness of a civil penalty as a deterrent.

(5) (a) When assessing a civil penalty or license action, the department considers any previous violation(s) for the following period ~~((of time))~~, depending on the severity of the previous violation(s):

- (i) Three years for low public health threat;
- (ii) Five years for intermediate public health threat; or
- (iii) No limit for high public health threat.

(b) The ~~((time))~~ period will begin on the date of adjudication or settlement of the previous violation(s), rather than the date on which the incident or conduct occurred.

(6) The department considers circumstances that increase the seriousness of a violation ~~((7))~~ including, but not limited to, the following aggravating factors:

(a) The extent to which the violation is part of a pattern of the same or substantially similar conduct;

(b) The extent to which previous education, technical assistance, or notice of correction has been provided for the same or substantially similar conduct; and

(c) The extent to which the violation caused serious and actual injury or death to a person or persons.

(7) If the department determines that one or more aggravating factors are present, ~~((then))~~ the department may assess the aggravated penalty or may increase the penalty to a level greater than listed in

the penalty schedule(~~(7)~~) including, but not limited to, revocation of the license.

(8) The department will consider circumstances that decrease the seriousness of a violation(~~(7)~~) including, but not limited to, the following mitigating factors:

(a) Voluntary disclosure of the violation;

(b) Complete cooperation and voluntary disclosure during the investigation of the violation; and

(c) (~~(Voluntary)~~) Voluntarily taking (~~(of)~~) remedial measures that will result in increased public health protection and that will result in a decreased likelihood that the violation will be repeated and that other violations will occur.

(9) If the department determines that one or more mitigating factors are present, (~~(then)~~) the department may assess the mitigated penalty or may decrease the penalty to a level less than listed in the penalty schedule.

(10) The maximum civil penalty that may be imposed by the department is (~~(five hundred dollars)~~) \$500 per day for each violation.

(11) The department considers each violation to be a separate and distinct event. Each day a violation is continued is a separate and distinct violation. When a person has committed multiple violations, the violations are cumulative for the purpose(~~(s)~~) of calculating the appropriate penalty. Penalties are added together, rather than served concurrently.

(12) Nothing in this section prevents the department from responding to a violation by:

(a) Declining to pursue an administrative penalty;

(b) Issuing a notice of correction instead of pursuing an administrative penalty; or

(c) Negotiating settlement of a case on such terms and for such reason as the department deems appropriate. Violations covered by a prior settlement agreement may be used for the purpose of determining the appropriate penalty for the current alleged violation(s), unless prohibited by the prior settlement agreement.

AMENDATORY SECTION (Amending WSR 01-04-054, filed 2/5/01, effective 3/8/01)

WAC 246-282-110 Administrative provisions. (1) If the department finds during an inspection that (~~(any)~~) an owner or person working on behalf of a shellfish operation fails to comply with any requirements of chapter 69.30 RCW, this chapter, or the NSSP Model Ordinance, (~~(then)~~) the department may issue a written statement of deficiencies or notice of correction (~~(to the owner, person in charge, or other employee of the operation who is present)~~).

(a) The statement of deficiencies or notice of correction (~~(specifies the manner in which)~~) must specify where the operation fails to comply with chapter 69.30 RCW (~~(and these rules. It specifies)~~), this chapter, or the NSSP Model Ordinance. The statement of deficiencies or notice of correction must also specify a reasonable period (~~(of time)~~) for the owner or person in charge to correct the violation(s).

(b) (~~(In the event)~~) If the owner or person in charge fails to correct the violation(s) specified in the statement of deficiencies or

notice of correction, the department may revoke the license and certificate of compliance for that shellfish operation or may initiate any other enforcement proceeding authorized by law.

(2) ~~((Any))~~ A authorized representative of the department, fish and wildlife patrol officer or ex officio patrol officer may, without previously providing a statement of deficiencies or notice of correction, immediately seize shellfish or issue written hold orders prohibiting the disposition or sale of shellfish whenever a commercial quantity of shellfish or any amount of shellfish for sale for human consumption is on the premises of, or in the possession of, ~~((any))~~ a person who:

(a) Fails to ~~((display))~~ show an original, electronic copy, or photocopy of a valid shellfish operation license;

(b) Is reasonably expected to have harvested the shellfish and fails to ~~((display))~~ show an original, electronic copy, or photocopy of a valid shellfish operation license and a valid harvest site certificate; or

(c) Fails to maintain each container of shellfish properly tagged or labeled as required by chapter 69.30 RCW, ~~((these rules))~~ this chapter, and the NSSP Model Ordinance.

(3) If the department determines during an inspection or investigation that there is reasonable cause to believe that shellfish is potentially unsafe for human consumption, ~~((then))~~ the department may issue a hold order prohibiting the disposition or sale of the shellfish pending further investigation by the department of the safety of the shellfish.

(a) The department must complete its further investigation within ~~((ten))~~ 10 days.

(b) At the conclusion of the investigation, the department may release the shellfish for sale or issue a written abatement order regarding the shellfish.

(c) Any person in possession of shellfish for which the department has issued a hold order must store the shellfish in a suitable place prescribed by the department and prevent the shellfish from being offered for human consumption or other use until:

(i) The hold order is lifted by the department or by a court of competent jurisdiction; or

(ii) The person disposes of the shellfish in accordance with an abatement order issued by the department.

(4) Shellfish that the department seizes or places under a hold order and determines are unsafe for human consumption are subject to such abatement as the department considers appropriate. The department may require ~~((any))~~ one or more of the following measures be taken by a person ~~((in possession of))~~ possessing shellfish that are the subject of an abatement order:

(a) Permanent prohibition on the disposition of the shellfish for human consumption;

(b) Immediate destruction of the shellfish by measures such as denaturing and placing in a sanitary landfill, witnessed by an authorized representative of the department who provides a record of destruction to the person; or

(c) Temporary prohibition on the disposition of the shellfish for human consumption pending relay to an approved growing area for a sufficient period ~~((of time))~~ to assure natural purification of the shellfish.

(5) The ~~((secretary))~~ department may issue an abatement order to the owner or person in charge of a shellfish operation whenever the

department, after conducting an appropriate investigation, determines that a shellfish operation, or person working on behalf of a shellfish operation, presents a potential risk for transmitting an infectious disease to consumers of shellfish.

(a) The ~~((secretary))~~ department may require any or all ~~((of))~~ the following measures be taken by the owner or person in charge of a shellfish operation who is issued the abatement order:

(i) Immediate closure of the shellfish operation until, in the opinion of the ~~((secretary))~~ department, no further danger of a disease outbreak exists;

(ii) Immediate exclusion of any person suspected to be infected with a disease agent transmissible through food from all activities with the shellfish operation; and

(iii) Restriction of the activities of ~~((any))~~ a person who is suspected to be infected with a disease agent transmissible through food to some area of the shellfish operation where there would be no danger of the person transmitting disease agents to shellfish consumers.

(b) As an alternative to the abatement order described in this section, the ~~((secretary))~~ department may require the owner, or ~~((any))~~ a person working on behalf of the shellfish operation to submit to adequate medical and laboratory examinations, including examination of their bodily discharges as needed to determine if the person is infected with a microbial agent transmissible through food.

(6) ~~((No))~~ A person ~~((may))~~ shall not remove or alter a notice or tag constituting a hold order or abatement order placed on shellfish by the department.

(7) ~~((No))~~ A person may not relabel, repack, reprocess, alter, dispose of, destroy, or release shellfish or containers of shellfish for which the department has issued a hold order or abatement order without:

(a) Permission of the department; or

(b) An order by a court of competent jurisdiction.

(8) If the owner or person in charge of a shellfish operation fails to comply with a hold order or an abatement order issued according to this section, ~~((then))~~ the department may revoke the license of the shellfish operation or initiate other legal enforcement proceedings authorized by law.

AMENDATORY SECTION (Amending WSR 01-04-054, filed 2/5/01, effective 3/8/01)

WAC 246-282-120 Penalty clause. ~~((Any))~~ A person found violating any of the provisions of ~~((these regulations))~~ this chapter or chapter 69.30 RCW is guilty of a gross misdemeanor, and upon conviction will be subject to:

(1) A fine; or

(2) Imprisonment in the county jail of the county in which the offense was committed; or

(3) Both fine and imprisonment.

AMENDATORY SECTION (Amending WSR 01-04-054, filed 2/5/01, effective 3/8/01)

WAC 246-282-130 ((Separability)) Severability clause. Should any section, paragraph, clause or phrase of these rules and regulations be declared unconstitutional or invalid for any reason, the remainder of these rules and regulations are not affected.

RCW 69.30.030 Rules and regulations —Duties of state board of health. (1) The state board of health shall adopt rules governing the sanitation of shellfish, shellfish growing areas, and shellfish plant facilities and operations in order to protect public health and carry out the provisions of this chapter. Such rules and regulations may include reasonable sanitary requirements relative to the quality of shellfish growing waters and areas, boat and barge sanitation, building construction, water supply, sewage and wastewater disposal, lighting and ventilation, insect and rodent control, shell disposal, garbage and waste disposal, cleanliness of establishment, the handling, storage, construction and maintenance of equipment, the handling, storage and refrigeration of shellfish, the identification of containers, and the handling, maintenance, and storage of permits, certificates, and records regarding shellfish taken under this chapter. The state board of health shall adopt rules governing procedures for the disposition of seized shellfish.

(2) The state board of health shall consider the most recent version of the national shellfish sanitation program model ordinance, adopted by the interstate shellfish sanitation conference, when adopting rules. [2011 c 194 s 3; 1995 c 147 s 2; 1955 c 144 s 3.]

RCW 43.20.050 Powers and duties of state board of health—Rule making—Delegation of authority—Enforcement of rules. (1) The state board of health shall provide a forum for the development of public health policy in Washington state. It is authorized to recommend to the secretary means for obtaining appropriate citizen and professional involvement in all public health policy formulation and other matters related to the powers and duties of the department. It is further empowered to hold hearings and explore ways to improve the health status of the citizenry.

In fulfilling its responsibilities under this subsection, the state board may create ad hoc committees or other such committees of limited duration as necessary.

(2) In order to protect public health, the state board of health shall:

(a) Adopt rules for group A public water systems, as defined in RCW 70A.125.010, necessary to assure safe and reliable public drinking water and to protect the public health. Such rules shall establish requirements regarding:

(i) The design and construction of public water system facilities, including proper sizing of pipes and storage for the number and type of customers;

(ii) Drinking water quality standards, monitoring requirements, and laboratory certification requirements;

(iii) Public water system management and reporting requirements;

(iv) Public water system planning and emergency response requirements;

(v) Public water system operation and maintenance requirements;

(vi) Water quality, reliability, and management of existing but inadequate public water systems; and

(vii) Quality standards for the source or supply, or both source and supply, of water for bottled water plants;

(b) Adopt rules as necessary for group B public water systems, as defined in RCW 70A.125.010. The rules shall, at a minimum, establish requirements regarding the initial design and construction of a public water system. The state board of health rules may waive some or all requirements for group B public water systems with fewer than five connections;

(c) Adopt rules and standards for prevention, control, and abatement of health hazards and nuisances related to the disposal of human and animal excreta and animal remains;

(d) Adopt rules controlling public health related to environmental conditions including but not limited to heating, lighting, ventilation, sanitary facilities, and cleanliness in public facilities including but not limited to food service establishments, schools, recreational facilities, and transient accommodations;

(e) Adopt rules for the imposition and use of isolation and quarantine;

(f) Adopt rules for the prevention and control of infectious and noninfectious diseases, including food and vector borne illness, and rules governing the receipt and conveyance of remains of deceased persons, and such other sanitary matters as may best be controlled by universal rule; and

(g) Adopt rules for accessing existing databases for the purposes of performing health related research.

(3) The state board shall adopt rules for the design, construction, installation, operation, and maintenance of those

on-site sewage systems with design flows of less than three thousand five hundred gallons per day.

(4) The state board may delegate any of its rule-adopting authority to the secretary and rescind such delegated authority.

(5) All local boards of health, health authorities and officials, officers of state institutions, police officers, sheriffs, constables, and all other officers and employees of the state, or any county, city, or township thereof, shall enforce all rules adopted by the state board of health. In the event of failure or refusal on the part of any member of such boards or any other official or person mentioned in this section to so act, he or she shall be subject to a fine of not less than fifty dollars, upon first conviction, and not less than one hundred dollars upon second conviction.

(6) The state board may advise the secretary on health policy issues pertaining to the department of health and the state. [2021 c 65 s 37; 2011 c 27 s 1; 2009 c 495 s 1; 2007 c 343 s 11; 1993 c 492 s 489; 1992 c 34 s 4. Prior: 1989 1st ex.s. c 9 s 210; 1989 c 207 s 1; 1985 c 213 s 1; 1979 c 141 s 49; 1967 ex.s. c 102 s 9; 1965 c 8 s 43.20.050; prior: (i) 1901 c 116 s 1; 1891 c 98 s 2; RRS s 6001. (ii) 1921 c 7 s 58; RRS s 10816.]

Explanatory statement—2021 c 65: See note following RCW 53.54.030.

Effective date—2009 c 495: "Except for section 9 of this act, this act is necessary for the immediate preservation of the public peace, health, or safety, or support of the state government and its existing public institutions, and takes effect immediately [May 14, 2009]." [2009 c 495 s 17.]

Findings—1993 c 492: "The legislature finds that our health and financial security are jeopardized by our ever increasing demand for health care and by current health insurance and health system practices. Current health system practices encourage public demand for unneeded, ineffective, and sometimes dangerous health treatments. These practices often result in unaffordable cost increases that far exceed ordinary inflation for essential care. Current total health care expenditure rates should be sufficient to provide access to essential health care interventions to all within a reformed, efficient system.

The legislature finds that too many of our state's residents are without health insurance, that each year many individuals and families are forced into poverty because of serious illness, and that many must leave gainful employment to be eligible for publicly funded medical services. Additionally, thousands of citizens are at risk of losing adequate health insurance, have had insurance canceled recently, or cannot afford to renew existing coverage.

The legislature finds that businesses find it difficult to pay for health insurance and remain competitive in a global economy, and that individuals, the poor, and small businesses bear an inequitable health insurance burden.

The legislature finds that persons of color have significantly higher rates of mortality and poor health outcomes, and substantially lower numbers and percentages of persons covered by health insurance than the general population. It is intended that chapter 492, Laws of

1993 make provisions to address the special health care needs of these racial and ethnic populations in order to improve their health status.

The legislature finds that uncontrolled demand and expenditures for health care are eroding the ability of families, businesses, communities, and governments to invest in other enterprises that promote health, maintain independence, and ensure continued economic welfare. Housing, nutrition, education, and the environment are all diminished as we invest ever increasing shares of wealth in health care treatments.

The legislature finds that while immediate steps must be taken, a long-term plan of reform is also needed." [1993 c 492 s 101.]

Intent—1993 c 492: "(1) The legislature intends that state government policy stabilize health services costs, assure access to essential services for all residents, actively address the health care needs of persons of color, improve the public's health, and reduce unwarranted health services costs to preserve the viability of nonhealth care businesses.

(2) The legislature intends that:

(a) Total health services costs be stabilized and kept within rates of increase similar to the rates of personal income growth within a publicly regulated, private marketplace that preserves personal choice;

(b) State residents be enrolled in the certified health plan of their choice that meets state standards regarding affordability, accessibility, cost-effectiveness, and clinical efficaciousness;

(c) State residents be able to choose health services from the full range of health care providers, as defined in RCW 43.72.010(12), in a manner consistent with good health services management, quality assurance, and cost effectiveness;

(d) Individuals and businesses have the option to purchase any health services they may choose in addition to those included in the uniform benefits package or supplemental benefits;

(e) All state residents, businesses, employees, and government participate in payment for health services, with total costs to individuals on a sliding scale based on income to encourage efficient and appropriate utilization of services;

(f) These goals be accomplished within a reformed system using private service providers and facilities in a way that allows consumers to choose among competing plans operating within budget limits and other regulations that promote the public good; and

(g) A policy of coordinating the delivery, purchase, and provision of health services among the federal, state, local, and tribal governments be encouraged and accomplished by chapter 492, Laws of 1993.

(3) Accordingly, the legislature intends that chapter 492, Laws of 1993 provide both early implementation measures and a process for overall reform of the health services system." [1993 c 492 s 102.]

Short title—Savings—Reservation of legislative power—Effective dates—1993 c 492: See RCW 43.72.910 through 43.72.915.

Severability—1992 c 34: See note following RCW 69.07.170.

Effective date—Severability—1989 1st ex.s. c 9: See RCW 43.70.910 and 43.70.920.

Savings—1985 c 213: "This act shall not be construed as affecting any existing right acquired or liability or obligation incurred under the sections amended or repealed in this act or under any rule, regulation, or order adopted under those sections, nor as affecting any proceeding instituted under those sections." [1985 c 213 s 31.]

Effective date—1985 c 213: "This act is necessary for the immediate preservation of the public peace, health, and safety, the support of the state government and its existing public institutions, and shall take effect June 30, 1985." [1985 c 213 s 33.]

Severability—1967 ex.s. c 102: See note following RCW 43.70.130.

Rules and regulations—Visual and auditory screening of pupils: RCW 28A.210.020.



PREPROPOSAL STATEMENT OF INQUIRY

CR-101 (October 2017)
(Implements RCW 34.05.310)

Do **NOT** use for expedited rule making

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: February 23, 2022

TIME: 1:43 PM

WSR 22-06-034

Agency: State Board of Health

Subject of possible rule making: Chapter 246-282 WAC, Sanitary control of shellfish. The State Board of Health (board) is considering revisions to the chapter to modify harvest control requirements by setting more proactive measures to prevent illnesses and protect public health. The rule revision may also include updating definitions, seed size and other technical and editorial changes as needed.

Statutes authorizing the agency to adopt rules on this subject: RCW 69.30.030 and RCW 43.20.050

Reasons why rules on this subject may be needed and what they might accomplish: *Vibrio parahaemolyticus* (Vp) is a naturally occurring bacteria found in marine waters. Molluscan bivalve shellfish acquire Vp through filter feeding. Humans who consume raw or undercooked shellfish containing Vp can develop an intestinal disease called vibriosis.

In 2021, there were a high number of vibriosis cases involving Washington shellfish largely due to very high temperatures during the summer months. The Department of Health (department) expects this trend to continue. This indicates a need to review the rule requirements to determine if the current controls are adequate to protect consumers and consider more proactive measures to prevent illness and protect public health.

Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies: The U.S. Food and Drug Administration (FDA) requires a *Vibrio parahaemolyticus* control plan for the state of Washington and requires that the plan be in compliance with requirements set forth in the NSSP Model Ordinance.

Process for developing new rule (check all that apply):

- ☐ Negotiated rule making
- ☐ Pilot rule making
- ☐ Agency study
- ☒ Other (describe) Collaborative

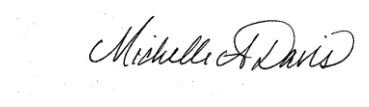
Interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication by contacting:

Name: Jocelyn W. Jones
Address: PO Box 47820 Olympia, WA 98504-7820
Phone: (360) 236-3020
Fax:
TTY: 711
Email: jocelyn.jones@doh.wa.gov
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Other:

(If necessary)

Name: Stuart Glasoe
Address: PO Box 47990 Olympia, WA 98504-7990
Phone: 360-236-41111
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TTY: 711
Email: stuart.glasoe@sboh.wa.gov
Web site:
Other:

Additional comments: The department convened its Vp Advisory Committee (VpAC) on November 22, 2021 to discuss the Vp illnesses caused from the 2021 harvest season. The department will work with the VpAC to develop recommendations to the board for revising the chapter. The VpAC is made up of representatives from tribal and non-tribal shellfish industries, Washington Sea Grant, Local Health Jurisdictions, the Food and Drug Administration, the National Oceanic and Atmospheric Administration, the department's Public Health Lab, and the Washington State Department of Fish and Wildlife. The department will consult with additional stakeholders and collaborate with tribes as needed on revisions to the chapter.

Date: 02/23/2022	Signature: 
Name: Michelle A. Davis	
Title: Executive Director	

Date: October 8, 2025

To: Washington State Board of Health Members

From: Kelly Oshiro, Board Member

Subject: Briefing – Newborn Screening Rulemaking for Ornithine Transcarbamylase Deficiency (OTCD), Guanidinoacetate Methyltransferase Deficiency (GAMT), and Arginase 1 Deficiency (ARG1-D) – Chapter 246-650 WAC

Background and Summary:

Newborn Screening is a program within the Department of Health (Department) that tests all babies for rare but treatable conditions using a dried blood sample. Under [RCW 70.83.050](#), the State Board of Health (Board) is responsible for establishing rules for the program. This is outlined in [chapter 246-650 WAC](#) and includes the list of conditions that all newborns must be screened for.

To determine which conditions to include in the newborn screening (NBS) panel, the Board convenes a multi-disciplinary technical advisory committee (TAC). This committee evaluates candidate conditions using the Board's guiding principles and established screening criteria.

At the Board's direction, Board and Department staff convened TACs to review the following conditions for possible inclusion in the NBS panel:

- [Ornithine Transcarbamylase Deficiency \(OTCD\)](#)
- [Guanidinoacetate Methyltransferase \(GAMT\) Deficiency](#)
- [Arginase 1 Deficiency \(ARG1-D\)](#)

The OTCD TAC met on June 16 and July 7, 2021, and recommended adding OTCD to the NBS panel. The Board approved this recommendation in October 2021. A CR-101 was filed on February 4, 2022, to begin rulemaking.

On September 8, 2023, TACs met to evaluate GAMT and ARG1-D. Both were recommended for inclusion in the NBS panel. The Board approved this recommendation on October 9, 2023, and a CR-101 was filed on November 28, 2023.

Before the Board can add new conditions and screening begins, the Department must secure legislative approval to increase the newborn screening fee. This fee funds new tests, staff time, follow-up for positive results, and related administrative costs. In addition, the Washington Health Care Authority (HCA) covers more than 40% of births in the state. HCA must also seek approval to adjust Medicaid managed care rates to cover the increased fee. During the 2025 legislative session, the Department and HCA secured funding to include the three new conditions.

I have invited Molly Dinardo, Board staff, and Megan McCrillis, Department staff, to provide background on these conditions and an update on the current progress of the rule update ahead of an anticipated rules hearing in November.

This is an informational briefing only. The Board will not take action at this meeting.

Staff

Molly Dinardo, Policy Advisor

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Rules Briefing: Newborn Screening

Chapter 246-650 WAC

Adding OTCD, GAMT, and ARG1-D

Molly Dinardo, Health Policy Advisor
October 8, 2025

WASHINGTON STATE 
BOARD OF HEALTH

Acronyms and Abbreviations

- Arginase 1 Deficiency (ARG1-D)
- Guanidinoacetate Methyltransferase (GAMT) Deficiency
- Newborn Screening (NBS)
- Ornithine Transcarbamylase Deficiency (OTCD)
- Revised Code of Washington (RCW)
- Tandem Mass Spectrometry (MS/MS)
- Technical Advisory Committee (TAC)
- Washington Administrative Code (WAC)
- X-linked recessive inheritance (located on the X chromosome)



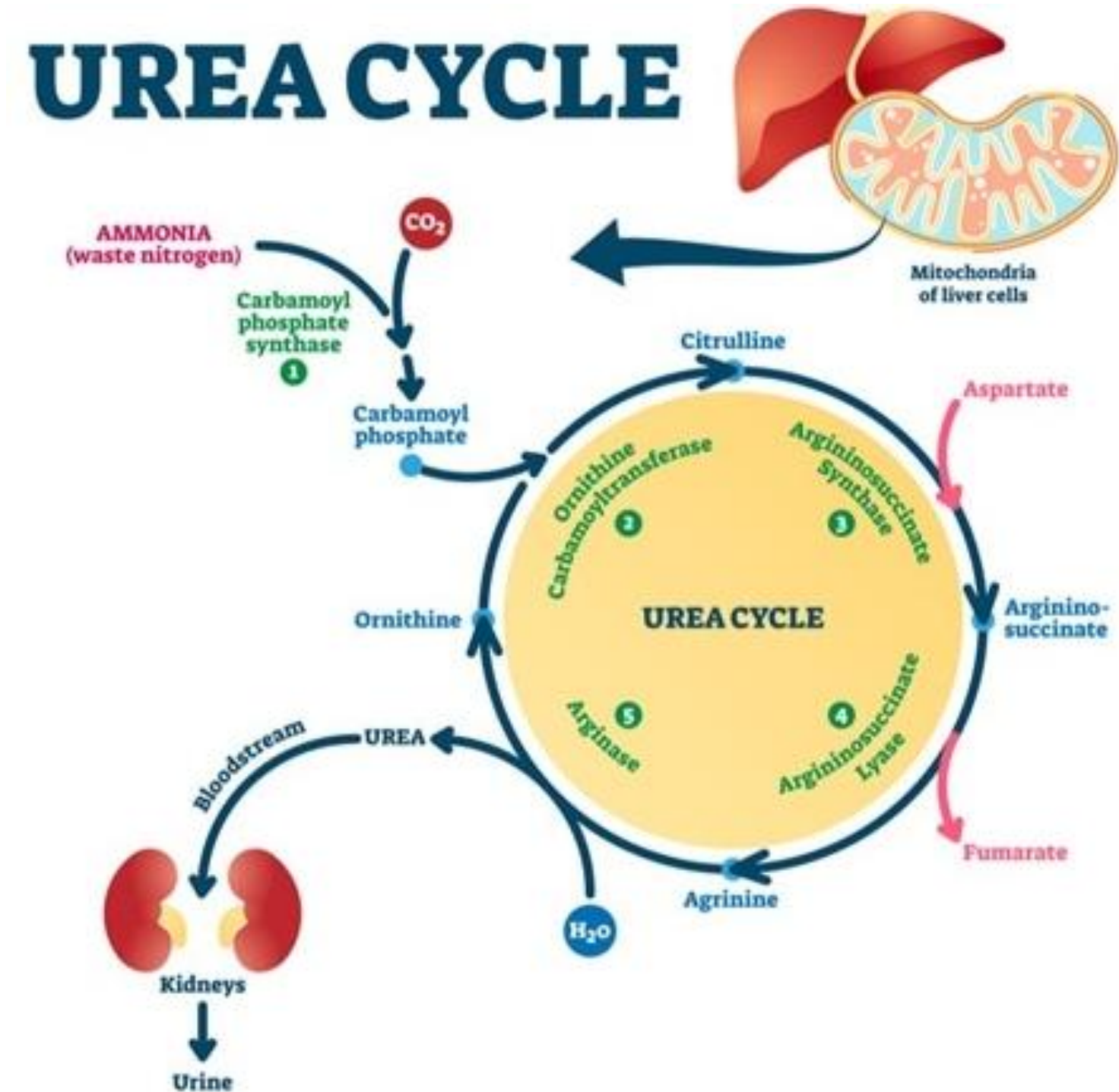
Overview

- Background on Conditions
- Rulemaking Progress
- Proposed Rule Changes
- Next Steps and Timeline



Ornithine Transcarbamylase Deficiency (OTCD)

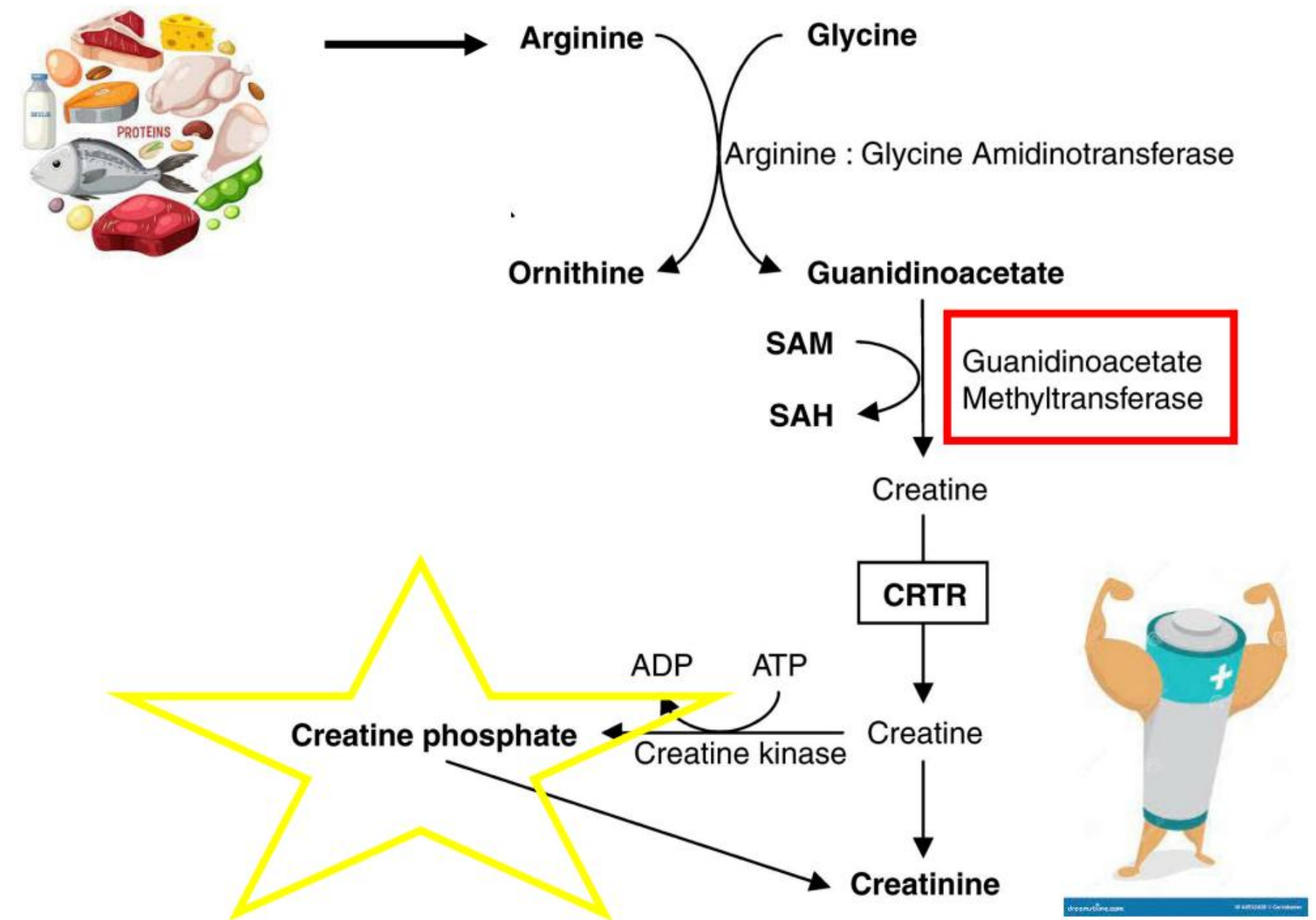
- Inherited urea cycle disorder.
- X-linked recessive inheritance pattern (more likely to affect male babies).
- Prevalence: ~1:56,000.
- Interferes with the body's ability to process ammonia (or nitrogen waste).
- High levels of ammonia are toxic to the brain and nervous system, and can lead to:
 - Tiredness/sluggishness
 - Sepsis-like symptoms
 - Comas
 - Developmental delays
 - Death



Source: News Medical, The Urea Cycle Step-by-Step

Guanidinoacetate Methyltransferase Deficiency (GAMT)

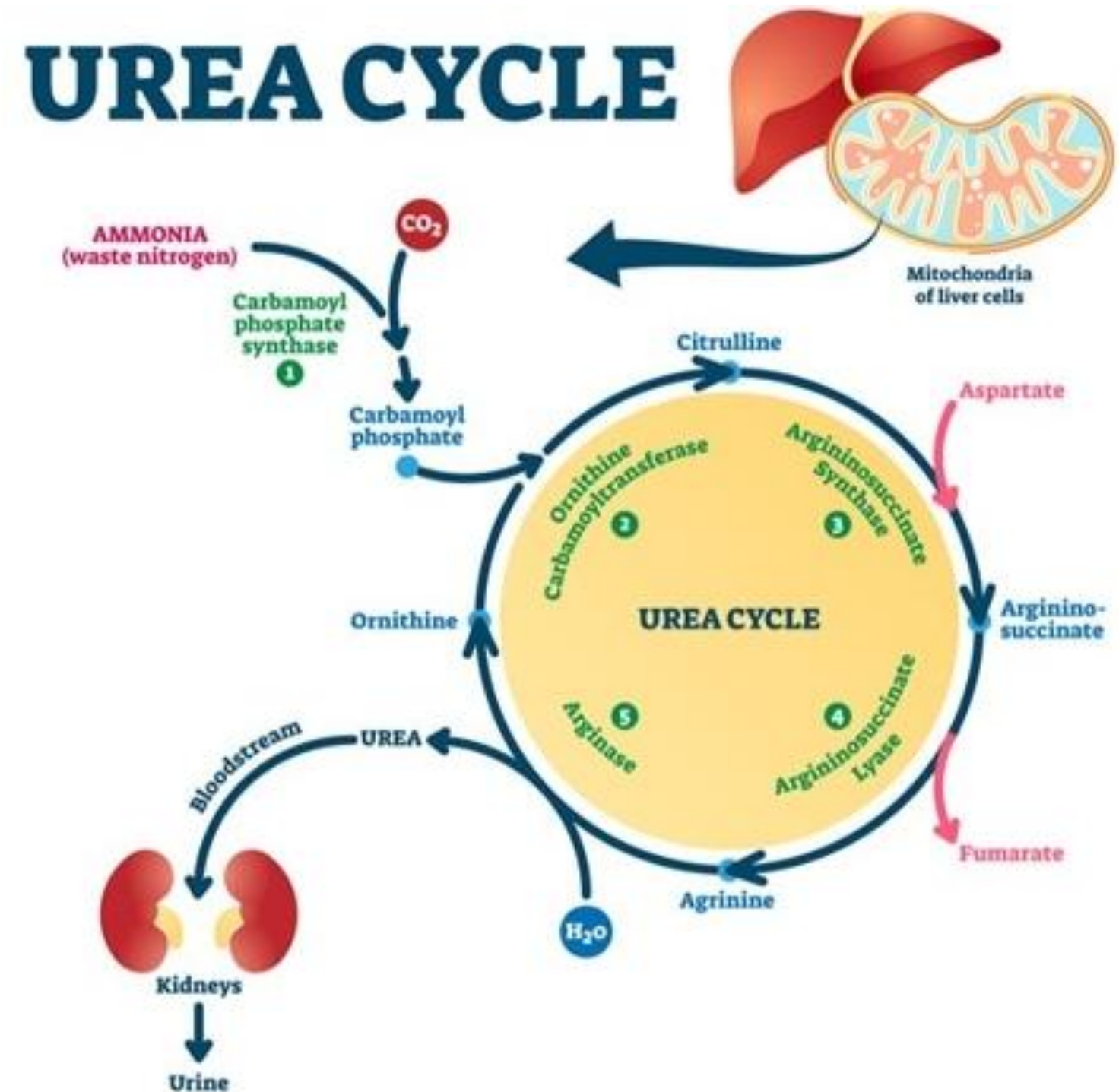
- Inherited disorder that prevents the body from metabolizing and transporting creatine.
- Autosomal recessive inheritance pattern (affects male and female babies equally).
- Prevalence: About 130 people diagnosed worldwide.
- Signs and symptoms of the condition vary; can start anywhere from 3 months to 2 years of age.
- If untreated, GAMT Deficiency leads to developmental delays and cognitive impairments (can be moderate or severe).



Source: Shelkowitz, E. GAMT Deficiency: Natural History, Diagnostic Testing and Treatment. SBOH NBS TAC Meeting. September 2023.

Arginase 1 Deficiency (ARG1-D)

- Inherited urea cycle disorder that causes the amino acid arginine and ammonia to accumulate in the blood.
- Autosomal recessive inheritance pattern (affects male and female babies equally).
- Prevalence: Less than 260 people diagnosed worldwide.
- Symptoms start off subtle and do not become apparent until early childhood (1-3 years of age). May include:
 - Spasticity in lower extremities (most common, affects 80 – 90% of those diagnosed)
 - Slowed cognitive development
 - Seizures
 - Stunted growth
 - Challenges with eating
 - Liver problems



Source: News Medical, The Urea Cycle Step-by-Step

Screening and Treatment Available

Screening

- All three conditions can be screened using tandem mass spectrometry technology (MS/MS)
 - Uses one 1/8" hole punch from a dried blood spot to test for 19 congenital disorders at the same time
 - Technology used in the WA Newborn Screening Program since 2004

OTCD Treatment

- Emergency treatment of high blood ammonia levels
- Dietary modifications
- Liver transplant

GAMT Treatment

- Dietary modifications and oral supplements (creatine, sodium benzoate, and/or ornithine).
- Physical, occupational, speech, and behavioral therapy

ARG1-D Treatment

- Dietary modifications and oral supplements
- Ammonia diversion therapy: nitrogen scavenging medications (sodium benzoate, sodium phenylbutyrate)
- Referrals to neurology and physical, occupational, and/or speech therapy

OTCD: Rulemaking Timeline

- **Fall 2020:** The Board directed staff to form a technical advisory committee (TAC) to review OTCD.
- **June–July 2021:** TAC reviewed OTCD and recommended adding it to the NBS panel.
- **October 2021:** Board approved the recommendation and directed staff to begin rulemaking.
- **February 2022:** Board staff file CR-101 to initiate rulemaking.
- **2022–2023:** Department requested spending authority to raise the NBS fee for OTCD screening; not approved by the Legislature.
- **2025:** Legislature approved funding to increase the NBS fee to include OTCD.

GAMT and ARG1-D: Rulemaking Timeline

- **March–April 2023:** The Board directed staff to form a TAC to review GAMT and ARG1-D.
- **September 2023:** TAC met and recommended adding both conditions to the NBS panel.
- **October 2023:** Board approved the recommendations and directed staff to begin rulemaking.
- **November 2023:** Board staff filed CR-101 to initiate rulemaking.
- **2025:** Legislature approved funding to increase the NBS fee to include GAMT and ARG1-D, in addition to OTCD.

Newborn Screening Fee Increase

- Current NBS fee is \$135.10 per baby (last updated July 1, 2023).
- NBS fee will increase by \$4.02 starting January 1, 2026.
- Fee increase includes salaries/benefits for lab and follow-up, cost of reagents, and biochemical genetics consulting.

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.

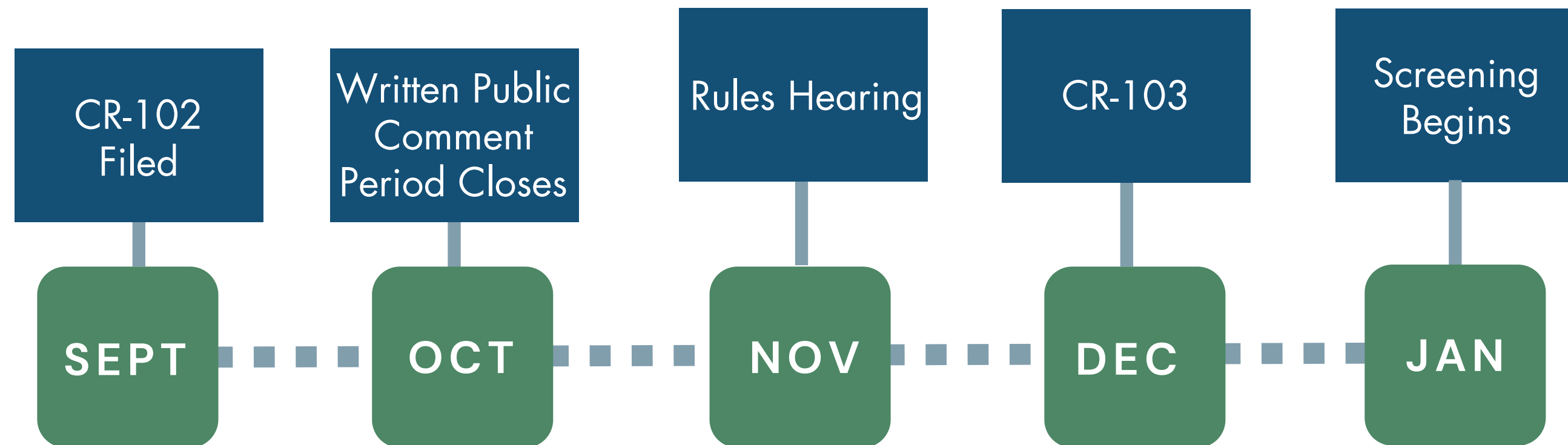


Proposed Changes: WAC 246-650-020, Performance of Screening Tests

- 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 alphabetical nature of the list.



Timeline



THANK YOU

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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.

Arginase 1 Deficiency (ARG1-D) Overview

ABOUT THE CONDITION

- ARG1-D is a rare and inherited metabolic disease that prevents the body from properly breaking down the amino acid arginine, an enzyme in the blood.¹²
- Arginase is one of six enzymes responsible for breaking down arginine and is part of an essential process in the body called the urea cycle.
- The urea cycle helps remove ammonia (or nitrogen) from the body, a waste product used to process protein.
- If the arginase enzyme isn't working properly, the body can't break down arginine and get rid of ammonia through the urea cycle.
- Irregularities in the urea cycle may cause levels of ammonia in the blood to increase.
- When ammonia levels become too high, it has toxic effects and can cause serious damage to the nervous system and other parts of the body.

SIGNS & SYMPTOMS

- Signs of ARG1-D can vary widely and may appear anytime from infancy to early childhood.
- Symptoms of ARG1-D include seizures, muscle tightness or stiffness, difficulty eating, vomiting, and trouble breathing.
- People with ARG1-D might also experience delays in both physical and cognitive development, loss of developmental milestones, and intellectual disabilities.

DIAGNOSIS

- ARG1-D can be detected through a newborn screening blood spot using tandem mass spectrometry.
- Diagnostic tests include testing for ammonia levels, amino acids, and urine organic acids (specifically orotic acid) after a positive newborn screening test.

TREATMENT

- May include a diet low in protein, special foods or formulas, eating regularly and avoiding missing meals, and medications to get rid of extra arginine and ammonia in the body.

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¹ Morales A, Sticco KL. Arginase Deficiency - NIH Bookshelf. In: *StatPearls*. StatPearls Publishing; 2023. Accessed August 25, 2023. <http://www.ncbi.nlm.nih.gov/books/NBK482365/>

² Health Resources and Services Administration. Arginase deficiency | Newborn Screening. Updated June 2023. Accessed August 25, 2023. <https://newbornscreening.hrsa.gov/conditions/arginase-deficiency>

Guanidinoacetate methyltransferase (GAMT) Deficiency Overview

ABOUT THE CONDITION

- GAMT Deficiency is a rare inherited amino acid disorder that prevents the body from properly producing creatine, which helps your organs store and use energy.^{3,4}
- Without enough creatine, the body's organs do not get enough energy to support its vital functions, which can cause damage.
- This damage primarily affects the brain and muscles, as these organs need the most energy.
- Without early treatment, GAMT deficiency can cause serious cognitive and neurological impairments.
- GAMT deficiency is caused by changes in the GAMT gene.

SIGNS & SYMPTOMS

- People with GAMT Deficiency may begin showing symptoms from early infancy to age three.
- Signs and symptoms can vary but may include mild to severe intellectual and developmental disabilities, delayed sitting or walking, delayed or limited speech ability, muscle weakness or low muscle tone, behavioral issues (anxiety, aggression, self-injury, hyperactivity), seizures, and uncontrollable movements.

DIAGNOSIS

- GAMT Deficiency can be detected through a newborn screening blood spot using tandem mass spectrometry.
- Diagnostic tests include testing for guanidinoacetate (GUAC) and low creatine in the blood after a positive newborn screening test.
- Molecular testing can also be helpful.

TREATMENT

- May include creatine and ornithine supplements, sodium benzoate (a medication that can reduce levels of an amino acid called glycine), medications to treat seizures, a lifelong diet low in protein, and speech, occupational, and behavior therapy.

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³ National Institutes of Health, Genetic and Rare Diseases Information Center. Guanidinoacetate methyltransferase deficiency - About the Disease. Updated February 2023. Accessed August 25, 2023. <https://rarediseases.info.nih.gov/diseases/2578/guanidinoacetate-methyltransferase-deficiency>

⁴ Health Resources & Services Administration. Guanidinoacetate methyltransferase deficiency | Newborn Screening. Updated June 2023. Accessed August 25, 2023. <https://newbornscreening.hrsa.gov/conditions/guanidinoacetate-methyltransferase-deficiency>

Ornithine Transcarbamylase Deficiency (OTCD) Overview

ABOUT THE CONDITION

- OTCD is an inherited metabolic disorder that prevents the body from properly removing ammonia waste.^{5,6}
- OTCD is an X-linked recessive condition, meaning it affects males more than females.
- OTC is an enzyme that is part of an essential process in the body called the urea cycle. The urea cycle removes ammonia (or nitrogen) from the body.
- People with OTCD do not make enough of the OTC enzyme.
- If the OTC enzyme isn't working properly, the body can't break down proteins during the urea cycle.
- Irregularities in the urea cycle may cause levels of ammonia in the blood to increase.
- When ammonia levels become too high, it has toxic effects and can cause serious damage to the nervous system and other parts of the body.

SIGNS & SYMPTOMS

- Signs of OTCD can vary widely and may appear anytime from infancy through adulthood.
- Symptoms of OTCD include seizures, floppy arms and legs (hypotonia), lack of energy, difficulty eating, vomiting, and trouble breathing.
- People with OTCD might also experience neurological and behavioral symptoms, intellectual disabilities, coma, or even death.

DIAGNOSIS

- OTCD can be detected through a newborn screening blood spot using tandem mass spectrometry.
- Diagnostic tests include testing for ammonia levels, amino acids, and urine organic acids (specifically orotic acid) after a positive newborn screening test.

TREATMENT

- May include a diet low in protein, special foods or formulas, amino acid supplements, medications and dialysis to get rid of ammonia in the body, and liver transplant.

To request this document in an alternate format or a different language, please contact the State Board of Health at (360) 236-4110 or by email at wsboh@sboh.wa.gov.
PO Box 47990, Olympia, WA 98504-7990
(360) 236-4110 • wsboh@sboh.wa.gov • sboh.wa.gov

⁵ Donovan K, Vagar S, Guzman, N. Ornithine transcarbamylase deficiency- NIH Bookshelf. In: StatPearls. StatPearls Publishing; 2024. Accessed July 17, 2024. <https://www.ncbi.nlm.nih.gov/books/NBK537257/>

⁶ Health Resources and Services Administration. Ornithine transcarbamylase deficiency | Newborn Screening. Updated July 2024. Accessed July 17, 2024 <https://newbornscreening.hrsa.gov/conditions/ornithine-transcarbamylase-deficiency>



PROPOSED RULE MAKING

CR-102 (June 2024)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: September 30, 2025

TIME: 10:09 AM

WSR 25-20-091

Agency: Washington State Board of Health

☒ **Original Notice**

☐ **Supplemental Notice to WSR**

☐ **Continuance of WSR**

☒ **Preproposal Statement of Inquiry was filed as WSR** WSR 22-05-012 and WSR 23-24-016 ; or

☐ **Expedited Rule Making--Proposed notice was filed as WSR** _____ ; or

☐ **Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or**

☐ **Proposal is exempt under RCW** _____.

Title of rule and other identifying information: (describe subject) Chapter 246-650 WAC, Newborn Screening. The Washington State Board of Health (Board) is proposing to amend the newborn screening (NBS) rules to add three conditions to the list of conditions that the Department of Health's Newborn Screening Program screens all babies for in Washington State. These conditions are Ornithine Transcarbamylase Deficiency (OTCD), Guanidinoacetate Methyltransferase (GAMT) Deficiency, and Arginase 1 Deficiency (ARG1-D).

Hearing location(s):

Date:	Time:	Location: (be specific)	Comment:
11/19/2025	11:00 am	Washington State Department of Health 111 Israel Road S.E. Tumwater, WA 98501 Building: Town Center Two (TC2, Rooms 166 & 167) Register to participate via Zoom here: https://us02web.zoom.us/webinar/register/WN_DII0Jo2yQUe1KBqX_flccw	The rules hearing will be hybrid. Individuals may attend either virtually or in-person.

Date of intended adoption: 11/19/2025 (Note: This is **NOT** the effective date)

Submit written comments to:

Name Molly Dinardo

Address PO Box 47990, Olympia, WA 98504-7990

Email molly.dinardo@sboh.wa.gov

Fax N/A

Other

<https://airtable.com/appUWFVMQBM3iV6S3/pagbZb1PlqDm5JhVf/form>

Beginning (date and time) Date and time of filing

By (date and time) October 27, 2025 at 11:59 p.m.

Assistance for persons with disabilities:

Contact Molly Dinardo

Phone 360-236-4110

Fax N/A

TTY 711

Email molly.dinardo@sboh.wa.gov

Other wsboh@sboh.wa.gov

By (date) 11/05/2025

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The purpose of this proposal is to amend chapter 246-650 WAC to add OCTD, GAMT Deficiency, and ARG1-D to the Washington State newborn screening panel.

The Board formed Technical Advisory Committees (TACs) in 2021 and 2023 to review these conditions. After reviewing evidence, hearing from families, and consulting experts, both TACs recommended adding the conditions to the screening panel. The Board considered these recommendations at its meetings in October 2021 and October 2023 and voted to proceed with rulemaking to amend chapter 246-650 WAC.

The Department of Health (Department) operates the newborn screening program, which, screens all babies for rare but treatable health conditions using a dried blood sample. State law ([RCW 70.83.050](#)) requires that the Board create rules for newborn screening. These rules are found in [chapter 246-650 WAC](#). To implement screening for these conditions, the Board must amend WAC 246-650-010 and WAC 246-650-020.

In addition, adding OTCD, GAMT deficiency, and ARG1-D to the newborn screening panel requires the Department to request an increase in the state's newborn screening fee. This fee, collected for each infant in Washington, covers the costs of laboratory screening, follow-up services, and coordination with specialty care. Additionally, the Washington State Health Care Authority (HCA) covers more than 40% of births in the state. Therefore, it must also seek approval to adjust Medicaid managed care rates to cover the increased fee. After multiple requests to the Legislature, the Department and HCA secured funding during the 2025 session to implement screening, which is expected to begin in early 2026.

Reasons supporting proposal: Population-based newborn screening is the most effective way to detect OTCD, GAMT, and ARG1-D early, when treatment can prevent severe illness, lifelong disability, or death. Without early screening, most affected infants are not diagnosed until after serious and irreversible health problems develop.

Alternatives such as waiting for symptoms or testing only infants with a known family history are not effective, as they miss most cases and delay treatment. Universal screening ensures timely diagnosis and care, giving babies the best chance for healthy development.

If this rule is not adopted, infants with these conditions will continue to face delayed diagnoses, preventable complications, and in some cases, loss of life.

Statutory authority for adoption: RCW 70.83.050

Statute being implemented: RCW 70.83

Is rule necessary because of a:

Federal Law?	☐ Yes	☒ No
Federal Court Decision?	☐ Yes	☒ No
State Court Decision?	☐ Yes	☒ No

If yes, CITATION:

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None

Name of proponent: (person or organization) Washington State Board of Health

Type of proponent: ☐ Private. ☐ Public. ☒ Governmental.

Name of agency personnel responsible for:

Name	Office Location	Phone
Drafting Molly Dinardo	111 Israel Road SE Tumwater WA 98501	360-236-4110
Implementation Megan McCrillis	1610 NE 150th Street, P.O. Box 55729, Shoreline, WA 98155	206-418-5410
Enforcement Megan McCrillis	1610 NE 150th Street, P.O. Box 55729, Shoreline, WA 98155	206-418-5410

Is a school district fiscal impact statement required under [RCW 28A.305.135](#)? ☐ Yes ☒ No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:

Name
Address
Phone

Fax
TTY
Email
Other

Is a cost-benefit analysis required under [RCW 34.05.328](#)?

☒ Yes: A preliminary cost-benefit analysis may be obtained by contacting:

Name Molly Dinardo
Address P.O. Box 47822, Olympia, WA 98504-7822

Phone 360-236-4110
Fax N/A
TTY 711
Email molly.dinardo@sboh.wa.gov
Other

☐ No: Please explain:

Regulatory Fairness Act and Small Business Economic Impact Statement

Note: The [Governor's Office for Regulatory Innovation and Assistance \(ORIA\)](#) provides support in completing this part.

(1) Identification of exemptions:

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see [chapter 19.85 RCW](#)). For additional information on exemptions, consult the [exemption guide published by ORIA](#). Please check the box for any applicable exemption(s):

☐ This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.061](#) because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.

Citation and description:

☐ This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by [RCW 34.05.313](#) before filing the notice of this proposed rule.

☐ This rule proposal, or portions of the proposal, is exempt under the provisions of [RCW 15.65.570](#)(2) because it was adopted by a referendum.

☒ This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025](#)(3). Check all that apply:

☐ RCW 34.05.310 (4)(b) (Internal government operations)	☐ RCW 34.05.310 (4)(e) (Dictated by statute)
☐ RCW 34.05.310 (4)(c) (Incorporation by reference)	☐ RCW 34.05.310 (4)(f) (Set or adjust fees)
☒ RCW 34.05.310 (4)(d) (Correct or clarify language)	☐ RCW 34.05.310 (4)(g) ((i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit)

☐ This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025](#)(4). (Does not affect small businesses).

☐ This rule proposal, or portions of the proposal, is exempt under RCW _____.

Explanation of how the above exemption(s) applies to the proposed rule: Proposed changes in WAC 246-650-010 add definitions for OTCD, GAMT and ARG1-D. These proposed changes are exempt from the SBEIS under RCW 34.05.310(4)(d) because they clarify the meaning of terms used in the rules. Defining these conditions is not setting screening standards.

(2) Scope of exemptions: Check one.

- ☐ The rule proposal: Is fully exempt. (Skip section 3.) Exemptions identified above apply to all portions of the rule proposal.
- ☒ The rule proposal: Is partially exempt. (Complete section 3.) The exemptions identified above apply to portions of the rule proposal, but less than the entire rule proposal. Provide details here (consider using [this template from ORIA](#)):
- ☐ The rule proposal: Is not exempt. (Complete section 3.) No exemptions were identified above.

(3) Small business economic impact statement: Complete this section if any portion is not exempt.

If any portion of the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

☒ No Briefly summarize the agency's minor cost analysis and how the agency determined the proposed rule did not impose more-than-minor costs.

A brief description of the proposed rule including the current situation/rule, followed by the history of the issue and why the proposed rule is needed. A description of the probable compliance requirements and the kinds of professional services that a small business is likely to need in order to comply with the proposed rule.

The Washington State Board of Health (board) in collaboration with the Department of Health (department) is proposing amendments to the newborn screening requirements in WAC 246-650-010 and WAC 246-650-020. The proposed rule expands the Washington State newborn screening (NBS) panel of required tests by adding three new conditions: Ornithine Transcarbamylase Deficiency (OTCD), Guanidinoacetate Methyltransferase (GAMT) Deficiency, and Arginase 1 Deficiency (ARG1-D). To implement screening for these conditions, the board must amend WAC 246-650-010 and WAC 246-650-020. Early detection of OTCD, GAMT deficiency, and ARG1-D is critical for saving lives and improving long-term health outcomes for affected infants and their families.

The NBS program, operated by the Washington State Department of Health (department), tests all babies for rare but treatable health conditions using a dried blood sample. Washington State law ([RCW 70.83.050](#)) requires that the board create rules for newborn screening. These rules are found in [chapter 246-650 WAC](#). Specifically, WAC 246-650-010 and WAC 246-650-020 define and list the conditions that the department must screen all babies for after birth.

Anyone may petition the board to review a condition for possible inclusion in the NBS panel, including members of the public, department staff, and board members. To evaluate candidate conditions, the board convenes a Technical Advisory Committee (TAC), which reviews evidence against guiding principles and established criteria. The TAC provides findings and recommendations for board consideration.

In 2021, the board formed a Technical Advisory Committee (TAC) to review OTCD following a petition from a family whose child had passed away from the condition. In 2023, the board formed another TAC to review GAMT Deficiency and ARG1-D after two parent advocates submitted petitions. After reviewing evidence, hearing from families, and consulting experts, both TACs recommended adding the conditions to the screening panel. The board considered these recommendations at its meetings in October 2021 and October 2023 and voted to proceed with rulemaking to amend chapter 246-650 WAC. Through this rulemaking, the board proposes amendments to chapter 246-650 WAC to support the addition of three new conditions to Washington's newborn screening panel: OTCD, GAMT deficiency, and ARG1-D. These amendments include adding formal definitions for each of the three conditions and incorporating them into the list of newborn screening tests performed by the Department of Health.

In addition, the Board is proposing minor housekeeping changes. These include updating the definition of amino acid disorders and reclassifying relevant conditions under a new definition, "urea cycle disorders" as OTCD, ARG1-D and citrullinemia type I (CIT) are specific types of urea cycle disorders. The rulemaking also removes outdated language related to prior screening requirements that sunset in 2020 and are no longer applicable.

Adding OTCD, GAMT deficiency, and ARG1-D to the newborn screening (NBS) panel requires an increase in the NBS fee. This fee is not adopted in rule, and falls under the department's fee authority established in RCW 43.70.250(2), which requires legislative approval to increase spending authority for department programs, permit fees, etc.

The department charges a one-time screening fee that covers all required newborn screens in Washington State, including repeat or follow-up screens when medically necessary. This fee, collected for each tested infant in Washington, covers the costs of laboratory screening, follow-up services, and coordination with specialty care.

The department bills the screening fee to the facility that collects the infant's initial specimen. This is typically the birth hospital but may also include a clinic, birth center, or laboratory. Facilities can usually recover the cost through insurance reimbursement or patient billing. Medical facilities may charge their own administrative fees for collecting or processing specimens, which are separate from the department's screening fee.

For specimens collected in an at home setting, the department bills the client's insurance directly when the specimen is accompanied by the insurance information. If the patient is uninsured, they must pay the screening fee out of pocket via check or money order.

To implement screening for these additional conditions, the department secured increased spending authority from the Legislature during the 2025 legislative session. Beginning January 1, 2026, the screening fee will increase by \$4.02 to cover the cost of testing for OTCD, GAMT deficiency, and ARG1-D. This increase is expected to be covered by public or private insurance, or by families directly.

The proposed rule does not impose any new compliance requirements on small businesses. It applies only to the Department of Health's administration of the NBS Program and updates the list of conditions for which newborns are screened. Healthcare providers, birthing centers, midwives, and hospitals already participate in the program, and have for decades, by collecting blood samples and sending them to the state laboratory—practices that will remain unchanged. The same blood sample is used to test for these new conditions. There are no new reporting, procedural, or equipment requirements for these entities. Because the proposed rule does not alter existing procedures for facilities, no additional professional services are anticipated to be needed by small businesses to comply.

Identification and summary of which businesses are required to comply with the proposed rule using the North American Industry Classification System (NAICS).

SBEIS Table 1. Summary of Businesses Required to comply to the Proposed Rule

NAICS Code (4, 5 or 6 digit)	NAICS Business Description	Number of businesses in Washington State	Minor Cost Threshold
524114	Direct Health and Medical Insurance Carriers ¹	61	\$111,059.38
621399	Offices of All Other Miscellaneous Health Practitioners ²	5,023	\$927.25

Analysis of probable costs of businesses in the industry to comply to the proposed rule and includes the cost of equipment, supplies, labor, professional services, and administrative costs. The analysis considers if compliance with the proposed rule will cause businesses in the industry to lose sales or revenue.

The following SBEIS Table 2 identifies rule sections or portions of rule sections that have been determined exempt based on the exemptions.

SBEIS Table 2. Exempted Sections

WAC Section and Title	Description of Proposed Changes	Rationale for Exemption Determination
WAC 246-650-010 – Definitions	Adding definitions for OTCD, GAMT deficiency, and ARG1-D; amending the definition of amino acid disorders; and adding a definition for urea cycle disorders.	Exempt from SBEIS under RCW 34.05.310 (4)(d) because the proposed changes clarify the meaning of terms used in the rules by add new definitions for OTCD, GAMT, and ARG1-D. Defining these conditions is not setting screening standards. Tests for screening (required newborn screening tests) are listed under WAC 246-650-020.

WAC 246-650-010 Definitions.

Description: Defines terms that apply throughout the rule chapter. The proposed rule adds definitions for OTCD, GAMT and ARG1-D. These proposed changes are exempt from the SBEIS under RCW 34.05.310(4)(d) because they clarify the meaning of terms used in the rules. Defining these conditions is not setting screening standards. Tests for screening (required newborn screening tests) are listed under WAC 246-650-020. The impacts of adding the new conditions are analyzed below.

WAC 246-650-020 Performance of Screening Tests.

Description: This section of the rule establishes the list of heritable conditions that all babies in Washington must be screened for within 48 hours after birth. It also sets the responsibilities of hospitals and birth care providers in conducting newborn screening, including parental notification, specimen collection, and timely submission. In addition, the rule details the department's newborn screening program duties upon receipt of specimens, including the specific heritable conditions to be tested.

¹ This U.S. industry comprises establishments primarily engaged in initially underwriting (i.e., assuming the risk and assigning premiums) health and medical insurance policies. Group hospitalization plans and HMO establishments that provide health and medical insurance policies without providing health care services are included in this industry.

² : This U.S. industry comprises establishments of independent health practitioners. We are using this code to account for midwives with their own practices, that collect the newborn screening blood spot sample, and send to the PHL.

The board is proposing to amend WAC 246-650-020(2)(b) to add three new candidate conditions, OTCD, GAMT, and ARG1-D to the list of conditions on the Washington State mandatory newborn screening panel.

Additionally, the board is proposing to repeal subsection (3) as the requirement for the attending health care provider to notify the department of the date which the test results were disclosed to the parent or guardian expired January 1, 2020.

Cost(s): Total cost of the rule: \$4.02 fee increase per baby * 83,000 estimated births annually in Washington = **\$333,660**.

These costs will be covered by either private insurance, Medicaid, or patients will pay out of pocket.

Summary of all Cost(s):

Approximately 50% of births in Washington are covered by Medicaid; the remaining 50% are assumed to be covered by private insurance. Based on this, the cost impact is estimated as follows:

- Medicaid: \$166,830
- Private Insurance: \$166,830

To estimate potential cost impacts for providers serving uninsured populations (i.e., not covered by Medicaid or private insurance), we assume an 8% uninsured rate, based on 2024 U.S. Census³ and CDC data.⁴ Accordingly, the estimated cost impact on health providers collecting newborn screening specimens for uninsured patients is: $\$333,660 * 0.08 = \$26,692$

SBEIS Table 3. Summary of Section 3 probable cost(s)

WAC Section and Title	Probable Cost(s)
WAC 246-650-020 – Performance of Screening Tests, Addition of OTCD	The cost of screening would be approximately \$594,241.00 per year, or \$8.03 per baby. Total expenses, including the costs of screening, courier service, and false positive diagnostic testing, would be \$633,179.55.
WAC 246-650-020 – Performance of Screening Tests, Addition of GAMT Deficiency	The cost of screening would be approximately \$82,008.19 per year, or \$0.99 per baby. Total expenses, including the costs of screening and those associated with false positives, would be \$84,186.94 per year.
WAC 246-650-020 – Performance of Screening Tests, Addition of ARG1-D	The cost of screening would be approximately \$82,008.19 per year, or \$0.99 per baby. This includes startup lab costs, laboratory staffing, and supplies. Total expenses, including the costs of screening and those associated with false positives, would be \$87,263.32 per year.

Analysis on if the proposed rule may impose more than minor costs for businesses in the industry. Includes a summary of how the costs were calculated.

No, the costs of the proposed rule (annual average per establishment of \$2,735) are less than the minor cost threshold (\$111,059.38) for direct health and medical insurance carriers.

No, the costs of the proposed rule (annual average per establishment up to \$126.50) are less than the minor cost threshold (\$927.25) for Offices of All other Miscellaneous Health Practitioners.

Summary of how the costs were calculated

Health insurance carriers

The total cost of the rule is \$4.02 per baby * 83,000 estimated births in Washington State (annual) = \$333,660

The following assumptions and calculations were used to estimate the potential average annual costs per businesses in this sector to comply with the proposed rule:

- Medicaid covers about fifty percent of the births in Washington state. The other half are assumed to be covered by private insurance.⁵ Total annual costs (\$333,660) / 2 (half of births) = \$166,830 annually.
- Average cost of establishment was calculated for each of the estimated 61 businesses, $\$166,830 / 61 \text{ businesses} = \$2,735$

Offices of miscellaneous health providers – including midwives and other health practitioners offices

This U.S. industry comprises establishments of independent health practitioners. The department and board selected this NAICS code to account for midwives with their own practices, that collect the newborn screening blood spot sample, and send to the public health lab. This NAICS code includes not only midwives' offices but also other health practitioner offices

³ U.S. Census Bureau Health Insurance Coverage by State: 2023 and 2024. [Health Insurance Coverage by State: 2023 and 2024](#)

⁴ Centers for Disease Control and Prevention (CDC). National Center for Health Statistics. FastStats Health Insurance Coverage. [FastStats - Health Insurance Coverage](#)

⁵ Uninsured births were not assumed in the calculated estimate, which likely leads to an overestimate.

that do not collect newborn blood spot specimens (e.g., dental hygienists' offices and herbalists' offices). According to the Midwives Association of Washington State there are approximately 211 licensed midwives practicing in Washington State.⁶ The total cost of the rule: \$4.02 fee increase per baby * 83,000 estimated births = \$333,660.

The following assumptions and calculations were used to estimate the potential average annual costs per businesses in this sector to comply with the proposed rule:

- Medicaid covers about fifty percent of the births in Washington state. The other half are assumed to be covered by private insurance. Total annual costs (\$333,660) / 2 (half of births) = \$166,830 annually.
- Assume that 8% of births annually are uninsured.⁷ Total costs \$333,660 * (0.08) = \$26,692
- Average cost of establishment was calculated for each of the estimated 5,023 businesses and the estimated 211 licensed midwife businesses operating in Washington State.
 - \$26,692 / 5,023 businesses = \$5.32
 - \$26,692 / 211 businesses = \$126.50

☐ Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses and a small business economic impact statement is required. Insert the required small business economic impact statement here:

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name Molly Dinardo
Address 111 Israel Road SE Tumwater WA 98501
Phone 360-236-4110
Fax N/A
TTY 711
Email molly.dinardo@sboh.wa.gov
Other

Signature:

Date: 9/29/2025
Name: Michelle A. Davis
Title: Executive Director



⁶ Midwives Association of Washington State. 2025 Licensed Midwifery in Washington State FAQ. [2025 LM Licensed Midwifery in Washington State Fact Sheet](#)

⁷ U.S. Census Bureau Health Insurance Coverage by State: 2023 and 2024. [Health Insurance Coverage by State: 2023 and 2024](#) & Centers for Disease Control and Prevention (CDC). National Center for Health Statistics. FastStats Health Insurance Coverage. [FastStats - Health Insurance Coverage](#)

WAC 246-650-010 Definitions. The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(1) "Amino acid disorders" means (~~(argininosuccinic acidemia (ASA), citrullinemia type I (CIT),~~) homocystinuria (HCY), maple syrup urine disease (MSUD), phenylketonuria (PKU), and tyrosinemia type I (TYR I), which may cause severe complications including intellectual disability, coma, seizures, and possibly death.

(2) "Board" means the Washington state board of health.

(3) "Biotinidase deficiency" means a deficiency of an enzyme (biotinidase) that facilitates the body's recycling of biotin. The result is biotin deficiency, which if undetected and untreated, may result in severe neurological damage or death.

(4) "Congenital adrenal hyperplasia" means a severe disorder of adrenal steroid metabolism which may result in death of an infant during the neonatal period if undetected and untreated.

(5) "Congenital hypothyroidism" means a disorder of thyroid function during the neonatal period causing impaired mental functioning if undetected and untreated.

(6) "Critical congenital heart disease" means an abnormality in the structure or function of the heart that exists at birth, causes severe, life-threatening symptoms, and requires medical intervention within the first year of life.

(7) "Cystic fibrosis" means a life-shortening disorder caused by mutations in the gene encoding the cystic fibrosis transmembrane conductance regulator (CFTR), a transmembrane protein involved in ion transport. Affected individuals suffer from chronic, progressive pulmonary disease and nutritional deficits. Early detection and enrollment in a comprehensive care system provides improved outcomes and avoids the significant nutritional and growth deficits that are evident when diagnosed later.

(8) "Department" means the Washington state department of health.

(9) "Fatty acid oxidation disorders" means carnitine uptake defect (CUD), long-chain L-3-OH acyl-CoA dehydrogenase deficiency (LCHADD), medium-chain acyl-CoA dehydrogenase deficiency (MCADD), trifunctional protein deficiency (TFP), and very long-chain acyl-CoA dehydrogenase deficiency (VLCADD). These disorders can lead to hypoglycemia and metabolic crises resulting in serious damage affecting the brain, liver, heart, eyes, muscle, and possibly death.

(10) "Galactosemia" means a deficiency of enzymes that help the body convert the simple sugar galactose into glucose resulting in a buildup of galactose and galactose-1-PO₄ in the blood. If undetected and untreated, accumulated galactose-1-PO₄ may cause significant tissue and organ damage often leading to sepsis and death.

(11) "Guanidinoacetate methyltransferase (GAMT) deficiency" means an inherited condition that affects the body's ability to produce creatine. Without enough creatine, the body cannot use or store energy properly. If undetected and untreated, severe neurological problems can occur.

(12) "Hemoglobinopathies" means a group of hereditary blood disorders caused by genetic alteration of hemoglobin which results in

characteristic clinical and laboratory abnormalities and which leads to developmental impairment or physical disabilities.

((+12+)) (13) "Newborn" means an infant born in any setting in the state of Washington.

((+13+)) (14) "Newborn screening specimen/information form" means a form provided by the department for collecting a newborn's dried blood spots and information used to screen for congenital disorders under this chapter. This includes the filter paper portion and associated dried blood spots.

((+14+)) (15) "Mucopolysaccharidosis I (MPS-I)" means a multisystem disorder caused by mutations in the alpha-L-iduronidase gene in which a lysosomal enzyme is deficient, leading to accumulation of mucopolysaccharides (a type of carbohydrate) and other metabolites. This includes Hurler, Hurler-Scheie, and Scheie syndromes.

((+15+)) (16) "Organic acid disorders" means 3-OH 3-CH₃ glutaric aciduria (HMG), beta-ketothiolase deficiency (BKT), glutaric acidemia type I (GA 1), isovaleric acidemia (IVA), methylmalonic acidemia (CblA,B), methylmalonic acidemia (mutase deficiency) (MUT), multiple carboxylase deficiency (MCD), and propionic acidemia (PROP). These disorders can lead to metabolic crises resulting in severe nerve damage, physical damage, and possibly death.

((+16+)) (17) "Pompe disease" means a neuromuscular disorder caused by mutations in the acid glucosidase gene which result in reduced or absent activity of the acid alpha glucosidase enzyme.

((+17+)) (18) "Significant screening test result" means a laboratory test result indicating a suspicion of abnormality and requiring diagnostic evaluation of the involved infant for a specific congenital disorder.

((+18+)) (19) "Severe combined immunodeficiency (SCID)" means a group of congenital disorders characterized by profound deficiencies in T- and B- lymphocyte function. This results in very low or absent production of the body's primary infection fighting processes that, if left untreated, results in severe recurrent, and often life-threatening infections within the first year of life.

((+19+)) (20) "Spinal muscular atrophy (SMA)" means a genetic disorder caused by mutations in the survival motor neuron 1 (SMN1) gene, which impairs the function of the survival motor neuron (SMN) protein. This results in the loss of motor neurons and causes progressive atrophy of skeletal muscles.

((+20+)) (21) "Urea cycle disorders" means argininosuccinic acidemia (ASA), arginase 1 deficiency (ARG1-D), citrullinemia type I (CIT), and ornithine transcarbamylase deficiency (OTCD). These disorders can lead to an elevation of ammonia in blood, which is toxic to the body and can lead to severe nervous system damage.

(22) "X-linked adrenoleukodystrophy (X-ALD)" means a peroxisomal disorder caused by mutations in the ABCD1 gene located on the X chromosome. If untreated this can lead to adrenocortical deficiency, damage to the nerve cells of the brain, paralysis of the lower limbs, mental decline, disability, or death.

WAC 246-650-020 Performance of screening tests. (1) Hospitals and other providers of birth and delivery services or neonatal care to infants shall:

(a) Inform parents or guardians, by providing a departmental information pamphlet or by other means, of:

(i) The purpose of screening newborns for congenital disorders;

(ii) Disorders of concern as listed in WAC 246-650-020(2);

(iii) The requirement for newborn screening;

(iv) The legal right of parents or guardians to refuse testing because of religious tenets or practices as specified in RCW 70.83.020; and

(v) The specimen storage, retention and access requirements specified in WAC 246-650-050.

(b) Obtain a blood specimen for laboratory testing as specified by the department from each newborn no later than forty-eight hours following birth.

(c) Use department-approved newborn screening specimen/information forms and directions for obtaining specimens.

(d) Enter all identifying and related information required on the newborn screening specimen/information form following directions of the department.

(e) In the event a parent or guardian refuses to allow newborn screening, obtain signatures from parents or guardians on the newborn screening specimen/information form.

(f) Forward the newborn screening specimen/information form with dried blood spots or signed refusal to the Washington state public health laboratory so that it will be received no later than seventy-two hours following collection of the specimen, excluding any day that the state laboratory is closed.

(2) Upon receipt of specimens, the department shall:

(a) Record the time and date of receipt;

(b) Perform appropriate screening tests for:

(i) Amino acid disorders;

(ii) Biotinidase deficiency;

(iii) Congenital hypothyroidism;

(iv) Congenital adrenal hyperplasia;

(v) Cystic fibrosis;

(vi) Fatty acid oxidation disorders;

(vii) Galactosemia;

(viii) Guanidinoacetate Methyltransferase (GAMT) deficiency;

(ix) Hemoglobinopathies;

~~((ix))~~ (x) Mucopolysaccharidosis type I (MPS-I);

~~((x))~~ (xi) Organic acid disorders;

~~((xi))~~ (xii) Pompe disease;

~~((xii))~~ (xiii) Severe combined immunodeficiency (SCID);

~~((xiii))~~ (xiv) Spinal muscular atrophy (SMA);

~~((xiv))~~ (xv) Urea cycle disorders;

(xvi) X-linked adrenoleukodystrophy (X-ALD).

(c) Report significant screening test results to the infant's attending health care provider or parent or guardian if an attending health care provider cannot be identified; and

(d) Offer diagnostic and treatment resources to health care providers attending infants with significant screening test results within limits determined by the department.

~~((3) Once the department notifies the attending health care provider of significant screening test results, the attending health care provider shall notify the department of the date upon which the results were disclosed to the parent or guardian of the infant. This requirement expires January 1, 2020.))~~

RCW 70.83.020

Screening tests of newborn infants.

(1) It shall be the duty of the department of health to require screening tests of all newborn infants born in any setting. Each hospital or health care provider attending a birth outside of a hospital shall collect and submit a sample blood specimen for all newborns no more than forty-eight hours following birth. The department of health shall conduct screening tests of samples for the detection of phenylketonuria and other heritable or metabolic disorders leading to intellectual disabilities or physical defects as defined by the state board of health: PROVIDED, That no such tests shall be given to any newborn infant whose parents or guardian object thereto on the grounds that such tests conflict with their religious tenets and practices.

(2) The sample required in subsection (1) of this section must be received by the department [of health] within seventy-two hours of the collection of the sample, excluding any day that the Washington state public health laboratory is closed.

[2014 c 18 § 1; 2010 c 94 § 18; 1991 c 3 § 348; 1975-'76 2nd ex.s. c 27 § 1; 1967 c 82 § 2.]

RCW 70.83.030

Report of positive test to department of health.

Laboratories, attending physicians, hospital administrators, or other persons performing or requesting the performance of tests for phenylketonuria shall report to the department of health all positive tests. The state board of health by rule shall, when it deems appropriate, require that positive tests for other heritable and metabolic disorders covered by this chapter be reported to the state department of health by such persons or agencies requesting or performing such tests.

[1991 c 3 § 349; 1979 c 141 § 113; 1967 c 82 § 3.]

RCW 70.83.050

Rules and regulations to be adopted by state board of health.

The state board of health shall adopt rules and regulations necessary to carry out the intent of this chapter.

[1967 c 82 § 5.]

WSR 22-05-012
PREPROPOSAL STATEMENT OF INQUIRY
STATE BOARD OF HEALTH

[Filed February 4, 2022, 7:10 a.m.]

Subject of Possible Rule Making: Chapter 246-650 WAC, Newborn screening. The Washington state board of health (board) is considering adding ornithine transcarbamylase deficiency [deficiency] (OTCD) to the list of mandatory conditions for newborn screening conducted by the department of health (department).

Statutes Authorizing the Agency to Adopt Rules on this Subject: RCW 70.83.050 and 70.83.020.

Reasons Why Rules on this Subject may be Needed and What They Might Accomplish: OTCD is a severe condition with rapid onset that can result in significant morbidity and mortality if not detected and treated early. OTCD is a urea cycle disorder which causes ammonia to accumulate in the blood, affecting the liver and other body systems. Newborn screening, resulting in possible early diagnosis, is essential to improve quality of life for infants and their families, and reduce infant mortality.

Process for Developing New Rule: Collaborative; the board convened with the department, a technical advisory committee of multidisciplinary members to assess OTCD against a set of criteria for inclusion on the newborn screening panel. The board discussed the committee's recommendations and voted to proceed with rule making to consider rules that would allow for screening for OTCD in the newborn screening program.

Interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication by contacting Samantha Pskowski, P.O. Box 47990, Olympia, WA 98504-7990, phone 360-789-2358, TTY 711, email samantha.pskowski@sboh.wa.gov, website <https://sboh.wa.gov/Rulemaking/CurrentRulesandActivity/NewbornScreeningOTCD>.

Additional comments: To be added to the listserv for notifications regarding this rule making, email Samantha.pskowski@SBOH.wa.gov with the subject line "Newborn Screening - OTCD." For more information, please view the website at <https://sboh.wa.gov/Rulemaking/CurrentRulesandActivity/NewbornScreeningOTCD>.

February 3, 2022
Michelle A. Davis
Executive Director



PREPROPOSAL STATEMENT OF INQUIRY

CR-101 (October 2017) (Implements RCW 34.05.310)

Do NOT use for expedited rule making

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: November 28, 2023

TIME: 12:37 PM

WSR 23-24-016

Agency: Washington State Board of Health

Subject of possible rule making: Chapter 246-650 WAC, Newborn Screening. The Washington State Board of Health (Board) is considering adding Guanidinoacetate methyltransferase deficiency (GAMT) and Arginase 1 deficiency (ARG1-D) to the list of mandatory conditions for newborn screening conducted by the Department of Health (Department).

Statutes authorizing the agency to adopt rules on this subject: RCW 70.83.050

Reasons why rules on this subject may be needed and what they might accomplish: The Board has the authority under RCW 70.83.050 to define and adopt rules for screening Washington-born infants for hereditary conditions. WAC 246-650-010 defines the conditions, and WAC 246-650-020 lists the conditions for which all Washington-born newborns are to be screened. GAMT deficiency and ARG1-D are rare inherited metabolic conditions that can result in severe disability and in some cases death if not detected and treated early. Early diagnosis of GAMT deficiency and ARG1-D through newborn screening is essential to save lives and to improve the quality of life for impacted infants and their families.

Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies: None

Process for developing new rule (check all that apply):

- ☐ Negotiated rule making
- ☐ Pilot rule making
- ☐ Agency study
- ☒ Other (describe) The Board will use a collaborative rulemaking approach in developing the proposed rules.

Interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication by contacting:

Name: Molly Dinardo

Address: PO Box 47990, Olympia, WA 98504-7790

Phone: 564-669-3455

Fax: 360-236-4088

TTY: 711

Email: molly.dinardo@sboh.wa.gov

Web site:

Other:

(If necessary)

Name:

Address:

Phone:

Fax:

TTY:

Email:

Web site:

Other:

Additional comments: To be added to the listserv for notifications regarding this rulemaking, email Molly.Dinardo@sboh.wa.gov with the subject line "Newborn Screening – GAMT & ARG1-D."

Date: 11/28/2023

Name: Michelle A. Davis

Title: Executive Director, Washington State Board of Health

Signature:

A handwritten signature in black ink, reading "Michelle A. Davis". The signature is written in a cursive, flowing style with a large initial "M".

Date: October 8, 2025

To: Washington State Board of Health Members

From: Paj Nandi, Board Member

Subject: Rules Briefing – Group A Public Water Supplies, [WAC 246-290-315](#) and [WAC 246-290-71006](#) PFAS Permanent Rulemaking.

Background and Summary:

[RCW 43.20.030\(2\)\(a\)](#) grants the Washington State Board of Health (Board) authority to adopt rules for Group A public water systems that are necessary to assure safe and reliable drinking water and to protect public health.

In October 2021 the Board adopted drinking water state action levels (SALs) for per- and polyfluoroalkyl substances (PFAS) in [chapter 246-290 WAC](#), Group A Public Water Supplies and related provisions in [chapter 246-390 WAC](#), Drinking Water Laboratory Certification and Data Reporting. WAC 246-290-315 includes criteria for monitoring, reporting, follow-up actions, and public notification relevant to SALs.

On June 12, 2024, the Board adopted emergency rules to correct criteria in the rule that apply when the Environmental Protection Agency (EPA) adopts a federal maximum contaminant level (MCL) for a contaminant that has a state action level set in rule.

The emergency rulemaking, filed as [WSR 24-14-016](#), changed this to state that *when a federal MCL becomes effective*, the MCL will supersede a SAL and its requirements. This change ensures that the protections Washington currently has in place for the SALs remain in place until the federal MCLs become effective in April 2029.

Along with the emergency rule, the Board initiated rulemaking to permanently adopt the revisions from the emergency rule. The Board also explored reducing the current SALs to align with the new federal MCLs. Doing this would ensure that customers served by systems with detections below the SAL, but above the new MCL, are still notified of potentially dangerous levels of PFAS in their water and can take action to protect themselves, such as securing a filter, using bottled water, or other protective measures.

Board staff worked closely with the Department of Health's Office of Drinking Water to review the rule, draft amendments, conduct a cost survey with water purveyors, draft a small business economic impact statement, as well as an Environmental Justice Assessment. These materials were included in the formal rule proposal, filed as WSR 25-20-085 on September 30, 2025, and provided in Board materials. The formal public comment period is currently underway. The Board will consider the proposed changes through a public hearing at the November 19, 2025, Board meeting.

Today, Mike Means, with the Department of Health Office of Drinking Water will brief the Board on the rulemaking and answer any questions the Board may have in preparation for the hearing.

This is an informational briefing only. The Board will not take action at this meeting.

Staff

Shay Bauman, Policy Advisor

To request this document in an alternate format or a different language, 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.

PO Box 47990 • Olympia, WA 98504-7990
360-236-4110 • wsboh@sboh.wa.gov • sboh.wa.gov



**PFAS Permanent Rule
WAC 246-290-315 and
WAC 246-290-71006**

State Board of Health Meeting
October 8, 2025

Presenter

Mike Means

Water Quality, Policy, and Certification Manager

Office of Drinking Water

Division of Environmental Public Health

Mike.Means@doh.wa.gov



@WADeptHealth

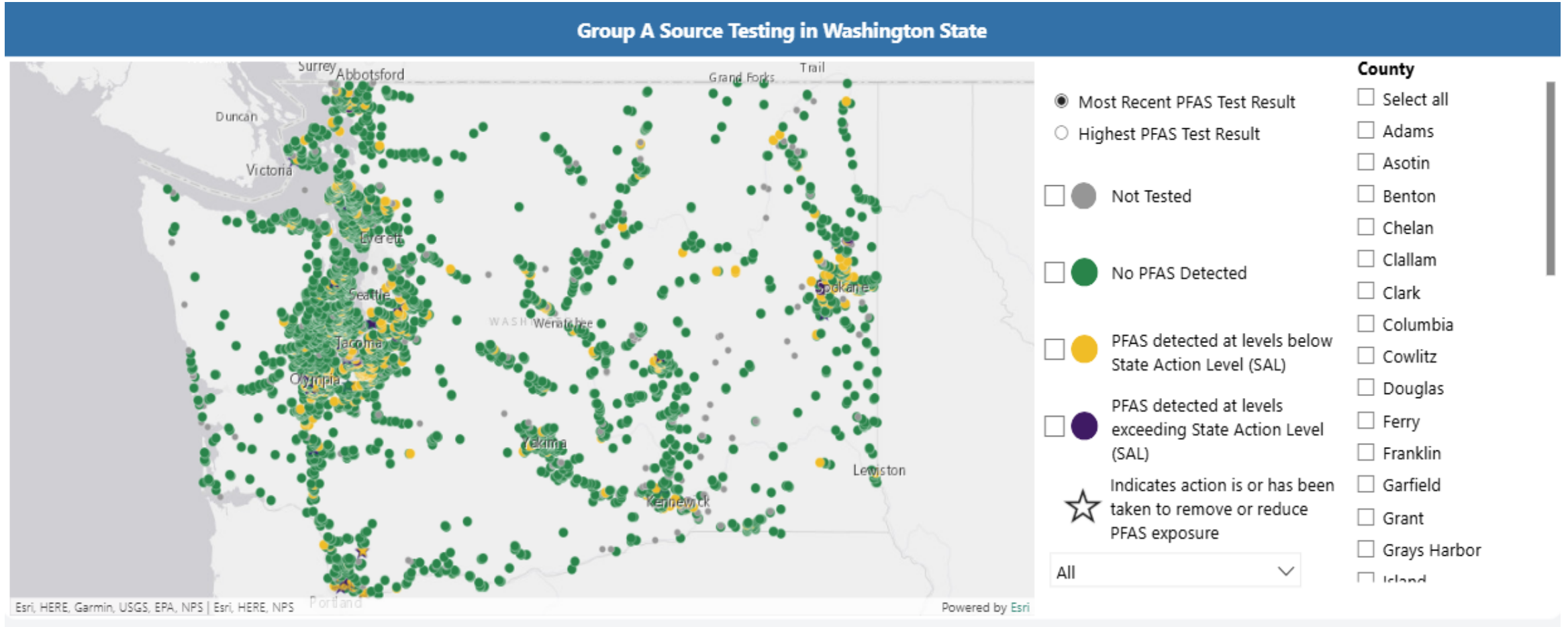
Background Information

- Per- and polyfluoroalkyl substances (PFAS) are chemicals that have been used in industry and consumer products such as carpeting, apparel, upholstery, food paper wrappings, fire-fighting foams, and metal plating worldwide since the 1950s. They are odorless and tasteless, so the only way to know if they are in a water system is to test for them.
- In November 2021, the Board adopted rules related to PFAS State Action Levels (SALs) establishing monitoring and notification requirements for public water systems in Washington in [WSR 21-23-097](#).
- In June 2024, the EPA adopted the first national regulations related to PFAS.
- The federal rules include PFAS requirements for monitoring, reporting, public notification, treatment, and violations. They also set federal Maximum Contaminant Levels (MCLs). Across almost all contaminants, the federal MCLs are stricter than the State Action Levels (SALs) currently in rule.

Background Information (cont.)

- The federal rules also include a MCL hazard index for certain PFAS chemicals, to account for the additive effects of some combinations of PFAS.
- Specific public water systems have five years to test for PFAS and ensure all water sources are below the MCLs. When the federal standards become effective, those water systems that still exceed a PFAS MCL will be in violation and required to notify the public and take action to reduce PFAS values to the MCL or lower.
- This affects the Board's rule and triggers the provision in WAC 246-290-315(8). The federal standards, however, have delayed effective dates for criteria and public health protections that are currently in place for Washington.
- The Board adopted an emergency rule, WSR 25-13-104 on June 18, 2025, to amend WAC 246-290-315 to keep state protections for drinking water in place until the EPA's new federal standards take effect. The Board adopted subsequent emergency rules while this rulemaking is ongoing in WSR-24-21-138, WSR 25-05-095, and WSR 25-23-104.

PFAS Testing Dashboard



EPA Effective Dates

Effective June 25, 2025

Analytical Requirements*

Effective April 26, 2027

Consumer Confidence
Reporting*

Ongoing compliance
monitoring*

Reporting and recordkeeping*

Initial monitoring results
reporting

Public notification for testing
and procedure violations

Effective April 26, 2029

PFAS MCL Violation

MCL Compliance Requirements

30-Day Public Notification for
MCL violations*

* Indicates Washington standards in place

Authority

RCW 43.20.050(2)(a) directs the Board to adopt rules for group A public water systems, as defined in RCW 70A.125.010, necessary to assure safe and reliable public drinking water and to protect the public health. In order to ensure Group A systems continue state required testing for PFAS, the Board must adopt rules that align the PFAS testing and reporting requirements with the new federal regulation.

Summary of Proposal

- The proposed rule ensures the current protections provided by monitoring and public notification under the SALs will remain in place until the MCLs are effective.
- The proposal aligns the current state action levels with the new standards by adopting the stricter values.
- The proposed rule ensures that we can require Group A public water systems, that the MCL does not apply to, sample and notify customers if they exceed the SAL in areas of PFAS risk.
- **Without the permanent adoption of the emergency rule, the current protections would go away until 2029. In addition, customers that receive water with PFAS levels above the new standards, but below the current SALs, would not be notified.**

Informal Comment Period

- The Board held an informal comment period from May 29, 2025 to June 11, 2025. The Board received five comments during the informal comment period.
- Two comments suggested keeping the current SAL values in place until the federal rule becomes effective, one supported the rules but shared concerns about adopting the provisions, and two comments suggested minor technical edits to clarify language within the rules.
- The minor technical edits clarifying language were incorporated into Table 9 in WAC 246-290-315 and Table 17 in WAC 246-290-71006.

Key Draft Changes: WAC 246-290-315

- The proposed changes to WAC 246-290-315(4) are to align the current SAL values with the federal MCL values. Washington currently regulates PFOA, PFOS, PFHxS, PFNA, and PFBS. The EPA adopted individual MCLs for four of these and added two new MCLs, (1) for HFPO-DA and (2) Hazard Index MCL, which modified how PFBS is evaluated when it is in the water supply. The table below shows the proposed changes:

Current WA PFAS	Current SAL Value	Federal PFAS	Federal MCL Value (proposed SAL Values)	Federal Method to Establish Exceedance of MCL Value
PFOA	10 ng/L	PFOA	4.0 ng/L	Running annual average
PFOS	15 ng/L	PFOS	4.0 ng/L	Running annual average
PFHxS	65 ng/L	PFHxS	10 ng/L	Running annual average
PFNA	9 ng/L	PFNA	10 ng/L	Running annual average
PFBS	345 ng/L	The new Hazard Index calculation for mixtures of specific PFAS is used to account for PFBS in the water supply.		Running annual average
		HFPO-DA	10 ng/L	Running annual average
		HAZARD INDEX (PFAS Mixtures)	1 (unitless)	Running annual average

Key Draft Changes: WAC 246-290-315 (cont.)

The proposed rule makes changes to WAC 246-290-315(8) to fix existing rule language so that current protections related to PFAS are kept in place until the new federal regulations are effective in April 2029. The language is below:

(8) When a federal MCL takes effect, the federal MCL will supersede a SAL or a less stringent state MCL. If the federal MCL is less stringent than a SAL or state MCL, the board may take one of the following actions:

(a) Adopt the federal MCL; or

(b) Adopt a state MCL, at least as stringent as the federal MCL, using the process in subsections (6) and (7) of this section.

Key Draft Changes: WAC 246-290-315 (cont.)

New language was proposed to WAC 246-290-315(9) and (10), to ensure that all water systems in Washington follow the relevant testing and notification requirements. Not all water systems in Washington are covered under the federal drinking water regulations. Transient non-community water systems like campgrounds, vacation homes, and corner stores may be required to sample under state rules but not under federal rules. The language is below:

(9) When a state MCL takes effect, it will supersede a SAL.

(10) When a federal or state MCL takes effect for a contaminant that has a SAL, public water systems that are not subject to the MCL shall continue to comply with SAL requirements.

Key Draft Changes: WAC 246-290-71006

The proposal makes changes to WAC 246-290-71006 to align the method the state uses to calculate an MCL exceedance with the method in the federal rule and changes the method to establish exceedance of a SAL value from a confirmed detection to a running annual average (RAA) in Table 17 to align with the changes made to Table 9 in WAC 246-290-315. The table below shows the proposed changes:

Contaminant or Group of Contaminants	Public Notice Tier	~~((Bioaccumulative))~~ SAL Exceedance Based on:
PFOA	Tier 2	~~((Yes))~~ <u>Running annual average</u>
PFOS	Tier 2	~~((Yes))~~ <u>Running annual average</u>
PFHxS	Tier 2	~~((Yes))~~ <u>Running annual average</u>
PFNA	Tier 2	~~((Yes))~~ <u>Running annual average</u>
~~((PFBS~~	~~Tier 2~~	~~Yes))~~
<u>HFPO-DA</u>	<u>Tier 2</u>	<u>Running annual average</u>
<u>Hazard Index PFAS (HFPO-DA, PFBS, PFHxS, and PFNA</u>	<u>Tier 2</u>	<u>Running annual average</u>

Cost Survey

- To gather information on the costs and benefits of the proposed rule changes, the board and the department collaborated to create a cost survey that was distributed to Group A water system operators. This survey was distributed via email which included a SurveyMonkey link. The survey was open from July 28th to August 8th.
- The Board asked Group A water systems, investor owned utilities (IOUs), and satellite management agencies (SMAs) to estimate the anticipated costs of several actions required in the proposed rule. We received **25 responses**.

Number of service connections indicated in survey response	Number of Group A water systems
Over 100,000	0
10,000-100,000	3
5,000-9,999	0
1,000-4,999	2
100-999	5
Less than 100	15

Cost Survey (cont.)

- The cost of sampling tests for PFAS can range from \$286.72 to \$694.56. This is because some tests require field blanks to be tested when there is a detection. The average cost for a sampling test that does not require a field blank to be tested with the sample is **\$344.79**.
- The largest applicable cost indicated is around testing. Based on the survey responses we anticipate a cost between **\$1,200-\$1,650** for water systems who may have to conduct additional testing.
- Multiple respondents also included the costs of treatment in their survey responses. These costs were not included in the costs calculated as they are outside the scope of rulemaking. Treatment is not required until the federal rule takes effect in 2029.

Next Steps

- Written Comment Period: October 3, 2025 to October 27, 2025
- Public Hearing: November 19, 2025, at 3:00pm.
- Date of intended adoption: November 19, 2025.
- CR-103 filing if adopted: Late December/early January
- If adopted, rules become effective 31 days after CR-103 filing.

Questions?



To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email civil.rights@doh.wa.gov.



PROPOSED RULE MAKING

CR-102 (June 2024)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: September 30, 2025

TIME: 10:00 AM

WSR 25-20-085

Agency: Washington State Board of Health

☒ Original Notice

☐ Supplemental Notice to WSR

☐ Continuance of WSR

☒ Preproposal Statement of Inquiry was filed as WSR 24-20-093 ; or

☐ Expedited Rule Making--Proposed notice was filed as WSR _____; or

☐ Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or

☐ Proposal is exempt under RCW _____.

Title of rule and other identifying information: Per- and polyfluoroalkyl substances (PFAS) – State action levels, state maximum contaminant levels and public notifications for Group A public water supplies in chapter 246-290 WAC.

The State Board of Health (board) is proposing amendments to WAC 246-290-315, State Action Levels (SALs) and State Minimum Contaminant Levels (MCLs) and WAC 246-290-71006, Public notice for contaminants with a SAL and other unregulated contaminants to align with the federal Environmental Protection Agency's (EPA) new federal standards for per- and polyfluoroalkyl substances (PFAS). The board adopted an emergency rule, WSR 25-13-104 on June 18, 2025, to amend WAC 246-290-315 to keep state protections for drinking water in place until the EPA's new federal standards take effect. The board adopted subsequent emergency rules while this rulemaking is ongoing in WSR-24-21-138, WSR 25-05-095, and WSR 25-23-104. The board is proposing permanent rule amendments to incorporate the changes from the emergency rulemaking to keep current state protections in place until the federal provisions take effect and to change the SALs to align with the new EPA standards before the federal effective date. The board is also considering editorial changes and updates to definitions to assure consistency of terms between federal and state rules in WAC 246-290-010 and 246-290-025.

Hearing location(s):

Date:	Time:	Location:	Comment:
November 19, 2025	3:00 pm	Washington State Department of Health 111 Israel Road S.E. Tumwater, WA 98501 Building: Town Center Two (TC2, Rooms 166 & 167)	The rules hearing will be hybrid. Individuals may attend either virtually or in-person. Register to participate via Zoom here: https://us02web.zoom.us/webinar/register/WN_DII0Jo2yQUe1KBgX_flccw

Date of intended adoption: November 19, 2025 (Note: This is **NOT** the effective date)

Submit written comments to:

Name Shay Bauman
Address P.O. Box 47990, Olympia, WA 98504-7790
Email drinkingwater@sboh.wa.gov
Fax
Other <https://fortress.wa.gov/doh/policyreview/>
Beginning: Date and time of filing
By: October 27, 2025

Assistance for persons with disabilities:

Contact
Phone
Fax
TTY
Email
Other
By (date)

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The purpose of this rule proposal is to incorporate changes from the previous emergency rulemakings to keep current state protections in place until the federal provisions take effect and to change the SALs to align with the new EPA standards before the federal effective

date. The rules are necessary to keep current protections related to SALs in place until the federal effective date, and not the adoption date. This is because many important federal provisions, including public notification of high contaminant levels, are not effective until 2029. The way the state rule was written, the protections that were in place under state SALs would go away until that date. The board is proposing to adopt the stricter contaminant values as SALs so that these customers can receive notifications sooner than the federal effective date to maintain and enhance vital public health protections for drinking water safety.

The board, in collaboration with the department, is aligning the PFAS testing and reporting requirements in WAC 246-290-315 and 246-290-71006 with the new federal regulation. Because the EPA evaluated the most current scientific data to develop PFAS MCLs, these represent the best approach for health protective standards. The PFAS SAL values will be updated to the EPA MCL values to provide optimal protection from PFAS in the state's public drinking water. The proposed changes will also maintain state efforts to ensure Group A systems continue state required testing for PFAS, make reporting requirements clearer and ease confusion about which set of health-based standards apply until the federal regulation becomes effective in April 2029.

Reasons supporting proposal: To ensure safe drinking water, water must be tested for contaminants. The board establishes SALs and MCLs to ensure contaminate levels are tested and actions are taken above a certain threshold. The board sets criteria for the adoption of SALs and MCLs in WAC 246-290-315, and includes criteria that would apply upon federal adoption of MCLs. WAC 246- 290-315(8) states that upon federal adoption of a MCL, the MCL will supersede a SAL and associated requirements, including monitoring and public notice. The emergency rule amended this language to state that when a federal MCL takes effect, the MCL will supersede a SAL and associated requirements, including monitoring and public notice. It is necessary to permanently adopt this language.

The federal government recently adopted MCLs related to per- and polyfluoroalkyl substances (PFAS). The MCLs are stricter than Washington's current SALs, but do not take effect until 2029. This means that people served by water systems that detect contamination levels above the MCL, but below the SAL, will not be notified within 30 days that their water contains elevated levels of PFAS. Because Washington already has a notification system in place for the SALs, the board is proposing to adopt the stricter contaminant values as SALs so that these customers can receive notifications sooner than the federal effective date.

Statutory authority for adoption: RCW 43.20.050(2)(a).

Statute being implemented: RCW 43.20.050(2)(a).

Is rule necessary because of a:

Federal Law?	☐ Yes	☒ No
Federal Court Decision?	☐ Yes	☒ No
State Court Decision?	☐ Yes	☒ No

If yes, CITATION:

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None

Name of proponent: State Board of Health

Type of proponent: ☐ Private. ☐ Public. ☒ Governmental.

Name of agency personnel responsible for:

Name	Office Location	Phone
Drafting Shay Bauman	101 Israel Rd SE Tumwater, WA 98501	564-669-8929
Implementation Mike Means	111 Israel Rd SE Tumwater, WA 98501	360-236-3178
Enforcement Mike Means	111 Israel Rd SE Tumwater, WA 98501	360-236-3178

Is a school district fiscal impact statement required under [RCW 28A.305.135](#)? ☐ Yes ☒ No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:

Name
Address
Phone
Fax
TTY
Email
Other

Is a cost-benefit analysis required under [RCW 34.05.328](#)?

☒ Yes: A preliminary cost-benefit analysis may be obtained by contacting:

Name Shay Bauman

Address PO Box 47990, Olympia, WA 98504-7790

Phone 564-669-8929

Fax 360-236-4088

TTY 711

Email shay.bauman@sboh.wa.gov

Other

☐ No: Please explain:

Regulatory Fairness Act and Small Business Economic Impact Statement

Note: The [Governor's Office for Regulatory Innovation and Assistance \(ORIA\)](#) provides support in completing this part.

(1) Identification of exemptions:

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see [chapter 19.85 RCW](#)). For additional information on exemptions, consult the [exemption guide published by ORIA](#). Please check the box for any applicable exemption(s):

☐ This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.061](#) because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.

Citation and description:

☐ This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by [RCW 34.05.313](#) before filing the notice of this proposed rule.

☐ This rule proposal, or portions of the proposal, is exempt under the provisions of [RCW 15.65.570](#)(2) because it was adopted by a referendum.

☐ This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025](#)(3). Check all that apply:

☐ [RCW 34.05.310](#) (4)(b)

(Internal government operations)

☐ [RCW 34.05.310](#) (4)(c)

(Incorporation by reference)

☐ [RCW 34.05.310](#) (4)(d)

(Correct or clarify language)

☐ [RCW 34.05.310](#) (4)(e)

(Dictated by statute)

☐ [RCW 34.05.310](#) (4)(f)

(Set or adjust fees)

☐ [RCW 34.05.310](#) (4)(g)

((i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit)

☐ This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025](#)(4). (Does not affect small businesses).

☐ This rule proposal, or portions of the proposal, is exempt under RCW _____.

Explanation of how the above exemption(s) applies to the proposed rule:

(2) Scope of exemptions: Check one.

☐ The rule proposal: Is fully exempt. (*Skip section 3.*) Exemptions identified above apply to all portions of the rule proposal.

☐ The rule proposal: Is partially exempt. (*Complete section 3.*) The exemptions identified above apply to portions of the rule proposal, but less than the entire rule proposal. Provide details here (consider using [this template from ORIA](#)):

☒ The rule proposal: Is not exempt. (*Complete section 3.*) No exemptions were identified above.

(3) Small business economic impact statement: Complete this section if any portion is not exempt.

If any portion of the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

☐ No Briefly summarize the agency's minor cost analysis and how the agency determined the proposed rule did not impose more-than-minor costs.

☒ Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses and a small business economic impact statement is required. Insert the required small business economic impact statement here:

The following is a brief description of the proposed rule including the current situation/rule, followed by the history of the issue and why the proposed rule is needed. A description of the probable compliance requirements and the kinds of professional services that a small business is likely to need in order to comply with the proposed rule.

The State Board of Health (board) in collaboration with the Department of Health (department) is proposing amending drinking water testing and reporting requirements. Amendments will align the state per- and polyfluoroalkyl substances

(PFAS) testing and reporting requirements in WAC 246-290-315 and 246-290-71006 with new federal regulations established in April 2024. Rule changes include updating the contaminant type classifications and updating the method of exceedance detection.

More than 6.2 million¹ Washington residents get their drinking water from Group A public water systems (Group A water systems). In Washington state, the [State Board of Health \(board\)](#) regulates Group A water systems under [Revised Code of Washington \(RCW\) 43.20.050](#).

Under [RCW 70A.125.080](#), the [Washington State Department of Health \(department\)](#) is directed to administer a Group A drinking water program with at least the elements necessary to assume primary enforcement responsibility of the federal Safe Drinking Water Act (SDWA).

The department administers the Group A drinking water program and regulates Group A water systems through a formal agreement with the U.S. Environmental Protection Agency (EPA) known as “primacy.”

The department and the board work closely on rulemaking for drinking water. The department provides expertise and resources for implementation, and makes recommendations to the board; and the board has the authority to adopt the proposed changes into rule.

In 2017, the board accepted a petition for rulemaking to set drinking water standards for per- and polyfluoroalkyl substances (PFAS) in chapter 246-290 WAC. PFAS are chemicals that have been used in industry and consumer products such as carpeting, apparel, upholstery, food paper wrappings, fire-fighting foams, and metal plating worldwide since the 1950s.

PFAS are odorless and tasteless, therefore, contaminant levels can only be assessed through water sampling and analytical testing. Recent studies² have linked PFAS exposure to widespread health effects, including reproductive effects such as decreased fertility or increased high blood pressure in pregnant women, developmental effects or delays in children, low birth weight, accelerated puberty, bone variations, behavioral changes, and depressed immune system function, including reduced vaccine response. Initial testing and then testing every three years thereafter across Washington state of Group A systems help the department identify impacted drinking water supplies and notify customers of those systems, as well as other nearby private and Group B wells that they may want to test³. This testing protocol starts the process of finding and mitigating local sources.

In April 2024, the federal government published the first National Public Drinking Water Regulation (NPDWR) for PFAS. The U.S. Environmental Protection Agency (EPA) provided all states with six legal Maximum Contaminant Levels (MCLs) for PFAS in public drinking water. An MCL is the maximum level of a contaminant allowable in a public water supply as defined by the Safe Drinking Water Act (42 U.S.C. § 300g-1), codified in 40 CFR Part 141, which sets the maximum legally permissible concentration of a contaminant in public water systems. Under the federal regulation, public water systems have five years from April 2024 to come into compliance with the National Public Drinking Water Regulations for PFAS by testing for PFAS and ensuring all water sources are below the MCLs. Under the federal regulation, beginning in April 2029 systems exceeding a PFAS MCL will be in violation of federal law and must notify the public and take action to reduce PFAS values to levels at or below the MCL.

This change in federal standard directly affects Washington’s rules by triggering the provision in WAC 246-290-315(8) under board authority stating that upon federal adoption of an MCL, the federal MCL will supersede a SAL or a less stringent state MCL, and the associated requirement. This proposed rule change addresses the discrepancy between the public notification requirements of the state level SAL compared to the April 2024 NPDWR.

As a result, Washington benefits from current state level health protections whereas the federal standards, though legally binding once effective, delay implementation until 2029. As a result, while states have until April 2029 to become compliant with the new MCLs, the 30 day public notification requirement is not effective. This creates a regulatory gap: if testing conducted before April 2029 identifies PFAS concentrations above the federal MCLs, public water systems would not be obligated under federal law to notify consumers, even though Washington’s state action level requirements already mandate notification within 30 days.

The board, in collaboration with the department, is proposing to align PFAS testing and reporting requirements in WAC 246-290-315 and 246-290-71006 with the new federal regulation. Because the EPA evaluated the most current scientific data to develop PFAS MCLs, these represent the best approach for health protective standards. The proposed changes update

¹ [Group A Public Water Supplies - PFAS Rulemaking | Washington State Department of Health](#)

² [Our Current Understanding of the Human Health and Environmental Risks of PFAS | US EPA](#)

³ A Group B water system is a public water system that does not meet the definition of a Group A water system. (See Table 1 under WAC 246-290-020 and chapter 246-291 WAC for further explanation of a Group B water system.) Group B water systems are regulated by local health jurisdictions under a joint plan of responsibility.

Washington rule to align PFAS SAL values with the EPA MCL values to provide optimal protection from PFAS in the state's public drinking water. The proposed changes also maintain state efforts to ensure Group A systems continue state required testing for PFAS, make reporting requirements clearer, and ease confusion about which set of health-based standards apply until the federal regulation becomes effective in April 2029.

SECTION 2

Identification and summary of which businesses are required to comply with the proposed rule using the North American Industry Classification System (NAICS).

SBEIS Table 1. Summary of Businesses Required to comply to the Proposed Rule

NAICS Code (4, 5 or 6 digit)	NAICS Business Description	Number of businesses in Washington State	Minor Cost Threshold
221310	Water supply and irrigation systems ⁴	149	\$3,282.48

SECTION 3

Analysis of probable costs of businesses in the industry to comply to the proposed rule and includes the cost of equipment, supplies, labor, professional services, and administrative costs. The analysis considers if compliance with the proposed rule will cause businesses in the industry to lose sales or revenue.

To gather information on the costs and benefits of the proposed rule changes, the board and the department collaborated to draft a cost survey that was distributed to Group A water operators (Group A water systems, investor owned utilities (IOUs), and satellite management agencies (SMAs) in Washington State. This survey was distributed via email which included a SurveyMonkey link. The survey was open from July 28th to August 8th.

The board asked Group A water operators to estimate the anticipated costs of several new requirements in the proposed rule. The respondents represent very small (less than 100 service connections) to very large (over 100,000 service connections) Group A water systems and represent all parts of Washington state. Table 1 shows the number of Group A water systems that responded (n=25) and the number of service connections served.

SBEIS Table 2: Respondents by number of Service Connections⁵

Number of cost survey respondents	Number of Service Connections Served
15	Less than 100
5	100-999
2	1,000-4,999
0	5,000-9,999
3	10,000-100,000
0	Over 100,000

The number of respondents that provided cost estimates are identified in the section-by-section analysis below. In cases where treatment was mentioned, the board and department removed responses deemed as outside the scope of the rule. The costs estimated from Group A water systems (n=6) are discussed in the relevant sectional analyses below.

Sectional Analysis

WAC 246-290-315 State action levels (SALs) and state maximum contaminant levels (MCLs).

Description: The proposed rule makes changes to subsection (4) to align with the newly adopted federal rules published by the EPA for PFAS on April 10, 2024. The proposed rule makes changes in order to align the federal PFAS testing and reporting requirements. Because the EPA evaluated the most current scientific data to develop PFAS MCLs, these represent the best approach for health protective standards. If a water system's testing levels exceed the SAL then they must notify their customers, which is further outlined in 246-290-71006. This does not impact all Group A water systems, only those who are at the current SAL and must begin testing to align with the EPA's testing requirements. The proposed rule does not change monitoring or treatment requirements.

The proposed rule also makes several changes to Table 9, which lists contaminants with a SAL. It removes PFBS as an individual contaminant and instead adds a Hazard Index metric, which is a tool used to assess the potential health risks from multiple PFAS chemicals. The hazard index accounts for PFBS in the water supply. It also adds HFPO-DA, an additional

⁴ NAICS defines water supply and irrigation systems as industry that comprises establishments primarily engaged in operating water treatment plants and/or operating water supply systems. The water supply system may include pumping stations, aqueducts, and/or distribution mains. The water may be used for drinking, irrigation, or other uses.

⁵ Three respondents did not identify their business or operation name and therefore are not included in this table.

contaminant for which the EPA adopted an MCL. The proposed rule changes the SAL values in Table 9 to the federal MCL values and adds values for HFPO-DA and the Hazard Index.

The proposed rule also changes the method to establish exceedance of a SAL value from a confirmed detection to a running annual average (RAA). Confirmed detection is when a contaminant is detected in an initial sample and detected again in a follow-up confirmation sample. Confirmed detection is best used for acute contaminants where a single exceedance can pose an immediate health risk. RAA is a method that uses the average of all sample results for the most recent four quarters for a specific contaminant. This change aligns with the regulations adopted by the EPA.

Cost(s): The board and department anticipate there will be costs for testing Group A water systems that have PFAS levels above the current SALs. The proposed rule changes the SALs to align with the federal MCLs from 10 ng/L to 4.0 ng/L for certain contaminants, there will be water systems that now exceed the SAL. Based on this, the department and board anticipate increased testing which increases costs incurred.

The cost⁶ of sampling tests for PFAS can range from \$286.72 to \$694.56⁷ which includes the cost for field blanks to be shipped with a sample when there is a detection. The average cost for a sampling test that does not require a field blank to be shipped with the sample is \$344.79.

The tables below show the costs to test for the contaminants listed in the proposed rule subsection (4). It is important to note, multiple survey respondents included the cost of water treatment when listing increased cost for changing the SAL for the contaminants listed. Those costs are outside the scope of this rulemaking and not included in the costs calculated below, as treatment is not required until the federal rule takes effect in 2029. Costs were cleaned and analyzed using Microsoft Excel. In cases where treatment was mentioned, the department removed responses deemed as outside the scope of the rule.

SBEIS Table 3: Estimated One-Time or Initial Cost to Test PFAS Contaminants

Contaminant or Group of Contaminants	Mean Cost (\$)	High Cost (\$)	Low Cost (\$) ⁸
PFOA	1,650	5,000 ⁹	500
PFOS	1,200	2,400	0
PFHxS	0	0	No Response
PFNA	0	0	No Response
HFPO-DA	0	0	No Response
Hazard Index PFAS (HFPO-DA, PFBS, PFHxS, and PFNA) ¹⁰	0	0	No Response

SBEIS Table 4: Estimated Annual Recurrent Costs to Test PFAS Contaminants

Contaminant or Group of Contaminants	Mean Cost (\$)	High Cost (\$)	Low Cost (\$) ¹¹
PFOA	2,320	5,000	500
PFOS	2,550	2,700	2,400
PFHxS	1,350	2,700	No Response
PFNA	0	0	No Response
HFPO-DA	0	0	No Response
Hazard Index PFAS (HFPO-DA, PFBS, PFHxS, and PFNA) ¹²	1,350	2,700	No Response

⁸ No response reflects that no respondents provided a cost estimate for the contaminant in both tables.

⁹ One respondent indicated a one-time or initial cost of \$20,000 for major filtration costs that is not included in the cost breakdown. Efforts were made to reach out to the respondent to further clarify costs, but we did not receive a response. However, since this rule does not require filtration, the board and department did not attribute the cost to the rule requirement.

¹⁰ The PFAS Mixture Hazard Index (HI) is the sum of component hazard quotients (HQs), which are calculated by dividing the measured component PFAS concentration in water by the relevant health-based water concentration when expressed in the same units (shown in ng/l for simplification). The HBWC for PFHxS is 10 ng/l; the HBWC for HFPO-DA is 10 ng/l; the HBWC for PFNA is 10 ng/l; and the HBWC for PFBS is 2000 ng/l.

¹¹ No response reflects that no respondents provided a cost estimate for the contaminant in both tables.

¹² Ibid.

Description: The proposed rule amends subsection (8) to state that when a federal MCL takes effect, the federal MCL will supersede a SAL or a less stringent state MCL. Under the current rule language, this would occur upon federal adoption of an MCL.

Cost(s): The board and department do not anticipate any additional costs for establishing that when a federal MCL takes effect, it will supersede a SAL or a less stringent MCL.

Description: The proposed rule adds new language, in subsection (9), to clarify that when a state MCL takes effect, it will supersede a SAL.

Cost(s): The board and department do not anticipate any additional costs for a state MCL superseding a SAL when it takes effect as it clarifies language on already established state requirements.

Description: The proposed rule adds new language in subsection (10) to state that when a federal or state MCL takes effect for a contaminant that has a SAL, public water systems that are not subject to the MCL have to continue to comply with the SAL requirements.

Cost(s): The board and department do not anticipate any additional cost for adding new language in subsection (10) as it clarifies that when a federal or state MCL takes effect for a contaminant that has a SAL, public water systems that are not subject to the MCL must continue to comply with the SAL requirements.

WAC 246-290-71006 Public notice for contaminants with a SAL and other unregulated contaminants.

Description: This section requires the purveyor to provide public notice to consumers following the detection of contaminants in a water system with a SAL. Eventually, the EPA standards will include a 30-day public notification of detections above the MCLs. The proposed rule updates the PFAS contaminants in Table 17 to align with the changes made by the EPA and reflected in Table 9 in WAC 246-290-315.

The proposed rule also changes the method to establish exceedance of a SAL value from a confirmed detection to a running annual average (RAA). Confirmed detection is when a contaminant is detected in an initial sample and detected again in a follow-up confirmation sample. Confirmed detection is best used for acute contaminants where a single exceedance can pose an immediate health risk. RAA is a method that uses the average of all sample results for the most recent four quarters for a specific contaminant. The delivery methods per the proposed amendments ensure every consumer is notified via direct delivery and additional methods reasonably calculated to reach all consumers.

Cost(s): If a Group A water systems falls between 10 ng/L and 4 ng/L, operators will be required by the proposed rule to conduct public notification for customers.

Table 5 shows the estimated costs for quarterly public notification from a previous analysis done in 2021, with estimates adjusted for inflation to 2025.

SBEIS Table 5: Estimated Costs for Public Notifications¹³

Action	Mean Cost (\$)	High Cost (\$)	Low Cost (\$)
Quarterly Public Notification	2,903	57,565	18
Annual Public Notification ¹⁴	11,611	230,257	35

Group A water systems must continue providing quarterly public notification as long as they continue to exceed a SAL. Although there are fixed costs included (such as developing required messaging) the variable cost of providing notices to all system users results in variable costs by size of system (e.g., larger costs for the larger systems and smaller costs for the smaller systems (based on the number of connections). Due to the inclusion of fixed costs (that were not separated from the estimate), it is likely that the annual public notification calculated in Table 3 is an overestimate.

SECTION 4

Analysis on if the proposed rule may impose more than minor costs for businesses in the industry. Includes a summary of how the costs were calculated.

Yes, the costs of the proposed rule (first year costs of compliance range between \$1,000 and \$5,000) are greater than the minor cost threshold (\$3,282.48).

Summary of how the costs were calculated

Costs were analyzed by individual business (SBEIS Table 6) with one-time costs added to annual costs to produce an estimated first year cost per business, ranging from \$1,000 to \$5,000.

SBEIS Table 6. Cost per business to comply with proposed rule*

¹³ Costs were adjusted from 2021\$ to 2025\$ using the U.S. Bureau of Labor Statistics Inflation Calculator on September 2, 2025 and then rounded up to next whole dollar. [CPI Inflation Calculator](#).

¹⁴ Annual costs were calculated by multiplying quarterly notification by 4 and then inflating to 2025\$.

Business Identifier	Type of Business	One-time cost (\$)	Annual cost (\$)	First year cost (\$)**
Business A	Small Business <=50	NA	2,700	2,700
Business B	Small Business <=50	5,000	NA	5,000
Business C	Small Business <=50	500	500	1,000
Business D	Large Business >=51	2,400	2,400	4,800
Business E	Small Business <=50	NA	5,000	5,000
Business F	Small Business <=50	2,000	1,000	3,000

*NA reflects that the value was left blank by survey respondents

**First year costs were calculated by adding up on-time costs and annual costs

When including the cost of annual public notification (ranging from \$35 to \$230,257) the range for one business to comply with the proposed rule is estimated between \$1,035 and \$235,257. The upper limit of the range exceeds the minor cost threshold for water supply and irrigation systems of \$3,282.48 (SBEIS Table 1).

SECTION 5

Determination on if the proposed rule may have a disproportionate impact on small businesses as compared to the 10 percent of businesses that are the largest businesses required to comply with the proposed rule.

No, the board and department do not anticipate the proposed rule will have a disproportionate impact on small businesses as compared to the 10 percent of businesses that are the largest businesses required to comply with the proposed rule.

Explanation of the determination

The board and department do not anticipate the proposed rule will have a disproportionate impact on small businesses because the correlation to employees and number of connections served is not indicative of a small business as defined in RCW 19.85.020 (3), which states a small business "means any business entity, including a sole proprietorship, corporation, partnership, or other legal entity, that is owned and operated independently from all other businesses, and that has fifty or fewer employees".¹⁵ Most water systems are not for profit businesses; they are cities, utility districts, and water and sewer districts. For example, Business A in the survey serves over 100 connections but still has less than 50 employees. The risk of disproportionate impact is not on smaller businesses versus larger businesses, but instead the impact lies based on the number of connections and customers served. Those with fewer customers may be impacted more by sampling costs since they are fixed costs, but larger systems may have much larger costs for public notification.

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name Shay Bauman

Address PO Box 47990, Olympia, WA 98504-7990

Phone 360-236-4110

Fax None

TTY 711

Email shay.bauman@sboh.wa.gov

Other N/A

Date: 9/29/2025

Name: Michelle Davis, MPA

Title: Executive Director, Washington State Board of Health

Signature:



¹⁵ [RCW 19.85.020: Definitions.](#)

WAC 246-290-315 State action levels (SALs) and state maximum contaminant levels (MCLs). (1) The department shall consider the following criteria to select a contaminant for developing a SAL:

(a) Drinking water contributes to human exposure to the contaminant.

(b) The contaminant is known or likely to occur in public water systems at levels of public health concern. Sources of occurrence information include, but are not limited to:

(i) Washington state department of agriculture;

(ii) Washington state department of ecology; and

(iii) Monitoring results reported in accordance with 40 C.F.R. 141.35.

(c) The contaminant has a possible adverse effect on the health of persons exposed based on peer-reviewed scientific literature or government publications, such as:

(i) An EPA health assessment such as an Integrated Risk Information System assessment;

(ii) Agency for Toxic Substances and Disease Registry toxicological profiles;

(iii) State government science assessment; and

(iv) EPA guidelines for exposure assessment such as the EPA exposure factors handbook.

(d) A certified drinking water lab can accurately and precisely measure the concentration of the contaminant in drinking water at and below the level of public health concern using EPA-approved analytical methods.

(2) After consideration of the criteria in subsection (1) of this section, the department may develop a SAL based on the following:

(a) Evaluation of available peer-reviewed scientific literature and government publications on fate, transport, exposure, toxicity and health impacts of the contaminant and relevant metabolites;

(b) An assessment based on the most sensitive adverse effect deemed relevant to humans and considering susceptibility and unique exposures of the most sensitive subgroup such as pregnant women, fetuses, young children, or overburdened and underserved communities; and

(c) Technical limitations to achieving the SAL such as insufficient analytical detection limit achievable at certified drinking water laboratories.

(3) The state board of health shall consider the department's findings under subsections (1) and (2) of this section when considering adopting a SAL under this chapter.

(4) Contaminants with a SAL.

(a) If a SAL under Table 9 of this section is exceeded, the purveyor shall take follow-up action as required under WAC 246-290-320. For contaminants where the SAL exceedance is determined based upon an RAA, the RAA will be calculated consistent with other organic contaminants per WAC 246-290-320(6) or other inorganic contaminants per WAC 246-290-320(3).

TABLE 9
STATE ACTION LEVELS

Contaminant or Group of Contaminants	SAL	SAL Exceedance Based On:
Per- and polyfluoroalkyl substances (PFAS)		
PFOA	~~((10))~~ 4.0 ng/L	~~((Confirmed detection))~~ Running annual average
PFOS	~~((15))~~ 4.0 ng/L	~~((Confirmed detection))~~ Running annual average
PFHxS	~~((65))~~ 10 ng/L	~~((Confirmed detection))~~ Running annual average
PFNA	~~((9))~~ 10 ng/L	~~((Confirmed detection))~~ Running annual average
~~((PFBS~~	345 ng/L	Confirmed detection))
HFPO-DA	10 ng/L	Running annual average
<u>Hazard Index PFAS (HFPO-DA, PFBS, PFHxS, and PFNA)¹</u>	<u>1 (unitless)¹</u>	<u>Running annual average</u>

¹ The PFAS Mixture Hazard Index (HI) is the sum of component hazard quotients (HQs), which are calculated by dividing the measured component PFAS concentration in water by the relevant health-based water concentration when expressed in the same units (shown in ng/l for simplification). The HBWC for PFHxS is 10 ng/l; the HBWC for HFPO-DA is 10 ng/l; the HBWC for PFNA is 10 ng/l; and the HBWC for PFBS is 2000 ng/l.

Hazard Index:
$$= \frac{(\text{HFPO-DA}_{\text{water}} \text{ ng/l}) / (10 \text{ ng/l}) + (\text{PFBS}_{\text{water}} \text{ ng/l}) / (2000 \text{ ng/l}) + (\text{PFNA}_{\text{water}} \text{ ng/l}) / (10 \text{ ng/l}) + (\text{PFHxS}_{\text{water}} \text{ ng/l}) / (10 \text{ ng/l})}{}$$

HBWC = health-based water concentration

HQ = hazard quotient

ng/L = nanograms per liter

PFAS_{water} = the concentration of a specific PFAS in water

(b) If a system fails to collect and submit a confirmation sample to a certified lab within ~~((ten))~~ 10 business days of notification of the sample results, or as required by the department, the results of the original sample will be used to determine compliance with the SAL.

(5) The department shall consider the following when developing a state MCL:

(a) The criteria in subsection (1) of this section;

(b) Whether regulating the contaminant presents a meaningful opportunity to reduce exposures of public health concern for persons served by public water systems;

(c) The need for an enforceable limit to achieve uniform public health protection in Group A public water systems; and

(d) The need for an enforceable limit to support source water investigation and clean-up of a contaminant in drinking water supplies by responsible parties.

(6) In addition to the requirements in subsection (5) of this section, the department shall:

(a) Meet the requirements of subsection (2) of this section;

(b) Comply with the requirements in RCW 70A.130.010 to establish standards for chemical contaminants in drinking water;

(c) Consider the best available treatment technologies and affordability taking into consideration the costs to small water systems; and

(d) Determine that the probable benefits of the rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs.

(7) The state board of health shall consider the department's findings under subsections (5) and (6) of this section and follow the requirements under chapters 34.05 and 19.85 RCW when adopting a state MCL under this chapter.

(8) (~~Upon federal adoption of an MCL~~) When a federal MCL takes effect, the federal MCL will supersede a SAL or a less stringent state MCL(~~(, and the associated requirements, including for monitoring and public notice)~~). If the (~~federally adopted~~) federal MCL is less stringent than a SAL or state MCL, the board may take one of the following actions:

(a) Adopt the federal MCL; or

(b) Adopt a state MCL, at least as stringent as the federal MCL, using the process in subsections (6) and (7) of this section.

(9) When a state MCL takes effect, it will supersede a SAL.

(10) When a federal or state MCL takes effect for a contaminant that has a SAL, public water systems that are not subject to the MCL shall continue to comply with SAL requirements.

WAC 246-290-71006 Public notice for contaminants with a SAL and other unregulated contaminants. (1) The purveyor shall provide public notice to the water system users when the department determines that a contaminant exceeds a SAL listed in WAC 246-290-315, Table 9.

(2) The public notice must be in conformance with the requirements under WAC 246-290-71001 through 246-290-71004 and based upon the public notice tier designation of the contaminant or group of contaminants in Table 17 of this section.

TABLE 17
PUBLIC NOTICE TIER DESIGNATION FOR CONTAMINANTS WITH A SAL

Contaminant or Group of Contaminants	Public Notice Tier	((Bioaccumulative)) SAL Exceedance Based on:
PFOA	Tier 2	((Yes)) <u>Running annual average</u>
PFOS	Tier 2	((Yes)) <u>Running annual average</u>
PFHxS	Tier 2	((Yes)) <u>Running annual average</u>
PFNA	Tier 2	((Yes)) <u>Running annual average</u>
((PFBS	Tier 2	Yes))
HFPO-DA	Tier 2	<u>Running annual average</u>
<u>Hazard Index PFAS (HFPO-DA, PFBS, PFHxS, and PFNA)</u>	Tier 2	<u>Running annual average</u>

(a) The purveyor shall complete public notice for an initial exceedance of a Tier 1 designated SAL within ((~~twenty-four~~)) 24 hours of confirmation, and for every subsequent quarter in which analytical results exceed a SAL.

(b) The purveyor shall complete public notification for an initial exceedance of a Tier 2 designated SAL as soon as practical, but no less than within ((~~thirty~~)) 30 days of exceeding the SAL per Table 9 in WAC 246-290-315, and every three months thereafter as long as the results continue to exceed the SAL per Table 9 in WAC 246-290-315, or as directed by the department.

(3) The department may require public notice for other unregulated contaminants that are reported per requirements in WAC 246-390-075.



PREPROPOSAL STATEMENT OF INQUIRY

CR-101 (October 2017)
(Implements RCW 34.05.310)

Do **NOT** use for expedited rule making

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: September 30, 2024

TIME: 1:57 PM

WSR 24-20-093

Agency: Washington State Board of Health

Subject of possible rule making: Per- and polyfluoroalkyl substances (PFAS) – State action levels, state maximum contaminant levels and public notifications for Group A public water supplies in chapter 246-290 WAC.

The State Board of Health (Board) is considering amending WAC 246-290-315, State Action Levels (SALs) and State Minimum Contaminant Levels (MCLs) and WAC 246-290-71006, Public notice for contaminants with a SAL and other unregulated contaminants to align with the federal Environmental Protection Agency's (EPA) new federal standards for per- and polyfluoroalkyl substances (PFAS). The Board adopted an emergency rule, WSR 24-14-016 on June 24, 2024, to amend WAC 246-290-315 to keep state protections for drinking water in place until the EPA's new federal standards take effect. The Board is considering permanent rule amendments to incorporate the changes from the emergency rulemaking to keep current state protections in place until the federal provisions take effect and to explore changing the SALs to align with the new EPA standards before the federal effective date. The Board may also consider editorial changes and updates to definitions to assure consistency of terms between federal and state rules in WAC 246-290-010 and 246-290-025.

Statutes authorizing the agency to adopt rules on this subject: RCW 43.20.050(2)(a).

Reasons why rules on this subject may be needed and what they might accomplish: The rules may be necessary to keep current protections related to SALs in place until the federal effective date, and not the adoption date. This is because many important federal provisions, including public notification of high contaminant levels, are not effective until 2029. The way the state rule was written, the protections that were in place under state SALs would go away until that date. This emergency rule prevents the notification requirements from lapsing, however emergency rules are only effective for 120 days.

To ensure safe drinking water, water must be tested for contaminants. The Board establishes SALs and MCLs to ensure contaminate levels are tested and actions are taken above a certain threshold. The Board sets criteria for the adoption of SALs and MCLs in WAC 246-290-315 and includes criteria that would apply upon federal adoption of MCLs. WAC 246- 290-315(8) states that upon federal adoption of a MCL, the MCL will supersede a SAL and associated requirements, including monitoring and public notice. The emergency rule amended this language to state that when a federal MCL takes effect, the MCL will supersede a SAL and associated requirements, including monitoring and public notice. It may be necessary to permanently adopt this language.

The federal government recently adopted MCLs related to per- and polyfluoroalkyl substances (PFAS). The MCLs are stricter than Washington's current SALs, but do not take effect until 2029. This means that people served by water systems that detect contamination levels above the MCL, but below the SAL, will not be notified within 30 days that their water contains elevated levels of PFAS.

Because Washington already has a notification system in place for the SALs, the Board is exploring adopting the stricter contaminant values as SALs so that these customers can receive additional protections sooner than the federal effective date.

The Board may also consider editorial changes and updates to definitions to assure consistency of terms between federal and state rules in WAC 246-290-010 and 246-290-025.

Identify other federal and state agencies that regulate this subject and the process

coordinating the rule with these agencies: The Board will coordinate and collaborate with the State Department of Health, which enforces the rule. The Board will also regularly update the State Department of Ecology, the State Department of Agriculture, and the State Department of Fish and Wildlife. These agencies regulate PFAS in other contexts. Some of the changes being considered come from new regulations from the EPA. The Board will work to ensure the changes align with the EPA's science and research.

Process for developing new rule (check all that apply):

- ☐ Negotiated rule making
- ☐ Pilot rule making
- ☐ Agency study
- ☒ Other (describe) The Board will use a collaborative rulemaking approach.

Interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication by contacting:

(If necessary)

Name: Shay Bauman

Name:

Address PO Box 47990

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Additional comments: To be added to the listserv for notifications regarding this rule-making, email drinkingwater@sboh.wa.gov with the subject line "PFAS Notification." The Board in collaboration with the Department of Health will complete an environmental justice assessment for this rule-making.

Date: September 30, 2024

Signature:

Name: Michelle Davis, MPA



Title: Executive Director, Washington State Board of Health

RCW 43.20.050 Powers and duties of state board of health—Rule making—Delegation of authority—Enforcement of rules. (1) The state board of health shall provide a forum for the development of public health policy in Washington state. It is authorized to recommend to the secretary means for obtaining appropriate citizen and professional involvement in all public health policy formulation and other matters related to the powers and duties of the department. It is further empowered to hold hearings and explore ways to improve the health status of the citizenry.

In fulfilling its responsibilities under this subsection, the state board may create ad hoc committees or other such committees of limited duration as necessary.

(2) In order to protect public health, the state board of health shall:

(a) Adopt rules for group A public water systems, as defined in RCW 70A.125.010, necessary to assure safe and reliable public drinking water and to protect the public health. Such rules shall establish requirements regarding:

(i) The design and construction of public water system facilities, including proper sizing of pipes and storage for the number and type of customers;

(ii) Drinking water quality standards, monitoring requirements, and laboratory certification requirements;

(iii) Public water system management and reporting requirements;

(iv) Public water system planning and emergency response requirements;

(v) Public water system operation and maintenance requirements;

(vi) Water quality, reliability, and management of existing but inadequate public water systems; and

(vii) Quality standards for the source or supply, or both source and supply, of water for bottled water plants;

(b) Adopt rules as necessary for group B public water systems, as defined in RCW 70A.125.010. The rules shall, at a minimum, establish requirements regarding the initial design and construction of a public water system. The state board of health rules may waive some or all requirements for group B public water systems with fewer than five connections;

(c) Adopt rules and standards for prevention, control, and abatement of health hazards and nuisances related to the disposal of human and animal excreta and animal remains;

(d) Adopt rules controlling public health related to environmental conditions including but not limited to heating, lighting, ventilation, sanitary facilities, and cleanliness in public facilities including but not limited to food service establishments, schools, recreational facilities, and transient accommodations;

(e) Adopt rules for the imposition and use of isolation and quarantine;

(f) Adopt rules for the prevention and control of infectious and noninfectious diseases, including food and vector borne illness, and rules governing the receipt and conveyance of remains of deceased persons, and such other sanitary matters as may best be controlled by universal rule; and

(g) Adopt rules for accessing existing databases for the purposes of performing health related research.

(3) The state board shall adopt rules for the design, construction, installation, operation, and maintenance of those

on-site sewage systems with design flows of less than three thousand five hundred gallons per day.

(4) The state board may delegate any of its rule-adopting authority to the secretary and rescind such delegated authority.

(5) All local boards of health, health authorities and officials, officers of state institutions, police officers, sheriffs, constables, and all other officers and employees of the state, or any county, city, or township thereof, shall enforce all rules adopted by the state board of health. In the event of failure or refusal on the part of any member of such boards or any other official or person mentioned in this section to so act, he or she shall be subject to a fine of not less than fifty dollars, upon first conviction, and not less than one hundred dollars upon second conviction.

(6) The state board may advise the secretary on health policy issues pertaining to the department of health and the state. [2021 c 65 s 37; 2011 c 27 s 1; 2009 c 495 s 1; 2007 c 343 s 11; 1993 c 492 s 489; 1992 c 34 s 4. Prior: 1989 1st ex.s. c 9 s 210; 1989 c 207 s 1; 1985 c 213 s 1; 1979 c 141 s 49; 1967 ex.s. c 102 s 9; 1965 c 8 s 43.20.050; prior: (i) 1901 c 116 s 1; 1891 c 98 s 2; RRS s 6001. (ii) 1921 c 7 s 58; RRS s 10816.]

Explanatory statement—2021 c 65: See note following RCW 53.54.030.

Effective date—2009 c 495: "Except for section 9 of this act, this act is necessary for the immediate preservation of the public peace, health, or safety, or support of the state government and its existing public institutions, and takes effect immediately [May 14, 2009]." [2009 c 495 s 17.]

Findings—1993 c 492: "The legislature finds that our health and financial security are jeopardized by our ever increasing demand for health care and by current health insurance and health system practices. Current health system practices encourage public demand for unneeded, ineffective, and sometimes dangerous health treatments. These practices often result in unaffordable cost increases that far exceed ordinary inflation for essential care. Current total health care expenditure rates should be sufficient to provide access to essential health care interventions to all within a reformed, efficient system.

The legislature finds that too many of our state's residents are without health insurance, that each year many individuals and families are forced into poverty because of serious illness, and that many must leave gainful employment to be eligible for publicly funded medical services. Additionally, thousands of citizens are at risk of losing adequate health insurance, have had insurance canceled recently, or cannot afford to renew existing coverage.

The legislature finds that businesses find it difficult to pay for health insurance and remain competitive in a global economy, and that individuals, the poor, and small businesses bear an inequitable health insurance burden.

The legislature finds that persons of color have significantly higher rates of mortality and poor health outcomes, and substantially lower numbers and percentages of persons covered by health insurance than the general population. It is intended that chapter 492, Laws of

1993 make provisions to address the special health care needs of these racial and ethnic populations in order to improve their health status.

The legislature finds that uncontrolled demand and expenditures for health care are eroding the ability of families, businesses, communities, and governments to invest in other enterprises that promote health, maintain independence, and ensure continued economic welfare. Housing, nutrition, education, and the environment are all diminished as we invest ever increasing shares of wealth in health care treatments.

The legislature finds that while immediate steps must be taken, a long-term plan of reform is also needed." [1993 c 492 s 101.]

Intent—1993 c 492: "(1) The legislature intends that state government policy stabilize health services costs, assure access to essential services for all residents, actively address the health care needs of persons of color, improve the public's health, and reduce unwarranted health services costs to preserve the viability of nonhealth care businesses.

(2) The legislature intends that:

(a) Total health services costs be stabilized and kept within rates of increase similar to the rates of personal income growth within a publicly regulated, private marketplace that preserves personal choice;

(b) State residents be enrolled in the certified health plan of their choice that meets state standards regarding affordability, accessibility, cost-effectiveness, and clinical efficaciousness;

(c) State residents be able to choose health services from the full range of health care providers, as defined in RCW 43.72.010(12), in a manner consistent with good health services management, quality assurance, and cost effectiveness;

(d) Individuals and businesses have the option to purchase any health services they may choose in addition to those included in the uniform benefits package or supplemental benefits;

(e) All state residents, businesses, employees, and government participate in payment for health services, with total costs to individuals on a sliding scale based on income to encourage efficient and appropriate utilization of services;

(f) These goals be accomplished within a reformed system using private service providers and facilities in a way that allows consumers to choose among competing plans operating within budget limits and other regulations that promote the public good; and

(g) A policy of coordinating the delivery, purchase, and provision of health services among the federal, state, local, and tribal governments be encouraged and accomplished by chapter 492, Laws of 1993.

(3) Accordingly, the legislature intends that chapter 492, Laws of 1993 provide both early implementation measures and a process for overall reform of the health services system." [1993 c 492 s 102.]

Short title—Savings—Reservation of legislative power—Effective dates—1993 c 492: See RCW 43.72.910 through 43.72.915.

Severability—1992 c 34: See note following RCW 69.07.170.

Effective date—Severability—1989 1st ex.s. c 9: See RCW 43.70.910 and 43.70.920.

Savings—1985 c 213: "This act shall not be construed as affecting any existing right acquired or liability or obligation incurred under the sections amended or repealed in this act or under any rule, regulation, or order adopted under those sections, nor as affecting any proceeding instituted under those sections." [1985 c 213 s 31.]

Effective date—1985 c 213: "This act is necessary for the immediate preservation of the public peace, health, and safety, the support of the state government and its existing public institutions, and shall take effect June 30, 1985." [1985 c 213 s 33.]

Severability—1967 ex.s. c 102: See note following RCW 43.70.130.

Rules and regulations—Visual and auditory screening of pupils: RCW 28A.210.020.

Statement of the Board on Possible Legislative Issues

2025 Legislative Session

It is the policy (Policy 01-001) of the Washington State Board of Health (Board) to comment on legislative proposals that affect the Board's:

- [Statutory authority](#) and rules, and
- [2024 State Health Report](#) Recommendations

This statement represents the Sense of the Board and is intended to guide staff and Board members in their communications on legislative and budget proposals. The statement is not an exhaustive list of anticipated legislative topics. It focuses on possible legislative issues that may impact the Board or the public health system.

Foundational Public Health Services

The Board believes that [Public Health is Essential](#) and supports the governmental public health system's efforts to fund the system for the delivery of Foundational Public Health Services (FPHS) so these services are available in every community. The governmental public health system must be able to monitor health, focus on prevention, assure health for all, and be capable of an all-hazards response. It is critical for the State to provide adequate, dedicated, stable funding for full implementation of FPHS statewide that keeps pace with inflation and demand for services and that provides resources to address inequities and innovate and modernize the governmental public health system. This includes increasing the Board's capacity to meet its statutory obligations under Chapter 43.20 RCW and other state laws. The Board **opposes** reductions to funding for the governmental public health system.

Advancing Health Justice and Equity in State Government

The Board recognizes that racism is a public health crisis and is embedded within the health care delivery and public health systems. Racism and other forms of discrimination have been and continue to be institutionalized and perpetuated through policies and practices that prevent meaningful community engagement and limit opportunity and access to important public services. Health inequities cannot be eliminated without addressing structural and institutional racism in these systems. The Board supports legislation prioritizing and operationalizing health justice and equity across state government.

The Board supports the efforts of the Governor's Interagency Council on Health Disparities (Council) to use a health justice framework to advance enduring health equity and social justice. Health justice centers the following principles: racial equity; collaboration across areas of study and work; upstream interventions that address root causes of inequities and injustice; adaptability; advocacy for systems change; and community-based strategies that uphold community power. The Board supports the Council's legislative proposal to update the Council's name, membership, duties, and authority in RCW 43.20 and related laws. The Board also supports ongoing funding for the Council in the state's operating budget to support the Council's operations; enhance community/partner engagement, communications, and collaboration; and provide language assistance services and community compensation.

Health Impact Reviews

Under RCW 43.20.285 the Board conducts [Health Impact Reviews](#) (HIRs) at the request of the Governor or a legislator. HIRs are objective, non-partisan, evidence-based analyses of proposed legislative or budgetary changes to determine the potential impacts on health and equity. FPHS funding covers 1.8 FTE of the three staff who conduct health impact reviews on behalf of the Board. HIRs improve the state's ability to use evidence to inform policy and to promote health and equity. The Board supports additional state and legislative efforts to assess equity impacts of legislative proposals, and the Board recognizes the unique value that HIRs add to legislative decision-making. The rigorous HIR research approach, which uses both quantitative and qualitative research, as well as lived experience, provides legislators with a nuanced understanding of how proposed policy may impact health and equity in the state. The Board supports the retention of HIRs and will continue to offer assistance and support to ensure any newly proposed tools align with and do not duplicate the work of HIRs.

The Board supports legislative action to ensure long-term, sustainable solutions to obtain peer-reviewed literature access for HIR work. The Board believes there is also a need for all state entities (agencies, boards, commissions, councils, etc.) to have access to research and published literature to inform evidence-based policy and program development.

School Environmental Health and Safety

The Board is committed to carrying out the school rule project funded in the 2024 operating budget and looks forward to hearing and considering the technical advisory committee's recommendations. Local health jurisdictions must have sufficient resources and capacity to conduct school environmental health and safety inspections to assure minimum health and safety protections for all school children across the state. Schools must have adequate funding for school modernization, repair, and remediation to improve school environmental health and safety. The Board supports legislation and capital and operating budget proposals to increase funding for schools to improve environmental health and safety and align school environmental health and safety and building efficiency standards. The Board also supports the Office of Superintendent of Public Instruction's request for ongoing support for equitable access to clean air and improving classroom air quality capital decision package, as well as continued funding to the Department of Health's grant program for school districts using small district modernization grants to make updates to existing heating, venting and air conditioning systems.

Commercial Tobacco Products, with Special Attention to Flavors

The Board supports efforts to prevent the marketing, sale, and use of commercial tobacco products to youth, including restrictions on flavored vapor and tobacco products (also known as commercial tobacco). The Board recognizes that the widespread availability of flavored commercial tobacco products and targeted marketing practices, such as the advertising of menthol products to Black and LGBTQIA+ communities and flavored vapor products to youth, raise significant health equity concerns. The Board supports legislation that would strengthen regulation of Washington's commercial tobacco product industry, including requiring ingredient disclosure and routine lab testing for vapor products, requiring health risk signage for commercial tobacco products, removing the preemption of vapor product retail licensing, allowing flavored commercial tobacco product bans and recalls, and establishing nicotine limits for products sold in Washington.

Newborn Screening

The Board has the authority to define and adopt rules for newborn screening in Washington, which include the list of conditions for which the Department of Health's Newborn Screening program screens all newborns. When the Board adds a new condition, the Department must assess the programmatic and fiscal impacts to the current program. The Washington Health Care Authority's Medicaid Program covers about forty percent of births in Washington. The addition of new conditions may require the Department and Health Care Authority to request an increase in the newborn screening fee to cover the costs of new screening tests, staff time, and follow-up services for babies with positive screens, as well as other programmatic and administrative costs. The Board supports funding requests to increase the newborn screening fee to cover the costs associated with new conditions.

Aquatic and Water Recreation Facilities

The Board recognizes that drowning is the leading cause of death for children ages one through four years and is a significant source of morbidity in children under 19 years. State and local regulations on aquatic facilities, water recreation facilities, and designated swim areas are necessary and important to protect the health, safety, and welfare of those who use them. The Board supports proposals to prevent injury, illness, and death at facilities including but not limited to swimming pools, hot tubs, splash pads, water parks, natural designated swim areas.

Drinking Water

The Board recognizes that safe, reliable drinking water systems and drinking water supplies are essential for public health protection and community wellbeing. The Board's Group A rules cover the state's largest public water systems, and its Group B rules apply to public systems that generally serve fewer than fifteen connections. The Board supports budget and policy proposals that strengthen implementation of these rules, drinking water infrastructure, and source water protection. Per- and polyfluoroalkyl substances (PFAS) are a family of more than 12,000 synthetic organic chemicals used in many products, including waterproof clothing, furniture, food packaging, and firefighting foam. Recent federal drinking water standards and proposed federal PFAS waste regulations will affect some Washington state cleanup sites. The Board supports the Department of Ecology's request for additional funding and staff resources to conduct sampling and identify contaminated sites, initiate clean up and provide safe drinking water as interim action during cleanups, and development of a strategy for reducing PFAS in the environment.

Immunizations

The Board recognizes the research and data that demonstrate that immunizations reduce the incidence of vaccine-preventable disease in our community and protect those who are immunocompromised and not vaccinated. The Board supports legislation that helps reduce the number of children out of compliance with state immunization documentation requirements, assists schools and childcares in monitoring the immunization status of children, and increases immunization rates across all age groups. The Board also supports additional funding to improve and maintain access to the Washington State Immunization System.