# WASHINGTON STATE

# Notice of Public Meeting

Wednesday, March 12, 9:30 a.m. – 4:00 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   |
|------------|---|---|
| 9:30 a.m.  | Call to Order & Introductions   | Patty Hayes, Board Chair  |
| 9:40 a.m.  | 1. Approval of Agenda<br>– Possible Action  | Patty Hayes, Board Chair  |
| 9:45 a.m.  | 2. Approval of January 8, 2025, Minutes<br>– Possible Action  | Patty Hayes, Board Chair  |
| 9:50 a.m.  | 3. Public Comment   | Please note: Verbal public comment may<br>be limited so that the Board can consider<br>all agenda items. The Chair may limit each<br>speaker's time based on the number<br>people signed up to comment. |
| 10:10 a.m. | 4. Announcements and Board Business   | Michelle Davis, Board Executive<br>Director   |
| 10:30 a.m. | 5. Department of Health Update  | Jessica Todorovich, Department of<br>Health, Interim Secretary of Health<br>Tao Kwan-Gett, Department of Health<br>Amy Ferris, Department of Health   |
| 11:00 a.m. | 6. Shellfish Rules Briefing   | Ash Noble, Board Staff<br>Kseniya Efremova, Department of<br>Health   |
| 11:20 a.m. | Break   |   |
| 11:35 a.m. | 7. Local Public Health Focus—Tacoma<br>Pierce Public Health Department  | Chantell Harmon Reed, Director of<br>Public Health Tacoma-Pierce Health<br>Department   |
| 12:05 p.m. | 8. Newborn Screening Technical<br>Advisory Committee (TAC)<br>Recommendations: Branched-Chain<br>Ketoacid Dehydrogenase Kinase<br>(BCKDK) Deficiency, and Process and<br>Criteria Updates – Possible Action | Kelly Oshiro, Board Vice Chair<br>Kelly Kramer, Board Staff<br>John Thompson, Department Staff<br>Megan McCrillis, Department Staff   |

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| Time       | Agenda Item   | Speaker  |
|------------|---|--|
| 12:45 p.m. | Lunch   |  |
| 1:45 p.m.  | 9. School Rule Project Update   | Patty Hayes, Board Chair<br>Andrew Kamali, Project Manager<br>Nina Helpling, Board Staff<br>Lauren Jenks, Assistant Secretary,<br>Department of Health |
| 2:45 p.m.  | Break   |  |
| 3:00 p.m.  | <ul> <li>10. Request for the Board to delegate rulemaking for <u>246-290 WAC</u>: Group A Public Water Supplies, and for <u>246-390</u> <u>WAC</u>: Drinking Water Laboratory Certification and Data Reporting to the Department of Health.</li> <li>– Possible Action</li> </ul> | Paj Nandi, Board Member<br>Ash Noble, Board Staff<br>Mike Means, Department of Health  |
| 3:20 p.m.  | 11. 2026 State Health Report Update   | Hannah Haag, Board Staff<br>Molly Dinardo, Board Staff   |
| 3:35 p.m.  | 12. Recognizing Board Member<br>Contributions<br>– Possible Action  | Patty Hayes, Board Chair<br>Michelle Davis, Board Executive<br>Director  |
| 3:45 p.m.  | 13. Board Member Comments and Updates   |  |
| 4:00 p.m.  | Adjournment   |  |

 To access the meeting online and to register: <u>https://us02web.zoom.us/webinar/register/WN\_XUdrkX7pSb61AMBr7h3-wQ</u>
 You can also dial-in using your phone for listen-only mode: Call in: +1 (253) 215-8782 (not toll-free) Webinar ID: 824 1653 1036 Passcode: 682856

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### 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 <u>reasonable modification</u>, please contact the State Board of Health at (360) 236-4110 or by email <u>wsboh@sboh.wa.gov</u>. 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 <u>Public Comment webpage</u> for details.



## Draft Minutes of the State Board of Health January 8, 2025

Hybrid Meeting ASL (or CART) 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 Dimyana Abdelmalek, MD, MPH Umair A. Shah, Secretary Michael Ellsworth, JD, MPA, Secretary's Designee Mindy Flores, MHCM Paj Nandi, MPH Stephen Kutz, BSN, MPH Peter Browning, MA

#### State Board of Health Members absent:

Socia Love, MD

#### State Board of Health staff present:

Michelle Davis, Executive Director Melanie Hisaw, Executive Assistant Michelle Larson, Communications Manager Anna Burns, Communications Consultant Molly Dinardo, Health Policy Advisor Shay Bauman, Health Policy Advisor Ash Noble, Health Policy Advisor Lilia Lopez, Assistant Attorney General Hannah Haag, Community Engagement Coordinator Ashley Bell, Deputy Director Cait Lang-Perez, Health Policy Analyst Lindsay Herendeen, Health Policy Analyst LinhPhụng Huỳnh, Health Disparities Council Manager Esmael López, Health Disparities Council Lead Community and Tribal Engagement Coordinator Jasmine Alik, Health Disparities Council Engagement Coordinator Judith Barba Perez, Health Disparities Council Engagement Coordinator Andrew Kamali, School Rules Project Manager Nina Helpling, School Rules Project Policy Advisor Kelly Kramer, Newborn Screening Project Policy Advisor

#### **Guests and other participants:**

Kelly Cooper, Department of Health Brynn Brady, Washington State Local Public Health Officials Lauren Jenks, Department of Health Annie Hetzel, Office of Superintendent and Public Instruction Vicki Lowe, American Indian Health Commission <u>Patty Hayes, Board Chair</u>, called the public meeting to order at 9:30 a.m. and read from a prepared statement (on file).

#### 1. APPROVAL OF AGENDA

**Motion:** Approve January 8, 2025, agenda **Motion/Second:** Member Kutz/Member Abdelmalek. Approved unanimously

#### 2. ADOPTION OF NOVEMBER 13, 2024, MEETING MINUTES

Motion: Approve the November 13, 2024, minutes Motion/Second: Member Abdelmalek/Member Kutz. Approved unanimously, Member Kutz and Member Nandi abstained.

#### 3. PUBLIC COMMENT

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

<u>Bill Osmunson</u> said two minutes is insufficient to discuss fluoridation and has been denied a forum to discuss fluoride for the last 15 years. Bill referenced the National Toxicology Program systematic review linking fluoride exposure and children's IQ. Bill said this is an emergency and the Board's silence is a form of censure. Bill discussed the risks of fluorosis and lower IQ, saying it costs Washington state \$4 million per day, and that does not include the increase in incarceration, homelessness, and more.

<u>Gerald Braude</u> discussed a 520-page Congressional report from the Select Committee on the Coronavirus Pandemic, which found that the COVID-19 vaccine mandates caused massive collateral damage and were likely counterproductive. Gerald talked about the missing information and misinformation from the Department of Health's COVID-19 reports and the demonizing and unjust treatment of providers who prescribed alternative treatments.

<u>Bob Runnells</u> said this is the tenth year advocating for fully informed consent and cited a journal article on pharmaceutical product recalls and vaccine-related death. Bob discussed the distortion of clinical trial data, the 37,000 deaths from the COVID-19 vaccine, and the Florida surgeon general's recommendation against the mRNA COVID-19 vaccine.

<u>Mariah Kunz</u> urged the Board to deny the fluoride rulemaking petition. Mariah talked about flawed studies and biased research that undermined results. Mariah talked about safe fluoride levels, said there is no relationship between fluoride and reduced IQ, and that community water fluoridation protects health.

<u>Erin Harnish</u> discussed the safety and efficacy of fluoridated water and said all major medical associations have reviewed and supported fluoridation. Erin said 52 of 72 studies opposing fluoride were of high bias risk, meaning they can be dismissed, and the remaining studies did not correlate with any IQ change. Erin said this is a level issue, that without water fluoridation there would be a 25% increase in cavities that causes many problems.

<u>Mary Long</u> talked about concerns with fluoridation and said there is no scientific evidence that shows the benefits outweigh risks. Mary said the National Institutes of Health shows a higher level of fluoride in pregnant women leads to lower IQ in babies. Mary talked about informed consent and said many people don't know about fluoridated water and advised water systems to remove public fluoride from water.

<u>Lisa Templeton</u> shared a report and comments by a physician regarding a severe bird flu case. Lisa highlighted the concerns in the study and said it showed gaps in critical analysis and transparency. Lisa said the report exemplifies how sensational narratives lead to an unbalanced approach and divert critical resources. Lisa talked about the importance of health professionals balancing between vigilance and guidance.

<u>Natalie Chavez</u> discussed a November 2024 report on the spread of Avian Influenza by migratory foul and the serious concerns surrounding the outbreaks. Natalie said the United State Department of Agriculture did not deny or refute these concerns and others want to debunk the study. Natalie talked about the documentary *My Biggest Battle* which tells the story of a world-class athlete that got Myocarditis. Natalie also shared the website Heikosepp.com.

<u>Stephen Baker</u> spoke in favor of water fluoridation. Stephen said the Food and Drug Administration has authority only over bottled water, not fluoridation. Stephen said fluoridation lowers impacts on the state budget and is safe for both children and adults. Stephen said the Centers for Disease Control considers water fluoridation as one of the top public health achievements of the 21st century.

<u>Derek Kemppainen</u> said fluoride is neurotoxin and shared support for the petition to amend the rule. Derek discussed the court cases and the risk of fluoride, saying the current level of fluoride is criminal.

#### 4. ANNOUNCEMENTS AND BOARD BUSINESS

<u>Michelle Davis, Board Executive Director</u>, welcomed the Board and directed their attention to the meeting materials. Executive Director Davis welcomed new Board Member Peter Browning and new staff for the Board and Health Disparities Council.

Executive Director Davis provided several updates, including a new Health Impact Review request received on January 7. Executive Director Davis noted budget restrictions impacting the Board, Dr. Shah's transition, and highlighted a graphic explanation of the State Health Report.

#### 5. DEPARTMENT OF HEALTH UPDATE

Patty Hayes, Board Chair, welcomed and thanked Secretary Shah for their work.

<u>Umair Shah, Board Member</u>, recognized Chair Hayes for their service on the Board. <u>Member Shah</u> reviewed the Department of Health's (Department) COVID-19 response, transformational plan, and various accomplishments over the last four years. <u>Member</u> <u>Shah</u> noted that the Department's work was guided by the principles of Equity, Innovation, and Engagement. <u>Member Shah</u> provided the Board with a two-year retrospective of the Department's transformational plan, along with a copy of the transformational plan. <u>Steve Kutz, Board Member</u>, commented that they will miss working with Dr. Shah and expressed gratitude for the leadership provided.

<u>Paj Nandi, Board Member</u>, asked what was next for Dr. Shah. <u>Member Shah</u> responded that the plan is to rest and focus on family and evaluate future opportunities.

Dimyana Abdelmalek, Board Member, extended gratitude to Dr. Shah for their work.

<u>Peter Browning, Board Member</u>, thanked Dr. Shah and noted the positive impact that the Department has had on Skagit County.

<u>Member Shah</u> reminded everyone to continue to 'find their apple' and make choices every day toward health and wellbeing.

The Board took a break at 10:43 a.m. and reconvened at 11:01 a.m.

# 6. GOVERNMENTAL PUBLIC HEALTH SYSTEM PARTNER 2025 LEGISLATIVE PRIORITIES

<u>Kelly Cooper, Department of Health</u>, discussed legislative priorities for the Washington State Department of Health (Department). Kelly noted that the state is in a post-election transition as the Governor-elect prepares to take office and shifts continue among legislators. Kelly said that the state government is faced with a \$10 to \$12 billion deficit in the budget. Legislative priorities for this session include behavioral health, housing, public safety, and education. On the healthcare side, the Legislature will focus on access to care and affordability. For the Department, the priority is maintaining the investments in the Foundational Public Health Services (FPHS) system. Kelly shared that Governor Inslee's budget also includes investments to sustain the Department's work including the 988 system, fruit and vegetable programs, health disparities mapping, school-based health centers, and environmental justice assessments. Kelly discussed the three bills that are agency request legislation for the Department. These include the safe medication takeback program, Women, Infants, and Children program hemoglobin testing, and updating the water recreation rules (in coordination with the Board).

<u>Brynn Brady, Washington State Association of Local Public Health Officials</u> (<u>WSALPHO</u>), discussed how WSALPHO identifies its legislative priorities. Brynn said WSALPHO will lead on two bills. The first is the child fatality review statute, with Senator Orwall and Representative Bernbaum committed to sponsoring the bill in the Senate and House, respectively. The second is related to Group B water systems, which will be coordinated with the Department and Board. Brynn stated that WSALPHO will also prioritize maintaining investments in the FPHS system. Additionally, Brynn shared that the Legislature will likely work on addressing barriers to healthcare access, and local health will prioritize these bills. Finally, Brynn highlighted several other issues, including banning flavored tobacco and nicotine products, that are also priorities for local health.

<u>Vicki Lowe, American Indian Health Commission (AIHC)</u>, stated that the top priority for Tribes is FPHS funding. Vicki shared that Tribes currently receive \$200,000 per year to

build their infrastructure and need additional funding to continue this work. Vicki noted that AIHC will hold a Legislative Education Day on January 22 and will discuss maintaining FHPS funding with Legislators. AIHC is also working with Senator Kauffman on a bill to direct the Health Care Authority (HCA) to apply for a Traditional Indian Medicine waiver for the Apple Health (Medicaid) program. Vicki discussed the importance of obtaining the waiver for the health of Tribal people. AIHC is also working on a data protection bill with Representative Lekanoff, building on previous work with the Department to establish a data-sharing agreement. Lastly, Vicki stated that AIHC will explore the ban on flavored nicotine products, but the bill is contentious among Tribes. AIHC is also looking at bills related to housing, opioids and fentanyl, and is working with the Governor's Interagency Council on Health Disparities (Council) to expand Tribal representation on the Council.

<u>Steve Kutz, Board Member</u>, emphasized the need to address black market vaping products that are laced with fentanyl and other drugs. <u>Member Kutz</u> stated the concern is about youth receiving adulterated products.

<u>Peter Browning, Board Member</u>, thanked WSALPHO for bringing the child fatality review statute back again, noting its historical value and the need for its continuation. Brynn agreed and said it is a good example of how FPHS funding can restore critical services.

<u>Patty Hayes, Board Chair</u>, asked Vicki about supporting AIHC and the Tribes work around sovereignty and FPHS and to explain how FHPS funding supports infrastructure building. <u>Chair Hayes</u> stated that the FPHS system has been asked about why we can't shift the money around within FPHS.

Vicki responded that the Tribes weren't ready as FPHS was being built. Former Secretary of Health Wiesman and Tribal leaders worked to bring Tribes into the conversation. However, healthcare and public health are not primary focuses for the Tribes. Tribal leaders are often stretched thin from advocating for Tribal rights. One Tribal leader prioritized this issue and AIHC passed a resolution to work on FPHS. AIHC had obtained a Tribal set-aside for Medicaid transformation, which allowed Tribes to consider a Tribal set-aside model for FPHS. COVID changed how Tribal leaders considered public health. A set-aside for \$200,000 allows a full-time staff to work on FPHS. We needed two years to work on that and get to where we have some infrastructure built and to create health codes within Tribes. Now, we need to move into more robust public health and work more with the system. That is the story that needs to be told and why now we need more than the 10% set aside to build the infrastructure that just really hasn't been there.

<u>Chair Hayes</u> said that sharing the story of why the work is paced and why it is needed now is important, especially with new legislators.

<u>Member Kutz</u> stated that Tribal lands are public health deserts. <u>Member Kutz</u> said that the work we do in public health does not have applicability to Tribal lands. The federal government sends money down to the public health system but sends it to the state, not to Tribes. Indian Health Service (IHS) and the federal government did not put public health systems into place for Tribes. So, there is some work, but it is piecemeal and not seen as public health. All people in Washington state deserve the same protections, but Tribal people do not have the same protection. <u>Member Kutz</u> stated that Tribes continue to get virtually no funding for public health.

Vicki said that after COVID, legislators were impressed with how the Tribes worked in communities and the way that Tribes work is public health oriented. Vicki said that there are opportunities to build on.

Brynn underscored that the governmental public health system partners have done tremendous work in the FPHS space to ensure decision-makers have an understanding. But we have a new Governor, new administration, and new legislators and they do not yet understand FPHS. There are challenges, including budget challenges, that the Legislature will have to work through. We do have advocates in the Legislature, but all of us need to talk about FPHS with the Governor's team, with the Health Care Committees (including new Chairs and Vice Chairs), and with new legislators to bring this awareness and education. We need to shift our minds to understand that we are starting from the beginning in some respects.

<u>Paj Nandi, Board Member</u>, asked if WSALPHO or FPHS Steering Committee could provide some consistent messaging or talking points for discussion with Legislators so that we can have a consistent voice and demonstrate the importance of this funding. Brynn responded that the FHPS Steering Committee is working on this and has used some consistent materials in the past.

#### 7. PETITION FOR RULEMAKING <u>WAC 246-290-220</u>, DRINKING WATER MATERIALS AND ADDITIVES

<u>Paj Nandi, Board Member</u>, said the Board will consider a new petition for rulemaking related to WAC 246-290-220 and turned it over to staff.

<u>Shay Bauman, Board staff</u>, provided an overview of previous petitions and presentations related to this topic that the Board has heard (see presentation on file). Shay invited Lauren to provide an update about the review of current and emerging research.

Lauren Jenks, Assistant Secretary for Environmental Public Health, Department of Health (Department), presented on the historical and current context of community water fluoridation and current research (see presentation on file). Lauren emphasized the need to reassess recommendations based on emerging research from the National Toxicology Program (NTP). Lauren discussed the Department's science review process which will consist of five meetings to evaluate the safety and benefits of fluoridation. The group in the science review process will bring their findings to the Board.

<u>Michelle Davis, Board Executive Director</u>, said that the Board briefly discussed the Department's approach to this review in November and found it helpful to see more details now.

<u>Member Nandi</u> thanked Lauren for the reminder about the importance of evidencebased policy, community input, and the need to dive deeper into the research and signals.

<u>Patty Hayes, Board Chair</u>, asked when Lauren anticipates coming back to the Board. Lauren responded that the meetings would be finalized by mid-March and the Department could then return to the Board.

<u>Steve Kutz, Board Member</u>, discussed being in public health for over 40 years and that we are in a time of information overload. <u>Member Kutz</u> said they are interested in having a deep dive into the science.

<u>Peter Browning, Board Member</u>, asked Lauren if the review would start with a peerevaluated literature study. Lauren responded that several literature reviews have been published recently, including those from NTP and Cochrane Review. Lauren stated the Department will review these but may not conduct or write their own literature review.

<u>Member Browning</u> stated having heard discussions about dose-related benefits and asked if the analysis may include information on which dose is beneficial or if all levels are harmful. Lauren responded that NTP and JAMA look at this and do see a dose-response and that the review will look at this relationship.

<u>Member Browning</u> also asked if the review would look at in-utero impacts versus primary exposure and whether more specific messaging is needed. Lauren responded that there is evidence for in-utero exposures and the Department already makes recommendations about preparing formula, so they will continue to evaluate needed messaging as well.

<u>Member Nandi</u> asked Lauren to share more about the composition of the science review committee. Lauren responded that several epidemiologists and toxicologists will participate, including from the Department's Office of Drinking Water and Oral Health Program. Lauren said that Dr. Tao Kwan-Gett will chair the group. Lauren also stated that Shay Bauman and Lindsay Herendeen will join from the Board. Tribes will be represented, including Dr. Tom Locke. WSALPHO has recommended local environmental health directors and health officers to participate as well.

<u>Member Kutz</u> stated that water in our world is a collection of all our impurities. <u>Member Kutz</u> stated not knowing what is safe drinking water that won't have some impact on somebody. Lauren responded that there is likely not 100% safe drinking water in this world. However, our drinking water goes through a lot of purification and when we are aware of something harmful, we can remove it.

Shay provided an overview of the Board's petition process and the petition currently before the Board related to WAC 246-290-220. Shay recommended the Board decline the petition for rulemaking pending the science review and monitoring Environmental Protection Agency action. Shay suggested that, following the science review, the Board could consider a review of the policy document.

<u>Member Kutz</u> asked how long the science review may take and when the Board can return to this. Lauren responded at least through mid-March. <u>Member Kutz</u> asked if this was a reasonable amount of time. Lauren responded yes.

<u>Kelly Oshiro, Vice Chair</u>, asked if the Board can expect to receive recommendations or ideas about updating strategies to explore in the future that could be in the policy document. Lauren responded that the Board will receive a clear summary and interpretation of the evidence. Lauren said the Board can use the science review to inform their policy discussion and decision. <u>Vice Chair Oshiro</u> stated it would help to know about the innovations from the past 10 years.

<u>Michael Ellsworth, Secretary's Designee</u>, asked if the science review will be public or hybrid and if community members can follow along. Lauren responded that it will be on Zoom but will need to follow up with the Board about whether these will be Open Public Meetings. <u>Member Ellsworth</u> asked if the Board has the authority to require community water fluoridation. Shay responded that the Board does not have the authority to require community water fluoridation.

<u>Member Nandi</u> asked if local water systems would be represented in the science review convention. Lauren responded the Department worked with the Washington State Local Public Health Officials (WSALPHO) for local representation and WSALPHO recommended local environmental health directors and health officers.

<u>Member Kutz</u> asked for a review of the timeline and whether the 60 days referred to how long we could keep a rule open. <u>Member Kutz</u> asked if accepting a petition would require immediate action.

Executive Director Davis clarified that the 60-day timeline is for the Board to review and accept or deny a petition and does not refer to rulemaking. If the Board were to accept a petition, staff would initiate the rulemaking process. If the Board were to deny a petition, the Board has a certain amount of time to notify the petitioner.

Shay stated that, once rulemaking has been initiated, the timeline may be extended.

<u>Member Nandi</u> asked Lauren if there would be an opportunity for community input during the science review. Lauren responded yes, the Department wants to hear feedback from the community.

<u>Dimyana Abdelmalek, Board Member</u>, asked for clarification on the Board's vote today, noting that one topic is to dive into the information, and the other concerns a specific petition with recommendations. <u>Member Abdelmalek</u> expressed appreciation for the Department and community to discuss the science. <u>Member Abdelmalek</u> also expressed interest in reassessing this rule and Board policy after the science review convention. <u>Member Abdelmalek</u> suggested separating a vote on a specific recommendation now versus getting more information in a structured way to inform potential future recommendations.

**Motion**: The Board declines the petition for rulemaking to amend WAC 246-290-220 for the reasons articulated by Board Members and directs further evaluation of the scientific information at a future Board Meeting to determine if the Board wants to take any other action. The Board directs staff to notify the petitioner of the Board's decision.

Motion/Second: Member Kutz/Member Abdelmalek. Approved unanimously.

<u>Member Nandi</u> asked if the Board could review its policy from 10 years ago after the Department finishes its review and shares its findings.

<u>Vice Chair Oshio</u> stated that, despite denying the petition today, the Board will continue to evaluate and remain committed to this work. <u>Vice Chair Oshio</u> said that Board staff should continue to bring recommendations.

<u>Mindy Flores, Board Member</u>, stated that fellow Board Members summarized and articulated the discussion.

<u>Member Ellsworth</u> asked what are the vehicles, such as legal and policy options, to evaluate where we want to go next. <u>Member Ellsworth</u> asked if the Board can review policy options while the science review is occurring. <u>Member Ellsworth</u> asked staff to prepare a landscape view of fluoridation policy and authority in the state.

<u>Chair Hayes</u> asked Lauren to also consider the Australian study that was just published. <u>Chair Hayes</u> asked Lauren to prepare to come back to the Board to present findings from the science review convention. <u>Chair Hayes</u> asked that Board Members review the 2015 recommendations and asked Shay to share the 2015 report with Members. <u>Chair</u> <u>Hayes</u> also asked Shay or the Department to present at a future meeting about what language is already used to provide recommendations to people related to fluoridation (e.g., to pregnant women).

<u>Member Kutz</u> said the policy document should be updated following the science review to meet current understanding. <u>Member Kutz</u> asked how long updating the policy document may take. Shay responded that it depends on the conclusions of the science review convention and how the findings relate to the 2015 recommendations. It will be a priority for staff to update the document based on the information. <u>Member Kutz</u> said that communities around the state make decisions based on the information we provide, so it is important to do that update promptly.

<u>Member Hayes</u> directed staff to communicate with the petitioner and to share the 2015 recommendations with Board Members. <u>Chair Hayes</u> asked Lauren to prioritize returning to the Board in an expedited manner.

#### 8. GOVERNOR'S INTERAGENCY COUNCIL ON HEALTH DISPARITIES (HDC) UPDATE

<u>LinhPhung Huỳnh, Council Manager</u>, and <u>Esmael López, Council Engagement Lead</u>, introduced themselves and provided an overview of the Governor's Interagency Council on Health Disparities (see presentation on file). LinhPhụng reviewed the Council's background, membership, responsibilities, and past recommendation areas. LinhPhụng also highlighted the ongoing partnership with the Board and shared updates since the Council's last presentation in 2023, including a redesign process started in 2022 to enhance collective impact. This process involved workshops and community engagement that contributed to the 2024 State Action Plan Update. LinhPhung emphasized that the redesign aims to support a health justice and equity approach to their work.

LinhPhung then provided updates on upcoming activities, including the Council's Agency Request Legislation (ARL) for 2025. LinhPhung added that on the funding side, the Council received \$1.1 million for operations from the 2024 session, marking the first budget increase since the Council's creation in 2006. This funding has allowed the Council to hire staff for administrative and community engagement roles. LinhPhung concluded that the Council is discussing plans to create a statewide vision for health and wellbeing. LinhPhung emphasized the need for coordination with other agencies and groups.

Esmael introduced the Council's Engagement and Partnership Coordinators, Judith Barba Perez and Jasmine Alik, who each introduced themselves to the Board. Esmael then spoke about Council staff's focus on strengthening internal capacity and developing a comprehensive engagement plan. Esmael emphasized the importance of tailoring engagement strategies to Washington's diverse communities, noting that there is no one-size-fits-all approach.

Esmael highlighted the need for co-creation through two-way conversations to foster mutual transformation. Esmael pointed out that the Council's presence in communities impacts both the communities and the way the Council operates, transforming their approach to engagement. Esmael then stressed the importance of meaningful community engagement, such as expanding opportunities for collaboration and acknowledging that many communities are seeking tangible change rather than just hearing about it.

Esmael requested the Board's support in elevating the Council's efforts by sharing engagement opportunities and called on the Board to engage authentically with communities and contribute to the Council's mission.

LinhPhung concluded by sharing a slide with ways for the Board to connect with the Council and its work.

<u>Patty Hayes, Board Chair</u>, expressed excitement about the Council's work, noting that while many agencies are grappling with similar challenges, the Council is in a unique position to bring them together and avoid duplicating efforts. <u>Chair Hayes</u> emphasized the importance of doing this work in a new way and offered her support.

<u>Paj Nandi, Board Member</u>, also a former Council member, suggested that future discussions could focus on how the Council has influenced and impacted communities. <u>Member Nandi</u> noted the fatigue around policy recommendations and stressed that legislators are most concerned with the tangible impact at the community and family levels. <u>Member Nandi</u> recommended leading with this perspective in future discussions.

Esmael acknowledged Member Nandi's point, stating that the Council is actively working to highlight its impact without overselling. Esmael emphasized the importance of making the community feel welcomed and encouraged to participate.

<u>Dimyana Abdelmalek, Board Member</u>, asked if the Council had a key takeaway from their work that Board Members could take back to their communities, local health jurisdictions, and others they serve.

LinhPhung responded, emphasizing the value of reaching out to the Council as the starting point for building relationships. LinhPhung encouraged sharing information about the Council and inviting others to get involved, as it opens possibilities for collaboration.

<u>Steve Kutz, Board Member</u>, expressed hope that the Council could make a meaningful difference, especially in ensuring that messages are effectively communicated with communities.

The Board recessed for lunch at 12:55 p.m. and reconvened at 1:25 p.m.

#### 9. HEALTH IMPACT REVIEW (HIR) RESOURCES

<u>Cait Lang-Perez</u> and <u>Lindsay Herendeen</u>, <u>Board staff</u>, introduced themselves and informed Board Members that they had received their first Health Impact Review (HIR) request from Representative Simmons regarding House Bill 1125. This bill proposes granting judicial discretion to modify sentences in the interest of justice. Cait noted that this request updates the proposal the team reviewed during the interim.

Cait shared an updated version of the HIR fact sheet and then updated the Board on new HIR resources for the HIR outreach toolkit in preparation for the 2025 legislative session. Cait encouraged Board Members to share the HIR fact sheet with legislators and their staff.

Cait also shared that the team developed an HIR Engagement guidance document in response to questions from Board Members. The document explains what Board Members can expect from HIR analysts, such as receiving email alerts about HIR activities, and details how Members can engage with and share HIR work with their networks and legislators.

Cait then highlighted a new video project developed by the HIR team in collaboration with the Board's Communications team. The video serves as an introduction to HIRs, explaining how they provide policy-specific information to decision-makers from a health equity perspective.

Patty Hayes, Board Chair, commended the HIR team for their work.

<u>Peter Browning, Board Member</u>, inquired about the email sent to Board Members notifying them about the team's current HIR request.

Cait explained that Board Members will receive regular alerts throughout the legislative session to keep them updated on incoming HIR requests and ongoing work from their

team. Cait encouraged Board Members to respond to these emails if they have relevant experience related to any HIR topics or if they know individuals the HIR team should connect with.

#### **10.2025 LEGISLATIVE STATEMENT**

<u>Michelle Davis, Board Executive Director</u>, provided an overview of the legislative statement and how it is used. This statement guides the Board and its team during the legislative session on issues to follow. Board staff looks at bills with the legislative statement in mind and will make recommendations for action items as a team.

Executive Director Davis reviewed the draft 2025 legislative statement, its current edits, and noted that the State Health Report holds recommendations that are also included in this statement. Board staff will send weekly updates to Board Members on bills and issues staff are following. Executive Director Davis provided the next steps to the Board.

<u>Patty Hayes, Board Chair</u>, clarified that this statement was originally longer but has now been more streamlined. <u>Chair Hayes</u> praised Executive Director Davis for their work on supporting the Board and limiting the amount of bills the Board follows.

<u>Steve Kutz, Board Member</u>, said the Health Disparities Council (Council) is part of the Board, but agencies need to recognize that the Council belongs to other agencies too. <u>Member Kutz</u> suggested having conversations on how agencies can use the Council.

<u>Kelly Oshiro, Vice Chair</u>, commended Executive Director Davis and Board staff on their work on the statement. <u>Vice Chair Oshiro</u> noted looking forward to weekly updates from the team.

<u>Dimyana, Abdelmalek, Board Member</u>, expressed appreciation for this version and that it is strong. It leads with Foundational Public Health Services that benefit everyone in Washington, it prioritizes community engagement and being intentional about inclusion for others.

**Motion:** The Board adopts the Statement of Policy on Possible 2025 Legislative Issues as discussed on January 8, 2025.

Motion/Second: Member Kutz/ Member Nandi. Approved unanimously.

#### 11. PER- AND POLYFLUOROALKYL SUBSTANCES (PFAS) EMERGENCY RE-FILE

<u>Paj Nandi, Board Member</u>, introduced the per- and polyfluoroalkyl (PFAS) emergency rule filing and explained that these changes need to be accepted today to be implemented in the next 120 days.

<u>Ash Noble, Board staff</u>, provided an update on the PFAS emergency rulemaking. The current emergency rule expires on February 19, 2025. Ash recommended to the Board to initiate a third emergency rulemaking to continue to clearly maintain the State Action Levels (SALs) and associate requirements. The anticipated effective date is February 19, 2025, and would expire June 19, 2025. Ash also reviewed the proposed language and future actions (see presentation on file).

<u>Steve Kutz, Board Member</u>, asked if water systems are using the emergency short-term rules to effectively manage their systems.

<u>Shay Bauman, Board staff</u>, clarified that these rules allow water systems to maintain their current plan of action.

<u>Member Nandi</u>, clarified that the permanent rule filings and the extension of rule filings are happening concurrently and are maintaining the status quo.

<u>Lilia Lopez, Assistant Attorney General</u>, added that the reason the emergency rule can keep going under the APA is because permanent rulemaking is taking place.

**Motion:** The Board directs staff to 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, or the Board completes its revision of the permanent rule.

Motion/Second: Member Kutz/Vice Chair Oshiro. Approved unanimously.

#### 12. PRO-EQUITY ANTI-RACISM (PEAR) PLAN

<u>Paj Nandi, Board Member</u>, introduced the topic and explained why the Board created a Pro-Equity Anti-Racism (PEAR) plan (see materials on file).

<u>Ashley Bell, Board Deputy Director</u>, presented an overview and explained the purpose of the PEAR plan. Ashley outlined its ultimate goals of driving systemic change, dismantling oppressive systems, and promoting equity in all facets of society (see presentation on file).

Ashley provided the Board Members with themes from community member feedback. Board staff followed up with panelists and other community members with connections to their community. While we didn't get a lot of feedback this time around, it sets us up for further conversations. Feedback addressed the connectedness of Board activities, the need for budget follow-through, more interaction with the Board and the public, and better, more equitable presentation of materials.

Ashley explained that the team added a graphic to the plan to make it more accessible for those who want an overview and shared this feedback with the Office of Equity. Ashley outlined the next steps for the Board to consider, including possible action. Ashley recommended that the Board adopt the PEAR strategic action plan, and to keep in mind that this is a continuous process. Each plan should get deeper and deeper. The next equity and engagement manager will begin work on the next plan.

<u>Member Nandi</u> expressed appreciation for the work that went into the draft and noted reviewing and commenting on the plan. <u>Member Nandi</u> reminded the Board that equity is in the details, and significant elements of the plan are tangible and action-oriented. Equity should be in broad policy decisions, but also in our other processes and procedures.

<u>Patty Hayes, Board Chair</u>, thanked Ashley for all the work on the plan and expressed appreciation that the team grounded the plan itself in community feedback. <u>Chair Hayes</u> agreed with Member Nandi that it is about the details.

<u>Chair Hayes</u> asked about Objective 2.1 Action 2, which states that the equity and engagement team will develop a review tool in partnership with impacted communities to assess draft rule language for equity impacts. <u>Chair Hayes</u> asked how the Board could work together with the Health Disparities Council on this so as not to overwhelm communities. <u>Chair Hayes</u> then asked how we spend time considering rules and talking about who the affected communities are.

<u>Michelle Davis, Board Executive Director</u>, expressed that there is a problem with transparency here. Board staff has worked on a project scoping document that outlines who rules affect, how, and how to address. Executive Director Davis noted that there is a desire for the Board to actively engage in developing that tool and could make it better.

<u>Member Nandi</u> added that every policy has an impact on a large swath of the population, but a more important question is who is disproportionately impacted. We need to focus policy from an equity and justice standpoint on who is most adversely impacted. It might not be a single tool, but an approach that we should take.

<u>Steve Kutz, Board Member</u>, noted that we need to look at where the inequities are and whether we are creating any. There is work to be done, but didn't see anything within the plan that we shouldn't be working on.

<u>Peter Browning, Board Member</u>, noted that we must set parameters on things that can and can't be done. It makes people more mad believing things will be fixed when they can't. The Board should provide a reasonable timeframe and transparency about limitations.

<u>Chair Hayes</u> noted that staff has done an exemplary job of doing what has been mentioned with the school rules project, and that rule process may make a good case study.

Ashley responded that we would take note of those suggestions.

<u>Chair Hayes</u> asked that staff look again at the goal to better address the process, and not a tool itself. If the public sees yet another tool, people might have an adverse reaction.

<u>Member Kutz</u> pointed out that Health Impact Reviews (HIRs) have good tools to use. Executive Director Davis responded that we cannot do HIRs on all our rules due to staff capacity.

<u>Mindy Flores, Board Member</u>, stated that Chair Hayes' comment was impactful and expressed uncertainty about approving the plan if it felt incomplete. <u>Member Nandi</u> clarified that the adoption would be 'as discussed' and could address the questions brought up by Board Members.

<u>Member Flores</u> asked if we had an implementation plan for when the other things might be figured out. Ashley responded that many do have implementation plans.

<u>Dimyana Abdelmalek, Board Member</u>, shared appreciation for all the work that went into the plan and asked if Objective 3.2 Action 1 is something that could be available to Board Members. Ashley confirmed.

<u>Kelly Oshiro, Vice Chair</u>, commended the work and timelines presented in the plan and stated that a monthly or quarterly report back on accomplishments would be helpful. <u>Vice Chair Oshiro</u> expressed excitement to see all that would be accomplished over the next two years.

Member Nandi opened the floor up to a motion.

Executive Director Davis noted that the PEAR plan is another example of Foundational Public Health Services (FPHS) dollars in action. Without FPHS, the Board wouldn't have an equity and engagement manager position (EEM). The requirement came out two years ago, without the EEM position we were not able to comply at that time.

<u>Chair Hayes</u> added that the adoption of the PEAR Plan will now allow us to move forward with our future strategic planning process.

**Motion:** The Board adopts the PEAR Strategic Action Plan, and directs staff to finalize the Plan as discussed, notify the Office of Equity, and file the Plan as requested.

Motion/Second: Vice Chair Oshiro/Member Kutz. Approved unanimously.

**13. AUDITORY SCREENING RULEMAKING UPDATE, <u>CHAPTER 246-760 WAC</u> <u>Kelly</u> <u>Kelly Oshiro, Vice Chair, introduced the topic (see materials on file).</u>** 

<u>Molly Dinardo, Board staff</u>, presented the purpose and scope of the auditory screening rules, including the ages and timing of testing, the reasons for the screenings, and their importance as a public health tool. Molly explained that the current Board rules only allow specific screening equipment, but the Chelan Lion's Club requested to add otoacoustic emission (OAE) screening technology. Given the research supporting its benefits, the Board initiated rulemaking to explore further. Molly also discussed the completed engagement and shared the rule alert American Sign Language (ASL) Announcement videos which were created based on discovery during the rule scoping document review.

Peter Browning, Board Member, asked for more information on OAE.

Molly shared insights from conversations with subject matter experts (SMEs), listening sessions, and outreach to other states that use OAE in their school districts. The team learned that while OAEs can be an effective tool they come with some disadvantages. These disadvantages include high training and equipment costs (\$5000- \$7000 per device), and annual maintenance fees of \$300-\$500. Some have reported that OAEs are sensitive to background noise and are delicate. Puretone remains the gold

standard. Molly explained that the rule would need to specify situations when OAEs could be used, as the outcomes are deficit-based and alternative language should be used.

Molly shared findings from the school screening staff survey, which represented 98 out of 295 Washington school districts that responded. The survey indicated overall general support for adding OAE as *an optional* method, but there are concerns about costs and training. Molly also discussed potential rule changes to chapter 246-760 WAC and provided an overview of the tentative timeline.

<u>Patty Hayes, Board Chair</u>, reflected on the Board's lack of authority to do anything about how schools are funded and appreciates how we look at this rule through the PEAR plan. <u>Chair Hayes agreed it makes sense for this to be an optional provision</u>.

<u>Paj Nandi, Board Member</u>, agreed that the Board should explore what this would look like and how we are being intentional about implementing equity into the process.

<u>Chair Hayes</u> complimented the ASL video. <u>Chair Hayes</u> reflected on a recent situation in the Seattle area where ASL interpretation was not provided when considering closing a school with many deaf and hard of hearing children. <u>Chair Hayes</u> appreciates the forethought in creating the video.

<u>Vice Chair Oshiro</u> encouraged Board Members to review the screening survey and noted that the Lion's Club wanted to provide screening for a school, but there was a barrier in the rule as OAEs were not on the list of acceptable devices. <u>Vice Chair Oshiro</u> noted that the Lion's Club reacted appropriately. This is a perfect testing ground for the PEAR plan.

<u>Steve Kutz, Board Member</u>, asked if we learned anything from schools that tested other students for other conditions. For example, adding to the rule that kids who are failing should have their eyesight and hearing checked. Molly clarified that the rule allows expanding screening to additional grade levels.

<u>Annie Hetzel, Office of Superintendent of Public Instruction (OSPI)</u>, shared that students who are referred to special education services must all be screened, but not necessarily all who are failing classes. Annie noted that school staff are in tune with students that need additional help and catch when students need vision or hearing exams. Nurses try to capture new students too, especially if they don't have records of screenings.

<u>Member Browning</u> said a lot of rural counties are developing medical reserve corps, like the Lion's Club, and that options exist that could be encouraged. <u>Member Browning</u> asked about the price of OAE. Molly <u>stated the \$5000-\$7000 cost per device and</u> responded that districts often own and lend out to schools, and some rent from companies.

<u>Member Browning</u> stated that hearing issues are so incapacitating and may not get the services they need and noted that this seems actionable.

The Board took a break at 3:12 p.m. and reconvened at 3:25 p.m.

### 14. SCHOOL RULES PROJECT UPDATE – DRAFT LANGUAGE

<u>Patty Hayes, Board Chair</u>, shared that the draft proposed rule has been developed. All minimal standards have been reviewed, and the comment period has been extended through February 9. Board staff will walk through the high-level changes. A joint meeting with the TAC is planned for April and efforts are underway to prepare both the TAC and the Board Members. <u>Chair Hayes</u> noted that Board staff will address the controversies in the draft rules. This will be a good case study for applying the PEAR Plan. <u>Chair Hayes</u> shared that the TAC has worked collaboratively together. There will be some challenges with the cost of this rule.

<u>Andrew Kamali, Board staff</u>, provided an update of the School Rules Project (see presentation on file). The update covered Board authority, a high-level overview of the project, proviso information, the timeline, and then details about the subject matter in the rule. The draft rules are out for informal public comment. The January TAC is a two-day fiscal summit, where the focus will be on going through the rule and assessing the cost.

Nina Helpling, Board staff, discussed the project deliverables in detail (see presentation on file). In April, the TAC will discuss the recommendations and report to the Board. Board staff will need to send the report to the Legislature and Governor's office in June. Two sections, covering noise and lighting, remain unchanged after expert consultation. No new recommendations were made for these areas. Nina shared three larger sections of the rule were reformatted, retitled, and expanded on. These sections focus on site assessments, plan reviews, and routine inspections. These sections now include specific tasks and timelines for schools and local health officers. A common concern raised by schools and local health jurisdictions (LHJs) was communication. Accountability was incorporated for all parties to help create collaborative partnerships between schools and LHJs. Two sections were also removed and new topics, including indoor air quality and ventilation, were introduced. Work continues on ventilation to avoid conflicts with other laws. Additional changes include addressing special ventilation and temperature needs for specialty rooms. Instead of rewriting changes into the rule, relevant laws are now referenced. Nina shared that the Department of Health's (Department) Healthy Environment for All (HEAL) team has supported listening sessions, coordination, engagement, and funding.

Andrew shared that school funding is complex and beyond the Board's control. There are potential conflicts, such as clean building performance standards, that the Board is working to clarify and will include in the final report. The TAC is calculating costs per square foot to make the rules applicable to schools of all sizes. They are considering factors such as regional cost differences and the age of school facilities.

Andrew also updated the Board on implementation recommendations. The focus is on determining which sections of the rule should be implemented based on the greatest benefit to the health and safety of students. Funding is a key consideration, as lower-cost measures are easier to implement. Final approval from the Board is needed on

June 11 after which all reports and materials will be submitted to the Legislature and the Governor's office.

<u>Chair Hayes</u>, provided additional context on the conflict surrounding the clean building performance standards. The Department of Commerce (Commerce) doesn't see a conflict, but schools do. Schools are required to meet Commerce standards for energy use, and penalties may apply if the standard isn't met. <u>Chair Hayes</u> shared that these things can be highlighted in the report, as the Legislature may make changes. <u>Chair Hayes</u> reminded Board Members that the goal for Legislative Session 2026 is to lift the bar on these rules. The implementation will be phased. Some sections will provide schools with a timeline to meet the standards.

Andrew provided additional information. Business and operations people have shared insights on Radon testing and pest mitigation plans.

<u>Steve Kutz, Board Member</u>, asked if the proposed draft includes prescribed maintenance requirements, such as air filters.

Andrew shared that the indoor air quality management plan in the rule includes filter requirements, such as checking and replacing filters as needed. It also includes ensuring ventilation systems are working properly. They are working closely with the Department which will help develop guidance and model plans for schools to meet the rule's requirements.

<u>Member Kutz</u> asked if the TAC was implementing flexible standards that reflect best practices.

Andrew clarified that they are setting minimal public health and safety standards while trying to remain flexible to accommodate schools' varying needs. Andrew shared that during the TAC's presentation to the Board, it will be important to show what the TAC has asked for and how the flexibility in meeting the standards were collected, as the goal was a collaboration between the school and local public health rather than public health, coming in with a checklist. The TAC wants flexibility to meet minimum standards. Sanitation standards for janitorial staff and space requirements were other things that were considered.

<u>Peter Browning, Board Member</u>, asked about asthma rates, headaches, and other things that are indicative of cleaner schools over time.

Andrew shared that the measures they are implementing would be the minimum public health and safety standards and that local public health would be responsible for how their program works and the Department will develop guidance and begin to look at indicators. The Board will watch but does not set up that piece.

<u>Chair Hayes</u> added that in collaboration with the University of Washington and some students there in the graduate nursing program, there was a report about school environmental safety that the TAC is going through now. It discusses some of those indicators, increased rates of absenteeism, and what those causes are related to. It's being reviewed, but it's not something that will necessarily be looked at as a measure of

effectiveness. It is known that some of the rationales for absenteeism are around health indicators.

#### **15. NEWBORN SCREENING PROJECT UPDATE**

<u>Kelly Oshiro, Board Vice Chair</u>, introduced upcoming work, including an upcoming technical advisory committee (TAC) meeting that's occurring next week.

Kelly Kramer, Board staff, shared updates to the newborn screening (NBS) project and the process and criteria document. All conditions that are on or added to the Recommended Uniform Screening Panel (RUSP) don't need prior evidence. A TAC will automatically convene to use these criteria to evaluate whether the RUSP condition should be added to Washington's panel within two years after the Health and Human Services Secretary recommends a condition be included on the RUSP. The Board will wait until the Federal Review is completed before Washington conducts its own review. Petitions for conditions that were previously reviewed and then denied for the RUSP, Board staff will work with a petitioner to address issues or concerns that were identified in the Federal review.

Kelly continued to share that current RUSP conditions or conditions on the RUSP that are not on Washington's mandatory newborn screening panel are MPS-II, which was added to the RUSP in August 2022. Krabbe Disease was also added to the RUSP. In June of 2024, Guanidinoacetate methyltransferase deficiency (GAMT) was added to the RUSP.

Kelly stated there is currently a CR-101 for GAMT that was filed in November of 2023, with the hearing for that condition currently pending legislative action. Congenital hearing loss is also a RUSP condition. The Board has previously reviewed hearing loss for the mandatory newborn screening panel and Board staff are currently working with the Department of Health (Department) to determine appropriate next steps to address hearing loss. The conditions that the Board is already set to review are branched-chain keto acid dehydrogenase kinase deficiency (BCKDK) and congenital Cytomegalovirus (cCMV), and Wilson's Disease, as petitioned, will be reviewed later this spring. The Board has accepted the newborn screening TAC recommendation so there are now two conditions on the RUSP that must be reviewed within the two-year time frame.

Kelly asked for the Board to consider a motion. The two-year review timeline begins from the November 2024 Board recommendation date. Instead of the date of the Federal recommendations.

<u>Steve Kutz, Board Member</u>, asked about methodologies and confirmed that it will be a part of the TACs process.

Kelly responded that the TAC will first review the condition BCKDK deficiency, and then will conduct a review of the five NBS criteria.

Kelly pointed the Board to the newborn screening process and criteria document on page 555 of meeting materials and reviewed amended sections. Kelly stated the Board

will receive a final version of this document for formal Board approval at the March meeting.

**Motion:** For the conditions MPS-II and Krabbe Disease that were added to the RUSP prior to the Board's recommendations, the two-year review timeline begins from the November 2024 Board recommendation date instead of date of the federal recommendations.

• The TACs for MPS-II and Krabbe Disease must be completed by November 2026.

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

#### 16.2025 BOARD MEETING SCHEDULE UPDATE

<u>Michelle Davis, Board Executive Director</u>, presented the updates to the 2025 Board Meeting Schedule. Changes reflect location and travel limitations based on the Governor's budget directive.

**Motion:** The Board approves meeting locations in the Olympia area, preferably state agencies, through June 2025, to reduce costs during the 2025 fiscal year.

Motion/Second: Member Kutz/Member Abdelmalek. Approved unanimously.

#### **17. BOARD MEMBER COMMENTS**

<u>Steve Kutz, Board Member</u>, discussed attending The National Institutes of Health (NIH), Bethesda (MD) meeting on Indian Boarding Schools and learning about the significant historical trauma and family dynamics.

<u>Patty Hayes, Board Chair</u> thanked Member Kutz for sharing and everyone for a full meeting today.

#### ADJOURNMENT

Patty Hayes, Board Chair, adjourned the meeting at 4:30 p.m.

#### WASHINGTON STATE BOARD OF HEALTH

Patty Hayes, Chair

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# **Public Comment**

Following are the Public Comments received by Noon on Friday, March 7, 2025 From: bill teachingsmiles.com Sent: 1/8/2025 6:50:42 PM To: DOH WSBOH Cc: Subject: Fluoridation Review

#### External Email

Dear Patty Hayes, Chair Washington State Board of Health and Lauren Jenks,

I owe you both a huge thank you for starting a review of fluoridation policy, benefit, risk and costs.

After 15 years of pleading with the Board, you did hear us. Thank you.

However, I do have some reservations listed based on my memory of the meeting.

#1.  $\Box\Box$ Theparty" is restricted in the first sessions and I have not been invited, please invite me to all sessions (I'm free).

1.

□□□**INO**T comfortable with the DOH dentist(s) having good knowledge on both sides of the dental scientific literature and objective open minds. I have tried in the past to meet with the DOH dental team and have not been permitted. They do not want to entertain any research which does not support fluoridation.

For example, the Dentists will raise probably three studies which do not report risk. The most recent,

#### by Do et al (2024)

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdoi.org%2F10.1177%2F00220345 on fluoride and IQ has bias concerns, for example (Do 2022 <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.iadr.org%2Fscience-

policy%2Fposition-statement-community-waterfluoridation&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7Cbf5a7378eea7499089ac08dd3057f09a%7 ). Do 2024 did not have sufficient statistical power to detect harm with its small control sample of 68 children without fluoridation exposure and 83 with dental fluorosis.

I contacted Do and we had a nice email exchange. Then I asked him how many of the 68 children of the control were part of the 83 with dental fluorosis? He has not responded.

The U.S. National Toxicology Program (NTP) systematic review of fluoride's developmental neurotoxicity found harm in 30 of 31 high-quality human studies, some

from community water fluoridation (NTP 2024

<a href="https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdoi.org%2F10.22427%2FNTP-MGRAPH-">https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdoi.org%2F10.22427%2FNTP-MGRAPH-</a>

8&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7Cbf5a7378eea7499089ac08dd3057f09a%7C11d0e21).

11.

11.

In contrast to the NTP-reviewed studies, Do (2024) did not measure individuallevel total fluoride exposure or its best proxy, urine fluoride concentration. Do (2024) also did not measure prenatal fluoride exposure, a life stage sensitive to developmental neurotoxicity.

11.

11.

The study's analyses of IQ and dental fluorosis did not account for factors affecting dental fluorosis risk, including: total intake, exposure timing, genetic variation, metabolism, body weight, and nutritional factors [Alvarez 2009

<a href="https://gcc02.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.medicinaoral.com%2Fmedora">https://gcc02.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.medicinaoral.com%2Fmedora</a>, Bhagavatula 2017

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdoi.org%2F10.1111%2Fjphd.1226, Huang 2008

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdoi.org%2F10.1111%2Fj.1600-0528.2007.00424.x&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7Cbf5a7378eea7499089ac08dd3057].

11.

11.

A second study is a lone outlier reporting an impossible 28 IQ point increase for boys (Ibarluzea 2022

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdoi.org%2F10.1016%2Fj.envres.2 ). If true, we would not see many boys/men in special education, incarceration,

homeless, or out of work. Experts in court suggested redoing the lab work. Ibarluzea was asked to be a witness in court and refused.

11.

□□□□Tboxicologists will have a difficult time asking the dentists the difficult dental questions and calling the dentist's bluff, assumptions, lack of science and attempting to get dentists to look outside their box evaluating benefit. The dental profession, ADA, advises dentists to support fluoridation or their license is in jeopardy. Yes, dentists lost their licenses because they openly objected to mercury fillings. They may not cause the license to be revoked for a position on fluoride, but they will discipline the dentist/hygienist for something simply to let them know who is boss. Loss of employment is serious, loss of license to never work in the profession again after 20+ years of education, is non-negotiable.

Why has the FDA not approved fluoride for ingestion? What are the RCT's of fluoride ingestion benefit?

1.

i. **D Tone** RCT of fluoride ingestion reporting no statistical benefit. Leverett DH, Adair SM, Vaughan BW, Proskin HM, Moss ME. Randomized clinical trial of the effect of prenatal fluoride supplements in preventing dental caries. Caries Res. 1997;31(3):174-9. doi: 10.1159/000262394. PMID: 9165186.

And CDC: Ingestion of fluoride is not likely to reduce tooth decay CDC (1999). Achievements in Public Health, 1900-1999: Fluoridation of Drinking Water to Prevent Dental Caries. MMWR, 48(41); 933-940, October 22 and many more concerns with the lack of efficacy.

And "In summary, we hold that fluoridation is an unreasonable risk. That is, the toxicity of fluoride is so great and the purported benefits associated with it are so small - if there are any at all – that requiring every man, woman and child in America to ingest it borders on criminal behavior on the part of governments." Dr. J. William Hirzy, Senior Vice-President, Headquarters Union, US Environmental Protection Agency, March 26, 2001

ii. Consider the latest on benefit of fluoridation: The Cochrane Collaboration, a non-profit organization of 30,000 expert researchers and health professionals from around the world, is considered the gold standard of evaluating effectiveness of health interventions. Its latest (2024)

<a href="https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Foralhealth.cochrane.org%2Fnews%review-water-fluoridation-prevention-dental-">https%3A%2F%2Foralhealth.cochrane.org%2Fnews%review-water-fluoridation-prevention-dental-</a>

caries&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7Cbf5a7378eea7499089ac08dd3057f09a%7C11d0 systematic review analyzed data from the 21 highest-quality studies. It found that fluoridation increased cavity-free results in primary (baby) teeth by only 4% and in permanent teeth by only 3%. [Not 60% reported when fluoridation started. Nor 25% claimed by the Board.] Neither result is statistically significant and include the possibility of no benefit at all. It also found no sufficient evidence that fluoridation benefitted lowincome families. <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Foralhealth.cochrane.org%2Fnews review-water-fluoridation-prevention-dental-

caries&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7Cbf5a7378eea7499089ac08dd3057f09a%7C11d

Updated review: Water fluoridation for the prevention of dental caries <a href="https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Foralhealth.cochrane.org%2Fnews%">https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Foralhealth.cochrane.org%2Fnews%</a> review-water-fluoridation-prevention-dentalcaries&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7Cbf5a7378eea7499089ac08dd3057f09a%7C11d0

Authors: Iheozor-Ejiofor Z, Walsh T, Lewis SR, Riley P, Boyers D, Clarkson JE, Worthington HV, Glenny A-M, O'Malley L. Does adding fluoride to water supplies prevent tooth decay?

oralhealth.cochrane.org

1.

1.

iii. Cochrane results are consistent with the 2024 LOTUS study <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fonlinelibrary.wiley.com%2Fdoi%2 , the largest ever done – analyzing 6.4 million people in the UK's National Health Service, reporting 2% lower cavity rate in permanent teeth of adolescents and adults drinking fluoridated water – with "no meaningful reduction in social inequities . . ." It is also consistent with the Iowa Fluoride Study (IFS), funded by the National Institutes of Health, the most comprehensive research project in the U.S. The 2018 IFS study found no significant correlation between ingested fluoride and cavity reduction, further validating its 2009 study that stated "recommending an 'optimal' fluoride intake is problematic."

<a href="https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fonlinelibrary.wiley.com%2Fdoi%2">https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fonlinelibrary.wiley.com%2Fdoi%2</a>

How effective and cost effectives water fluoridation for adults and adolescents? The LOTUS 10 yearetrospective cohort study - Moore - 2024 - Community Dentistry and Oral Epidemiology - Wiley Online Library <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fonlinelibrary.wiley.com%2Fdoi%2

1 BACKGROUND. Permanent dentition caries, the most prevalent condition globally, results in extensive negative impacts for both individuals and society. 1 The first studies of initiation of community water fluoridation reported that it reduced the mean number of teeth affected by up to two-thirds. 2, 3 Fluoridation of drinking water is therefore justifiably recognized as one of the 20th ...

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i□□□

13.

□□□**T**₩€BOH/DH review committee must have experts on both sides of the controversy on the theory of dental benefit from fluoride ingestion. 14.

□□□□□Ch**pick**ing believers of any subject to evaluate the subject will have a forgone conclusion. Fluoridation efficacy has been reviewed multiple times, all members chosen were believers and all conclusions the same. 15.

<a href="https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fnap.nationalacademies.org%2Fca">https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fnap.nationalacademies.org%2Fca</a> in-drinking-water-a-scientific-review-of-epas-

standards&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7Cbf5a7378eea7499089ac08dd3057f09a%7C review of fluoride in water for the EPA included 3 of the twelve members who had published or written concerns on fluoride exposure, one dentist, one psychologist and one toxicologist and they had expressed reservations. The report did not agree with the EPA's maximum contaminant goal for fluoride. EPA ignored the committee's advice even though the vote was unanimous that EPA's MCLG was not protective.

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fnap.nationalacademies.org%2Fcation-drinking-water-a-scientific-review-of-epas-standards&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7Cbf5a7378eea7499089ac08dd3057f09a%7C

Fluoride in Drinking Water: A Scientific Review of EPA's Standards <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fnap.nationalacademies.org%2Fcat in-drinking-water-a-scientific-review-of-epasstandards&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7Cbf5a7378eea7499089ac08dd3057f09a%7C

The National Academies of Sciences, Engineering, and Medicine are the nation's pre-eminent source of high-quality, objective advice on science, engineering, and health matters.

nap.nationalacademies.org

16.

□□□Asktimg Pope to gather the Cardinals to evaluate the virgin birth has a foregone conclusion. Asking all Chevy dealers what is the best truck has a foregone conclusion. Cherry picking like minded believers is not a forum, although, party maybe the best term.

17.

□□□□Laurenentioned today that science is not inclusion, but a process. Yes, maybe for toxicology (although I'm not a toxicologist) because perhaps toxicologists are more statistically, mathematically, and research oriented and educated. Dentists are not. To evaluate a long held treasured public health policy (theory) and dental treasured belief, different skill sets are also required. Yes, a process, and with judgment. 18.

The second meeting, I understand, will be on TSCA and the Court trial. Dr. Taylor's report (one of the NTP authors) is essential, a must for reviewers, especially dentists and public health authorities to review. Presented in clear and precise terms. https://www.healthandenvironment.org/che-webinars/96797 <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.healthandenvironment.org% webinars%2F96797&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7Cbf5a7378eea7499089ac08dd3057

Fluoride, Neurodevelopment, and Cognition: A National Toxicology Program Monograph from December 3, 2024. 19.

The third meeting on impact of CWF, I presume benefit and dental risks. Be sure to have committee members view the evidence which changed my mind: https://youtu.be/rQHiIJLSujc <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fyoutu.be%2FrQHiIJLSujc&data=0

□□□□**a10r**op Box https://www.dropbox.com/scl/fi/pajvqu1k0a6usueh535q4/Fluoridation-Osmunson-9-2024-movie.m4v?rlkey=8dekyj3y5ah48sebe9vosrzsq&st=s8ro6tc7&dl

Please ask to have me included as a voting member on the committee/party.  $\Box$ Nccost.  $\Box$ 

#2. DDLaurenentioned in the Board meeting today that there is a "signal" which should be investigated. A nice term for a freight train of evidence.

#3.□□□Tbemeetings are a reasonable start. When will the cost-benefit-risk evaluation
be reviewed? Consider: Community Water Fluoridation a Cost-Benefit-Risk Consideration
Osmunson - 2024 - Public Health Challenges - Wiley Online Library
<a href="https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fonlinelibrary.wiley.com%2Fdoi%2">https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fonlinelibrary.wiley.com%2Fdoi%2</a>

<a href="https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fonlinelibrary.wiley.com%2Fdoi%2">https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fonlinelibrary.wiley.com%2Fdoi%2</a>

Community Water Fluoridation a Cost–Benefit–Risk Consideration <a href="https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fonlinelibrary.wiley.com%2Fdoi%2">https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fonlinelibrary.wiley.com%2Fdoi%2</a>

A US Environmental Protection Agency funded study [] (1987), with fluoride concentrations between 1.0 and 4.0 mg/L, evaluated the cost of treating dental fluorosisfinding: "A mean cost for all consultants shows that the estimated costs for restoring function exceeds the cosmetic costs in all categories except the minimum later costs.

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<a href="https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fnap.nationalacademies.org%2Fcation-drinking-water-a-scientific-review-of-epas-">https%3A%2F%2Fnap.nationalacademies.org%2Fcation-drinking-water-a-scientific-review-of-epas-</a>

standards&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7Cbf5a7378eea7499089ac08dd3057f09a%7C report of fluoride be reviewed?

#5. DDWhewill the total exposure from all sources be reviewed? Risk can only seriously be considered when total fluoride exposure, dose is understood. The NRC 2006

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fnap.nationalacademies.org%2Fca in-drinking-water-a-scientific-review-of-epas-

standards&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7Cbf5a7378eea7499089ac08dd3057f09a%7C is the best source of total fluoride to date. The Court added uncertainty factors and intraspecific factors of 10 and maybe 100. However, 1,000 is necessary to protect infants. The fetus is of even more serious concern.

Malin (2024) Maternal Urinary Fluoride and Child Neurobehavior at Age 36 Months - PubMed

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fpubmed.ncbi.nlm.nih.gov%2F387 Key Points Question Is prenatal fluoride exposure associated with child neurobehavior in a US-based sample? Findings In this cohort study of 229 pregnant women and their

a US-based sample? Findings In this cohort study of 229 pregnant women and their children, a 0.68 mg/L (ie, 1 IQR) increase in specific gravity-adjusted maternal urinary fluoride during pregnancy was associated with nearly double the odds of T scores for total child neurobehavioral problems being in the borderline clinical or clinical range. Meaning These findings suggest that prenatal fluoride exposure may increase risk of neurobehavioral problems among children living in an optimally fluoridated area in the USA.

Remember, during pregnancy a mother's bones (especially the third trimester) resorb to give the fetus calcium if not enough is absorbed in the diet. The osteoclastic activity releases stored calcium and fluoride which both go to the fetus. Fluoride does cross the placenta and can harm the developing fetus. So much more.

#6. DDWhewill oversight jurisdiction and laws be considered? FDA, EPA, CDC, NSF, BOH, DOH, Legislature, etc? No Federal or State agency accepts jurisdiction over the dosage, safety, label, manufacturing, purity, and benefit of fluoridation and fluoride exposure.

#7. DDDTMeourt and NTP both took 8 to 10 years. The Court 9 days of trial with very expensive experts, specialists in their field on both sides of the issue. The EPA expert agreed fluoride is a developmental neurotoxin but was uncertain about dosage. The judge asked, "what would it take for you to change your mind?" The expert responded, "1 or 2 more studies." We've had over a dozen since his inclusion.

#8. DDDT2e015 workshop did not include the public, at least I did not know about it.

#9.  $\square$   $\square$  Pattor someone on the Board) asked about language from other authorities and I will get that and forward to you.

#10. And when you have time, what is the link to the Department's statement that fluoridated water should not be used to make infant formula?

Those are a few quick thoughts and I must quit for tonight.

Thank you for stepping out and reviewing fluoridation.

Bill 425.466.0100 From: Bob Runnells Sent: 1/10/2025 9:22:25 PM To: DOH WSBOH Cc: Subject: Comments on Covid shot recommendation policy - corrected

attachments\6B1FAC9438DE47F1\_SBOH Comments - R. Runnells 10Jan25.pdf

*Itachments*\0F0C2ED9877D43E8\_rhodes-parry-2024-pharmaceutical-\_PRDTOOL\_NAMETOOLONG.pdf

External Email

Hello,

Given the shortened time to speak at the Jan 8 meeting, I am submitting my comments in entirety for board records and for members to consider as the Covid Shot recommendations head closer to being withdrawn from the market.

There will come a time when they are withdrawn, so the DOH and the BOH should gather this information to explain to those who still have trust in your institution.

Please read the attached.

Regards,

Bob Runnells

Informed Choice Washington

Dear State Board of Health Happy New Year

I'm Bob Runnells -

- a Director with Informed Choice Washington. We are in the 10<sup>th</sup> year of advocating for fully informed consent.

On November 6, 2024, the International Journal of Risk & Safety in Medicine published a well-cited article by Rhodes and Parry, medical professors from Australia, titled "Pharmaceutical product recall and educated hesitancy towards new drugs and novel vaccines" It illustrates pharmaceutical company fines and compares reports of death that occurred before various drugs and vaccines were finally withdrawn from the market.

The authors summarize their results as "Parallels with past drug withdrawals and gene-based vaccines include distortion of clinical trial data, with critical adverse event data absent from high-impact journal publications. Delayed regulatory action on pharmacovigilance data to trigger market withdrawal occurred with Vioxx (rofecoxib) and is apparent with the gene-based COVID-19 vaccines."

Their list of recalled products includes:

- a polio vaccine withdrawn after the Cutter Incident of 1955 with 10 deaths,
- Swine flu vaccine 1976, with 53 deaths,
- Diethylstilbestrol (DES) in 1975 with 214 deaths,
- Bextra, 2005, with 1,051 deaths in just one year
- Vioxx was on the market for 5 years before recall in 2004 after 6,639 deaths, with an underreporting factor of 5 to 9.
- And the Covid-19 vaccine, still on the market after at least 37,644 reports of vaccine-related death.

What can the DoH and this Board of Health do with this information? Can you depart of the CDC Recommendations?

Florida's Surgeon General acted on this distortion of the drug regulatory system. As of last September 12, their department of health said: **"Based on the high rate of global immunity and** currently available data, the State Surgeon General advises against the use of mRNA COVID-19 vaccines."

Citing many specific safety and efficacy concerns.

Other countries are discouraging the shots, and especially for youth. Other jurisdictions in the U.S. are doing so.

There will come a time when the Department of Health can stop recommending against the COVID-19 mRNA shots. This journal paper and other mounting evidence of contaminants from the manufacturing process and the general lack of uptake can help you justify dropping COVID shot promotion and recommendation.

Thank you, Bob Runnells Informed Choice Washington

# Pharmaceutical product recall and educated hesitancy towards new drugs and novel vaccines

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Peter Rhodes<sup>1,2</sup> and Peter I Parry<sup>3,4</sup>

#### Abstract

**Background:** Of many pharmaceutical products launched for the benefit of humanity, a significant number have had to be recalled from the marketplace due to adverse events. A systematic review found market recalls for 462 pharmaceutical products between 1953 and 2013. In our current and remarkable period of medical history, excess mortality figures are high in many countries. Yet these statistics receive limited attention, often ignored or dismissed by mainstream news outlets. This excess mortality may include adverse effects caused by novel pharmaceutical agents that use gene-code technology.

**Objective:** To examine key pharmaceutical product withdrawals and derive lessons that inform the current use of genebased COVID-19 vaccines.

**Methods:** Selective narrative review of historical pharmaceutical recalls and comparative issues with recent COVID-19 vaccines.

**Results:** Parallels with past drug withdrawals and gene-based vaccines include distortion of clinical trial data, with critical adverse event data absent from high-impact journal publications. Delayed regulatory action on pharmacovigilance data to trigger market withdrawal occurred with Vioxx (rofecoxib) and is apparent with the gene-based COVID-19 vaccines.

**Conclusion:** Public health requires access to raw clinical trial data, improved transparency from corporations and heightened, active pharmacovigilance worldwide.

#### **Keywords**

conflict of interest, COVID-19, clinical trials, drug-related side effects and adverse reactions, messenger ribonucleic acid vaccines, pharmaceutical industry, pharmacovigilance, safety-based drug recalls

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All pharmaceutical products are continuously experimental, observed and tracked by pharmacovigilance systems worldwide.<sup>1</sup>

#### Introduction

Strong science, characterised by open mindedness, objectivity, curiosity and freedom of debate, can be corrupted by capitalist opportunism, deception, political ideology and censorship. Regulatory protections are required for good science to flourish. Corporate enthusiasm and authoritarian policy directives, such as vaccine mandates, must be balanced with humane medical ethics and protection of individual autonomy.

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The global pharmaceutical industry has grown in recent decades and now represents one of the most valuable in the world. Revenue of the worldwide market in just 2 decades has risen from 390 billion USD (2001) to 1482 billion USD (2022).<sup>2</sup>

New additions to the global marketplace appear with entrepreneurial enthusiasm. Yet withdrawals of these products are also significant. In the last 7 decades, from 1953 onwards, more than 462 medicinal products have had to be recalled from sale because of adverse drug effects that frequently include fatalities. The median interval between the first reported adverse reaction and the year of first withdrawal for a drug is 6 years (IQR, 1-15).<sup>3</sup>

Globally, whether drugs are recalled or not, pharmaceutical industry violations have become a multibillion-dollar industry of litigation, legal fees, and court penalties. Some of the most impressive corporate criminal trials include<sup>4</sup>:

- Cardinal Health, McKesson, AmerisourceBergen, Johnson & Johnson (2022), inappropriate opioid prescription, addiction crisis, settlement of \$26 billion USD;
- GlaxoSmithKline (2012), unlawful promotion of Paxil (paroxetine), Wellbutrin (buproprion) and Avandia (rosiglitazone), and failure to report safety information, settlement of \$3 billion USD;
- Eli Lilly, Takeda Pharmaceuticals (2015), concealment of data on carcinogenicity of Actos (pioglitazone), settlement of \$2.4 billion USD;
- **Pfizer (2009)**, false promotion of Bextra (valdecoxib) tablets, Geodon (ziprasidone) capsules, Lyrica (pregabalin), and Zyvox (linezolid), payment of financial kickbacks, submission of false claims to government, illegal drug promotion, settlement of \$2.3 billion USD;
- Johnson & Johnson (2013), misbrand of antipsychotic drug Risperdal (risperidone), payment of financial kickbacks, settlement of \$2.2 billion USD.

Direct to public commercials in the USA for legal support are now widespread, e.g.<sup>4</sup>:

"Call a Dangerous Drug Attorney at O'Connor, Acciani & Levy.

If you believe you were harmed after using a certain pharmaceutical product, call a skilled dangerous drug attorney for help in starting a personal injury claim."

In this selective narrative review, our goal is to consider some of the milestones in drug recall from the market, litigation for, and republication of, hidden data, and potential lessons that may be learnt. We assess recall of various pharmaceutical agents, proven over time to be monumental events. In particular, we focus on the cases of Merck's Vioxx (rofecoxib), and the new gene-based COVID-19 vaccines.

#### Results

#### Diethylstilbestrol (DES)

Marketed widely in the 1950s and 1960s, diethylstilbestrol (DES) (Eli Lilly), prescribed by the medical profession for prevention of miscarriage, led to extensive harm that would prove fatal for some and would span generations. Supplied to millions of pregnant women over 3 decades, DES became the first identified cause of "prenatal drug-induced cancer in humans". The drug was recalled in 1971. The full intergenerational impact of these prescriptions is still not known.<sup>5</sup>

#### Thalidomide

Thalidomide is one of the saddest chapters in pharmaceutical history and an example of how premature safety claims can have tragic consequences. Created as a sedative and marketed in Germany in 1957 by Chemie Grünenthal, thalidomide would soon be launched in the UK (Distillers, UK), and many other countries would follow. At this stage, the first thalidomide-affected baby had already been born in Germany, 25 December 1956, to a Chemie Grünenthal employee. By 1958, thalidomide was licensed and promoted in the UK as a "wonder drug" to treat headaches, insomnia, and nausea in pregnant women – advertisements emphasised safety, with catch phrases such as "non-toxic" and "no known toxicity".

The first publication to link thalidomide and birth defects appeared in 1961 in *The Lancet*, as a letter from an Australian, William McBride.<sup>6</sup> This same year the drug was formally withdrawn in Germany and in the UK, the Thalidomide Society was established in the UK, and efforts began to secure compensation for victims. In 1968, Chemie Grünenthal was brought to trial in Germany, charged with intent to commit bodily harm and involuntary manslaughter, but in 1970 this trial was ended prematurely by the German government, who stated that it was "not in the public interest".<sup>7</sup>

Efforts have continued in the UK to secure compensation from the 1970s through to the present. It was only on 29 November 2023 that the Australian Prime Minister announced a "formal national apology to all Australians impacted by the Thalidomide Tragedy", more than half a century on from the earliest harms.<sup>8</sup>

Through the diligent work of FDA scientist Frances Kelsey, who demanded further safety trials prior to market authorisation, thalidomide was never approved for release in the USA. She protected an entire nation.<sup>9</sup>

#### Paroxetine

The Selective Serotonin Reuptake Inhibitor (SSRI) antidepressant, paroxetine, became a very successful commercial product for SmithKlineBeecham (SKB) (later GlaxoSmithKline, GSK). In the late 1990s, the company conducted two randomised, controlled trials in adolescents with depression (Study 329 & Study 377). Company documents, subpoenaed through litigation, reported that Study 377 "failed to demonstrate any separation from placebo" and consequently the company had "no plans to publish data from Study 377". Study 329 showed "trends in efficacy" but the differentiation from placebo "was not statistically significant".<sup>10</sup> This Study 329 was ghost written and then published by Keller and 21 co-authors in 2001, with the conclusion that paroxetine was "generally well tolerated and effective" for adolescents with depression, <sup>11</sup> Although SKB/GSK decided not to present the studies' data to the FDA for a label change to treat adolescent depression, they used the Keller et al. publication to promote off-label prescriptions for depressed teens. Later, independent researchers gained access to raw data from Study 329 and found increased suicidality and no significant efficacy.<sup>12</sup> Despite calls for retraction of the original Study 329 publication, the *Journal of the American Academy of Child and Adolescent Psychiatry (JAACAP)* has refused to do so.<sup>13</sup>

GSK suppressed negative data about their drug paroxetine and effects on depression and suicide. An internal GSK document advised staff to withhold data that indicated paroxetine had no beneficial effect in adolescents.<sup>14</sup> In 2012, GSK pleaded guilty to fraud allegations and failure to report safety data, with payment of \$3 billion in criminal fines, the largest fraud settlement in US history at the time.<sup>15</sup>

There have been further disputes over the increased suicidality caused by SSRIs in adolescents and young adults, with calls to remove the FDA Black Box label. However, both Study 329 data re-analysis<sup>13</sup> and separate further data support continuation.<sup>16</sup>

This GSK paroxetine chapter is by no means an isolated case of hidden data. In 2015, Eli-Lilly and Takeda Pharmaceuticals were fined \$2.4 billion USD for concealment of the carcinogenic effects of pioglitazone (Actos).<sup>17</sup>

#### Avandia (rosiglitazone)

Avandia (rosiglitazone) gained FDA approval for management of diabetes in May 1999 and was widely prescribed for control of blood glucose, until it was shown to increase risk of myocardial infarction by 43% and increase risk of death from cardiovascular causes by 64%.<sup>18</sup> In May 2007, Steven Nissen of the Cleveland Clinic published controlled trial data that showed, in the rosiglitazone group, as compared with control, the odds ratio for myocardial infarction was 1.43 (95% confidence interval (CI), 1.03 to 1.98; p = 0.03), and the odds ratio for death from cardiovascular causes was 1.64 (95% CI, 0.98 to 2.74; p = 0.06).<sup>19</sup>

In July 2007, a panel of FDA advisers voted 22 to 1 against removal of Avandia from the marketplace. As late as 2009, GSK continued with promotion of Avandia as "safe and free from cardiovascular side effects".<sup>20</sup> In contrast, by February 2010, a US senate finance committee was able to conclude that GSK had "full knowledge of the cardiac risks of Avandia in late 2004 or early 2005". David Graham, FDA scientist, has estimated combined US heart attacks, strokes and deaths caused by Avandia to be in the order of 100,000 events.<sup>21</sup> The drug was removed from the European market in September 2010, based on cardiovascular risks, and remains banned to this day.

Pursuit of surrogate end points can be dangerous, exemplified here with a focal target of blood glucose control, yet accompanied by significant adverse events.

While such corporate products and medical prescriptions as diethylstilbestrol, thalidomide, paroxetine and rosiglitazone are now infamous chapters in medical history, still greater events loom over more recent history, and we consider two of these, Merck's Vioxx (rofecoxib) scandal, and the roll out of gene-based COVID-19 vaccines.

## Vioxx (rofecoxib)

Developed by Merck, the cyclooxygenase-2 (COX 2) inhibitor Vioxx (rofecoxib) marketed as a non-steroidal antiinflammatory drug (NSAID) for pain relief in 1999, obtained FDA approval (21 May 1999) based on equivalence to other NSAIDs in short term use. Efforts to explore long term value in rheumatoid arthritis further supported sales, with fewer gastrointestinal side effects when compared with typical NSAID naproxen.<sup>22</sup>

In this VIGOR paper,<sup>22</sup> Merck concealed adverse cardiovascular events in the Vioxx arm of the study that would prove to be a serious statistical signal. Just prior to publication, Merck informed the FDA of three adverse cardiovascular events, published on an FDA website, but *The New England Journal of Medicine (NEJM)* article was neither retracted nor corrected.

The full VIGOR data unmasked high rates of cardiovascular events with Vioxx (rofecoxib) compared to naproxen, with a relative risk of 2.38 (95% CI 1.39–4.00) for rofecoxib against naproxen over a 12-month study period.<sup>23</sup> The time lag between initial FDA approval and the appearance of this more complete VIGOR trial data in print was over 18 months.

Initial responses to this data from Merck included claims that naproxen had a protective effect against heart attacks and strokes, that was not possessed by Vioxx, and that the increased cardiovascular risks seen with Vioxx occurred only in people with known cardiovascular disease.<sup>24</sup> This was later found to be untrue, once data for healthy individuals who had suffered harm on Vioxx had been uncovered.

Merck tried to influence lead American physicians with support and finance for research, and they defamed, withdrew support, and tried to discredit or "neutralise" those who failed to promote use of Vioxx, a matter uncovered by the Federal Court in Melbourne, Australia.<sup>25</sup> In contrast, the Chair of the Study Data and Safety Board (SDSB) for the study, Michael Weinblatt, owned \$72,000 in Merck stock and was on a \$60,000 contract for 12 days' work for the company.<sup>26</sup>

Internal Merck emails are now known to have shown as early as 18 November 1999 (unblinded minutes), that an interim safety analysis of VIGOR showed excess deaths and cardiovascular adverse experiences – 79 cardiac events for rofecoxib compared with 41 for the control group on a traditional NSAID, naproxen.<sup>26,27</sup> Yet Merck made a press release on 22 May 2001, entitled "*Merck Reconfirms Favourable Cardiovascular Safety of Vioxx*". Merck even created a "fake journal" with the medical publisher Elsevier: The *Australasian Journal of Bone and Joint Medicine*, with six issues between 2002 and 2005, that collated articles favourable to Merck's drugs Vioxx and Fosamax.<sup>28</sup>

The FDA appears to have been complicit with Merck in early suppression of the adverse event data of VIGOR. Eventually the FDA did instruct Merck (April 11<sup>th</sup>, 2002) to include a precaution about cardiovascular risks in their package insert.<sup>24</sup> Dr David Graham, an FDA scientist in its Office of Drug Safety, revealed this interplay in his testimony to the US Senate (below).

Vioxx remained on the market until the completion of the APPROVE study in 2004. The intention was to promote use of Vioxx to treat polyps of the colon. But again, the drug demonstrated at least double the cardiovascular risk compared with placebo, this time in a patient population considered to be at low risk of cardiovascular disease.<sup>29</sup>

Merck announced withdrawal of Vioxx on 30 September 2004, the largest prescription drug recall in history to date. Over 20 million people in the US are believed to have taken the drug, of whom an estimated 88,000 to 139,000 suffered myocardial infarctions, with 30–40% fatality rate (testimony of Dr Graham to the US Senate).<sup>30</sup> His figures on estimated cardiac arrests were also published in *The Lancet*, despite opposition from the FDA.<sup>31</sup> Dr Graham further testified to the Senate that conflicts of interest at the FDA had delayed the Vioxx recall.<sup>32</sup> Discovery documents in litigation reveal corporate pharma may conceal data early, at any cost to achieve market growth.<sup>33,34</sup> Here the FDA appeared complicit and slow to withdraw the product.<sup>24,35</sup> Published in the *NEJM*, prominent cardiologist Eric Topol included strokes as well as myocardial infarctions to estimate 160,000 events per 10 million people prescribed Vioxx, and he noted a global cohort of up to 80 million had been prescribed Vioxx.<sup>24</sup>

By August 2005, 13,000 class action lawsuits had been filed against Merck. By November 2007, Merck had created a settlement fund of \$4.85 billion USD, the largest ever in US history at the time. Merck agreed to compensate victims in exchange for a no-fault agreement – specifically, no legal admission of fault. Yet payment of \$4.85 billion USD in compensation to claimants could clearly be interpreted as an admission of fault.<sup>25,26</sup>

When the Vioxx scandal broke, Merck had a capital market value of between \$40 and \$50 billion USD. Despite the greatest drug scandal in the world, enormous fines and atrocious damage to image, Merck has continued to grow in the last 2 decades and has increased its value six-fold to over \$300 billion USD.

## COVID-19 gene-based vaccines

Initially marketed December 2020, as Emergency Use Authorisation (EUA) in the USA, and provisional authorisation in Australia and other nations, the gene-based COVID-19 vaccines of modified mRNA type, (Pfizer-BioNTech's BNT162b2, Moderna's mRNA-1273) and viral-vector-DNA type (AstraZeneca's ChAdOx1-S, Janssen's Ad26.COV2.S, Gamaleya's Sputnik V) have constituted the majority of over 13 billion doses of all COVID-19 vaccines.<sup>36-41</sup> In contrast, COVID-19 vaccines that employ traditional well-tested inactivated virus or

recombinant protein antigen-based technologies have been utilised mainly in a few non-Western nations (e.g., Bharat Biotech's Covaxin, Sinovac's CoronaVac, Cinnagen-Vaxine's SpikoGen, Cuba's Genetic Engineering and Biotechnology Centre's Abdala).<sup>42</sup>

Purposed for protection against transmission of the SARS-CoV-2 virus and reduced disease severity, official sales narratives included – "safe and effective", and "millions of lives saved". Indications of serious harm appeared from 2021 with record high adverse event reports to pharmacovigilance. These included suspected death reports as indicated by VAERS data<sup>43</sup> (Figure 1), peer-reviewed VAERS and EudraVigilance data,<sup>44</sup> excess mortality above expected from collation of official death statistics by Our World in Data<sup>45</sup> and insurance data for excess mortality and disability<sup>46</sup> correlated with COVID-19 vaccination. Montano (2022) compared COVID-19 vaccines (Janssen, Moderna, Pfizer-BioNTech) with influenza vaccines, and found extremely high elevated relative risk for serious and fatal adverse events across most organ systems [<sup>44</sup>, in Table 3b]. Excess mortality is defined as mortality above normal background rates at ourworldindata.org which is under the jurisdiction of Oxford University, UK.

Market restrictions on recommendations began September 2022, with COVID-19 booster vaccines generally limited to over age 50 and the vulnerable in Nordic nations and Switzerland, e.g., the Danish Health Authority declared it was "no longer possible … for children and adolescents aged under 18" to get the COVID-19 vaccine "from 1 September 2022".<sup>47</sup> By contrast, the USA, Canada, Australia and some other nations still market for children. The key failure is to have mandated injections in young and healthy adults; these mandates correlate with excess mortality.<sup>44–46</sup> A recent peer-reviewed study in *BMJ Public Health* on excess mortality from 47 Western nations, finds over three million excess deaths from January 2020 to December 2022. Notably, when stratified by year, the highest number of excess deaths was reported in 2021, the year in which mass vaccination began. Especially in late 2021 which saw imposition of vaccine mandates in many nations (first graph p. 5).<sup>45</sup> Additional lessons potentially are that rushed "warp speed" development of novel technologies is unwise; narrative and groupthink can distort judgement; suppression of clinical trial data is harmful; heightened active pharmacovigilance must be encouraged.<sup>48–50</sup>

Use of the term "vaccine" for novel experimental agents that deploy gene codes may convey a false sense of assurance in the absence of supportive data and thus may mislead. In pharmacological design terms, these products are "pro-drugs".<sup>51</sup> They must enter cells and undergo translation of genetic code before intended outcomes

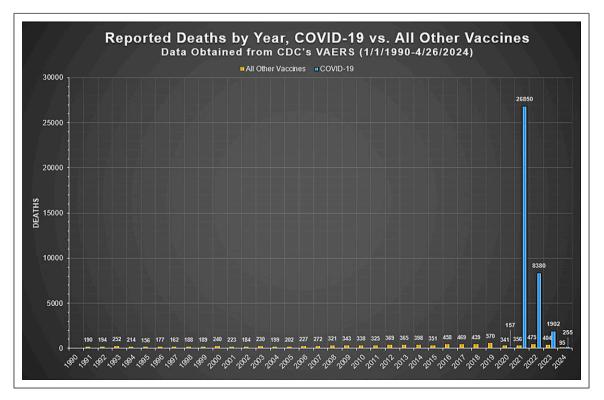


Figure 1. Reported suspected deaths from vaccines to VAERS since 1990 comparing all other vaccines combined with COVID-19 vaccines. From VAERS Analysis<sup>43</sup> (with permission).

unfold<sup>52</sup> (Figure 2), and in this sense they operate as "synthetic viruses".<sup>53</sup> Unintended consequences are thus possible.<sup>53–57</sup>

A systematic review of the peer-reviewed literature: "Serious harms of the COVID-19 vaccines: a systematic review" by Gotzsche and Demasi (2024) [<sup>58</sup> preprint] found that with the notable exception of Fraiman et al.,<sup>59</sup> "most studies were of poor quality" (abstract) and used methodologies such that "serious harms are vastly underreported" (p. 7). They conclude:

Adenovirus vector vaccines increased the risk of venous thrombosis and thrombocytopenia, and the mRNA-based vaccines increased the risk of myocarditis, ... serious neurological harms (occurred), which are likely due to autoimmune reaction. ... Severe harms were underreported in the randomised trials [published in the NEJM].

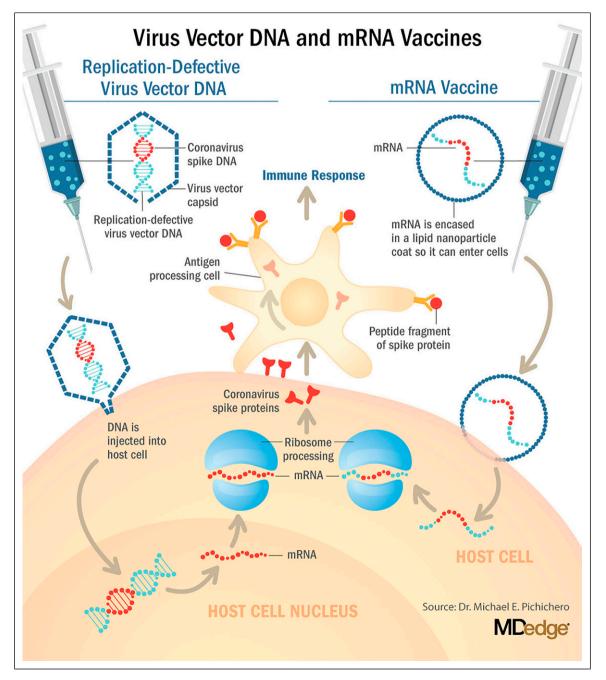


Figure 2. COVID-19 virus vector DNA and mRNA vaccines: mechanism of action. From Pichichero ME (with permission).<sup>51</sup>

As authorisation and promotion of the COVID-19 mRNA vaccines continue, the authors call for randomised trials of COVID-19 booster doses in high-risk groups that thoroughly examine serious adverse events.<sup>59</sup> The authors also state that "Authorities ... do not consider that the balance between benefits and harms becomes negative in low-risk groups such as children [and those with natural immunity]" (abstract). This point has been well made by Bardosh et al. (2024)<sup>60</sup> who argued against universal vaccine mandates and noted that based on the Pfizer-BioNTech vaccine booster trial data,<sup>61</sup> to prevent one COVID-19 hospitalisation, 18.5 students would suffer a serious adverse event.<sup>60</sup>

These products are novel and experimental, whether modified mRNA gene codes encased in lipid nanoparticles (LNP) (Pfizer-BioNTech and Moderna), or viral-vector-DNA gene codes encased in adenovirus shells (AstraZeneca, Janssen, Sputnik V). These gene sequences produce the spike protein antigen of the SARS-CoV-2 virus, which must be extruded from the cell surface as foreign protein to stimulate an immune response. This is a new mechanism for public vaccination, completely distinct from traditional vaccine technologies.

Moreover, rigorous assessment of long-term safety of these experimental gene-based products has been effectively sabotaged by the early dissolution of the placebo arm in phase III clinical trials.<sup>62</sup> Despite this, the interim and extensive publication of these abbreviated clinical trials in the *NEJM* has been used to support marketing and the public health message of "safe and effective".

In terms of efficacy, failure to prevent infection or transmission of the COVID-19 variants<sup>63–66</sup> eventually led the US Centers for Disease Control and Prevention (CDC) to reinvent their definition for "vaccine" as no longer the provision of "immunity," but as "protection" against disease severity<sup>67,68</sup> – now a narrative challenged by more recent data. Promotion of the belief that millions of lives would be saved by these agents has been based on hypothetical, predictive epidemiological models which have a track record of miscalculation.<sup>46,53,73</sup> Official data from New South Wales state in Australia by late 2022 during the omicron variant wave did not concord with the message that these agents prevent serious disease or death, and even suggested the opposite.<sup>53</sup>

For the wealthy western nations who have utilised these novel agents in particular, the haste and scale of development, production, distribution, and administration is unprecedented.<sup>69</sup> Yet haste, especially at "warp speed", should be alien to good medical science. It is likely that novel technology, haste in vaccine development and mass production all contributed to the reported phenomenon of "batch toxicity" based on official pharmacovigilance data.<sup>70</sup>

#### Key failures – Coercion and mandates, ridicule of educated hesitancy

Perhaps the greatest failure of gene-based vaccine use is the political act to mandate therapy. Mandates are relatively rare in medical history. Vaccine passports to engage in normal life resemble measures under totalitarian rule. The deadlines for COVID-19 vaccine mandate compliance correlated closely with excess morbidity and mortality.<sup>1,44,46</sup>

Given the novel nature of gene-based COVID-19 vaccines, it may be no surprise that "vaccine hesitancy" among those with tertiary qualifications was highest with PhD doctorates (January–April 2021, 14.6%),<sup>71</sup> and among healthcare workers was highest for "emergency medical technicians/paramedics" (April–May 2021, 45.4%).<sup>72</sup> Reflective of both research and coalface clinical experience. This could thus be referred to as "educated hesitancy", found in a cohort most familiar with the imperfections of corporate sponsorship, market authorisation and medical literature, and a cohort on the frontline. Educated hesitancy towards these products has been ridiculed. It is particularly tragic that mandates have been applied to the young, fit, and healthy in our workforce, at minimal risk from the coronavirus itself, some of whom have paid the ultimate price with loss of life.<sup>43–46</sup> In fact, at a global level the median pre-vaccination infection fatality rate (IFR) was estimated at 0.03% for the 0 – 59-year-old population, while for children aged 0–19 years the median IFR was 0.0003%.<sup>73</sup> These observations indicate that children and adolescents are essentially at zero risk of COVID-19 mortality.

The limitations in the peer-reviewed literature to identify and quantify the harms of the gene-based COVID-19 vaccines [58, preprint], means greater consideration must be given to analyses of public datasets of passive and active pharmacovigilance and insurance and actuarial data. A graph of Western Australian Vaccine Safety Surveillance (WAVSS) (Figure 3 in our prior paper)<sup>1</sup> illustrates this, and it should be noted that due to remote geography and border closures, the state of Western Australia was essentially free of the SARS-CoV-2 virus in 2021.<sup>1</sup>

Similarly, a strong temporal correlation was evident between the imposition of COVID-19 vaccine mandates for employment in the third quarter of 2021 in the USA and high excess mortality for working age (25–64 years old) Americans, in the data collated by the US Society of Actuaries Research Institute, as shown in the table from *Cause Unknown* by Edward Dowd<sup>46</sup> (p. 80) (Figure 3).

With Vioxx, the key publication of the VIGOR clinical trial in the *NEJM* excluded three subjects with severe cardiovascular adverse events, a data suppression that obscured the true risk. Similarly with the phase III clinical

|                   | Q2   | Q3   | Q4   | Q1   | Q2   | Q3   | Q4   | Q1   | 4/20- | %     | % Non- | %     |
|-------------------|------|------|------|------|------|------|------|------|-------|-------|--------|-------|
| Age               | 2020 | 2020 | 2020 | 2021 | 2021 | 2021 | 2021 | 2022 | 3/22  | COVID | COVID  | Count |
| 0-24              | 116% | 124% | 104% | 101% | 119% | 127% | 110% | 91%  | 111%  | 3.3%  | 8.1%   | 2%    |
| 25-34             | 127% | 132% | 121% | 118% | 131% | 178% | 131% | 125% | 133%  | 13.3% | 19.6%  | 2%    |
| 35-44             | 123% | 134% | 128% | 129% | 133% | 200% | 156% | 136% | 142%  | 23.1% | 19.2%  | 4%    |
| 45-54             | 123% | 127% | 129% | 133% | 119% | 180% | 151% | 143% | 138%  | 27.4% | 10.8%  | 9%    |
| 55-64             | 117% | 123% | 130% | 130% | 114% | 153% | 141% | 137% | 131%  | 24.0% | 6.7%   | 18%   |
| 65-74             | 117% | 115% | 133% | 130% | 108% | 131% | 125% | 122% | 122%  | 18.6% | 3.9%   | 17%   |
| 75-84             | 114% | 114% | 133% | 123% | 106% | 119% | 121% | 121% | 119%  | 14.0% | 4.6%   | 20%   |
| 85+               | 112% | 103% | 124% | 111% | 92%  | 104% | 105% | 103% | 107%  | 10.3% | -3.5%  | 27%   |
| All <sup>11</sup> | 116% | 115% | 129% | 123% | 107% | 134% | 126% | 122% | 121%  | 17.1% | 4.3%   | 100%  |

Figure 3. Table 5.7 Excess mortality by detailed age band. From p.80 Dowd E (2022)<sup>46</sup> (with permission).

trials for the Pfizer, AstraZeneca and Moderna COVID-19 vaccines it is now known that three subjects with serious adverse events were excluded [ $^{49,58}$  preprint,<sup>74</sup>] from key papers<sup>36,37,39</sup> in the *NEJM*, which influenced health policy globally. These omissions occurred in the context of a non-random excess of 251 exclusions from the vaccine arm compared to placebo arm (311 vs 60) in the Pfizer clinical trial<sup>75</sup> and reported unblinding at one of the clinical trial sites.<sup>76</sup>

Two phase III clinical trials subjects who suffered severe adverse events from the vaccine arms of the Pfizer-BioNTech trial and the AstraZeneca trial [<sup>49,58</sup> preprint], and one from the Moderna trial<sup>74</sup> came forward to say their adverse event data was not published in the *NEJM* peer-reviewed papers of the clinical trials, and likely not reported to the FDA either. In the case of AstraZeneca, this was despite appeals to the journal.<sup>49</sup> A further case of a 12-year-old in the adolescent Pfizer COVID-19 clinical trial, suffered permanent severe polyneuropathy and is wheelchair bound [<sup>58</sup> preprint,<sup>77,78</sup>], is recorded in the *NEJM* paper as "functional abdominal pain".

Additionally, the Pfizer-BioNTech phase III trial report submitted to the FDA for Emergency Use Authorisation listed 2 deaths in the mRNA vaccine arm and 4 deaths in the placebo arm. However, documents released under court order revealed a further 4 deaths in the vaccine arm and 1 death in the placebo arm, to give the total number of deaths before the data cut-off date actually 11 (6 vaccine, 5 placebo) versus the 6 disclosed. Closer examination of relevant documentation available for each patient showed a pattern of delay in death notification, a clear violation of trial protocols and legal requirements.<sup>48</sup> By the end of the truncated Pfizer phase III trial there were 21 deaths in the vaccine arm and 17 in the placebo arm and the difference was accounted for by cardiovascular mortality.

## Discussion

In this selective narrative review, we have chosen some of the most well-known drug recalls and data suppression scandals. We have sought insights from these events that may help better appraise the current gene-based COVID-19 vaccines, which have together formed the largest ever launch of novel pharmaceutical product in history.

## Medical research

Quality of research in medical science is problematic. The scientific "replication crisis", which is also a publication crisis, has been studied, debated and recognised in surveys of scientists<sup>79,80</sup> ever since Ioannidis' highly cited 2005 paper asserted that at least half the published medical literature may simply be wrong.<sup>81</sup> The crisis rests on pressure to publish, failure to publish negative and/or unfavourable data, lack of data transparency, poor methodological design of studies, statistical errors, carelessness, inexperience of peer reviewers and editors, commercial interest, ideological biases, failure to declare conflicts of interest and fraud.<sup>81,82</sup> Tanver et al. noted lack of data transparency in the COVID-19 vaccine trials<sup>83</sup> and cast doubt on their use in public health, as did senior and chiefeditors of the *BMJ*.<sup>50</sup>

Distorted data, particularly due to commercial bias, is regularly published in medical journals. A Cochrane Review metaanalysis found odds ratios exist for a *sponsored* drug trial to find results, (OR 2.05) and provide conclusions (OR 2.69) in favour of the drug versus an *independent* trial for the same agent.<sup>84</sup>

#### Corporate integrity and data transparency

Concerns exist related to data transparency, access to raw data, and the potential for hidden data, deleted data or indeed failure to record data.<sup>10,12,15,24,30,33,34,49,50,74–90</sup> The track record of the pharmaceutical industry in these areas has been weak. Internal industry documents released after criminal convictions of the companies concerned, reveal a systemic pattern geared towards "marketing-based medicine" that is at odds with "evidence-based medicine".<sup>33</sup>

Among many examples, an internal AstraZeneca email discussed "*burial*" of data from four clinical trials. We quote John J A Tumas, Publications Manager, AstraZeneca, 6 December 1999,

There is pressure from outside the industry to provide access to all data from clinical trials conducted by the industry; thus far we have buried trials 15, 31, 56 and are now considering COSTAR.<sup>90</sup>

#### Illusion of evidence-based medicine

Jureidini and McHenry, in a prominent article in the *BMJ* asserted that Medicine has been "corrupted by corporate interests, failed regulation and commercialisation of academia", to cause an "illusion of evidence-based medicine".<sup>85</sup> The evidence base for clinical and public health decisions has long been corrupted, in the view of former chief-editors of *The Lancet*,<sup>91</sup> the *BMJ*<sup>86</sup> and *NEJM*.<sup>87</sup> Peer review cannot possibly police commercial and ideological conflicts of interest.

#### Pharmaceutical companies, publication and statistics

Manipulation of statistics in the medical literature has been lamented.<sup>18</sup> Widespread promotion of relative rather than absolute risk and use of surrogate endpoints are examples.<sup>18,75</sup>

Concerns exist over the transparency of COVID-19 mRNA vaccine trial data. Available figures from Pfizer and Moderna trials listed at clinicaltrials.gov have been evaluated (NCT04368728 and NCT04470427). As originally published in *NEJM*, the Pfizer and Moderna mRNA COVID-19 vaccine interim phase III clinical trial reports suggested a favourable risk/benefit ratio. Based on exactly the same data, Fraiman and colleagues publish in *Vaccine* that:

mRNA COVID-19 vaccines were associated with an excess risk of serious adverse events of special interest of 10.1 and 15.1 per 10,000 vaccinated over placebo baselines of 17.6 and 42.2 (95% CI -0.4 to 20.6 and -3.6-33.8), respectively.

From which they conclude a need for formal risk-benefit analyses.<sup>59</sup>

The FDA has been publicly criticised for their slow response to follow up potential increases in serious adverse events in elderly people related to Pfizer's mRNA COVID-19 vaccine [<sup>58</sup> preprint,<sup>92,93</sup>].

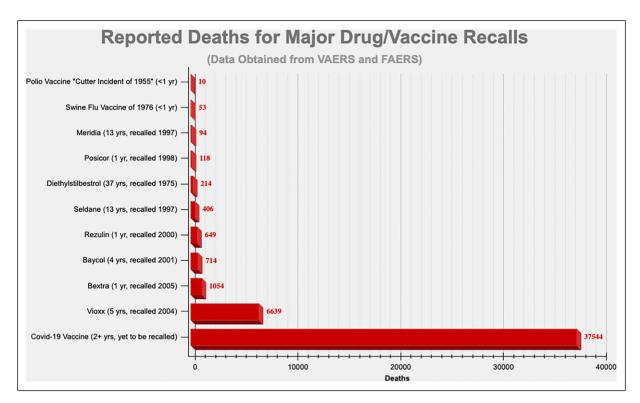
There are even indications that initial clinical trial work, published in the *NEJM*, may have been performed with mRNA products that differed from those eventually mass-produced. The clinical trial mRNA gene codes were created by PCR "Process 1" technology, but the vials for the public were produced by "Process 2" E. coli plasmid DNA manufacture, which has led to plasmid DNA contamination of vaccine vials.<sup>94</sup>

Beyond any clinical trial data and the process required to obtain initial approval from regulatory authorities, is the absolutely vital need to recognise that all therapeutic agents must be continuously monitored and subject to the red flags of vigilant surveillance.

## Lack of recognition of pharmacovigilance data

Historic precedence in pharmacovigilance, safety and product recall has not been followed with respect to the COVID-19 gene-based vaccines, as shown by reports on https://www.vaersanalysis.info/ which collates weekly updates of data from the US CDC's Vaccine Adverse Event Reporting System (VAERS) (Figure 4). The methodology used by vaersanalysis.info is presented in the supplemental materials.

A polio vaccine was withdrawn after just 10 death reports,<sup>95</sup> the Swine Flu vaccine of 1976 was recalled after just 25 of the ultimate 53 death reports.<sup>96</sup>



**Figure 4.** Reported suspected deaths for major drug/vaccine recalls versus COVID-19 vaccine reported suspected deaths. From VAERS Analysis<sup>43</sup> (with permission).

Not only are adverse events exceedingly high for the COVID-19 vaccines compared to all other vaccines (Figure 1), but deaths related to vaccines based *per million doses* show an unprecedented performance for the COVID-19 genebased agents. Comparison with the influenza vaccine for which more doses have been dispensed is noteworthy (Figure 5).

The red bars provide a comparison of ratios of adverse events/distributed doses of vaccines. The COVID-19 vaccines have data for both distributed doses (solid bar) and administered doses (taller dotted line bar) which might be a more accurate comparison given the reported high proportion of non-used COVID-19 vaccine doses.<sup>97,98</sup>

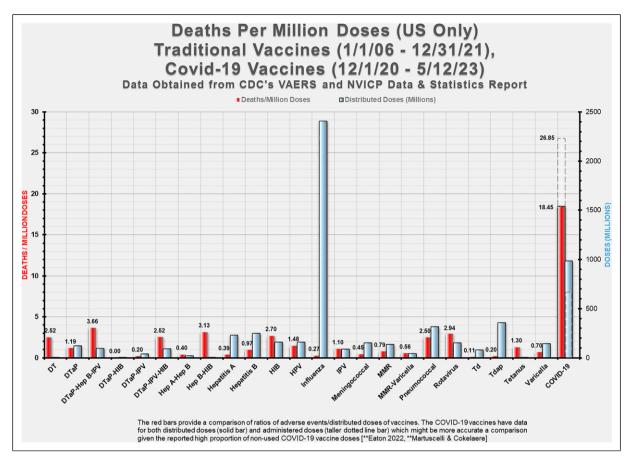
#### Pharmacovigilance underestimation factor

Vioxx data suggests the FDA's adverse event database (FAERS) *underestimates deaths by a factor of 5- to 9-fold*.<sup>88,99</sup> With deaths from strokes added to heart attacks, the under-estimation factor is likely to have been greater.<sup>24</sup> Yet, since the advent of the COVID-19 vaccines, health authorities have strenuously suggested the unprecedented adverse events are over-reported and thus overestimated. For example, the Australian Therapeutics Goods Administration (TGA) claim of overestimation by its *passive* system Database of Adverse Event Notifications (DAEN) is directly contradicted by the Australian National Centre for Immunisation Research and Surveillance (NCIRS), who operate the *active* prompted submissions to the AusVaxSafety database. While active AusVaxSafety data for Pfizer,<sup>100</sup> Moderna,<sup>101</sup> and AstraZeneca<sup>102</sup> vaccines failed to question around severe adverse events, and is thus incomplete, it still reflects far greater numbers of adverse events than the passively collected TGA DAEN figures.

In the US, government quality assurance suggests that the CDC's VAERS *under-reports by a factor of 10- to 100-fold* – that only 1%–10% of all serious vaccine injuries are recorded.<sup>103</sup> VAERS sensitivity to capture serious adverse events well-known to be caused by vaccines, namely anaphylaxis and Guillain-Barré syndrome, ranged from 12% to 76%, but mostly around 25% for several vaccines. In other words, an *underestimation factor of 4-fold*.<sup>104</sup>

These pharmacovigilance databases err decidedly on the side of underestimation, not overestimation.

In this context, the TGA confirms 14 of 1004 deaths (to 29 October, 2023) reported as potentially associated with the COVID-19 vaccines authorised in Australia,<sup>105</sup> which implies the other 990 deaths (98.6%) reported, mostly by clinicians,



**Figure 5.** Suspected deaths per million doses of vaccine. Distributed doses in millions. Traditional versus COVID-19 vaccines. From: VAERS Analysis<sup>43</sup> (with permission). See also supplementary materials for further information on this graph.

are attributable to an *overestimation factor*. The TGA dismissal of the severity of its own DAEN data is at odds with all prior research and with the active surveillance systems.

The active surveillance AusVaxSafety survey data showed a dose response effect of increased mRNA in the higher ratio of adverse events from Moderna than Pfizer COVID-19 vaccines and in the higher rate after the second dose that follows soon after the first. Graphical representations of the statistics reveal high rates of "missing work, study or routine duties". A graph from the AusVaxSafety survey for the Moderna vaccine<sup>101</sup> is presented in Figure 6. AusVaxSafety had a limited range of adverse events typical of reactogenicity to vaccines for respondents to select. Inability to perform normal activities is generally considered a criterion for serious adverse events, even though the survey did not specifically list them.

Educated hesitancy has been mocked. Figure 7 from the VAERS analysis data shows that the rate of adverse events per vaccine dose reported did not vary substantially across the age range. This contrasts with the severity of COVID-19 viral illness which was a relatively mild illness for younger age cohorts.

#### Pharmacovigilance and the future

Broadly, all pharmaceutical products are continuously experimental, observed and tracked by pharmacovigilance systems worldwide. The population ultimately becomes the long-term experiment.<sup>1</sup>

Gene-based medicine in blanket form, with mass production at extremely low cost, is expected to become a significant market trend.<sup>106</sup> With the many gene-based therapeutic technologies planned, a vast new era of pathology may lie ahead.

Time honoured medical ethics and the precautionary principle must be reasserted. Commercial pressure, distortion of evidence base, authority bias and groupthink bureaucratic lockstep policy, all mitigate against cautious, safe-practice medical science.

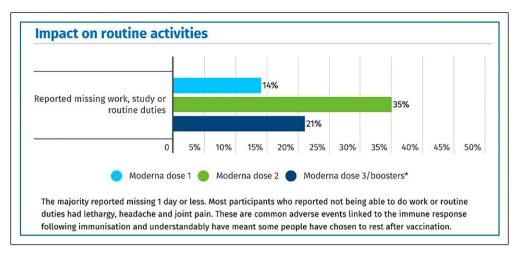


Figure 6. Impact on routine activities of Moderna doses 1, 2 and booster. AusVaxSafety data as January 26, 2023.<sup>101</sup>

Access to raw data, open discussion, freedom from censorship and heightened, active pharmacovigilance must be nurtured, if the health of humanity is to be better protected and if trust in the medical profession is to be fully restored.

## Limitations

In this selective narrative review, limitations are embodied in the very nature of our subject matter – an exploration of conflicts between scientific integrity, data transparency and timely action on pharmacovigilance and adverse events, versus corporate ambitions to advertise, compete and market pharmaceutical agents for financial gain. The authors acknowledge limitations of free access to confidential data, a reliance upon Freedom of Information requests (themselves dependent upon

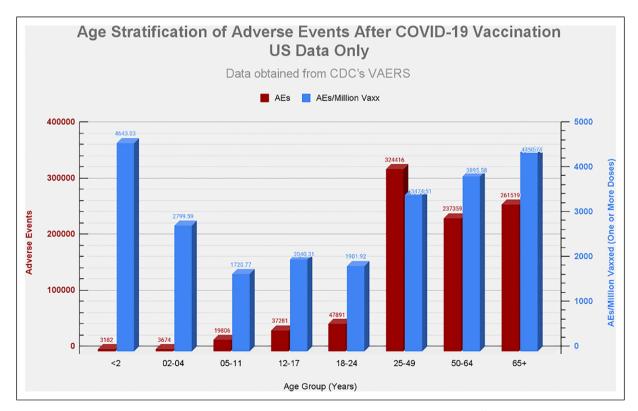


Figure 7. Age stratification of adverse events after COVID-19 vaccination. From: VAERS Analysis<sup>43</sup> (with permission).

the time, will and energies of interested parties), and of course dependency upon peer reviewed medical literature, an uncertain proportion of which has been shown to be unreliable, either because of exuberant optimism, publication haste or by deliberate design.<sup>25–28,30,32–35,57–74</sup>

The methodology for the graphs from https://www.vaersanalysis.info/ used in this paper, and limitations in the raw data used to compile those graphs, are described in the supplemental materials.

## Conclusion

The fullest context is one in which the pharmaceutical industry has provided many remarkable drugs for the benefit of humanity. From this backdrop, we have selected a few of the most significant events in pharmaceutical recall history, in which commercial interest has dominated market strategy, and we have sought to derive key lessons from these.

A host of mechanisms are used by the pharmaceutical industry to promote and market their products. These include changes to the definitions or boundaries of disease, introduction of bias long before data collection begins, concealment of raw data, failure to collect safety data, or decisions not to report negative or unfavourable results.<sup>33,89,90</sup>

Gene codes for foreign protein production throughout the body are particularly novel. Close attention to pharmacovigilance data is imperative. Failure to withdraw the gene-based COVID-19 vaccines from the market, despite clear indications of harms, is not without precedent – as has been seen with Merck's Vioxx (rofecoxib).

Excess mortality figures are high at present in many countries that have deployed the novel and experimental gene-based COVID-19 vaccines. As open-mindedness, objectivity and curiosity are essential to good science, we must immediately include new corporate products in our discussions about excess mortality and its possible causes. Drug recalls have been significant and numerous over recent decades. It may well be high time for the recall of still more.

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#### **Supplemental Material**

Supplemental material for this article is available online.

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## Thursday, September 12, 2024

# Updated Guidance for COVID-19 Boosters for the Fall and Winter 2024–2025 Season

**Tallahassee, Fla. –** The Florida Department of Health (Department) is reminding health care providers of the importance of remaining up to date with current literature related to COVID-19 vaccines and boosters, and the importance of providing patients with informed consent.

On <u>August 22, 2024</u>, the United States Food and Drug Administration (FDA) approved and authorized updated versions of mRNA vaccines from Pfizer-BioNtech and Moderna. The FDA approved the vaccine for people 12 and older and provided emergency use authorization for children 6 months to 11 years old. The stated target of these boosters is the Omicron variant which is not causing a <u>significant number of infections</u>.

The most recent booster <u>approval</u> was granted in the absence of booster-specific clinical trial data performed in humans. Furthermore, this booster does not protect against the currently <u>dominant strain</u>, accounting for approximately 37% of infections in the United States. There are currently limited data to inform whether these boosters offer any substantial protection against the virus and subsequent <u>circulating variants</u>. Although randomized clinical trials are normally used to approve therapeutics, the federal government has not required COVID-19 vaccine manufacturers to demonstrate their boosters prevent hospitalizations or death from COVID-19 illness.

Additionally, the federal government has failed to provide sufficient data to support the safety and efficacy of COVID-19 boosters, or acknowledge previously demonstrated safety concerns associated with COVID-19 vaccines and boosters, including:

- prolonged circulation of mRNA and spike protein in some vaccine recipients,
- · increased risk of lower respiratory tract infections, and
- increased risk of autoimmune disease after vaccination.

Health care providers are encouraged to share information in this guidance in discussions with patients regarding the mRNA COVID-19 vaccines and boosters.

Based on the high rate of global immunity and currently available data, the State Surgeon General advises against the use of mRNA COVID-19 vaccines. Any provider concerned about the health risks associated with COVID-19 for patients over the age of 65 or with underlying health conditions should prioritize patient access to non-mRNA COVID-19 vaccines and treatment.

#### Safety and Efficacy Concerns

Providers and patients should be aware of outstanding mRNA COVID-19 vaccine safety and efficacy concerns:

- The mRNA COVID-19 vaccines present a risk of <u>subclinical</u> and clinical <u>myocarditis</u> and other cardiovascular conditions among otherwise healthy individuals.
- The mRNA COVID-19 vaccine may be associated with an increased risk of <u>postural orthostatic tachycardia syndrome</u> (POTS).
- The mRNA COVID-19 vaccine may be associated with an increased risk of <u>autoimmune diseases</u> including systemic lupus erythematosus (SLE), rheumatoid arthritis, and psoriasis.
- Throughout the pandemic, studies across geographic regions found that the mRNA COVID-19 vaccines are associated with <u>negative effectiveness</u> after four to six months. As efficacy waned, studies showed that COVID-19 vaccinated individuals developed an <u>increased risk</u> for infection.
- <u>Elevated levels</u> of mRNA and spike protein from the mRNA COVID-19 vaccine <u>persist</u> among some individuals for an indefinite period, which may carry <u>health risks</u>.
- Potential <u>DNA integration</u> from the mRNA COVID-19 vaccines pose unique and elevated risk to human health and to the integrity of the human genome, including the risk that DNA integrated into sperm or egg gametes could be passed onto offspring of mRNA COVID-19 vaccine recipients.
- There is unknown risk of potential adverse impacts with each additional dose of the mRNA COVID-19 vaccine; currently individuals may have received five to seven doses (and counting) of this vaccine over a 3-year period.

Improving habits and overall health help manage and reduce the risk of heart disease, type 2 diabetes, and obesity, risk factors for serious illness from COVID-19.

The State Surgeon General and the Department continue to encourage Floridians to prioritize their overall health by:

- Staying physically active,
- Minimizing processed foods,
- Prioritizing vegetables and healthy fats, and
- Spending time outdoors to support necessary vitamin D levels.

From: bill teachingsmiles.com Sent: 2/21/2025 7:44:45 PM To: DOH WSBOH Cc: Subject: Utah Bans Fluoridation

External Email

Please pass this on to the Board Members,

https://le.utah.gov/~2025/bills/static/HB0081.html <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fle.utah.gov%2F~2025%2Fbills%2

Bill Osmunson DDS MPH

From: Derek Kemppainen Sent: 1/29/2025 12:34:24 PM To: Burnham, Brad H (DOH),DOH EPH DW Info,Helpling, Nina D (SBOH),DOH WSBOH,Schut, Andy (DOH) Subject: Fwd: Fluoride Memes (Another Conspiracy Theory Bites the Dust!)

External Email

Dear Washington State BOH / DOH / DWAG,

I wanted to pass along some memes I thought you and the science party / fluoridation review board might enjoy related to water fluoridation.

Derek Kemppainen

360-975-2011

------ Forwarded message -------From: Citizen Satirist <covidsteria@substack.com <mailto:covidsteria@substack.com> >

Date: Mon, Jan 27, 2025 at 6:02 AM To: <derekkempp@gmail.com <mailto:derekkempp@gmail.com> >

<https://eotrx.substackcdn.com/open?token=eyJtIjoiPDIwMjUwMTI3MTQwMTMyLjMuZmVIMWI4NDY0Mzdk IiwidSI6MjI2MTA0OTAsInIiOiJkZXJla2tlbXBwQGdtYWIsLmNvbSIsImQiOiJtZy1kMC5zdWJzdGFjay5jb20iLCJwJ WbNA0LKL1s>

Eats through concrete & steel BUT safe to drink. Why is it in our water (HINT: The government)? Nothing to see here folks (move along) & more fluoride memes as another conspiracy theory becomes true!

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CONSPIRACYsteria: Best Fluoride Memes (Another Conspiracy Theory Bites the Dust!) <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fapp-link%2Fpost%3Fpublication\_id%3D400307%26post\_id%3D154459094%26utm\_source%3Dpost-email-title%26utm\_campaign%3Demail-post-title%26isFreemail%3Dtrue%26r%3Ddgmd6%26token%3DeyJ1c2VyX2lkIjoyMjYxMDQ5MCwicG9zdF9pZCI0

government)? Nothing to see here folks (move along) & more fluoride memes as another conspiracy theory becomes true!

Jan 27

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fapplink%2Fpost%3Fpublication\_id%3D400307%26post\_id%3D154459094%26utm\_source%3Dsubstack%26is reaction%26r%3Ddgmd6&data=05%7C02%7Cwsboh%40sboh.wa.gov%7C32d4fea3e6074d9e55bc08dd40

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<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fopen.substack.com%2Fpub%2Fcc best-fluoride-memes%3Futm\_source%3Demail%26redirect%3Dappstore%26utm\_campaign%3Demail-read-inapp&data=05%7C02%7Cwsboh%40sboh.wa.gov%7C32d4fea3e6074d9e55bc08dd40a4501c%7C11d0e217

READ IN APP <https://substackcdn.com/image/fetch/w\_36,c\_scale,f\_png,q\_auto:good,fl\_progressive:steep/https%3A%</pre>

Oh what a difference a few months can make as now it's no longer conspiracy theory that fluoride lowers the IQs of children:

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b4842015622c%3Fj%3DeyJ1IjoiZGdtZDYifQ.geQYrNLIxrZwAPFV\_Xe5FCcYnyCnwfzLGCxNRvp-7JI&data=05%7C02%7Cwsboh%40sboh.wa.gov%7C32d4fea3e6074d9e55bc08dd40a4501c%7C11d0e2172

Conspiracy Fact? Higher Fluoride Levels Linked To Lower IQ Scores In Children, New Review Finds <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fredirect%2Fd16 4d70-413e-87ddafb8bc5c9e3f%3Fj%3DeyJ1IjoiZGdtZDYifQ.geQYrNLIxrZwAPFV\_Xe5FCcYnyCnwfzLGCxNRvp-

7JI&data=05%7C02%7Cwsboh%40sboh.wa.gov%7C32d4fea3e6074d9e55bc08dd40a4501c%7C11d0e217

The new analysis

<a href="https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fredirect%2F2d2">https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fredirect%2F2d2</a> ea11-4905-8c30-

d8cf00e36d63%3Fj%3DeyJ1IjoiZGdtZDYifQ.geQYrNLIxrZwAPFV\_Xe5FCcYnyCnwfzLGCxNRvp-7JI&data=05%7C02%7Cwsboh%40sboh.wa.gov%7C32d4fea3e6074d9e55bc08dd40a4501c%7C11d0e217 , published in JAMA Pediatrics on Monday, found that fluoride exposure exceeding 1.5 milligrams per liter (mg/L) was associated with reduced intelligence among children.

The study, conducted by the U.S. National Toxicology Program (NTP), took nine years to complete and is the largest meta-analysis <a href="https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fredirect%2F18c4728-4fcf-b341-">https%3A%2F%2Fsubstack.com%2Fredirect%2F18c4728-4fcf-b341-</a>

3b9acc5f51bd%3Fj%3DeyJ1IjoiZGdtZDYifQ.geQYrNLIxrZwAPFV\_Xe5FCcYnyCnwfzLGCxNRvp-7JI&data=05%7C02%7Cwsboh%40sboh.wa.gov%7C32d4fea3e6074d9e55bc08dd40a4501c%7C11d0e2172 to date on the health effects of fluoride.

The studies reviewed measured fluoride levels in drinking water and in urine. The authors used urinary fluoride as a proxy for total fluoride exposure.

74 Studies Reviewed

Among the 74 reviewed studies, 64 found that higher levels of fluoride exposure were linked to lower IQ in children. The strength of this association is considered moderate to large.

Thirty-one studies reviewed noticed a dose-response, such that increased fluoride levels in drinking water were linked to further decreases in children's IQ results.

REMEMBER: Its mostly the poor and minorities drinking fluorinated tap water. Rural folks have their own wells while rich white folks (and "rich persons of color...") drink filtered or bottled water...

And now for some fluoride memes...

Nothing to see here folks, move along:

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Stop thinking too much!:

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Ohhh:

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## External Email

Why is it that all health care providers, businesses, governments, and even the public have standards of care, policies to ensure quality care is the only care, regulations, requirements, and even procedures to follow.

Yet,

None of that applies to prisons, Inmates suffering while incarcerated, nor the vendors/contractors/"providers"? Not even actual employees, hired by the state of Washington to provide "essential and cost effective care" are held accountable. There's not even an agency to ensure that Inmates are actually treated humanely,, receiving quality care, in a timely manner.

## It's not right.

Noone should be stuck in solitary confinement for 29 days because the prison system "forgot" that the bone was protruding from your leg.

He should have been sent to the nearest hospital the day it was broken. Not shipped across the state, stuck in a punative area, and forced into solitary confinement, unable to make any calls, watch TV, or interact with other humans. No person should be forced into a cage and forgotten .about, ESPECIALLY not while their fibia and tibia are literally sticking out through their leg, forming external bone blisters and abscesses as the body attempts to battle infection & heal itself.

It's not right.

From: bill teachingsmiles.com Sent: 3/5/2025 3:06:04 PM To: DOH WSBOH Cc: Subject: Public Comment 3/12/25 Osmunson

External Email

Osmunson's Reasons 3,2,2025PDF Page 1 of 5

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From: shellies4@netzero.com Sent: 2/26/2025 12:19:09 PM To: DOH WSBOH Cc: Subject: Public Comments for the Environmental Health Committee

External Email

Dear Board,

I would just like to remind you that the PEOPLE of this state have vote DOWN Fluoride 3 separate times and we DO NOT WANT Fluoride in our drinking water! Thank you!

You guys are doing a great job! Have an amazing day! From: Derek Kemppainen Sent: 1/29/2025 1:09:09 PM To: Burnham, Brad H (DOH),DOH EPH DW Info,Helpling, Nina D (SBOH),DOH WSBOH,Schut, Andy (DOH) Cc: Subject: Fwd: Fluoridation - \$556 Per Person Per Year Net Economic Loss

## External Email

Dear Washington State BOH / DOH / DWAG,

I am writing to share an overview of a recent publication, "Community Water Fluoridation: A Cost-Benefit-Risk Consideration <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fonlinelibrary.wiley.com%2Fdoi%2 " by Osmunson and Cole (2024). This article highlights critical concerns about community water fluoridation (CWF), estimating a net economic loss of \$556 per person per year once the costs of harm are fully accounted for.

I'd encourage you to read the full article linked above, but here are a few of the main points:

Key Points

1. Cost vs. Benefits:

\* While cost savings of fluoridation are estimated at \$8-\$41 per person per year, these evaluations only consider benefits related to cavity prevention.

\* The analysis identifies costs related to harms such as dental fluorosis and reduced IQ that have never been included in previous economic assessments.

\* These omitted costs significantly outweigh any perceived benefits, challenging claims that fluoridation is cost-effective.

2. Developmental Neurotoxicity and IQ Loss:

\* Fluoride exposure has been linked to developmental neurotoxicity, with research showing a 3-point reduction in IQ among children in fluoridated areas.

\* Reduced IQ is correlated with a range of adverse societal outcomes, including:

- \* Increased rates of incarceration.
- \* Higher incidences of homelessness.
- \* Greater reliance on public assistance programs.

\* Diminished earning potential, estimated at a lifetime income loss of \$60,000 per individual exposed to fluoridated water.

\* Lower IQ also impacts broader societal productivity, weakening the "Hive Mind" effect that drives economic growth and technological innovation.

3. Dental Fluorosis: Prevalence and Costs:

\* Approximately 60% of U.S. children and adolescents exhibit dental fluorosis, with 95% of those affected desiring treatment for the condition.

\* Cosmetic and functional dental fluorosis treatment costs range from \$6,000 to \$72,000 per individual over a lifetime, depending on the severity.

\* Moderate to severe cases often require repeated treatments, including veneers, crowns, and other restorative procedures, which insurance typically does not cover.

\* Fluorosis not only imposes financial burdens but also negatively affects individuals' self-esteem and quality of life.

4. Global Comparison and Alternatives:

\* While over half of the U.S. population consumes fluoridated water, 97% of Europe has rejected this practice without experiencing higher rates of dental caries.

\* Alternative methods such as fluoride toothpaste, varnishes, and oral health education are not only more effective but also avoid the systemic harms associated with fluoridation.

\* Innovative options like fluoride-free biomimetic hydroxyapatite toothpaste are emerging as safer and sustainable choices for cavity prevention.

5. Ethical and Legal Considerations:

\* Fluoridation policies fail to account for individual differences in fluoride exposure, as water consumption varies widely between individuals and groups.

\* Vulnerable populations, including children, pregnant women, and those with preexisting health conditions, are at greater risk of harm.

\* The lack of randomized controlled trials on fluoridation safety raises significant ethical concerns about imposing such a policy without informed consent.

\* Unlike fluoride toothpaste, fluoridated water is not approved by the FDA and does not include dosage guidance or warning labels.

The article shows that the costs of harm, including dental fluorosis and developmental neurotoxicity, have been systematically ignored in previous evaluations of fluoridation. When these costs are factored in, fluoridation is not only ineffective but actively harmful to individuals and society.

Given these findings, I urge you to evaluate this question:

How can you demonstrate that fluoridation aligns with your responsibility to protect public health while acknowledging the net economic loss caused by water fluoridation via lowered IQ and dental fluorosis?

I look forward to your response,

Sincerely, Derek

Derek Kemppainen

360-975-2011

From: Arne Christensen Sent: 1/29/2025 3:42:50 PM To: DOH WSBOH Cc: Subject: Americans' Trust in Scientists, Positive Views of Science Continue to Decline

External Email

The Board of Health should read this item: https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.pewresearch.org%2Fscience% trust-inscientists&data=05%7C02%7Cwsboh%40sboh.wa.gov%7C3328fc6110854006cd0308dd40bea2c8%7C11d

-positive-views-of-science-continue-to-decline/

What do you think has happened in the 2020s to erode Americans' trust in science? Lying about covid and deploying vaccine mandates and other regulatory weapons under the guise of fighting covid just might be a contributing factor.

From: Emiley McCorkle Sent: 3/4/2025 3:55:02 PM To: DOH WSBOH Cc: Subject: My Public Comments

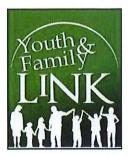
*attachments\31EF040A8B604532\_WA State Board of Health Support Letter for CWF.pdf* 

External Email

I've attached my letter for Community Water Fluoridation support.

Emiley McCorkle, Director of Operations Youth and Family Link (360) 423-6741 907 Douglas Street Longview, WA 98632

This email and any attachments to it may be confidential and are intended solely for the use of the individual to whom it is addressed. Please contact the sender if you believe you have received this email in error.



# Youth and Family Link

907 Douglas • Longview, WA 98632 Phone: (360) 423-6741 • Fax: (360) 501-6510

www.linkprogram.org

Washington State Board of Health 101 Israel Rd SE Tumwater, WA 98501

Dear Members of the Washington State Board of Health,

I am writing to express my strong support for community water fluoridation (CWF) as an essential public health measure that ensures equitable access to preventive dental care, particularly for underserved communities. As the Access to Baby and Child Dentistry (ABCD) Coordinator for Cowlitz and Wahkiakum Counties at Youth and Family Link, I have seen firsthand how oral health disparities impact families in our region. Maintaining fluoridation in public water systems is one of the most effective ways to prevent early childhood cavities and ensure that all children, regardless of income or background, have the opportunity for a healthy start.

Fluoride in public water systems is a cost-effective and scientifically proven method of reducing tooth decay. The Centers for Disease Control and Prevention has recognized fluoridation as one of the greatest public health achievements of the 20th century, benefiting individuals across all socioeconomic backgrounds. However, it is especially critical for families who face barriers to accessing dental care, including low-income households, rural communities, and communities of color. Many of the families I work with struggle to find pediatric dental providers, and the preventive protection that fluoridation offers is invaluable in reducing the need for expensive and invasive treatments.

The increasing political opposition to CWF is concerning, especially as misinformation continues to spread. I appreciate that the Department of Health is conducting a scientific review, and I hope that the process affirms what decades of research have already shown: that water fluoridation is safe, effective, and necessary.

I strongly encourage the Board to continue supporting fluoridation policies and to prioritize evidencebased decision-making in public health matters. Thank you for your time and consideration.

Sincerely,

nueuf McCarlee

Emiley McCorkle Access to Baby and Child Dentistry (ABCD) Coordinator Youth and Family Link Cowlitz & Wahkiakum Counties



# **Marcus DeHart**

**Communications Consultant** 

Marcus DeHart joined the Washington State Board of Health (Board) as a Communications Consultant for the School Rule Project on June 17, 2024. Marcus transitioned to a full-time staff position with the Board on February 18, 2025.

Before joining the Board, Marcus worked for Amazon as a Sr. Program Manager. In this role, Marcus supported a global editorial team through the development of processes, tools, and quality assurance. He used his expertise in communications to develop editorial workflows, collaborate with developers to build the team's content management system, develop training and documentation for tools and processes, and establish content quality control metrics and improvement plans. Before Amazon, Marcus' career encompassed many forms of communications ranging from writing, design, illustration, video, to animation, and a brief stint as the radio voice for Olympia's First Friday events.

Marcus grew up in Washington and graduated from Western Washington University in 1989, where he received his Bachelor of Arts in English with an emphasis on education. He lives in Olympia, Washington with his wife of 34 years and two adult daughters. During the pandemic, he took up pottery, and now partners with his wife's business to sell their creations.



### Crystal Ogle

Administrative Assistant

Crystal Ogle joined the Washington State Board of Health (Board) as an Administrative Assistant for the School Rule Project on June 17, 2024. Crystal transitioned to a full-time staff position on February 18, 2025. She is excited for the opportunity to continue supporting the important and extremely interesting work of the Board.

Crystal appreciates the opportunity to learn new things and work with new people. By training and education, Crystal is a Licensed Midwife in Washington State who will be retiring from practice. She holds a Bachelor of Science in Midwifery from the Midwives College of Utah and has a background in Social Justice work, board leadership, and secondary education.

Crystal lives on Whidbey Island with her family and enjoys time with her children, grandchildren, amazing husband, a growing herd of goats, and a flock of chickens.



### STATE OF WASHINGTON WASHINGTON STATE BOARD OF HEALTH

PO Box 47990 • Olympia, Washington 98504-7990

January 22, 2025

William Osmunson, DDS, MPH

Sent Via Email

Dear Dr. Osmunson:

This letter provides formal notice that the Washington State Board of Health (Board) denied your petition for rule making, submitted on November 24, 2024, at its regular business meeting on January 8, 2025, for the reasons described below.

The petition asked the Board to amend WAC 246-290-220, Group A Public Water Supplies - Drinking water materials and additives, by adding a new subsection (8) to the rule that would state: "[i]n keeping with the federal safe drinking water act S433 and the Food Drug and Cosmetic Act, Title 21, the Board does not recommend any substance be added to water with intent to treat humans, unrelated to treatment of water as defined in RCW 18.64.011(14)(15) or U.S. Code title 21, section 321(g)(1), unless approved by the Food and Drug Administration in compliance with the U. S. Food, Drug and Cosmetic Act. This recommendation does not apply to substances added to water to make water safer as determined by the U.S. Environmental Protection Administration in compliance with the Safe Drinking Water Act."

Prior to the meeting, Board members were provided with the petition and all supporting materials. These materials were also included in the Board's meeting materials and posted to the Board's website. At the Board meeting, Board staff provided an overview of the topic including information about the scope and intent of the existing rule and discussed policy recommendations resulting from a series of workshops in 2015. Assistant Secretary Lauren Jenks with the Department of Health provided additional background information on work underway to review recently emerging science related to fluoride.

Board members stated that they support the upcoming review being conducted by the Department of Health. Members noted that they are interested to see the outcome of the technical review of the NTP Monograph before considering whether any changes to the drinking water rules are warranted. Board members asked that the Department provide the Board with a report explaining the findings of the review and noted that it may prompt an internal review of existing policy recommendations to align with new information. Members noted interest in hearing about new or innovative information

January 22, 2025 Page 2

since the last policy recommendations were made. Board members further affirmed that Board work on oral health is something it will continue to review.

The Board has asked staff to provide additional information and policy recommendations at the completion of the review being conducted by the Department of Health.

Available options for appeal or other review may be determined by consulting the Administrative Procedure Act, chapter 34.05 RCW.

Sincerely,

Path, Hayes

Patty Hayes, MPH Chair

# WASHINGTON STATE BOARD OF HEALTH

### HEALTH PROMOTION COMMITTEE SPECIAL MEETING SUMMARY NOTES

What: Health Promotion (HP) Committee

When: February 27, 2025

**Attending:** Board of Health (Board) Members Dimyana Abdelmalek (Committee Chair); Mindy Flores, Patty Hayes, Steve Kutz, and Peter Browning; Board staff Molly Dinardo, Andrew Kamali, Michelle Davis, Kelly Kramer, Nina Helpling, Anna Burns, Michelle Larson, Shay Bauman, and Ash Noble; Department of Health (Department) staff; Samantha Fuller, approximately four members of the public also attended the meeting.

#### Summary Notes:

#### Legislative Session Update

- Michelle Davis, Board Executive Director, shared an update on the current Legislative Session and upcoming cutoffs. Executive Director Davis also briefly discussed Governor Ferguson's budget plan, announced earlier in the day. The Governor's budget plans to reduce the Federal Public Health Service dollars by \$50 million annually.
- Steve Kutz, Committee Member, asked whether the Board's budget would be affected by the Department of Health's (Department) budget proposal. Executive Director Davis responded that it would not.
- Executive Director Davis discussed a few key bills the Board is tracking.
- Executive Director Davis shared that the Washington State Public Health Association is hosting an education day for "public health day" on the Hill on March 6.
- Molly Dinardo, Board staff, summarized the number of bill analyses staff have completed and how many bills are being tracked.

#### **Preview March and April Board Meetings**

- Dimyana Abdelmalek, Committee Chair, announced the dates and locations for the March and April Board meetings.
- Board staff then provided an update on HP-related agenda items expected to be discussed at the March and April meetings.
- Andrew Kamali, Board staff, shared a high-level overview of the status of the School Rules project, recent developments, and what Committee Members can expect for the March and April meetings.
- Nina Helpling, Board staff, reported on the School Rules process. Nina shared that their team has resolved much of the rule language with Technical Advisory Committee (TAC) members, completed a draft fiscal analysis (currently being

(Continued on the next page)

Health Promotion Committee Special Meeting Summary Notes Page 2

refined), held community listening sessions, and is finalizing the environmental justice assessment and final report for the Legislature.

- Andrew strongly encouraged Board Members to attend the April TAC meeting in person to engage with members from the state's education and public health sectors.
- Patty Hayes, Committee Member, thanked the School Rules TAC and its members and encouraged Board Member attendance in person.
- Hannah Haag, Board Staff, previewed the 2026 State Health Report (SHR) Planning. The team plans to involve community voices earlier and adopt a core team model for report development. Hannah asked Board Members to consider sponsoring the report and integrating it with the Board's other work.
- Member Hayes highlighted the current challenges for public health at the state and federal levels, noting that the SHR provides a key opportunity to frame discussions, especially with the state budget crisis and other compounding issues. Member Hayes highlighted that we must address the impact of federal disruptions on people's health.
- Executive Director Davis noted that this aspect had not been considered for the upcoming report. Executive Director Davis also shared that the Department is working on the State Health Improvement Plan (SHIP). As part of this work, Executive Director Davis is involved in the SHIP Alliance, which is currently developing priorities for the report. Executive Director Davis added that funding for FPHS has allowed local health jurisdictions to complete community health assessments and plans, which could be tied into the SHR.
- Member Hayes expressed concern that with a new Secretary and ongoing disruptions at the federal level, local community health assessments and reports may focus solely on past data, overlooking current and future impacts. Member Hayes emphasized the need for more urgent community engagement and a shift in approach to address current challenges.
- Chair Abdelmalek agreed, noting reduced participation in some settings. Survey responses for the point-in-time count were fewer than in previous years. Chair Abdelmalek emphasized that it's crucial to ensure that data is representative of community needs. Chair Abdelmalek said that in public health, we must build trust and work with trusted community messengers.
- Hannah confirmed that staff will focus on working with community messengers and trusted voices. Hannah added that the 2024 SHR included a community responsiveness summary, and the team aims to expand this by gathering more feedback.
- Executive Director Davis asked whether community health assessment and improvement plan information are centralized anywhere.
- Chair Abdelmalek questioned whether the Department tracks this information and whether different FPHS groups could assist.
- Member Kutz noted that this report can impact all aspects of the system and, if done correctly, is much larger than just the Department or the Board.
- Mindy Flores, Committee Member, shared insights from the previous SHR, highlighting areas where more impactful work can be done.

Health Promotion Committee Special Meeting Summary Notes Page 3

- Member Kutz suggested tracking issues that move in the wrong direction, such as programs being removed, to identify necessary adjustments (e.g., school-based immunizations).
- Kelly Kramer, Board Staff, provided updates on the Newborn Screening Project for the March and April meetings. In January, the Board and Department convened a TAC on Branched Chain Ketoacid Dehydrogenase Kinase Deficiency (BCKDKD), which recommended not adding BCKDKD to the state's mandatory newborn screening panel at this time. In March, the Board will review updates recommended by the TAC to the newborn screening criteria and will receive a draft legislative report on BCKDKD in April. The TAC also began rereviewing Congenital Cytomegalovirus in February and will conclude this review by the end of March.
- Molly shared updates on the Board's Auditory Screening rulemaking work. Molly reminded committee members that the Board is considering adding otoacoustic emission screening technology (OAE) as an approved screening technology and making other necessary updates. The draft proposed rules will be sent for informal comment soon, with a briefing for Board Members in April and a potential hearing in June.

#### **Rulemaking and Other Project Updates**

• Molly provided updates on the Board's active rulemaking projects for newborn screening, vital statistics, and auditory screening standards and shared information about an upcoming rulemaking project.

#### **Discuss Committee Leadership**

- Chair Abdelmalek announced that they will be transitioning back to clinical work, focusing on serving the underserved next week, and will no longer be a Board member. However, they will continue to support the Board's work as a community member.
- Member Hayes expressed deep gratitude for Chair Abdelmalek's contributions, highlighting Chair Abdelmalek's role in enhancing engagement and communication between the Board and local health officers.
- Member Flores thanked Chair Abdelmalek for sharing their expertise, providing valuable lessons, and being a patient and great teacher.

#### **Committee Member Comments, Questions, and Next Steps**

• The next Health Promotion Committee meeting is scheduled for Thursday, May 1, from 2-4 p.m.

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 <u>wsboh@sboh.wa.gov.</u> TTY users can dial 711

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



### Pro-Equity Anti-Racism (PEAR) Strategic Action Plan







Washington State Board of Health

January 2025

### **Table of Contents**

| Washington Board of Health Statement   | 3  |
|--|----|
| Informing the Plan: Identified Issues and Impacts  | 5  |
| Engagement - Limitations and Opportunities<br>Root Causes of Health and Other Inequities<br>Addressing Key Concerns<br>Barriers, Challenges, and Solutions             |    |
| PEAR Strategic Action Plan:  |    |
| Goals, Objectives, Actions, and Performance Measurements   | 9  |
| Goal 1: Create avenues for communities to participate and<br>inform Board activities.  |    |
| Goal 2: Build relationships with Tribes, community-based<br>organizations, and Washingtonians.   |    |
| Goal 3: Ensure hiring and professional development activities<br>increase Board and Board staff understanding of equity<br>and anti-racism principles by January 2027. |    |
| Appendices   | 14 |
| Team Members   |    |
| PEAR Plan Components   |    |

### 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.

To request this document in another format, call (360) 236-4110. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email <u>wsboh@sboh.wa.gov</u>

For more information or additional copies of this report, contact Board of Health Staff at <u>wsboh@sboh.wa.gov</u>

## WASHINGTON STATE



### Statement on Pro-Equity, Anti-Racism

For years, the Washington State Board of Health has recognized the need to focus on and accelerate diversity, equity, and inclusion initiatives to help advance health equity and wellbeing for all Washingtonians. The State Board of Health's mission is to provide statewide leadership in advancing policies that protect and improve the public's health. The Board achieves this mission by monitoring the public's health to understand and prevent disease across the state; serving as a public forum to engage the public in policy development; and adopting foundational public health rules that prevent disease, promote public health, and keep people safe.

Board staff have been working on thoughtful community, Tribal, and other partner engagement through multiple projects and policies. The development of the Pro-Equity, Anti-Racism (PEAR) Strategic Action Plan gives staff the opportunity to become more intentional with our equity work. Most differences in health status and outcomes are due to systemic inequities, which refers to how unequal and unfair distribution of resources across society creates worse health outcomes for certain communities, including but not limited to communities who are Black, Indigenous, and People of Color, LGBTQ+, individuals with disabilities, those with limited English proficiency, and refugee and immigrant communities. These health inequities are often a result of laws and other policies that intentionally or unintentionally favor/prioritize some communities over others. Board Members and staff recognize that barriers to public participation in policy development, language access, lack of trusting and authentic relationships with community-based organizations and Tribes, and adequate workforce training and development often contribute to or exacerbate existing inequities.

In 2022, Governor Jay Inslee issued <u>Executive Order 22-04</u>, which directs state agencies, boards and commissions to implement the <u>Washington State Pro-Equity Anti-Racism Plan and Playbook</u>. The PEAR strategic plan intends to drive changes in systems, policies and practices by addressing upstream, root cause issues that perpetuate systemic inequities. This executive order provides the Board with resources to elevate this work and create a transparent and actionable plan. The plan details how the Board can move closer to becoming an equitable government agency and ultimately enable all people in Washington to flourish and thrive.

This strategic action plan exists to guide our work and create meaningful, positive changes for and with communities who are disproportionately affected by systemic inequities. Because equity is in the details, it embeds equity into our decision-making, policy planning and development, and public meetings and engagement. Coordinated and culturally responsive engagement strategies will improve the Board's ability to have key messengers from multiple communities - who have been historically and are currently at a disadvantage - share their perspectives and voices heard, thus moving the Board closer to equitable rulemaking practices. Additionally, there will be a focus on investing in a workforce that represents communities most impacted by our policies, while expanding staff and Board Members' knowledge of pro-equity and anti-racism principles. This plan centers communities from across Washington state, creating an internal environment that allows the unique innovations, lived experiences and voices of diverse, multicultural perspectives to inform our work. By creating a foundation for pro-equity anti-racism work, future iterations of the plan will dive deeper by continuing to enhance access, equitable rulemaking, and professional development, with community voices at the center. The PEAR Strategic Action Plan is an evolving document that will be reviewed every year to ensure we are following through with our commitments, continuing to assess our equity impact, making informed investments, being transparent and accountable, and shifting practices as necessary.





### Informing the Plan: Identified Issues and Impacts

The Washington State Board of Health (Board) has completed the baseline equity review of our agency's core business areas to determine where needs are greatest. The PEAR Team reviewed the Board's work and took an inventory of current equity efforts. The Team then reviewed and analyzed gaps in equitable service and grouped identified gaps into buckets. Those buckets then informed goals, objectives, actions and performance measures.

### Engagement-Limitations and Opportunities

The Board has existing relationships with community partners and has been in conversation with them through additional projects, such as the development of the <u>State Health Report</u>. Trusted messengers from community-based organizations, participants of previous panels, Board Members, and Board staff had the opportunity to identify and discuss root causes for inequities, as well as talk about possible next steps to help inform the draft plan.

The Board of Health was unable to consult and/or collaborate with Tribal governments and Recognized American Indian Organizations. This is because the Board had a shortened timeline to develop its first plan. The Board recognizes a gap in connections with Tribes and Native communities. As a result, the Board has been working on making connections with Tribes during this process and has identified investing in relationships with Tribes as well as Urban Indian Health Organizations as a key goal. We will work in collaboration with Tribes and Urban Indian Health Organizations when completing objectives and for future strategic plan iterations.

### **Root Causes of Health and Other Inequities**

The Board intends to decrease root causes of inequities in our work - and by extension public health at large - by improving access to government practices, information, and participation and by increasing engagement in agency policy and rule development that address the broader factors influencing health and health outcomes. Additionally, the Board wishes to address workforce inequities and enhance community engagement knowledge, skills, and abilities among all staff. These investments can have a positive impact on communities and community members who experience systemic racism, social and economic exclusion, discrimination, exploitation, and other forms of oppression based on several factors like age, disability, education, geographic location, language/literacy, experience in/with the criminal legal system, gender identity, sexual orientation, housing, national origin, race/ethnicity, and socio-economic status.

Barriers related to language services and accessible meeting locations have prevented individuals and communities from participating in government forums and policy decisions. Without the ability to participate in a public forum, participants and attendees, particularly from historically underserved and marginalized communities, have been unable to engage in policy

decisions, bring forward policy ideas, and share health topics that affect them and the communities they live, work, and play in. The Board and the work it does in and for Washington state also lack visibility in many communities. Community members shared the importance of connecting with the Board and its work. Although the Board is a public forum, the lack of visibility in communities and the culture of using technical and academic public health language remains a barrier.

Board Members and Board staff identified a need for professional development and hiring practices that elevate equity, social determinants of health, and the ability to authentically connect with and listen to communities with cultural humility. Staff acknowledged the need for training and professional development centered on equity, so Board Members and staff alike can build stronger relationships and make collaborating with the Board a less intimidating process.

Trusted community messengers shared that broader efforts towards language justice are connected to staff development and training. When staff are trained in principles of language justice and access, it can foster trust and safety with community members by developing inclusive communications; increasing awareness of power imbalances between government and community and the work needed to reduce them; and enhanced understanding of cultural contexts, nuances and cultural humility, just to name a few. Other community members noted that a lack of trusting relationships between the Board and community is reflective of ineffective engagement practices. This lack of trusting relationships highlights the need for investing time in and with communities around the state.

### **Addressing Key Concerns**

**Access barriers:** All work identified in the Board's PEAR Plan will follow the State Department of Health and Office of Equity language access guidelines. Language access should be present and consistent throughout all our written and spoken work. This will ensure our documents and materials are clear and understandable and can increase engagement in Board activities. This will require creating policies and procedures related to accessible meetings, materials, and addressing language needs.

**Meeting venues:** When state budget allows, meetings will be held in spaces that match agenda topics and the interest/priority of community members. Meetings will be held in spaces that are reflective of Board agenda topics, accessible, and welcoming spaces. The goal is to create an environment for individuals to attend meetings and engage with our work more easily, instead of expecting community members to travel to us. We will ensure our public-facing activities are proactively inclusive for all to attend by providing language interpretation services, compensation

for community members' time and attendance, having inclusive and accessible presentation standards for materials and presenters, and creating mechanisms for broader public input.

**Community and Tribal engagement:** The Board can further strengthen relationships by ensuring we intentionally build and maintain them, are inclusive in our rulemaking process, and proactively meet Tribes and communities where they are. Our investments and engagement can bring diverse community voices to the table during the rulemaking process. Because of our renewed focus on cultivating new and ongoing relationships, we will be able to better identify and reach community groups who wish to be present during Board activities. Developing community and Tribal engagement procedure guides can improve connections with communities and Tribes alike and facilitate meaningful information reaching Tribal and community leaders. This will require Board staff to create practical policies and procedures for community engagement, Tribal engagement, government-to-government work, and equitable rulemaking.

**Professional development:** Investing in community relationship training for Board Members will help them engage with communities and Tribes in ways that avoid perpetuating harm. Additionally, the Board will invest in professional development for staff that centers equity and engagement in practice. Researching and implementing updated hiring best practices can help promote equity by reaching and recruiting highly qualified candidates from diverse backgrounds, identities and lived experiences, while still maintaining compliance with state and Department of Health requirements. This will require a review of existing internal hiring practices and may include, as one example, recommendations for additional job postings and outreach through non-traditional channels. By providing focused education and training around equity and engagement-related activities, Board Members and Board staff will be better prepared to collaborate with community groups who are currently and have been historically marginalized.

### Barriers, Challenges, and Solutions

**CLAS assessment:** Currently, the Board lacks capacity to conduct a Culturally and Linguistically Appropriate Standards (CLAS) assessment. Without this assessment, some barriers to community participation will likely remain. The Board will need to request additional funding to hire an outside contractor or consultant to complete a CLAS assessment and make recommendations.

**Rulemaking process:** Communities have requested a co-creation role in the rulemaking process. However, the Board's rulemaking must follow the Administrative Procedures Act, which may limit the ability for meaningful community co-creation. The Board will need to find creative ways to develop equitable policy and rules while maintaining authentic relationships with Tribes

and communities. To address this issue, the Board has started using Community Responsiveness Summaries. These summaries help determine if community participants felt that the Board was responsive to their needs. Community members reflect on successes and difficulties faced while working with the Board, and that information is used by the outreach coordinator to hold conversations and adjust future engagement strategies. The Board will continue to use these and responsiveness feedback surveys that can collectively help address this challenge.

*Human resources:* The Board of Health has a memorandum of understanding with the Department of Health for recruitment, hiring, and other human resources needs. As a result, the Board does not have control over many of its human resources practices. The Board will need to evaluate areas where equity- and access-focused changes can be made to these practices.





### **PEAR Strategic Action Plan:**

Goals, Objectives, Actions, and Performance Measures



Create avenues for communities to participate and inform Board activities.

- Objective 1.1: Ensure that language access is present and consistent in all our written and spoken work by January 2027.
  - Action 1: Complete a Culturally and Linguistically Appropriate Standards (CLAS) assessment of our public-facing communications and materials.
    - Performance Measurement 1: Complete a CLAS assessment, contingent on the availability of state funds, with an external consultant by the end of 2025.
  - Action 2: Ensure translations of primary and secondary documents are accurate and culturally appropriate according to CLAS procedures identified in our CLAS assessment.
    - Performance Measurement 2: Track compliance with CLAS recommendations and maintain an 85% or higher compliance rate prior to January 2027.
  - Action 3: Communications will "plain talk" all our external-facing public communications, such as presentations, documents, websites, and summaries, using internal guidance documents.
    - Performance Measurement 3: Guidance around plain talked presentations, documents, websites, and summaries will be created in collaboration with the executive director, deputy director, equity and engagement manager, and communications manager and will be in use by all staff by January 2026.
  - Action 4: The equity and engagement team will develop internal guidance documents, setting language access standards for Board work, prior to January 2026.
    - Performance Measurement 4: Guidance documents shared with agency partners on a regular basis, including for all presenters at Board meetings, and used in conjunction with other agencies' best practices by January 2026.

### • Objective 1.2: Ensure our meeting spaces reflect the topics we work on and communities who may be directly affected by our work by January 2026.

 Action 1: The equity and engagement team will establish, implement, and consistently use meeting scoping procedures to ensure the Board meets in community spaces that remove access barriers and promote equity.



- Performance Measurement 1: The equity and engagement team will develop a meeting location scoping form, with 90% use by January 2026.
- Action 2: Admin will incorporate meeting space location scoping procedures into internal staff pre- and post-meeting evaluations, by creating a form to evaluate Board meeting spaces during briefings and debriefings.
  - Performance Measurement 2: The equity and engagement team will develop a meeting location scoping form, with 90% use by January 2026.
- Action 3: Outreach coordinators will support opportunities for Board Members and Board staff to be more visible and accessible in communities, using guidance documents created by the equity and engagement team prior to January 2026.
  - Performance Measurement 3: The equity and engagement team will support and document Board Members and Board staff visits to 85% of the state's counties by January 2026, as funding allows.

### Objective 1.3: Ensure all public activities are proactively inclusive of impacted, nonregulated parties by January 2026.

- Action 1: The equity and engagement manager will ensure the community compensation process is standardized and applied broadly across all Board work.
  - Performance Measurement 1: The equity and engagement manager will create internal guidance documents for staff and provide training for all staff on use of these tools prior to January 2026. These documents should be in use by all staff prior to January 2026.
- Action 2: The equity and engagement team will create and implement accessibility and equity standards for presenters, such as verbal delivery and presentation standards, at Board meetings prior to January 2026.
  - Performance Measurement 2: Verbal delivery and presentation standards will be created and in use for all Board meetings prior to 2026.
- Action 3: The equity and engagement manager will review current practices and make recommendations to the Board to increase access to public comment period and rulemaking processes, including expanded timelines to incorporate Disability Justice practices into the Board's public activities prior to July 2025.
  - Performance Measurement 3: The equity and engagement manager's recommendations will be presented to the Board prior to July 2025.



Build relationships with Tribes, community-based organizations, and Washingtonians.

### • Objective 2.1: Center community partnership during rule development by January 2027.

- Action 1: Board staff will review current rulemaking policies and procedures with an equity lens to ensure they are creating equitable, accessible opportunities for participation.
  - Performance Measurement 1: Staff's recommendations for increased equity and accessibility will be presented to policy advisors by June 2026. Policy advisors will demonstrate at least four different methods of community engagement employed for each rulemaking project.
- Action 2: The equity and engagement team will review and update the Board's review tool in partnership with impacted communities to assess draft rule language for likely equity impacts.
  - Performance Measurement 2: Draft "Rule Language Assessment Tool" will be presented to policy advisors by June 2026.
- Action 3: Policy advisors or project managers will coordinate with community engagement staff to ensure people with direct lived experiences are equitably included on our Technical Advisory Committees (TACs) and in other rulemaking activities.
  - Performance Measurement 3: Community engagement staff will create guidance and minimum participation requirements for Board staff. This guidance and related requirements will be in use by all policy and management staff by June 2026.

• Objective 2.2: Develop new and ongoing relationships with communities who are currently and have been historically marginalized and oppressed by January 2027.

- Action 1: The equity and engagement team will create and maintain a community engagement database to coordinate engagement with community across all Board staff by January 2026.
  - Performance Measurement 1: The equity and engagement team will document usage standards and provide training on use of the database for all policy and management staff by June 2025. The team will track engagement opportunities and total engagement numbers on a yearly basis.
- Action 2: All Board staff will engage with community-based organizations and other trusted messengers prior to all Board activities, such as using social media, emails, community events, and other culturally responsive and accessible avenues.
  - Performance Measurement 2: Outreach guidance and minimum standards will be created by equity and engagement staff and in use by all staff prior to June 2026.

- Action 3: The equity and engagement team will create opportunities for Board Members to interact with and build relationships with communities, including community panels at Board meetings, and document a process by January 2027.
  - Performance Measurement 3: Guidance and process documentation will be created by June 2026. Once documents are created, Board Members and staff will be trained by January 2027. Equity and engagement staff will facilitate at least three opportunities for Board Members to interact and build relationships with communities by January 2027.
- Objective 2.3: Build stronger ties with sovereign Tribes, Tribal organizations, and Tribal communities by January 2026.
  - Action 1: The Tribal liaison will create a Tribal engagement plan that centers Tribal sovereignty for the Board by January 2026.
    - Performance Measurement 1: A draft Tribal engagement plan will be presented to Board members by October 2025 for comments and approval.
  - Action 2: The Tribal liaison will provide guidance to Board Members and staff around the Board's Tribal engagement procedures and processes by July 2026.
    - Performance Measurement 2: The Tribal liaison will create written guidance and procedures and provide them to Board Members and staff by July 2026. The liaison will provide training to Board Members and staff on this guidance by October 2026.
  - Action 3: Board staff will provide quarterly updates to Tribal partners that are intentional and meaningful, as identified by the Tribes, by July 2026.
    - Performance Measurement 3: The Tribal liaison will ask for feedback and direction from Tribal partners, by July 2026.



Goal 3:

Ensure hiring and professional development activities increase Board and Board staff understanding of equity and anti-racism principles by January 2027.

### Objective 3.1: Provide additional opportunities for candidates from marginalized backgrounds to consider working at the Washington State Board of Health by January 2027.

- Action 1: The executive director, or designee, will document at least two new job posting opportunities, beyond traditional avenues, prior to January 2025.
  - Performance Measurement 1: The deputy director will provide written documentation of new job posting opportunities by January 2025.
- Action 2: The executive director, or designee, will research and incorporate recruitment processes and best practices intended to remove biases and promote a representative and inclusive workforce by January 2026.
  - Performance Measurement 2: The deputy director will document changes to hiring processes and practices by January 2026.
- Action 3: The executive director, or designee, will write guidance for hiring managers and panels intended to remove biases and promote equity, including intersectionality on the hiring panel, by January 2027.
  - Performance Measurement 3: The deputy director will document changes to hiring processes and practices by October 2026.

### • Objective 3.2: Invest in Board staff professional development and retention by providing equity-centered education and training by January 2027.

- Action 1: The equity and engagement manager will provide, or arrange, quarterly training on topics such as: anti-bias, cultural humility, pro-equity and anti-racism, etc. prior to January 2027.
  - Performance Measurement 1: The deputy director will set aside funding from the Foundation Public Health Services equity and engagement fund for ongoing training prior to July 2025.
- Action 2: The equity and engagement team will provide training for Board Members and staff on the Board's approach to engaging with communities, by providing on-boarding training and quarterly training to both Board Members and staff, prior to January 2027.
  - Performance Measurement 2: The equity and engagement team will provide learning and growth surveys to assess Board Members and staff knowledge on community engagement strategies and change in understanding, at the end of training and professional development opportunities for both Board Members and staff.



### Appendix A

### **Team Members**

### **Board of Health Members**

Patty Hayes, Board Chair Paj Nandi, Board Member and Sponsor

### **Board of Health Staff**

Michelle Davis, Executive Director Ashley Bell, Deputy Director Melanie Hisaw, Executive Secretary Cait Lang-Perez, Health Policy Analyst Molly Dinardo, Policy Advisor Shay Bauman, Policy Advisor Hannah Haag, Community Outreach Coordinator Michelle Larson, Communications Manager

### **Governor's Interagency Council on Health Disparities Staff**

LinhPhụng Huỳnh, Health Disparities Council Manager Jo-Ann Huynh, Administrative Coordinator

### **External Partners**

Dominique Horn, Southwest Accountable Community of Health Mohamed Shidane, Deputy Director, Somali Health Board Zeenia Junkeer, Mount Baker Foundation

### **State Agency Partners**

Office of Equity Washington State Department of Health





### Appendix B

### **PEAR Plan Components**

The PEAR Plan requires that agencies make investments in key responsibility areas. These investments identify service lines that have the potential to positively contribute to determinants of equity. The Board has core business responsibilities in **communications**, **engagement**, and **policy** development, and an internal focus on human resources and professional development so staff can assist in achieving the Board's mission. The PEAR Playbook and Office of Equity website has additional information on these areas.

#### **PEAR Service Line**

The Office of Equity provides statewide guidance on creating PEAR plans. To see the whole list of PEAR Services Lines, or for more information about their guidance, <u>click here to see Office of</u> <u>Equity materials</u>.

The Board's PEAR Team has identified these service lines as where the Board needs to make the greatest changes.

- Engagement & Community Partnerships
- Public Communications & Education
- Plans, Policies, and Budgets
- Policy Agenda
- Tribal Government Relations
- Leadership, Operations, & Services
- Workforce Equity
- Capacity Building

### **PEAR Determinants of Equity**

These have been identified as PEAR Determinants of Equity that are supported by investments in core business areas. For more information, <u>click here to see Office of Equity guidance</u>.

- Community & Public Safety
- Equity in State & Local Practices
- Healthy Built & Natural Environments
- Health & Human Services
- Housing & Home Ownership
- Parks, Recreation & Natural Resources
- Equity in Jobs & Job Training

Washington State Board of Health



### **PEAR Determinants of Equity Groups**

The Office of Equity has identified Determinants of Equity (DoE). From their full list of DoE, the Board's PEAR Team has identified the following DoE as areas that will be strengthened by the work of this PEAR Plan. For more information, <u>click here to see Office of Equity guidance</u>.

- Soil & Nutrients Government practices
- Root System Community Infrastructure
- Trunk Community support systems
- Branches Family support systems





### **2024 Variance Report**

### Summary of Variances to WAC 246-260

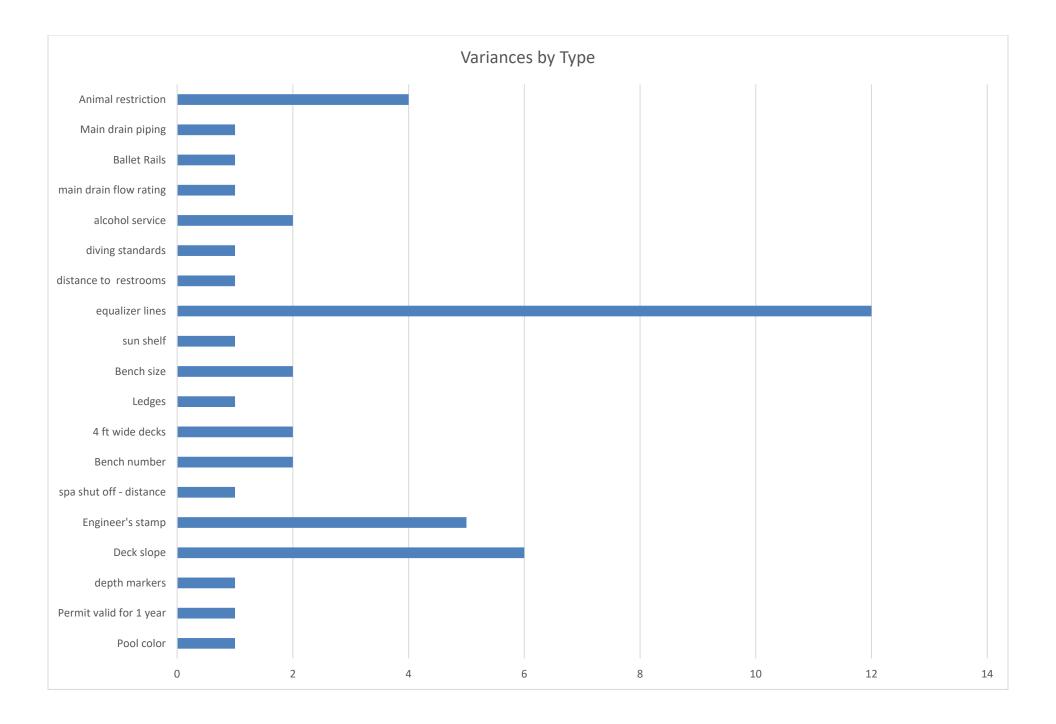
This is the annual report to the State Board of Health providing a summary of the variances processed in 2024 as stipulated in WAC 246-260-201(2). Under this authority, the Department of Health (DOH) and local health officers review and approve or deny variances to the design, construction, and operation requirements related to water recreation facilities. The approved variances reflect an applicant's ability to provide adequate documentation that the variance to the rule is consistent with the overall intent of the chapter and our goal of providing a safe environment for users.

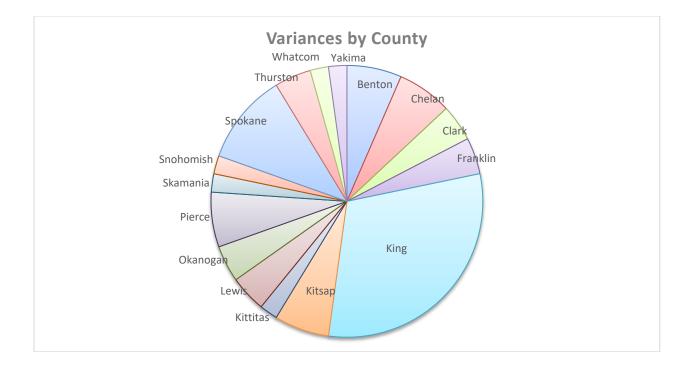
Annual reports were received from 36 of the 39 local health jurisdictions. Six local health jurisdictions processed variance requests: Clark County Public Health (CCPH), Tacoma-Pierce County Health Department (TPCHD), Public Health Seattle King County (PHSKC), Snohomish County Health Department (SCHD), Spokane Regional Health District (SRHD), and Kitsap Public Health (KPH) in addition to those processed by DOH. Forty-six variances were approved in 2024: CCPH granted 2; PHSKC granted 14; SRHD granted 5; SCHD granted 1; KPH granted 1 and DOH granted 20.

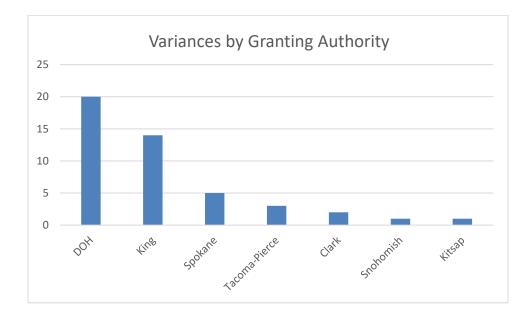
The most common variance in 2024 was for modifying skimmer equalizer lines to comply with suction entrapment prevention requirements. Twelve variances were granted for removal of skimmer equalizer lines (WAC 246-260-031(8)(d)(iii)). Six variances were granted to allow pool deck slopes of less than  $\frac{1}{2}$  inch per foot; these were granted to comply with ADA access requirements. Five variances were granted to allow for simple projects to be reviewed without the need for engineered plans. And 4 variances were granted in Spokane County, where end-of-season dog swims continue to be popular, to allow animals in pools.

This report is not required to include variances granted by the Board of Health. In a desire to be thorough, we remind the board that 6 variances for water features regulated under Chapter 246-262 WAC, Recreational Water Contact Facilities, were also granted by the BOH.

The following pages provide additional details on variances granted under Chapter 246-260 WAC, Water Recreation Facilities in 2024.







|          | Variance Details   |   |                               |  |   |          |  |  |  |  |
|----------|--------------------|---|-------------------------------|--|---|----------|--|--|--|--|
| County   | Granting<br>Entity | Name                                    | WAC                           | Descriptor   | Mitigation Proposed   | Action   |  |  |  |  |
| Lewis    | DOH                | Pleasant<br>Valley<br>Christian<br>Camp | WAC 246-<br>260-<br>031(6)    | Pool Color   | Lifeguards  | Approved |  |  |  |  |
| Skamania | DOH                | Tenzen                                  | WAC 246-<br>260-<br>021(7)    | DOH may grant construction permit renewals which are valid for one year.   | Final construction permit extension.  | Approved |  |  |  |  |
| Chelan   | DOH                | Wenatchee<br>Valley<br>YMCA             | WAC 246-<br>260-<br>041(8)(b) | Pool depth markings located on the<br>horizontal surface of pool coping or deck of<br>pools within eighteen inches of the water's<br>edge, easily readable while standing on the<br>deck facing the water, in numbers at least<br>four inches high | 1/2 inch extra room needed for a gutter system designed to provide improved indoor air quality. | Approved |  |  |  |  |
| Benton   | DOH                | Affinity at<br>Badger<br>Mountain       | WAC 246-<br>260-<br>031(3)(b) | Minimum slope requirement of 2%.   | meets ADA   | Approved |  |  |  |  |
| Thurston | DOH                | Tanglewilde<br>Apartments               | WAC 246-<br>260-<br>021(1)(b) | Variance from engineering stamp requirement for proposed work  | meets limited scope standard  | Approved |  |  |  |  |
| Benton   | DOH                | Crosspointe<br>Apartments               | WAC 246-<br>260-<br>021(1)(b) | Plans stamped and signed by and engineer<br>or architect. CR completed by an engineer or<br>architect.   | meets limited scope standard  | Approved |  |  |  |  |
| Kitsap   | DOH                | Ridgetop<br>Apartments                  | WAC 246-<br>260-<br>051(5)(e) | A clearly marked emergency shutoff switch<br>for turning off all<br>pumps. The switch must be within twenty<br>feet of each spa, accessible<br>to the public, and triggering an audible<br>alarm.  | sign posted and distance is MAHC compliant.   | Approved |  |  |  |  |

| Kittitas | DOH | Unity Park                           | WAC 246-<br>260-<br>031(3)(b) | Walking surfaces sloping less than 2%   | ADA compliant   | Approved |
|----------|-----|--------------------------------------|-------------------------------|---|---|----------|
| Yakima   | DOH | Aquatic<br>Center at<br>MLK Jr. Park | WAC 246-<br>260-<br>031(3)(b) | A minimum 2% for all walking surfaces   | ADA compliant   | Approved |
| Chelan   | DOH | The Springs                          | WAC 246-<br>260-<br>031(3)(b) | A minimum 2% for all walking surfaces   | ADA compliant   | Approved |
| Chelan   | DOH | Wenatchee<br>Valley<br>YMCA          | WAC 246-<br>260-<br>091(2)(b) | bench size limit  | Bench designed for instructional area - lifeguards provided.  | Approved |
| Lewis    | DOH | Maple<br>Grove<br>Resort             | WAC 246-<br>260-<br>021(1)(b) | Require engineer/architect's stamp on plans and completed construction report.  | meets limited scope standard  | Approved |
| Whatcom  | DOH | Cobblestone<br>Hotel &<br>Suites     | WAC 246-<br>260-<br>031(3)(b) | Minimum slope requirement of 2%.  | ADA compliant   | Approved |
| Kitsap   | DOH | Parkwood<br>Community<br>Pool        | WAC 246-<br>260-<br>041(2)(a) | requires owners to design and maintain<br>walking deck surfaces that must be at least<br>four feet wide around the entire perimeter<br>of pool. | Decks on 3 sides. Allowed for 1 year.   | Approved |
| Benton   | DOH | Hills West<br>Recreation<br>Club     | WAC 246-<br>260-<br>021(1)(b) | Engineer/architect prepared plans with signature and stamp.   | meets limited scope standard  | Approved |
| Thurston | DOH | Wilderness<br>West<br>Apartments     | WAC 246-<br>260-<br>021(1)(b) | Requires plans and specifications be prepared, stamped and signed by an engineer.   | Scope of work include new finishes<br>in restroom and walking path,<br>engineer/architect stamp not<br>required based upon scope of work. | Approved |
| Franklin | DOH | Affinity at<br>Broadmoor             | WAC 246-<br>260-<br>031(3)(b) | deck slope  | ADA compliant   | Approved |
| Franklin | DOH | Affinity at<br>Broadmoor             | WAC 246-<br>260-<br>031(3)(b) | deck slope  | ADA compliant   | Approved |

| Okanogan | DOH | Hobzek Air<br>B&B | WAC 246-<br>260-<br>091(2) | Only a single bench is allowed and 5% of the perimeter of a free form pool                     | benches marked as require in code.<br>Use restricted to small groups<br>renting the house.   | Approved |
|----------|-----|-------------------|----------------------------|--|--|----------|
| Okanogan | DOH | Hobzek Air<br>B&B | WAC 246-<br>260-<br>091(3) | Ledges are only allowed i general use pools<br>when they meet FINA rest ledge<br>requirements. | ledges are structural. and comply<br>with MAHC. Ledges will be marked.<br>pool use restricted to small groups<br>renting the home. | Approved |

|         |                    |  |                     | Spokane Regional Health District |   |          |
|---------|--------------------|--|---------------------|----------------------------------|---|----------|
| County  | Granting<br>Entity | Name   | WAC                 | Descriptor                       | Mitigation Proposed   | Action   |
| Spokane | SRHD               | Spokane<br>Parks & Rec<br>- Comstock<br>Pool, 2900<br>S. Howard,<br>Spokane  | WAC 246-260-<br>151 | Restriction on animals in pools  | Conditions: 1) lifeguards. 2)<br>No humans in the water. 3)<br>disinfection residuals must<br>conform to WAC 246-260, 4)<br>the recirculation system<br>must remain on. 5) dogs<br>must be evaluated by a<br>veterinarian. 6) dogs must<br>be bathed. 7) all dogs must<br>be older than six months<br>and vaccinated against<br>rabies. | Approved |
| Spokane | SRHD               | Spokane<br>Parks & Rec<br>- Liberty<br>Pool, 500 S.<br>Pittsburg,<br>Spokane | WAC 246-260-<br>151 | Restriction on animals in pools  | Conditions: 1) lifeguards. 2)<br>No humans in the water. 3)<br>disinfection residuals must<br>conform to WAC 246-260, 4)<br>the recirculation system<br>must remain on. 5) dogs<br>must be evaluated by a<br>veterinarian. 6) dogs must<br>be bathed. 7) all dogs must<br>be older than six months<br>and vaccinated against<br>rabies. | approved |

| Spokane | SRHD | Spokane<br>Parks & Rec<br>- Shadle<br>Pool, 2005<br>W.<br>Wellesley,<br>Spokane                     | WAC 246-260-<br>151       | Restriction on animals in pools | Conditions: 1) lifeguards. 2)<br>No humans in the water. 3)<br>disinfection residuals must<br>conform to WAC 246-260, 4)<br>the recirculation system<br>must remain on. 5) dogs<br>must be evaluated by a<br>veterinarian. 6) dogs must<br>be bathed. 7) all dogs must<br>be older than six months<br>and vaccinated against<br>rabies. | approved |
|---------|------|---|---------------------------|---------------------------------|---|----------|
| Spokane | SRHD | City of<br>Spokane<br>Valley -<br>Mission<br>Pool, 11123<br>E. Mission<br>Ave,<br>Spokane<br>Valley | WAC 246-260-<br>151       | Restriction on animals in pools | Conditions: 1) lifeguards. 2)<br>No humans in the water. 3)<br>disinfection residuals must<br>conform to WAC 246-260, 4)<br>the recirculation system<br>must remain on. 5) dogs<br>must be evaluated by a<br>veterinarian. 6) dogs must<br>be bathed. 7) all dogs must<br>be older than six months<br>and vaccinated against<br>rabies. | Approved |
| Spokane | SRHD | City of<br>Cheney -<br>Cheney<br>Aquatic<br>Center, 115<br>N. 8th<br>Street,<br>Cheney, WA<br>99004 | WAC 246-260-<br>031(3)(b) | Minimum deck slope              | Meets ADA requirements<br>are for a maximum of ¼"<br>per foot of slope. The deck<br>is to be flooded during the<br>pre-occupancy inspection to<br>ensure there is no ponding<br>of water on the deck.   | Approved |
| Spokane | SRHD | Spokane<br>Parks & Rec<br>- Comstock<br>Pool, 2900<br>S. Howard,<br>Spokane                         | WAC 246-260-<br>151       | Restriction on animals in pools | Conditions: 1) lifeguards. 2)<br>No humans in the water. 3)<br>disinfection residuals must<br>conform to WAC 246-260, 4)<br>the recirculation system<br>must remain on. 5) dogs   | Approved |

|  |  |  | must be evaluated by a      |  |
|--|--|--|-----------------------------|--|
|  |  |  | veterinarian. 6) dogs must  |  |
|  |  |  | be bathed. 7) all dogs must |  |
|  |  |  | be older than six months    |  |
|  |  |  | and vaccinated against      |  |
|  |  |  | rabies.                     |  |

|        |   |   | Та   | coma-Pierce County Health Department |  |          |
|--------|---|---|--|--------------------------------------|--|----------|
| County | Granting<br>Entity                                  | Name                                    | WAC  | Descriptor                           | Mitigation Proposed  | Action   |
| Pierce | Tacoma-<br>Pierce<br>County<br>Health<br>Department | Canterwood<br>Golf &<br>Country<br>Club | WAC 246-260-<br>131(3)                                     | Alcohol service                      | <ul> <li>1. Facility must have a written operations plan 2. Food/alcohol only in the designated eating area.</li> <li>3. Total bather capacity limited to 120 people.</li> <li>4. The pool deck must be clearly marked A minimum pool deck surface area of 1,920 square feet in which no food/beverage consumption may occur.</li> <li>5. Signage must be posted describing the food and alcohol consumption rules.</li> <li>6. Annual notification regarding alcohol rules sent to members 7. Alcohol rules violators must immediately be removed from the pool area and may have pool privileges revoked.</li> <li>8. No glass containers. Alcohol service is only offered from 12 – 6 pm during the pool season.</li> </ul> | Approved |
| Pierce | Tacoma-<br>Pierce<br>County<br>Health<br>Department | Eatonville<br>High School               | WAC 246-260-<br>031(8)(e)(iv)(D)                           | main drain flow rating requirement   | Flow rate may never exceed 576 gpm.  | Approved |
| Pierce | Tacoma-<br>Pierce<br>County                         | Patriots<br>Landing                     | WAC 246-260-<br>091(8)<br>031(8)(d)(i)<br>031(8)(e)(iv)(A) |                                      | 1. Pool ballet rails.<br>a. Special rules required<br>b. "No diving" markers<br>required   | Approved |

|        | Health<br>Department |                          | 031(14)<br>031(8)(d)(iii)<br>031(8)(e)(ii) |   | <ul> <li>2. Pool skimmer must be set<br/>at 85-90% of flow through<br/>the skimmers</li> <li>3. Equipment room floor<br/>drain.</li> <li>a. spills must be cleaned<br/>immediately.</li> <li>b. A spill kit is required.</li> <li>4. Spa autofill/equalizer.</li> <li>a. Water level in the spa<br/>must be inspected visually<br/>every day and replenished<br/>as needed.</li> </ul> |          |
|--------|----------------------|--------------------------|--|---|--|----------|
|        |                      |                          |  | Public Health Seattle King County   |  |          |
| County | Granting<br>Entity   | Name                     | WAC  | Descriptor  | Mitigation Proposed  | Action   |
| King   | SKCPH                | Cedar<br>Heights         | 246-260-<br>031(8)(d)(iii)                 | Skimmers must be equipped with a device, such<br>as an equalizer line, to prevent air lock in the<br>recirculation suction line. If equalizer lines are<br>used, they must be protected with a suction<br>outlet that conforms to the suction fitting<br>standard | Plugged equalizer lines at<br>skimmer basket and wall of<br>pool. Plaster pool to match<br>pool wall surface. Operator<br>must monitor and maintain<br>water level in pool at all<br>times.  | Approved |
| King   | SKCPH                | Centenial<br>Towers Pool | 246-260-031<br>(8)(d)(iii)                 | Skimmers must be equipped with a device, such<br>as an equalizer line, to prevent air lock in the<br>recirculation suction line. If equalizer lines are<br>used, they must be protected with a suction<br>outlet that conforms to the suction fitting<br>standard | Plugged equalizer lines at<br>skimmer basket and wall of<br>pool. Plaster pool to match<br>pool wall surface. Operator<br>must monitor and maintain<br>water level in pool at all<br>times.  | Approved |
| King   | SKCPH                | Centenial<br>Towers Spa  | 246-260-031<br>(8)(d)(iii)                 | Skimmers must be equipped with a device, such<br>as an equalizer line, to prevent air lock in the<br>recirculation suction line. If equalizer lines are<br>used, they must be protected with a suction<br>outlet that conforms to the suction fitting<br>standard | Plugged equalizer lines at<br>skimmer basket and wall of<br>pool. Plaster pool to match<br>pool wall surface. Operator<br>must monitor and maintain<br>water level in pool at all<br>times.  | Approved |

| King | SKCPH | Echo<br>Mountain<br>pool | 246-260-031<br>(8)(d)(iii) | Skimmers must be equipped with a device, such<br>as an equalizer line, to prevent air lock in the<br>recirculation suction line. If equalizer lines are<br>used, they must be protected with a suction<br>outlet that conforms to the suction fitting<br>standard | Plugged equalizer lines at<br>skimmer basket and wall of<br>pool. Plaster pool to match<br>pool wall surface. Operator<br>must monitor and maintain<br>water level in pool at all<br>times. | Approved |
|------|-------|--------------------------|----------------------------|---|---|----------|
| King | SKCPH | Grandview<br>Spa         | 246-260-031<br>(8)(d)(iii) | Skimmers must be equipped with a device, such<br>as an equalizer line, to prevent air lock in the<br>recirculation suction line. If equalizer lines are<br>used, they must be protected with a suction<br>outlet that conforms to the suction fitting<br>standard | Plugged equalizer lines at<br>skimmer basket and wall of<br>pool. Plaster pool to match<br>pool wall surface. Operator<br>must monitor and maintain<br>water level in pool at all<br>times. | Approved |
| King | SKCPH | Grandview<br>Pool        | 246-260-031<br>(8)(d)(iii) | Skimmers must be equipped with a device, such<br>as an equalizer line, to prevent air lock in the<br>recirculation suction line.  | Plugged equalizer lines.<br>Operator must monitor and<br>maintain water level in pool<br>at all times.  | Approved |
| King | SKCPH | Klanhanie<br>Pool        | 246-260-031<br>(8)(d)(iii) | Skimmers must be equipped with a device, such<br>as an equalizer line, to prevent air lock in the<br>recirculation suction line.  | Plugged equalizer lines.<br>Operator must monitor and<br>maintain water level in pool<br>at all times.  | Approved |
| King | SKCPH | Standard<br>Pool         | 246-260-031<br>(8)(d)(iii) | Skimmers must be equipped with a device, such<br>as an equalizer line, to prevent air lock in the<br>recirculation suction line.  | Plugged equalizer lines.<br>Operator must monitor and<br>maintain water level in pool<br>at all times.  | Approved |
| King | SKCPH | Standard<br>Spa          | 246-260-031<br>(8)(d)(iii) | Skimmers must be equipped with a device, such<br>as an equalizer line, to prevent air lock in the<br>recirculation suction line.  | Plugged equalizer lines<br>Operator must monitor and<br>maintain water level in pool<br>at all times.   | Approved |

| King | SKCPH | Lake Union<br>Summit<br>Apartments<br>Spa | WAC 246-260-<br>031(21)(f) | (f) Restroom facilities must be located<br>convenient to, and no further than one hundred<br>feet away from, the main pool.   | Full restroom and shower<br>located 115 feet from spa<br>via elevator. Must have slip<br>resistant corridor to<br>restroom, and posted map<br>of location.   | Approved |
|------|-------|---|----------------------------|---|--|----------|
| King | SKCPH | One Pacific<br>Towers                     | 246-260-031<br>(8)(d)(iii) | Skimmers must be equipped with a device, such<br>as an equalizer line, to prevent air lock in the<br>recirculation suction line. If equalizer lines are<br>used, they must be protected with a suction<br>outlet that conforms to the suction fitting<br>standard | Plugged equalizer lines.<br>Operator must monitor and<br>maintain water level in pool<br>at all times.   | Approved |
| King | SKCPH | Regency<br>Newcastle                      | 246-260-031<br>(8)(d)(iii) | Skimmers must be equipped with a device, such<br>as an equalizer line, to prevent air lock in the<br>recirculation suction line.  | Plugged equalizer lines.<br>Operator must monitor and<br>maintain water level in pool<br>at all times.   | Approved |
| King | SKCPH | Regency<br>Newcastle                      | WAC 246-260-<br>041(2)(a)  | For pools less than fifteen hundred square feet,<br>walking deck surfaces must be at least four feet<br>wide around the entire perimeter of pools;  | No furniture placed along<br>wall behind double<br>handrails. Buddy system in<br>place. A minimum of two<br>people in pool area<br>whenever pool is in use.<br>Emergency equipment<br>provided at all times. | Approved |
| King | SKCPH | Wedgwood<br>Swim Pool                     | WAC 246-260-<br>041(5)(b)  | Diving wells to meet CNCA minimum dimension<br>requirements for when the user would enter<br>from the deck level over 12 inches from water<br>level or has a platform or diving board provided<br>at a height less than 1/2 meter.                                | Reduction in length of diving<br>board and height of stand,<br>will provide additional<br>bather safety. Diving board<br>is not used for competitive<br>diving.  | Approved |

|           |          |            |           | Clark County Public Health                    |                                     |          |
|-----------|----------|------------|-----------|---|-------------------------------------|----------|
|           | Granting |            |           |   |                                     |          |
| County    | Entity   | Name       | WAC       | Descriptor                                    | Mitigation Proposed                 | Action   |
|           |          | Goldfish   | WAC       | "[benches] May not exceed twenty percent      | A submerged bench extends           |          |
|           |          | Swim       | 246-260-  | of the length of the side it is located on or | along the entire 75ft length of     |          |
|           |          | School     | 091(2)(b) | five percent of the perimeter of a free form  | the pool on both sides. Primary     |          |
|           |          |            |           | pool;"  | use of pool is for swimming         |          |
|           |          |            |           |   | lessons; underwater benches aid     |          |
|           |          |            |           |   | in instruction. Leading edge of     |          |
|           |          |            |           |   | bench will be marked with 2         |          |
|           |          |            |           |   | rows of continuous contrasting      |          |
|           |          |            |           |   | color marking for visibility.       |          |
|           |          |            |           |   | Signage on the deck will indicate   |          |
|           |          |            |           |   | "Bench Caution" at every depth      |          |
|           |          |            |           |   | marker location to note it's        |          |
|           |          |            |           |   | presence to pool users.             |          |
|           |          |            |           |   | Additional signage noting the       |          |
|           |          |            |           |   | bench will be posted on pool        |          |
| Clark     | ССРН     |            |           |   | enclosure walls.                    | Approved |
|           |          | Prose      | WAC       | Request for Baja/Sunshelves - not addressed   | Plan approved following MAHC        |          |
|           |          | Apartments | 246-260-  | in WAC. Closest reference is for underwater   | 4.5.18 requirements for             |          |
|           |          |            | 091       | bench or ledge.                               | underwater shelves                  |          |
| Clark     | ССРН     |            |           |   |                                     | Approved |
|           |          |            |           | Snohomish County Health Department            |                                     |          |
|           | Granting |            |           |   |                                     |          |
| County    | Entity   | Name       | WAC       | Descriptor                                    | Mitigation Proposed                 | Action   |
|           |          |            |           |   |                                     |          |
|           |          |            |           |   | 1. Each bench needs to be designed  |          |
|           |          |            | WAC 246-  | A single bench or seat that is recessed from  | to meet all applicable requirements |          |
|           |          | Aqua Tots  | 260-      | the general wall of the swimming pool may be  | in chapter WAC 246-260-091(2)(a, c, |          |
|           |          |            | 091(2)    | built into the shallow area of the pool       | & d) and the 2023 CDC Model         |          |
|           |          |            |           | · ·   | Aquatic Health Code (4.5.16). 2.    |          |
|           |          |            |           |   | Detailed lifeguarding plan          |          |
| Snohomish | SCHD     |            |           |   |                                     | Approved |

| Kitsap Public Health |                            |                                       |                            |  |  |          |
|----------------------|----------------------------|---------------------------------------|----------------------------|--|--|----------|
| County               | Granting<br>Entity         | Name                                  | WAC                        | Descriptor   | Mitigation Proposed  | Action   |
| Kitsap               | Kitsap<br>Public<br>Health | Kitsap Golf<br>and<br>Country<br>Club | WAC 246-<br>260-<br>131(3) | To allow the facility to have alcohol service at the pool. | <ul> <li>Alcohol consumption is not allowed<br/>in water or in the perimeter of the<br/>decking.</li> <li>Consumption must occur at<br/>designated tables away from the pool<br/>area and signs must be posted to<br/>denote that area. A sign should be<br/>posted to denote that area.</li> <li>Facility must notify users of the<br/>increased risk of drowning associated<br/>with alcohol consumption. A sign<br/>must be posted stating the dangers<br/>of alcohols usage associated with<br/>swimming.</li> </ul> | Approved |



Date: March 12, 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

#### Background and Summary:

The State Board of Health (Board) and the 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).

<u>RCW 69.30.030</u> authorizes the Board to adopt rules governing shellfish sanitation, shellfish growing areas, and shellfish operations to protect public health and safety. Further, <u>RCW 43.20.050</u>, establishes the 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 <u>WSR 22-06-034</u>, to start rulemaking to update <u>chapter 246-282 WAC</u>, 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.

Board staff coordinated with the Department's Office of Environmental Health and Safety to draft potential changes and gather feedback. An informal public comment period was open from April 12, 2024, to May 24, 2024. After the informal public comment period, Board staff coordinated with the Department to host additional Rules Advisory Committee meetings to gather feedback and continue to revise the draft.

Today, Kseniya Efremova, Department staff, will brief the Board on updates to the rulemaking's progress and next steps.

#### **Recommended Board Actions:**

This is an informational update, not requiring any Board action.

#### Staff

Ash Noble, Policy Advisor

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## SANITARY CONTROL OF SHELLFISH RULES BRIEFING

March 12, 2025

## Presenter



#### Kseniya Efremova

**Rules** Coordinator

**EPH Rules Team** 

## 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.
- The Board delegated emergency rulemaking authority to the Department if heat wave conditions occur before July 1.

## Timeline

• February 23, 2022 – CR-101 for permanent rulemaking filed

 October 2022 – April 2023 – Rules Advisory Committee meetings held

- April 2024 First draft of rule sent to Rules Advisory Committee for informal comment
- June 12, 2024 Department rules briefing to the Board

• October 8, 2024 – Last rules briefing to the Board

Washington State Department of Health | 4

## Recent Activity

 Rules workshops held in December 2024 and January 2025 for large/medium growers, small growers, and Tribal partners

- Debrief meeting held in February with large/medium, small, and Tribal groups to discuss key themes and resolve differences
- Revision of draft rule language based on feedback from the Rules Advisory Committee

Learning opportunities through tours and shadow inspections

Washington State Department of Health | 5

## Next Steps

Second informal comment period

• Further revision of draft rule language

Orafting of CR-102 package

- Significant Analysis
- Small Business Economic Impact Statement

Additional learning opportunities

Washington State Department of Health | 6

## Questions?



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## Director of Public Health and Health Officer

### New leadership taking shape at Tacoma-Pierce County Health Department.

#### **Director of Public Health**

Chantell Harmon Reed, a doctoral candidate in public health at Tulane University, is our director of public health.

An energetic and visionary leader, Reed's diverse background includes roles in public health, healthcare administration and compliance.

As the deputy director of the Public Health Division of the Multnomah County Health Department in Oregon, Reed supported COVID-19 recovery efforts, infrastructure improvements and achieving accreditation from the Public Health Accreditation Board.

Throughout her career, Reed has helped to close disparity gaps through centering social determinants of health. She honed this approach through various roles with Program for All-Inclusive Care for the Elderly (PACE) of Greater New Orleans.

She also improved operational efficiency in behavioral health care initiatives at JeffCare Community Clinics, a Medicare Certified Federally Qualified Health Center. Her work has improved maternal and infant mortality rates and enhanced the doula workforce.

Reed is committed to community service and has served on many committees and boards, including the New Orleans Regional Leadership Institute, the Loyola Center for Counseling and Education, and the Oregon Public Health Association. Reed has a bachelor's in business from Northwood University in Cedar Hill, Texas, and a master's in healthcare management from the University of New Orleans.

### **Health Officer**



rector of Publ c Health and Health Off cer - Tacoma-P erce County Health epartment

Dr. James S. Miller, an internal medicine physician and medical epidemiologist, is our health officer.

He earned his medical degree from Harvard Medical School and a master's in public health from the London School of Hygiene and Tropical Medicine. He completed internal medicine residency and a fellowship in global medicine at the Massachusetts General Hospital.

Dr. Miller previously worked as an Epidemic Intelligence Service Officer at the Centers for Disease Control and Prevention (CDC) and as a Regional Medical Officer at the Washington State Department of Health. In Washington, he

has helped with the state's response to COVID-19, mpox, and other communicable diseases, including extensive work on communicable diseases in correctional facilities.

Dr. Miller has dedicated much of his career to working with traditionally underserved communities. He spent several years working with community health workers in Uganda and has experience providing forensic medical and psychiatric evaluations for people applying for asylum in the United States. He provided clinical care for Native communities with the Maniilaq Association in Northwest Alaska and with the Seattle Indian Health Board. He also provided care for people experiencing homelessness as part of the Boston Healthcare for the Homeless COVID-19 response in the spring of 2020.

In addition to his role as health officer, Dr. Miller is also a Clinical Assistant Professor at the University of Washington where he works at the Harborview Medical Center After Care Clinic.

#### Powers and duties of local health officers

- <u>RCW 70.05.070</u>
- <u>RCW 70.28.031</u>

## Public Health in Pierce County Tacoma-Pierce County Health Department

Washington State Board of Health March 12, 2025 Chantell Harmon Reed



# Agenda

- Welcome and introductions.
- Tacoma and Pierce County.
- Our Department and Strategic Plan.
- Program highlights.
- Septic O&M and water quality.
- School Safety Program.
- Questions.



# Director of Public Health

## **Chantell Harmon Reed**

- Started in March 2024.
- Previously Deputy Director of Multnomah County Health Department.
- From New Orleans.
- Committed to improving:

   Overall health of Pierce County.
   Community connections.
   Efficiency.



# **Health Officer**

## Dr. James (Jay) Miller

- Started in May 2024.
- Previously Regional Medical Officer at WA Dept. of Health.
- Internal medicine physician, completed residency and global health fellowship in Massachusetts.
- Committed to improving:

   Overall health of Pierce County.
   Communicable disease spread.
   Health outcomes.



## **Welcome to Pierce County**

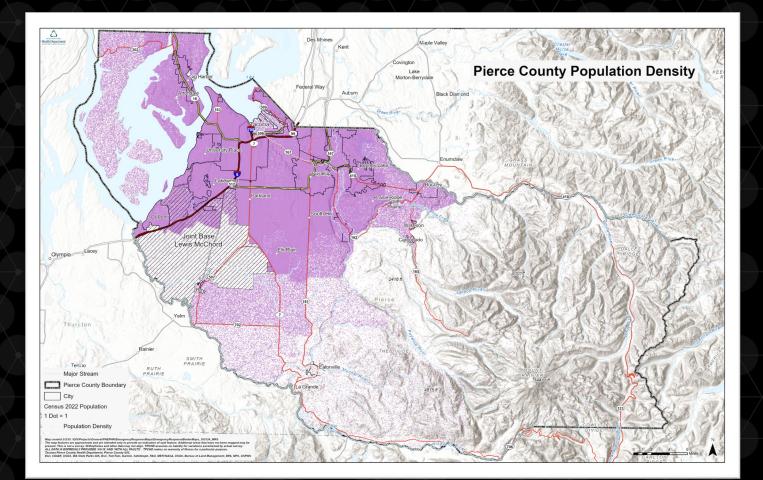


- Mixture of densely populated cities and rural areas.
- Second most populous county in Washington state.
- Home to:

  Mount Rainier.
  Joint Base Lewis-McChord.
  Port of Tacoma.
  Puyallup Tribe of Indians.

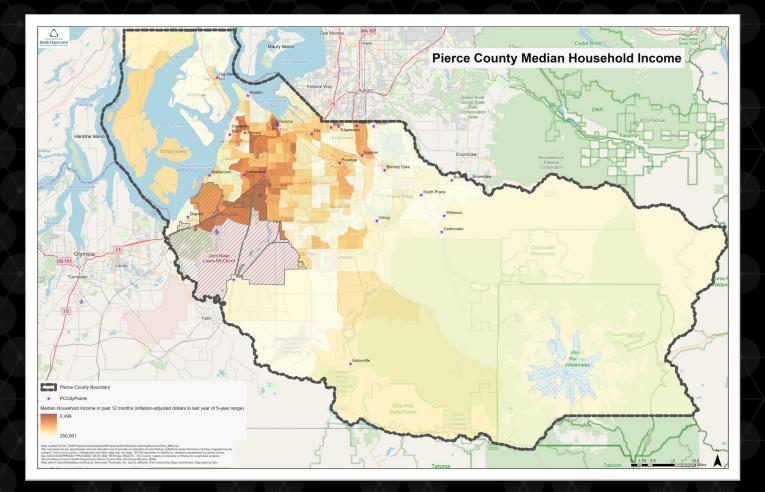


# **Pierce County population density**





# **Pierce County median income**





## Tacoma-Pierce County Health Department

- Independent local health jurisdiction (LHJ) established through interlocal agreement with Tacoma and Pierce County.
- We tackle known and emerging health risks through policy, programs, and treatment to protect public health.

MAIN ENTRANCE TACOMA PIERCE COUNTY HEALTH DEPARTMENT



## 2025–2029 Strategic Plan

#### Vision

Healthy People in Healthy Communities.

#### **Mission**

We protect and improve the health of all people and places in Pierce County.

#### Values

- Equity.
- Integrity.
- Respect.
- Leadership.

## Improve health outcomes.

- Improve organizational culture.
- Increase efficiency and effectiveness.



**Strategic Initiatives** 

# **Program highlights**



# **Street Medicine**

Multidisciplinary approach to bring comprehensive care to those in need.

- Team.
  - Primary provider.
  - RN with mental health expertise.
  - Certified peer navigator.
- Services.
  - Acute care treatment.
  - Treatment and referrals for chronic conditions.
  - Behavioral health care treatment and referrals.
  - o More!



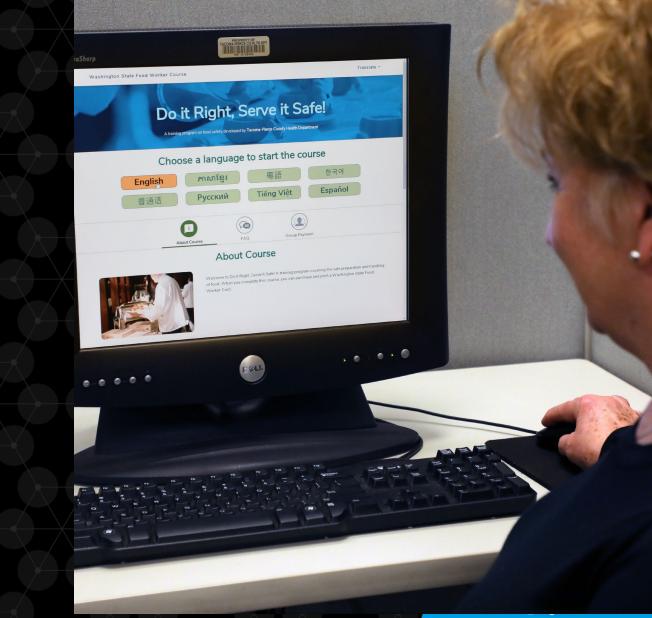
# Do it Right, Serve it Safe!

• Provide online food worker card training program for all LHJs in Washington state.

• Covers safe preparation and handling of food.

• Everyone who completes can purchase and print a Washington State Food Worker Card.

•Learn more at <u>foodworkercard.wa.gov</u>.



Tacoma-Pierce County Health Department Healthy People in Healthy Communities

# **Provider Resources WA**

- Helps LHJs across state:
   Publich health alorts an
  - Publish health alerts and advisories.
  - Provide resources for local health care workers in their community.
- Since launching, we've expanded to work with 10 jurisdictions.

Tacoma-Pierce County

Departmen

- On track to continue adding 2 to 4 partners each year.
- Lear more at providerresourceswa.org

## Get the facts about fentanyl



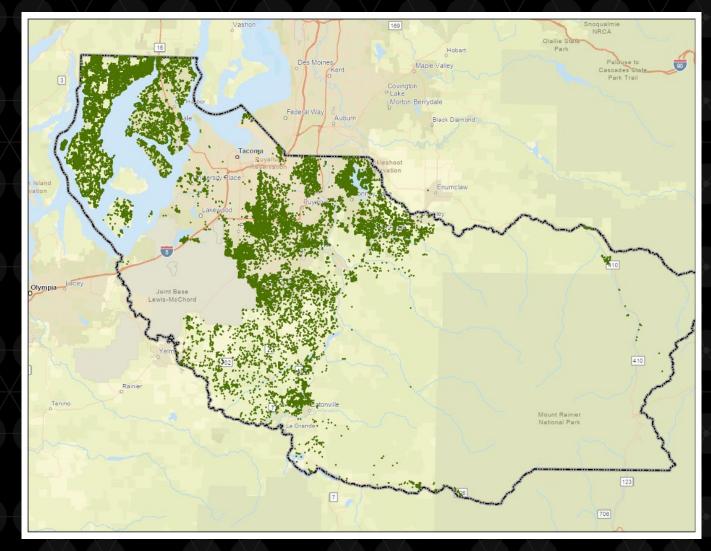
- Created award-winning media campaign to bring awareness to dangers of fentanyl.
- Adapting for other local health jurisdictions.
- Learn more at <u>fentanylfacts.org</u>.



## Septic O&M and water quality



## Septic systems throughout Pierce County enrolled in routine O&M



Tacoma-Pierce County Health Department Healthy People in Healthy Communities

# Safe and healthy water benefits you and your community

Regular septic system inspections, pumping, and repairs:

- Reduce risk of sewage contamination to drinking water, lakes, rivers, and Puget Sound.
- Keep you, your family, neighbors, and pets from getting sick.
- Keep shellfish harvested from public waters safe to eat.
- Help decrease nutrient pollution that cause toxic algal blooms in lakes.
- Prevent costly repairs of your septic system—ultimately saving you money.



# **Minter Bay Protection District**

- Became a shellfish protection district in 2020.
- Surrounded by 1,427 parcels.
  - $\circ$  818 of which have known septic systems.
- Minterbrook Oyster Company was impacted by a septic system failure.
- Our septic staff worked with the owners to identity and correct the issues.



## **School Safety Program**



# Why we do plan reviews and inspections

- WAC 246-366 requires it.

   LHJs must review and approve plans before schools construct or remodel a facility.
   The code requires LHJs make periodic inspections of schools.
- Prevents injury.
- Ensures a safe and healthy learning environment.



# How often we review and inspect

Plan reviews:

- Site review (before the building).
- New school building.
- Remodel.
- Portable classroom.
- Playground.
- On average, we complete 45 every year.
   Routine inspections:
- On average, we complete 140 every year.



# **School rule revision**

Updated rules will provide:
LHJs with better resources to conduct plan reviews and inspections.
A higher level of protection for health and safety for students across our county.



# **Questions?**

Chantell Harmon Reed

creed@tpchd.org



# WASHINGTON STATE

Date: March 12, 2025

To: Washington State Board of Health Members

From: Kelly Oshiro, Board Member

**Subject:** Recommendations of the Branch-Chain Ketoacid Dehydrogenase Kinase Deficiency Newborn Screening Technical Advisory Committee

#### Background and Summary:

The Washington State Board of Health (Board) has the authority under RCW 70.83.050 to 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 on the state's required newborn screening panel.

During the 2023-2024 legislative session, Senate Bill 6234 passed, which directed the Board to conduct a review of branch-chain ketoacid dehydrogenase kinase (BCKDK) deficiency for Washington's mandatory newborn screening panel. BCKDK deficiency is a rare inherited genetic disorder that leads to a deficiency of branched-chain amino acids. It is caused by changes in the BCKDK gene, which produces the BCKDK enzyme. The BCKDK enzyme regulates the metabolism of branched-chain amino acids. Mutations with the BCKDK enzyme cause an overactive breakdown of branched-chain amino acids<sup>1</sup>. Without enough amino acids, proteins can't form properly, which impairs neurodevelopmental growth and development<sup>1,2</sup>. Signs and symptoms can vary but may include autism spectrum disorder, language impairment, seizures, and microcephaly<sup>2</sup>. There are 21 cases of BCKDK deficiency identified worldwide, with no cases yet identified in the United States<sup>2</sup>.

On <u>January 14, 2025</u>, a technical advisory committee (TAC) convened to consider this condition against the Board's five newborn screening criteria. During the committee meeting, TAC Members heard presentations on the natural history of the condition, diagnostic testing and treatment, available screening technology, and cost-benefit analysis for adding this condition to the state's screening panel. The TAC then voted on individual criteria for BCKDK deficiency as well as an overall recommendation to the Board.

I have invited Megan McCrillis, Policy Analyst for the Department of Health's Newborn Screening Program, and Kelly Kramer, Policy Advisor to the Board, to present information from the BCKDK deficiency TAC for Board Member consideration.

#### **Recommended Board Actions:**

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

The Board directs staff to file a CR-101 to initiate rulemaking for chapter 246-650 WAC to consider adding branch-chain ketoacid dehydrogenase kinase (BCKDK) deficiency to the Washington state newborn screening panel.

Washington State Board of Health March 12, 2025, Meeting Memo Page 2

#### OR

The Board determines that branch-chain ketoacid dehydrogenase kinase (BCKDK) deficiency should not be considered for addition to the newborn screening panel at this time.

#### Staff

Kelly Kramer, Policy Advisor

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- 1. Novarino, G., et al. Mutations in BCKD-kinase lead to a potentially treatable form of autism with epilepsy. Science 338: 394-397, 2012. [PubMed: <u>22956686</u>]
- 2. Tangeraas, T., et al. BCKDK deficiency: a treatable neurodevelopmental disease amenable to newborn screening. Brain 146: 3003-3013, 2023. [PubMed: <u>36729635</u>]



Date: March 12, 2025

To: Washington State Board of Health Members

From: Kelly Oshiro, Board Chair

**Subject:** Newborn Screening Technical Advisory Committee, Review of Newborn Screening Criteria

### Background and Summary:

The Washington State Board of Health (Board) has 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 newborns are to be screened.

To determine which conditions to add to the rule, the Board convenes a technical advisory committee (TAC) to review conditions and make recommendations to the Board regarding possible inclusion in the newborn screen (NBS) panel. The TAC evaluates candidate conditions using the Board's <u>guiding principles and an established</u> <u>set of criteria</u>.

Due to a recent increase in condition review requests and anticipated workload, the Board and the Department of Health (Department) acknowledged the need to review and update the current process. The Board and Department convened a TAC to identify strategies to streamline the condition review request process, modernize the evaluation criteria, and strengthen the overall process to address current program demands.

The TAC met on January 14 and February 11, 2025, to conduct a review of the criteria used to evaluate conditions for the newborn screening panel. At the request of the TAC, the Department provided suggested updates to the criteria, along with the addition of a sixth criterion. The TAC suggested minor edits to the proposed updates and voted to recommend that the Board accept the changes to the newborn screening evaluation criteria.

I have invited Kelly Kramer, Board staff, to provide an overview of the TAC's criteria review recommendations.

### **Recommended Board Actions:**

The Board may wish to consider one of the following motions:

The Board accepts the Newborn Screening Technical Advisory Committee's recommendation to adopt updated criteria for evaluating conditions for the newborn screening panel, as presented, with any changes requested by the Board.

Washington State Board of Health March 12, 2025 Page 2

The Board declines the Newborn Screening Technical Advisory Committee's recommendation for the Board to adopt the updated criteria for evaluating conditions for the newborn screening panel.

### Staff

Kelly Kramer, Policy Advisor

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### 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.

[ <u>2014 c 18 § 1;</u> <u>2010 c 94 § 18;</u> <u>1991 c 3 § 348</u>; 1975-'76 2nd ex.s. c 27 § 1; <u>1967 c 82 §</u> <u>2</u>.]

### 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.

[<u>1991 c 3 § 349;</u> <u>1979 c 141 § 113;</u> <u>1967 c 82 § 3.</u>]

### 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.

[ <u>1967 c 82 § 5.</u>]



## Washington State Board of Health

**Overview of BCKDK Deficiency and Criteria Review** 

Kelly Kramer, Policy Advisor – March 12, 2025



### **Overview**

- Branch Chain Keto Acid Dehydrogenase Kinase Deficiency Review ullet
- Voting Results
- Review of Criteria to Evaluate Conditions for the Newborn Screening Panel  $\bullet$
- Voting Results



## Background: Branch-Chain Ketoacid Dehydrogenase Kinase (BCKDK) Deficiency

- Senate Bill 6234 (2024 legislative session)
  - Directed the Board of Health to conduct a review of BCKDK Deficiency to determine if this condition should be added to our mandatory newborn screening panel
- No state program screens for BCKDK
- Federal Recommended Uniform Screening Panel has not reviewed



## **Overview of BCKDKD**

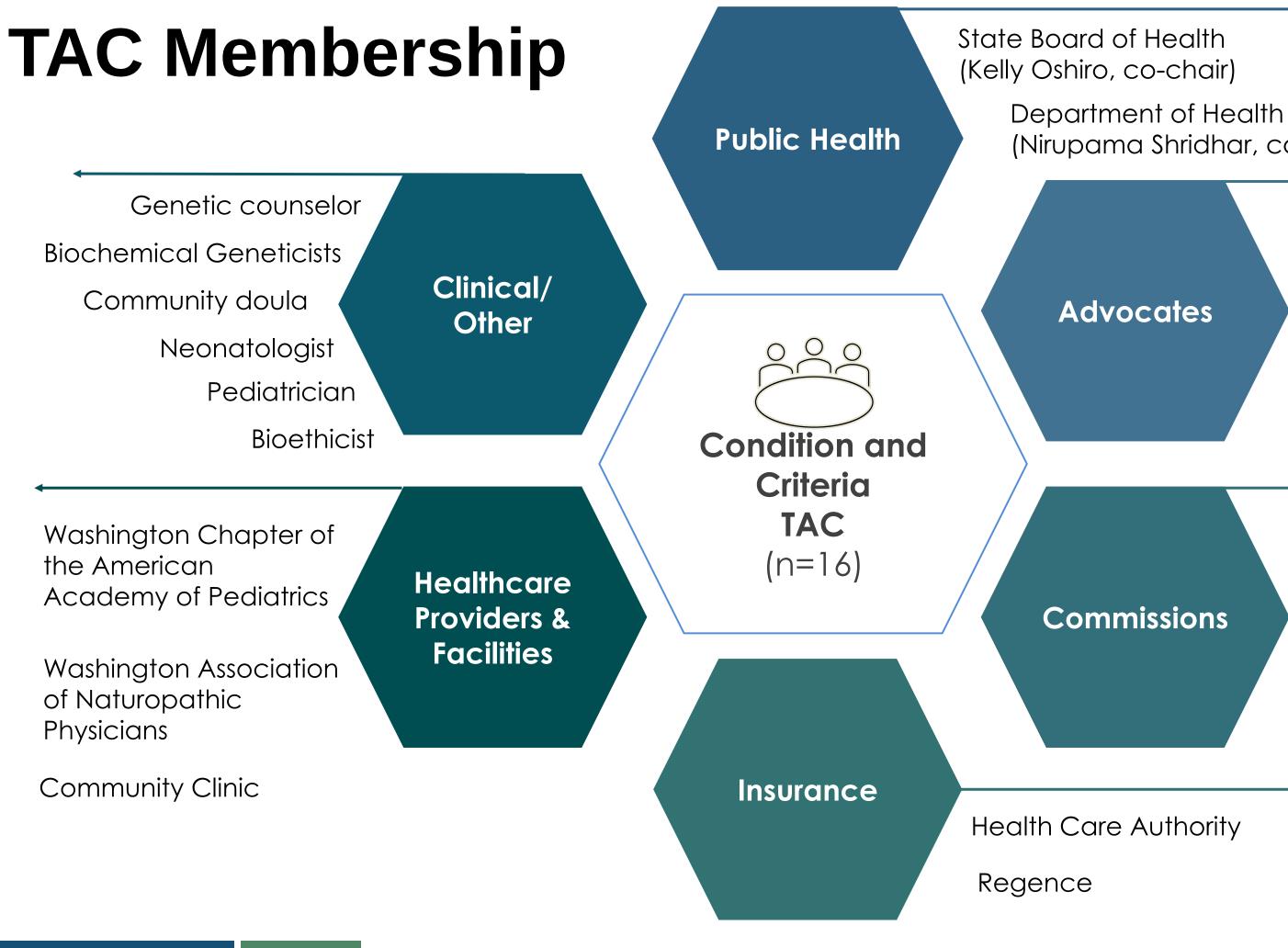
- Branch-chain ketoacid dehydrogenase kinase deficiency (BCKDKD)
  - Rare, genetic amino acid disorder
    - 21 cases identified worldwide
  - Characterized by epilepsy, autism and intellectual disability
  - Reduced levels of branched chain amino acids
    - Prevents protein production, inhibits development and growth
- Screening method
  - Tandem mass spectrometry using dried bloodspot
  - Low amino acid levels
- Diagnostic Test  $\bullet$ 
  - Plasma amino acid test
  - DNA testing
- Treatment for BCKDKD: •
  - High protein diet
  - Supplement branch-chain amino acids
- Novarino G, et al. Mutations in BCKD-kinase lead to a potentially treatable form of autism with epilepsy. Science. 2012 Oct 19;338(6105):394-7. doi: 10.1126/science.1224631. Epub 2012 Sep 6. PMID: 22956686; PMCID: PMC3704165.
- Trine Tangeraas, et al BCKDK deficiency: a treatable neurodevelopmental disease amenable to newborn screening, Brain, Volume 146, Issue 7, July 2023, Pages 3003–3013, https://doi.org/10.1093/brain/awad010



## Cost Benefit, Cost Effectiveness Analysis

Megan McCrillis, MPH Policy Analyst for the Department of Health's Newborn Screening Program





(Nirupama Shridhar, co-chair)



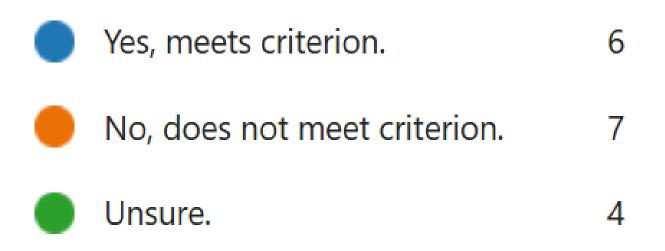
Save Babies Through Screening Foundation

American Indian Health Commission

Commission on Hispanic Affairs

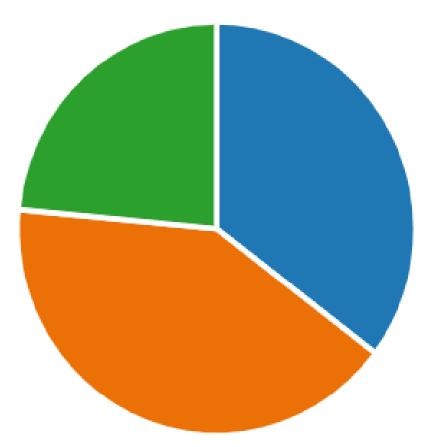
### **1. Available Screening Technology** Sensitive, specific, and timely tests are available for the condition that can be adapted to mass screening.

Screening test: tandem mass spectrometry Analyte: low branch chain amino acids



Themes:

Screening technology is available, but performance, i.e., sensitivity and specificity, are unknown.

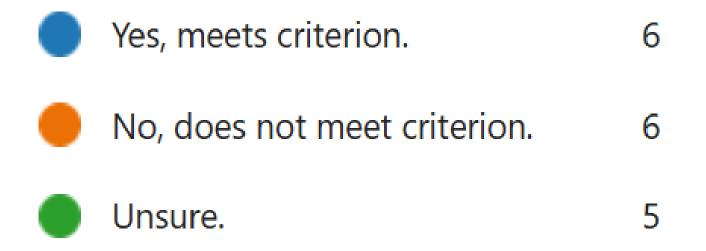




## **2. Diagnostic Testing and Available Treatment**

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

Diagnostic tests: plasma amino acids, genetic testing Treatment: high protein diet, supplementation



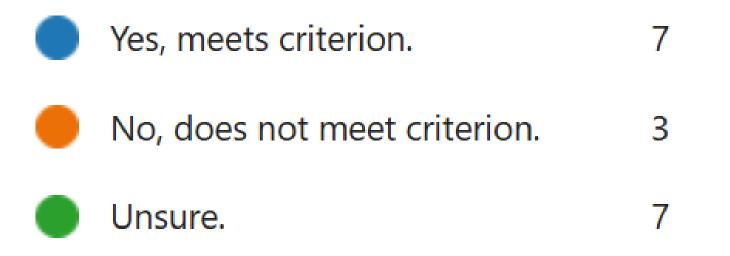
Themes:

Limited data on the effectiveness of follow-up care and outcomes for early diagnosis of BCKDK deficiency.

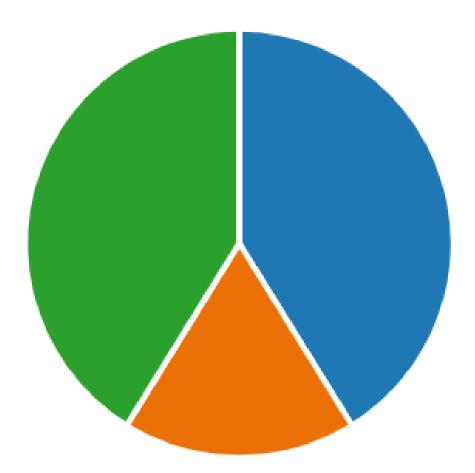


## **3. Prevention Potential and Medical Rationale**

The newborn identification of the condition allows early diagnosis and intervention.



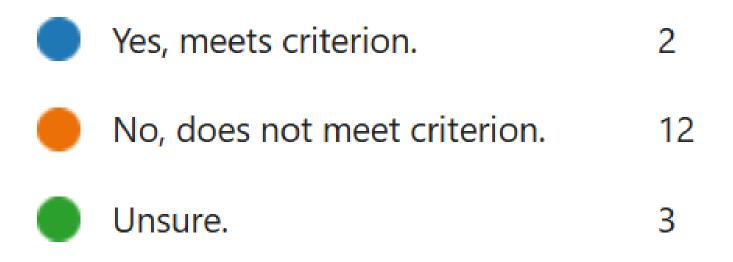
Themes: Limited data in literature.



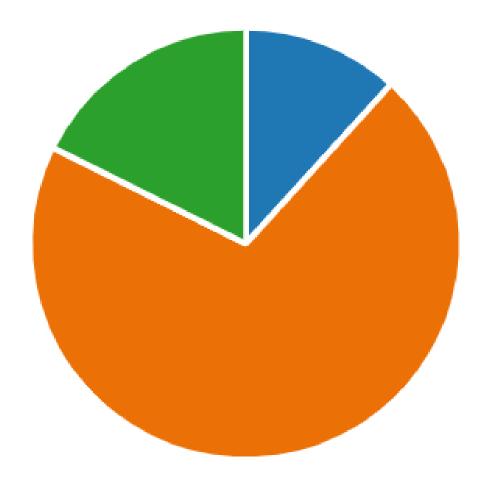


### **4. Public Health Rationale**

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



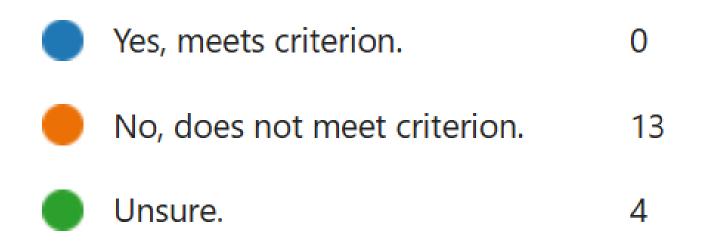
Themes: Limited data in literature.





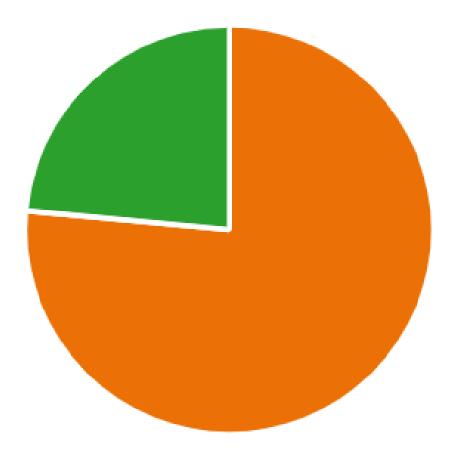
## **5. Cost-benefit and Cost- effectiveness**

The outcomes outweigh the costs of screening. All outcomes, both positive and negative, need to be considered in the analysis.



Themes:

Unable to determine cost/benefit ratio due to limited data.





## **Overall Recommendation for BCKDK Deficiency**

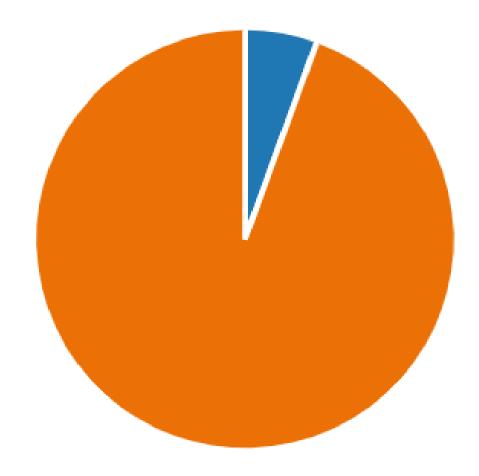
Each TAC member voted as to whether they recommend BCKDK deficiency to Washington's mandatory newborn screening panel.

I recommend the Board add BC... 1

do not recommend the Board... 17

Themes:

Inadequate information to recommend to the Board to add BCKDK deficiency to the newborn screening panel.





## **Board Member Next Steps**

## Possible action: The Board may consider the following-

• The Board **accepts** the Newborn Screening TAC's recommendation for the Board to **not** add BCKDK deficiency to the NBS panel

### OR

• The Board **declines** the Newborn Screening TAC's recommendation for the Board and directs staff to initiate rulemaking to include BCKDK deficiency on the NBS panel.





### Washington State Board of Health

### **Overview of Criteria Review**

## WASHINGTON STATE **BOARD**OF**HEALTH**

## Newborn Screening Criteria

1) Available Screening Technology

2) Diagnostic Testing and Treatment Available

3) Prevention Potential and Medical Rationale

4) Public Health Rationale

5) Cost-Benefit and Cost Effectiveness



6) Public Health Readiness





## **1. Available Screening Technology**

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

- The sensitivity of the screening test is estimated to be ≥95%.
- The specificity of the screening test is considered acceptable based on the estimated number of false positive results and their potential impact on the families, healthcare system, and newborn screening program.
- A timely test is one that enables intervention before irreversible harm develops, within the current standard timeframes for specimen collection, receipt, testing, and reporting.
- There is adequate peer reviewed evidence to evaluate this criterion.





## 2. Diagnostic Testing and **Available Treatment**

Accurate diagnostic tests, medical expertise, and effective treatment are available for evaluation and care of all infants identified with the condition. A diagnostic test accurately identifies who needs treatment and is readily

- available to all newborns screened.
- The available treatment is effective in reducing morbidity or mortality and outweighs any risks or harms of the treatment.
- The medical expertise needed to diagnose and care for those with a positive newborn screen is reasonably available to all newborns screened.
- The appropriate consultants and treatment centers have been identified and have capacity for the expected increase in diagnostic testing and/or referrals.



# **3. Prevention Potential and Medical Rationale**

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

- There is sufficient time between birth and onset of irreversible harm to allow for diagnosis and intervention.
- The condition must have an onset form that occurs in infancy (within the first year of life); newborn screening is not appropriate for conditions that only present after the first year of life.
- The benefits of detecting and treating early onset infantileonset forms of the condition (within one year of life) balance the impact of detecting later onset forms of the condition.
- Newborn screening is not appropriate for conditions that only present in adulthood.
- There is adequate evidence of acceptable quality to evaluate this criterion.



## **4. Public Health Rationale**

- The nature of the condition justifies population-based screening rather than risk-based screening or other approaches.
- All available risk-based screening tools for the condition have been considered and are found to be inferior to universal newborn screening.
- There is adequate evidence of acceptable quality to evaluate this criterion.



## **5. Cost-benefit and Cost-effectiveness**

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

- The economic analysis considers:
  - $\circ$  The prevalence of the condition among newborns.
  - The positive and negative predictive values of the screening and diagnostic tests.
  - $\circ$  Variability of clinical presentation by those who have the condition. Dollar values for costs and benefits of screening vs. no screening.
- The impact of ambiguous results, adverse effects, or unintended consequences of screening, such as emotional or economic impacts on the family and medical system, must also be considered.
- The results of the economic analysis shows that the outcomes, financial or otherwise, outweigh the costs of screening
- There is adequate evidence of acceptable quality to evaluate this criterion
- The impact of ambiguous results. For example, the emotional and economic impact on the family and medical system.
- Adverse effects or unintended consequences of screening.



## **6. Public Health Readiness**

- The Newborn Screening Program's capacity to implement screening within a reasonable timeframe has been considered.
- The systems and staffing necessary to perform the test and report screening results have been identified.
- Resources needed to implement short/long term follow up protocols by the newborn screening program have been identified.
- The accessibility to treatment for anyone diagnosed with the condition is considered acceptable based on the frequency of treatment needed.



## **Board Member Next Steps**

## Possible action: The Board may consider the following-

• The Board accepts the Newborn Screening Technical Advisory Committee's (TAC's) recommendation for the Board to adopt the updated criteria used to evaluate conditions for the newborn screening panel.

### OR

 The Board declines the Newborn Screening Technical Advisory Committee's (TAC's) recommendation for the Board to adopt the updated criteria used to evaluate conditions for the newborn screening panel. The Board directs NBS TACs to continue to use the current established criteria.





## **THANK YOU**

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- 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.

### WASHINGTON STATE **BOARDOFHEALTH**





WASHINGTON STATE

Newborn Screening Technical Advisory Committee (TAC)

### Meeting to Review Branch-Chain Ketoacid Dehydrogenase Kinase (BCKDK) Deficiency for the Newborn Screening Panel

### **TAC Member Voting Summaries and Comments**

The following is a compilation of comments from TAC members provided when voting on each individual criteria, and an overall recommendation. Comments have been summarized and are organized by each criterion and then overall comments provided.

| <b>Criteria</b><br>1. Available Screening Technology |   | Major themes  |
|--|---|---|
|  |   | • Tests and technology are available for measuring BCA serum levels,  |
| Yes, meets criterion.                                | 6 | but their performance, sensitivity, and specificity are unclear.  |
| No, does not meet criterion.                         | 7 | • While the upper limits of normal BCA levels are defined, lower limits can be estimated from population norms, and tandem mass spectrometry is already used to directly measure BCA plasma levels. |
| Unsure.  | 4 | spectrometry is already used to directly measure BCA plasma levels.   |
|  |   |   |

| 2. Diagnostic Testing and Treatment Available |   | • | There is very limited evidence available for this disorder, making it  |
|---|---|---|--|
| Yes, meets criterion.                         | 6 |   | unclear whether diagnostic criteria are met.   |
| No, does not meet criterion.                  | 6 | • | positives/negatives, and treatment effectiveness is insufficient, and  |
| Unsure.                                       | 5 |   | the small sample size makes it difficult to verify the disorder's validity.  |
|   |   |   |  |
| 3. Prevention Potential and Medical Rationale |   | • | There is a lack of sufficient data on the prevalence, long-term outcomes with early treatment, and the number of patients in the |
| Yes, meets criterion.                         | 7 |   | literature, making it difficult to assess the relevant criteria.   |
| No, does not meet criterion.                  | 3 |   |  |
| Unsure.                                       | 7 |   |  |
|   |   |   |  |

Washington State Board of Health March 12, 2025, Meeting Materials Page 3

| 4. Public Health Rationale                                |            | • | <ul> <li>Not enough information to assess this criterion. Rarity gives pause<br/>but true prevalence is unknown.</li> </ul> |  |  |
|---|------------|---|---|--|--|
| Yes, meets criterion.                                     | 2          |   |   |  |  |
| No, does not meet criterion.                              | 12         |   |   |  |  |
| Unsure.   | 3          |   |   |  |  |
|   |            |   |   |  |  |
| 5. Cost Benefit / Cost Effective<br>Yes, meets criterion. | eness<br>0 | • | including the lack of BCA testing, limited prevalence information, and  |  |  |
| No, does not meet criterion.                              | 13         | • | only 21 patients reported in the literature.<br>Screening is not being conducted, and there are concerns about              |  |  |
| Unsure.   | 4          |   | unintended consequences for conditions on the newborn screening panel.  |  |  |
|   |            |   |   |  |  |

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### COST BENEFIT ANALYSIS FOR BCKDK DEFICIENCY

Megan McCrillis, MPH Policy Analyst, WA State Newborn Screening Program John D. Thompson, PhD, MPA, MPH Director, Newborn Screening Program

### The criterion

**5. Cost-benefit/Cost-effectiveness:** The outcomes outweigh the costs of screening. All outcomes, both positive and negative, need to be considered in the analysis. Important considerations to be included in economic analyses include:

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

### Washington State Department of Health | 2

### The cost-benefit model

O Decision Tree

Compares status quo v. screening model

OData from:

• Primary literature

- States currently screening or pilot studies
- Expert opinion
- Sensitivity analysis vary assumptions
   O High and low estimates for parameters

### The cost- benefit model

Decision Tree

Compares status quo v. screening model

• Data from:

 $\circ$  Primary literature  $\rightarrow$  extremely limited

- $\circ$  States currently screening or pilot studies  $\rightarrow$  none
- $\circ$  Expert opinion  $\rightarrow$  mostly not accessible
- Sensitivity analysis vary assumptions
   O High and low estimates for parameters

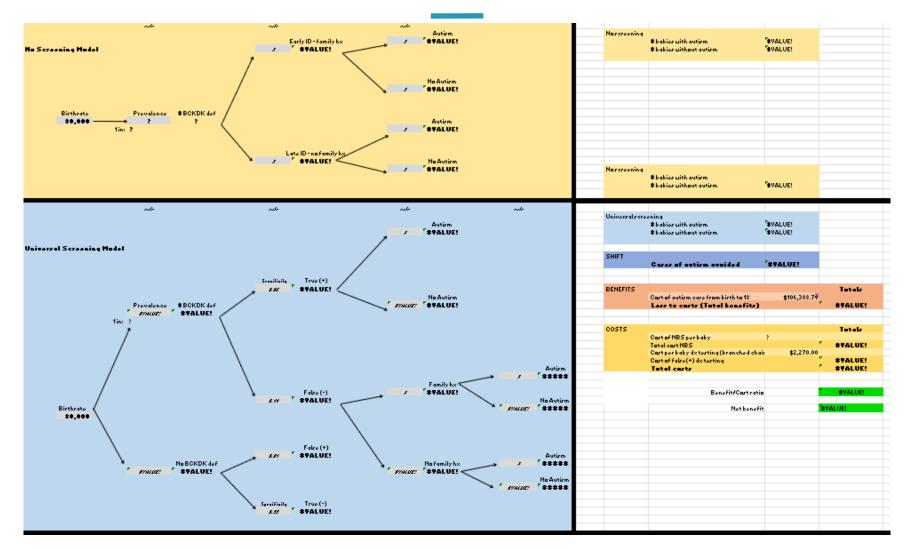
### The cost-benefit model

• Consult:

 Anna Hidle, Public Health Economist, Washington Department of Health

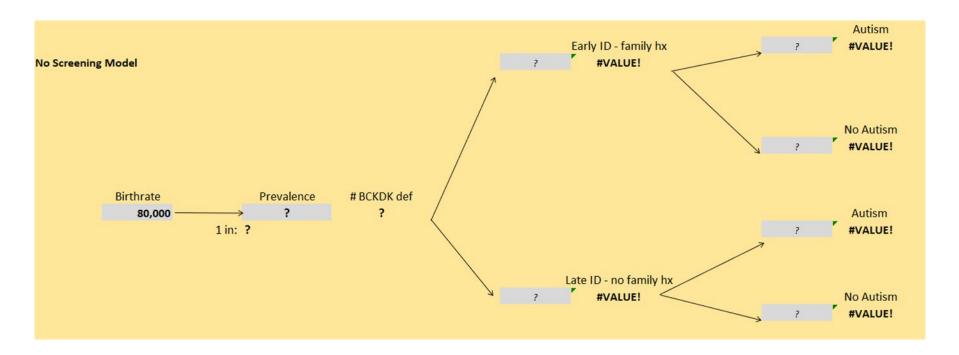
Washington State Department of Health | 5

### The cost-benefit model

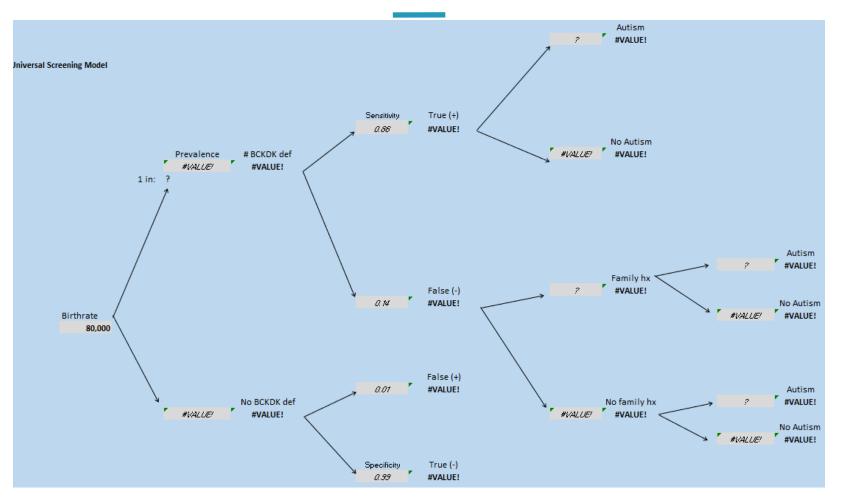


Washington State Department of Health | 6

# Status quo: No screening model



# Newborn screening model



# Benefits and Costs

| No screening   | # babies with autism<br># babies without autism                        | #VALUE!            |           |
|----------------|--|--------------------|-----------|
|                |  |                    |           |
| Universal scre | ening<br># babies with autism<br># babies without autism               | #VALUE!<br>#VALUE! |           |
| SHIFT          |  |                    |           |
| 51111          | Cases of autism avoided  | #VALUE!            |           |
|                |  |                    |           |
|                |  |                    |           |
| BENEFITS       |  |                    | Totals    |
|                | Cost of autism care from birth to 18<br>Less tx costs (Total benefits) | \$106,388.79       | #VALUE!   |
|                |  |                    |           |
| COSTS          |  |                    | Totals    |
| 00313          | Cost of NBS per baby   | ?                  | Totals    |
|                | Total cost NBS   |                    | #VALUE!   |
|                | Cost per baby dx testing (branched chai                                | ı \$2,270.00       |           |
|                | Cost of false(+) dx testing  |                    | #VALUE!   |
|                | Total costs  |                    | #VALUE!   |
|                |  |                    |           |
|                |  |                    | -         |
|                | Benefit/Cost ratio   |                    | ″ #VALUE! |
|                | Net benefit  |                    | #VALUE!   |
|                |  |                    |           |
|                |  |                    |           |

# Summary

- The quality of the results are only as good as the data in the model
- We did not provide a cost-benefit ratio to the NBS Technical Advisory Committee
- The model is built
  - Parameters for missing assumptions could be entered in the future when data is available

# Questions?

# Washington State Board of Health

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

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

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

# QUALIFYING ASSUMPTION

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

# THREE GUIDING PRINCIPLES

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

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

# CRITERIA

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



# Washington State Board of Health

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

Last updated November 13, 2024

# Amended Section (Approved November 2024)

The Washington State Board of Health <u>(Board)</u> has the duty under RCW 70.83.050 to define and adopt rules for screening Washington-born infants for heritable conditions. Chapter 246-650-020 WAC lists conditions for which all newborns must be screened. Members of the public, staff at Department of Health <u>(Department)</u>, and/or Board members can request that the Board review a particular condition for possible inclusion in the <u>newborn</u> <u>screening (NBS)</u> panel. In order to To determine which conditions to include in the <u>newborn screening NBS</u> panel.<sub>37</sub> the Board convenes an <u>newborn screening technical</u> advisory committee <u>(TAC)</u> to evaluate candidate conditions using guiding principles and an established set of criteria.

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

# QUALIFYING ASSUMPTION

# Amended Section (Approved November 2024)

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

# New Section (Approved November 2024)

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

## New Section (Pending Board Approval)

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

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

# THREE GUIDING PRINCIPLES

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

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

# CRITERIA

- 1. Available Screening Technology: Sensitive, specific and timely tests are available that can be adapted to mass screening.
  - The sensitivity of the screening test is estimated to be  $\ge$  95%.

- The specificity of the screening test is considered acceptable based on the estimated number of false positive results and their potential impact on the families, healthcare system, and newborn screening program.
- A timely test is one that enables intervention before irreversible harm develops, within the current standard timeframes for specimen collection, receipt, testing, and reporting.
- There is adequate peer reviewed evidence to evaluate this criterion.

2. **Diagnostic Testing and Treatment Available**: Accurate diagnostic tests, medical expertise, and effective treatment are available for evaluation and care of all infants identified with the condition.

- A diagnostic test accurately identifies who needs treatment and is readily available to all newborns screened.
- The available treatment is effective in reducing morbidity or mortality and outweighs any risks or harms of the treatment.
- The medical expertise needed to diagnose and care for those with a positive newborn screen is reasonably available to all newborns screened.
- The appropriate consultants and treatment centers have been identified and have capacity for the expected increase in diagnostic testing and/or referrals.

3. **Prevention Potential and Medical Rationale**: The newborn identification of the condition allows early diagnosis and intervention.

- There is sufficient time between birth and onset of irreversible harm to allow for diagnosis and intervention.
- The condition must have an onset form that occurs in infancy (within the first year of life); newborn screening is not appropriate for conditions that only present after the first year of life.
- The benefits of detecting and treating early onset infantile-onset forms of the condition (within one year of life) balance the impact of detecting later onset forms of the condition.
- Newborn screening is not appropriate for conditions that only present in adulthood.
- There is adequate evidence of acceptable quality to evaluate this criterion.

4. **Public Health Rationale:** Nature of the condition justifies population-based screening rather than risk based screening or other approaches.

- All available risk-based screening tools for the condition have been considered and are found to be inferior to universal newborn screening.
- There is adequate evidence of acceptable quality to evaluate this criterion.

5. **Cost-benefit/Cost-effectiveness**: The outcomes outweigh the costs of screening. All outcomes, both positive and negative, need to be considered in the analysis. Important considerations to be included in the economic analyses include:

• The economic analysis considers:

- The prevalence of the condition among newborns.
- The positive and negative predictive values of the screening and diagnostic tests.
- $\circ$   $\,$  Variability of clinical presentation by those who have the condition.
- Dollar values for costs and benefits of screening vs. no screening.
- The impact of ambiguous results, adverse effects, or unintended consequences of screening, such as psycho-social or economic impacts on the family and medical system, must also be considered.
- The results of the economic analysis shows that the outcomes, financial or otherwise, outweigh the costs of screening
- There is adequate evidence of acceptable quality to evaluate this criterion
- The impact of ambiguous results. For example, the emotional and economic impact on the family and medical system.
- Adverse effects or unintended consequences of screening.

6. **Public Health Readiness:** The Newborn Screening Program's capacity to implement screening within a reasonable timeframe has been considered.

- The systems and staffing necessary to perform the test and report screening results have been identified.
- Resources needed to implement short/long term follow up protocols by the newborn screening program have been identified.
- Accessibility to treatment for anyone diagnosed with the condition is considered acceptable based on the frequency of treatment needed.

|  |               | Opinion          |                     |          |
|--|---------------|------------------|---------------------|----------|
| Criterion  | Meets         | Does not<br>meet | More info<br>needed | Comments |
| 1.   |               |                  |                     |          |
| Available Screening Technology                     |               |                  |                     |          |
| Sensitive, specific and timely tests are available | e that can be | adapted to mas   | ss screening        |          |
| The sensitivity of the screening test is           |               |                  |                     |          |
| estimated to be ≥95%                               |               |                  |                     |          |
| The specificity of the screening test is           |               |                  |                     |          |
| considered acceptable based on the estimated       |               |                  |                     |          |
| number of false positive results and their         |               |                  |                     |          |

| potential impact on families, the healthcare             |                   |                  |   |
|--|-------------------|------------------|---|
| system, newborn screening program.                       |                   |                  |   |
| A timely test is one that enables intervention           |                   |                  |   |
| before irreversible harm develops, within the            |                   |                  |   |
| current standard timeframes for specimen                 |                   |                  |   |
| collection, receipt, testing, and reporting              |                   |                  |   |
| There is adequate evidence of acceptable                 |                   |                  |   |
| quality to evaluate this criterion                       |                   |                  |   |
| Overall impression of criterion 1:                       |                   |                  |   |
| 2.   |                   | 1                |   |
| Diagnostic Testing and Treatment Available               |                   |                  |   |
| Accurate diagnostic tests, medical expertise, and effect | ive treatment are | available for ev | aluation and care of all infants identified |
| with the condition                                       |                   |                  |   |
| A diagnostic test accurately identifies who              |                   |                  |   |
| needs treatment, and is readily available to all         |                   |                  |   |
| newborns <b>screened</b> .                               |                   |                  |   |
| The available treatment is effective in reducing         |                   |                  |   |
| morbidity or mortality, and outweighs any risks          |                   |                  |   |
| or harms of the treatment.                               |                   |                  |   |
| The medical expertise needed to diagnose and             |                   |                  |   |
| care for those with a positive newborn screen            |                   |                  |   |
| is reasonably available to everyone screened             |                   |                  |   |
| The availability and proximity to treatment for          |                   |                  |   |
| anyone diagnosed with the condition is                   |                   |                  |   |
| considered acceptable based on the frequency             |                   |                  |   |
| of treatment needed                                      |                   |                  |   |
| The appropriate consultants and treatment                |                   |                  |   |
| centers have been identified and have capacity           |                   |                  |   |
| for the expected increase in diagnostic testing          |                   |                  |   |
| and/or referrals   |                   |                  |   |
| There is adequate evidence of acceptable                 |                   |                  |   |
| quality to evaluate this criterion                       |                   |                  |   |
| Overall impression of criterion 2:                       |                   |                  |   |
|  |                   |                  |   |

| 3.   |                        |                      |                                       |
|--|------------------------|----------------------|---------------------------------------|
| Prevention Potential and Medical Rationale         |                        |                      |                                       |
| The newborn identification of the condition allow  | s early diagnosis and  | intervention.        |                                       |
| There is sufficient time between birth and         |                        |                      |                                       |
| onset of irreversible harm to allow for            |                        |                      |                                       |
| diagnosis and intervention                         |                        |                      |                                       |
| The condition must have an onset form that         |                        |                      |                                       |
| occurs in infancy (within the first year of life); |                        |                      |                                       |
| newborn screening is not appropriate for           |                        |                      |                                       |
| conditions that only present after the first year  |                        |                      |                                       |
| of life.   |                        |                      |                                       |
| The benefits of detecting and treating infantile-  |                        |                      |                                       |
| onset forms of the condition balance the           |                        |                      |                                       |
| impact of detecting later onset forms of the       |                        |                      |                                       |
| condition  |                        |                      |                                       |
| There is adequate evidence of acceptable           |                        |                      |                                       |
| quality to evaluate this criterion                 |                        |                      |                                       |
| Overall impression of criterion 3:                 |                        |                      |                                       |
| 4.   |                        |                      |                                       |
| Public Health Rationale                            |                        |                      |                                       |
| Nature of the condition justifies population-base  | d screening rather tha | in risk based screen | ing or other approaches               |
| Any available risk-based screening tools for the   |                        |                      |                                       |
| condition have been considered and are             |                        |                      |                                       |
| inferior to universal newborn screening            |                        |                      |                                       |
| There is adequate evidence of acceptable           |                        |                      |                                       |
| quality to evaluate this criterion                 |                        |                      |                                       |
| Overall impression of criterion 4:                 |                        |                      |                                       |
| 5.   |                        |                      |                                       |
| Cost-benefit/Cost-effectiveness                    |                        |                      |                                       |
| The outcomes outweigh the costs of screening. A    | All outcomes, both po  | sitive and negative, | need to be considered in the analysis |
| The <b>economic analysis considers:</b>            |                        |                      |                                       |
| o The prevalence of the condition                  |                        |                      |                                       |
| among newborns.                                    |                        |                      |                                       |

| o The positive and negative predictive          |                             |                 |                             |
|---|-----------------------------|-----------------|-----------------------------|
| values of the screening and diagnostic tests.   |                             |                 |                             |
| o Variability of clinical presentation by       |                             |                 |                             |
| those who have the condition.                   |                             |                 |                             |
| o Dollar values for costs and benefits of       |                             |                 |                             |
| screening vs. no screening                      |                             |                 |                             |
| The impact of ambiguous results, adverse        |                             |                 |                             |
| effects, or unintended consequences of          |                             |                 |                             |
| screening , such as emotional or economic       |                             |                 |                             |
| impacts on the family and medical system,       |                             |                 |                             |
| must also be considered.                        |                             |                 |                             |
| The results of the economic analysis shows      |                             |                 |                             |
| that the outcomes, financial or otherwise,      |                             |                 |                             |
| outweigh the costs of screening                 |                             |                 |                             |
| There is adequate evidence of acceptable        |                             |                 |                             |
| quality to evaluate this criterion.             |                             |                 |                             |
| Overall impression of criterion 5:              |                             |                 |                             |
| 6.  |                             |                 |                             |
| Public Health Readiness                         |                             |                 |                             |
| The Newborn Screening Program's capacity to in  | nplement screening within a | a reasonable ti | meframe has been considered |
| The systems and staffing necessary to perform   |                             |                 |                             |
| the test and report screening results have been |                             |                 |                             |
| identified                                      |                             |                 |                             |
| Resources needed to implement short/long        |                             |                 |                             |
| term follow up protocols by the newborn         |                             |                 |                             |
| screening program have been identified          |                             |                 |                             |
| Accessibility to treatment for anyone           |                             |                 |                             |
| diagnosed with the condition is considered      |                             |                 |                             |
| acceptable based on the frequency of            |                             |                 |                             |
| treatment needed                                |                             |                 |                             |
| <b>Overall impression of criterion 6:</b>       |                             |                 |                             |
| Overall impression of the condition:            |                             |                 |                             |
| Recommendation:                                 |                             |                 |                             |
|   |                             |                 |                             |





# **Newborn Screening** Technical Advisory Committee (TAC)

WASHINGTON STATE

**BOARDOFHEALTH** 

# Meeting to Review Criteria to Evaluate Conditions for the Newborn Screening Panel

# **TAC Member Voting Summaries and Comments**

The following is a compilation of comments from TAC members provided when voting on each individual criteria, and an overall recommendation. Comments have been summarized and are organized by each criterion and then overall comments provided.

| Criterion #1 - Available Screening Tec                         | •••          | ensitive, specific and<br>to mass screening                   | timely                       | tests | are     | ava   | ilabl | e tha  | at ca | ın be            | e ada  | apteo |  |  |  |
|--|--------------|---|------------------------------|-------|---------|-------|-------|--------|-------|------------------|--------|-------|--|--|--|
| Suggested edits  |              | Votes whether to app  | rove pro                     | pos   | ed c    | han   | ges   | to cr  | iteri | on               |        |       |  |  |  |
| The sensitivity of the screening test is estimated to be ≥95%. |              |   |                              |       |         |       |       |        |       |                  |        |       |  |  |  |
|  |              | I am unsure or need more inform                               | nation                       |       |         |       |       |        |       |                  |        |       |  |  |  |
|  | l would li   | ke to omit the proposed changes<br>criterion or suggest edits | to the                       |       |         |       |       |        |       |                  |        |       |  |  |  |
|  | I approve of | the proposed changes to the crit                              | erion                        |       |         |       |       |        |       |                  |        |       |  |  |  |
|  |              |   | 0                            | 2     | 4       | 6     | 8     | 10     | 12    | 14               | 16     | 18    |  |  |  |
|  |              | I approve of the proposed changes to the criterion            | l woul<br>propos<br>criterio |       | nges to | o the |       | l am u |       | or nee<br>nation | d more | e     |  |  |  |
|  | Votes        | 16  |                              | 1     |         |       |       |        |       | 0                |        |       |  |  |  |

The specificity of the screening test is considered acceptable based on the estimated number of false positive results and their potential impact on I am unsure or need more information families, the healthcare system, I would like to omit the proposed changes to the and the newborn screening criterion or suggest edits program. I approve of the proposed changes to the criterion Note: original suggested update read 0 2 4 6 8 10 12 14 16 18 as "...their potential impact on the I would like to omit the proposed healthcare system, the newborn I approve of the proposed I am unsure or need more changes to the criterion or changes to the criterion information screening program, and families." The suggest edits TAC suggested the change in order to 17 Votes 0 0 reflect importance of the impact on families. A timely test is one that enables intervention before irreversible harm develops, within the current standard timeframes for specimen collection, I am unsure or need more information receipt, testing, and reporting. I would like to omit the proposed changes to the criterion or suggest edits I approve of the proposed changes to the criterion 0 Λ 6 8 10 12 14 16 18 I would like to omit the proposed I approve of the proposed I am unsure or need more changes to the criterion or changes to the criterion information suggest edits 17 0 0 Votes

|                                      |    | I approve of the proposed changes to the criterion  | prop  |   | anges | it the<br>to the<br>t edits |   | lam |    | or nee<br>matior | ed more | e  |
|--------------------------------------|----|---|-------|---|-------|-----------------------------|---|-----|----|------------------|---------|----|
|                                      |    | to omit the proposed changes to<br>criterion or suggest edits<br>rove of the proposed changes to<br>criterion | _     | 2 | 4     | 6                           | 8 | 10  | 12 | 14               | 16      | 18 |
| evidence to evaluate this criterion. | la | im unsure or need more informa  | ition |   |       |                             |   |     |    |                  |         |    |

| Suggested edits   | · · · · · · · · · · · · · · · · · · · | Votes whether to app   | rove p | oropo                            | osed   | char   | nges | s to c | riter             | ion               |        |    |
|---|---------------------------------------|--|--------|----------------------------------|--------|--------|------|--------|-------------------|-------------------|--------|----|
| A diagnostic test accurately identifies<br>who needs treatment and is readily<br>available to all newborns screened.                | l would like                          | am unsure or need more informa<br>to omit the proposed changes to<br>criterion or suggest edits<br>prove of the proposed changes to<br>criterion | o the  | 2                                | 4      | 6      | 8    | 10     | 12                | 14                | 16     | 18 |
|   |                                       | l approve of the proposed changes to the criterion   | prop   | ould like<br>oosed cl<br>rion or | nanges | to the |      | l am u | nsure c<br>inform | or need<br>nation | l more |    |
|   | Votes                                 | 17   |        |                                  | 0      |        |      |        | (                 | 0                 |        |    |
| The available treatment is effective in<br>reducing morbidity or mortality and<br>outweighs any risks or harms of the<br>treatment. |                                       | I am unsure or need more inforn<br>ke to omit the proposed changes<br>criterion or suggest edits<br>the proposed changes to the crit             | to the | ) 2                              | 4      | 6      | 8    | 10     | 12                | 14                | 16     | 18 |
|   |                                       | I approve of the proposed changes to the criterion   | pro    | ould lik<br>posed c<br>erion or  | hanges | to the |      | l am   |                   | or nee<br>mation  |        | e  |
|   | Votes                                 | 17   |        |                                  | 0      |        |      |        |                   | 0                 |        |    |

| The medical expertise needed to<br>diagnose and care for those with a<br>positive newborn screen is<br>reasonably available to all newborns<br>screened.               |          | I am unsure or need more inform<br>ike to omit the proposed changes<br>criterion or suggest edits<br>f the proposed changes to the crit | to the          | 0     | 2 4                                 | 6      | 8    | 10     | 12                | 14    | 16 | 18 |
|--|----------|---|-----------------|-------|-------------------------------------|--------|------|--------|-------------------|-------|----|----|
|  |          | I approve of the proposed changes to the criterion  | pro             | posed | ike to on<br>changes<br>or sugges   | to the |      | I am u | nsure c<br>inform |       |    | !  |
|  | Votes    | 17  |                 |       | 0                                   |        |      |        | (                 | )     |    |    |
| The appropriate consultants and<br>treatment centers have been<br>identified and have capacity for the<br>expected increase in diagnostic<br>testing and/or referrals. |          | I am unsure or need more inform<br>ike to omit the proposed changes<br>criterion or suggest edits<br>f the proposed changes to the crit | to the<br>erion | 0     |                                     | 6      | 8    | 10     | 12                | 14    | 16 | 18 |
|  |          | l approve of the proposed changes to the criterion  | pro             | posed | ike to on<br>I changes<br>or sugges | to the |      | l am u | nsure o<br>inform |       |    | b. |
|  | Votes    | 17  |                 |       | 0                                   |        |      |        | (                 | )     |    |    |
| Comments:  | Apprecia | te the inclusion of "read   | dily av         | ailat | ole' an                             | d "rea | ason | ably a | availa            | able" | 1  |    |

| Suggested edits   |           | Votes whether to approve proposed changes to criterion   |       |          |   |  |  |         |  |                         |              |    |
|---|-----------|--|-------|----------|---|--|--|---------|--|-------------------------|--------------|----|
| There is sufficient time<br>between birth and onset of<br>irreversible harm to allow for<br>diagnosis and intervention.   | No propos | ed changes.  |       |          |   |  |  |         |  |                         |              |    |
| The condition must have an<br>onset form that occurs in<br>infancy (within the first year of<br>life); newborn screening is not<br>appropriate for conditions that<br>only present after the first year<br>of life. |           | I am unsure or need more inform<br>Id like to omit the proposed changes<br>criterion or suggest edits<br>e of the proposed changes to the crite<br>I approve of the proposed changes<br>to the criterion | o the | to the c |   |  |  | l<br>10 |  | 14<br>or need<br>mation | 16<br>d more | 18 |
|   | Vote      | s 17   |       |          | 0 |  |  |         |  | 0                       |              |    |

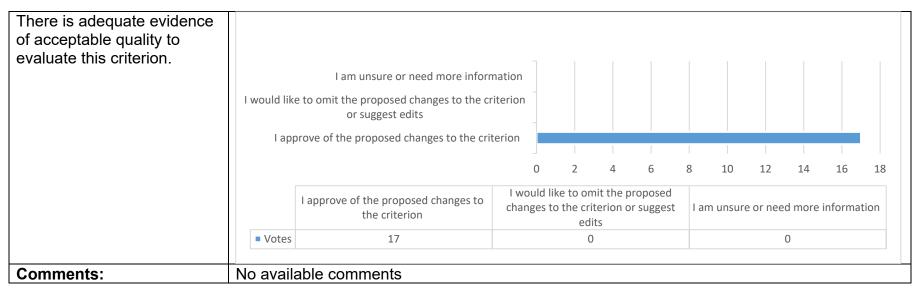
| The benefits of detecting and<br>treating <i>infantile-onset</i> forms<br>of the condition (within one<br>year of life) balance the<br>impact of detecting later onset<br>forms of the condition. |                 | I am unsure or need more inform<br>Id like to omit the proposed changes<br>criterion or suggest edits<br>e of the proposed changes to the crite | o the                     | 2                                | 4        | 6 8                    | 10   | 12                | 14                  | 16     | 18 |
|---|-----------------|---|---------------------------|----------------------------------|----------|------------------------|------|-------------------|---------------------|--------|----|
|   |                 | I approve of the proposed changes<br>to the criterion   |                           | like to om<br>to the crit<br>edi | terion o | oroposed<br>or suggest | l a  | m unsur<br>info   | e or nee<br>rmation |        |    |
|   | Vote            | es 17   |                           | 0                                |          |                        |      |                   | 0                   |        |    |
| Newborn screening is not<br>appropriate for conditions that<br>only present in adulthood.<br>( <i>Strike sub-criteria</i> )   |                 | I am unsure or need more inforr   | nation                    |                                  |          |                        |      |                   |                     |        |    |
| Note: see comments  | I would like to | o omit the proposed changes to the cr<br>or suggest edits   | iterion                   |                                  |          |                        |      |                   |                     |        |    |
|   | l appro         | ve of the proposed changes to the cri   | terion                    |                                  |          |                        |      |                   |                     |        |    |
|   |                 |   | 0                         | 2                                | 4        | 6                      | 8    | 10                | 12                  | 14     | 16 |
|   | I a             | pprove of the proposed changes to the criterion   | I would lik<br>changes to |                                  |          |                        | l ar | n unsure<br>infoi | or need<br>mation   | d more |    |
|   | Votes           | 14  |                           | 3                                |          |                        |      |                   | 0                   |        |    |

| There is adequate evidence of acceptable quality to evaluate this criterion. |                      |  | 7   |       | 1     |         |      | 1                               |       |      |    |    |
|--|----------------------|--|---|-------|-------|---------|------|---------------------------------|-------|------|----|----|
|  |                      | I am unsure or need more infor   | mation  |       |       |         |      |                                 |       |      |    |    |
|  |                      | e to omit the proposed changes to the c<br>or suggest edits<br>prove of the proposed changes to the cr                     | _   |       |       |         |      |                                 |       |      |    |    |
|  |                      |  |   |       |       |         |      |                                 |       |      |    |    |
|  |                      |  | 0   | 2     | 4     | 6       | 8    | 10                              | 12    | 14   | 16 | 18 |
|  |                      | I approve of the proposed changes to the criterion   | I would like to omit the proposed<br>changes to the criterion or suggest<br>edits |       |       |         |      | I am unsure or need more inform |       |      |    |    |
|  | Votes                | 17   |   | 0     |       |         |      |                                 |       | 0    |    |    |
| Comments:  | should s<br>After ad | n screening not being appro<br>still be included in Criterion #<br>ditional discussion, there ma<br>n for sub-criterion 3. | <sup>1</sup> 3, just m  | ake s | ure p | oints a | re n | ot rec                          | dunda | ant. |    |    |

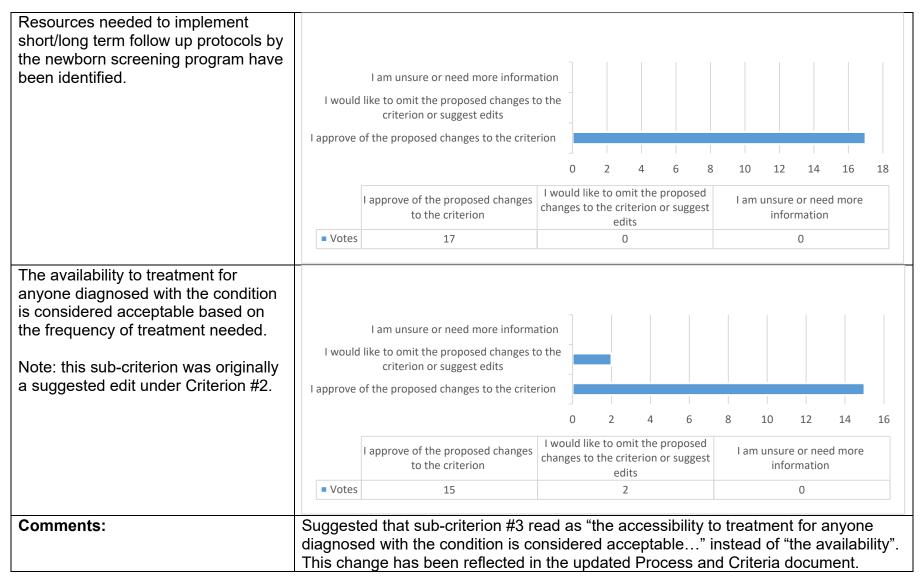
| Criterion # 4 – Public Health  |             |   | justi    | ies po                            | pulatio | on-bas | ed so   | reeni | ng ratl | ner tha | n risk |  |  |  |
|--|-------------|---|----------|-----------------------------------|---------|--------|---|-------|---------|---------|--------|--|--|--|
| based screening or other ap  |             |   |          |                                   |         |        |   |       |         |         |        |  |  |  |
| Suggested edits  | Votes w     | hether to approve propos  | ed ch    | anges                             | to crit | erion  |   |       |         |         |        |  |  |  |
| All available risk-based   |             |   |          |                                   |         |        |   |       |         |         |        |  |  |  |
| creening tools for the   |             |   |          |                                   |         |        |   |       |         |         |        |  |  |  |
| condition have been  |             |   |          | 1 1                               |         |        |   |       | 1 1     |         |        |  |  |  |
| considered and are found to  |             | I am unsure or need more infor  | mation   |                                   |         |        |   |       |         |         |        |  |  |  |
| be inferior to universal newborn screening.  | I would lik | e to omit the proposed changes to the c<br>or suggest edits   | riterion |                                   |         |        |   |       |         |         |        |  |  |  |
| -  | Lapi        | prove of the proposed changes to the cri  | terion   |                                   |         |        |   |       |         |         |        |  |  |  |
|  |             | ·····   |          |                                   |         |        |   |       |         |         |        |  |  |  |
|  |             |   |          | 0 2                               | 4       | 6      | 8   | 10    | 12 14   | 16      | 18     |  |  |  |
|  |             | I approve of the proposed changes to the criterion  |          | ild like to o<br>es to the o<br>e |         |        |   |       |         |         |        |  |  |  |
|  | Votes       | 17  | 0        |                                   | 0       |        |   |       |         |         |        |  |  |  |
| There is adequate evidence<br>of acceptable quality to<br>evaluate this criterion. |             | I am unsure or need more infor<br>e to omit the proposed changes to the c<br>or suggest edits<br>prove of the proposed changes to the cri | riterion | 0 2                               | 4       | 6      | 8   | 10    | 12 14   | 16      | 18     |  |  |  |
|  |             | I approve of the proposed changes to the criterion  |          | ild like to d<br>es to the d<br>e |         |        | st I am unsure or need more informat<br>0  1 am unsure or need more informat  8 10 12 14 16  d st I am unsure or need more informat |       |         |         |        |  |  |  |
|  | Votes       | 17  |          |                                   | 0       |        |   |       | 0       |         |        |  |  |  |
| Comments:  | Apprecia    | ate the addition of the first s   | ub-crit  | erion p                           | oint.   |        |   |       |         |         |        |  |  |  |

| Criterion # 5 - Cost-benefit/C   |         |   | outweigh                 | the o  | costs     | of sci | reen | ing. A  | All ou   | tcom   | es, bo  | oth  |
|--|---------|---|--------------------------|--------|-----------|--------|------|---------|----------|--------|---------|------|
| positive and negative, need  |         |   |                          |        |           |        |      |         |          |        |         |      |
| Suggested edits  |         | hether to approve propose   | ed chang                 | jes to | o crite   | erion  |      |         |          |        |         |      |
| <ul> <li>The economic analysis considers:</li> <li>The prevalence of the condition among newborns.</li> <li>The positive and negative predictive values of the screening and diagnostic tests.</li> <li>Variability of clinical presentation by those who have the condition.</li> </ul> | No prop | osed changes.   |                          |        |           |        |      |         |          |        |         |      |
| Dollar values for costs and<br>benefits of screening vs. no<br>screening.  |         | I am unsure or need more inforr<br>te to omit the proposed changes to the cr<br>or suggest edits<br>prove of the proposed changes to the crit | iterion                  |        |           |        |      |         |          |        |         |      |
|  |         |   | 0                        | 2      | 4         | 6      | 8    | 10      | 12       | 14     | 16      | 18   |
|  |         | I approve of the proposed changes to the criterion  | I would li<br>changes to |        | iterion o |        | l ai | m unsur | e or nee | d more | informa | tion |
|  | Votes   | 17  |                          | C      | )         |        |      |         |          | 0      |         |      |

| The impact of ambiguous<br>results, adverse effects, or<br>unintended consequences of<br>screening, such as<br>psychosocial or economic<br>impacts on the family and<br>medical system, must also<br>be considered. |                           | I am unsure or need more inform<br>e to omit the proposed changes to the cr<br>or suggest edits<br>prove of the proposed changes to the crit   | iterion                   | 2        | 4              | 6          | 8  | 10            | 12             | 14                    | 16      | 18          |
|---|---------------------------|--|---------------------------|----------|----------------|------------|----|---------------|----------------|-----------------------|---------|-------------|
|   | <ul> <li>Votes</li> </ul> | I approve of the proposed changes to<br>the criterion<br>16  | I would lil<br>changes to |          | terion o<br>ts |            |    | m unsur       | e or nee       |                       |         | _           |
| The results of the economic<br>analysis shows that the<br>outcomes, financial or<br>otherwise, outweigh the<br>costs of screening.  |                           | I am unsure or need more inform<br>e to omit the proposed changes to the cr<br>or suggest edits<br>prove of the proposed changes to the crit<br>I approve of the proposed changes to | iterion                   |          |                |            | 8  | 10<br>m unsur | 12<br>e or nee | <br> <br>14<br>d more | 16      | 18<br>Ition |
|   | Votes                     | the criterion<br>16  | changes to                | edi<br>0 | ts             | ir suggest | Id | m unsur       |                | 1                     | Intorna |             |



| Suggested edits  | Votes w | hether to approve pro   | posed c                                      | hang | jes to                | criteri | on   |   |                         |        |    |  |  |
|--|---------|---|--|------|-----------------------|---------|------|---|-------------------------|--------|----|--|--|
| #6 - Public Health Readiness: The<br>Newborn Screening Program's<br>capacity to implement screening<br>within a reasonable timeframe has<br>been considered. | l would | I am unsure or need more inform<br>like to omit the proposed changes<br>f the proposed changes to the crit                                | nation<br>to the                             | 2    |                       | 6 8     | 10   | 12                                      | 14                      | 16     | 18 |  |  |
|  | r       |   | -  | _    |                       |         |      |   |                         |        |    |  |  |
|  |         | I approve of the proposed changes to the criterion  | -  |      | e criteri             |         | l am | I am unsure or need more<br>information |                         |        |    |  |  |
|  | Votes   |   |  |      |                       |         |      |   | 0                       |        |    |  |  |
| to perform the test and report   |         |   |  |      |                       |         |      |   |                         |        |    |  |  |
| to perform the test and report<br>screening results have been<br>identified.   |         | I am unsure or need more inform<br>like to omit the proposed changes<br>criterion or suggest edits<br>if the proposed changes to the crit | to the<br>erion<br>0<br>I would lil          |      |                       |         | 10   | 12                                      | 14                      | 16     | 18 |  |  |
| screening results have been  |         | like to omit the proposed changes<br>criterion or suggest edits   | to the<br>erion<br>0<br>I would lii<br>chang |      | e criteri<br>st edits |         |      | unsure                                  | 14<br>or need<br>mation | d more | 18 |  |  |



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# WASHINGTON STATE BOARD OF HEALTH

Date: March 12, 2025

To: Washington State Board of Health Members

From: Patty Hayes, Board Chair

Subject: School Environmental Health and Safety Rule Review Project

#### Background and Summary:

During the 2024 legislative session, the Legislature included a proviso in the <u>2024 supplemental</u> <u>operating budget</u> (Section 222, subsection 159, page 491- 492) that directed the State Board of Health (Board) to review and draft new proposed rules to set minimum health and safety standards for K-12 schools. The proviso requires the Board to conduct the rule review in collaboration with the Department of Health and a multi-disciplinary technical advisory committee (TAC).

The proviso also tasks the Board with developing a report in collaboration with the Office of Superintendent and Public Instruction (OSPI), the Department of Health, the TAC, and local health jurisdictions. The report must prioritize the sections or subject areas that provide the greatest health and safety benefits for students and any other implementation recommendations. The Board must also complete an environmental justice assessment. This work must be completed and submitted to the Legislature and the Governor's office by June 30, 2025.

Since August of 2024, the Board's School Environmental Health and Safety TAC has conducted 13 full meetings and three subcommittee meetings to complete the draft rule. The rule has undergone an informal comment period, and the TAC reviewed those comments and considered them when making content changes to the proposed rule. In developing this rule, the Board has developed a fiscal analysis in collaboration with the TAC, OSPI, and industry partners.

The Board has also conducted substantial community outreach and offered several listening sessions across the state and online. Staff has shared the feedback collected at these sessions with the TAC for their consideration. Listening session participants included parents, students, teachers, and support staff, their perspectives were critically important to developing the practical aspects of the proposed rule.

Today, I have invited Project Manager Andrew Kamali, Board staff Nina Helpling, and the Department's Assistant Secretary of Environmental Public Health Lauren Jenks, to provide a more in-depth discussion on the process and outcomes of the school rule project.

#### **Recommended Board Actions:**

This is an informational update, not requiring any Board action.

#### Staff

Andrew Kamali, School Rule Project Manager

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

# **School Environmental Health and Safety Rule Project** – 2024-2025

# 2024 Supplemental Operating Budget

Section 222, Subsection 159, Page 4921

### Proviso Language:

- (a) \$750,000 of the general fund—state appropriation for fiscal year 2025 is provided solely to review and update the rules for school environmental health and safety. The state board of health and the department shall conduct the review in collaboration with a multi-disciplinary technical advisory committee. The proposed new rules shall establish the minimum statewide health and safety standards for schools. The state board of health shall consider the size of school districts, regional cost differences, the age of the schools, the feasibility of implementing the proposed rules by section or subject area, and any other variables that may affect the implementation of the rules. In developing proposed rules, the state board of health shall:
  - (i) Convene and consult with an advisory committee consisting of, at minimum, representatives from:
    - (A) The office of the superintendent of public instruction;
    - (B) Small and large school districts;
    - (C) The Washington association of school administrators;
    - (D) The Washington state school directors' association;
    - (E) The Washington association of maintenance and operations administrators; and
    - (F) The Washington association of school business officials;
  - (ii) After the development of the draft rules, the state board of health shall meet at least one time with the advisory committee and provide the opportunity for the advisory committee to comment on the draft rules;
  - (iii) Collaborate with the office of the superintendent of public instruction and develop a fiscal analysis regarding proposed rules that considers the size of school districts, regional cost differences, the age of the schools, range of costs for implementing the proposed rules by section or subject area, and any other variables that may affect costs as identified by the advisory committee; and
  - (iv)Assist the department in completing environmental justice assessments on any proposed rules.
- (b) The office of the superintendent of public instruction, the department, the state board of health, the advisory committee, and local health jurisdictions shall work collaboratively to develop and provide a report to the office of the governor and appropriate committees of the legislature by June 30, 2025, detailing prioritized sections or subject areas of the proposed rules that will provide the greatest health and safety benefits for students, the order in which they should be implemented, and any additional recommendations for implementation.

<sup>&</sup>lt;sup>1</sup> <u>https://fiscal.wa.gov/statebudgets/2024proposals/Documents/co/5950-S.SL.pdf</u>

# School Environmental Health and Safety Rule Project 2024 2025

# Summary of Changes

## WAC 246-370-001 Purpose

• **Combined**: Introduction statement with Purpose statement

## WAC 246-370-005 Definitions

- Added: 24 New definitions
- **Removed**: 5 Obsolete definitions
- Modernized: 3 Existing definitions
- No Change: 2 Existing definitions

## WAC 246-370-010 Applicability

- **Referenced**: Exceptions to chapter 246-370 WAC including:
  - Facilities licensed under Title 110 WAC Department of Children, Youth, and Families
  - Home-based instruction
  - Locations that provide education services, but education is not the primary function of the facility
  - Private tutoring
  - Post secondary schools
  - State-tribal education compact schools
- **Referenced**: Existing regulations that contain legal requirements for schools to follow for environmental health and safety on:
  - Food handling and preparation
  - Water recreation
  - Sewer and liquid waste disposal
  - Carbon monoxide detection
  - Drinking water

## WAC 246-370-015 Guidance

• **Updated**: Language—no substantive changes.

## WAC 246-370-020 Site Assessment

- Added: Local Health Officer (LHO) may require a site assessment for construction projects on existing school facilities.
- Added: School officials must:
  - Have a Phase 1 Site Assessment
  - Notify LHO at least 90 days prior to planning new construction
  - Submit site assessments to LHOs
- Added: LHOs must:
  - o Review site assessments
  - Provide written approval to a school official within 60 days of receiving a completed site assessment

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# School Environmental Health and Safety Rule Project 2024 2025

## WAC 246-370-030 Construction Plan Review New, Alterations, and Portable

- Added: Specifications for types of construction that might require plan review
- Added: Set timelines for school officials and LHOs to review construction plans

#### WAC 246-370-040 Routine Inspection

- Added: Routine inspection frequency
- Added: Allow a trained LHO designee to perform additional inspections

#### WAC 246-370-050 General Building Requirements

- Added: Backflow devices on housekeeping sinks
- Added: Bathrooms and handwashing facilities are available during school hours and scheduled events

#### WAC 246-370-060 Showers and Restrooms

- **Added:** At new construction or renovation
  - Must have 1 shower per 15 individuals per each gender participating in physical education or sports teams.
  - Must have 1 toilet per 15 individuals with up to 10% of the fixtures being urinals.

#### WAC 246-370-080 Indoor Air Quality

- **New Section**: Sets prescribed indoor air quality requirements like radon testing and pest management planning
- New Section: Sets prescribed ventilation requirements like outdoor air intake rates.

#### WAC 246-370-090 Temperature

- Added: Maximum and minimum temperature requirements
- Added: Requirement for the implementation of an extreme temperature readiness plan.

#### WAC 246-370-100 Noise

• Updated: Language—no substantive changes.

#### WAC 246-370-110 Lighting

• **Updated**: Language—no substantive changes.

#### WAC 246-370-120 Injury Prevention

- Added: Fall protection from balconies or orchestra pits and storage of unsecured equipment
- Added: Updated language for chemical storage
- Added: Fragrance-free and low-hazard cleaning requirements
- Added: Injury and communicable disease prevention planning when animals are allowed in school

#### WAC 246-370-130 Imminent Health Hazard

• **New Section**. Sets prescribed imminent health hazard requirements for hazards like sewage spillage

# School Environmental Health and Safety Rule Project 2024 2025

#### WAC 246-370-140 Playgrounds

• New Section: Sets prescribed installation and maintenance requirements for playgrounds

## WAC 246-370-150 Specialized Rooms

• **New Section**: Sets prescribed requirements for specialized rooms like health rooms, laboratories, and wood shops

### WAC 246-370-160 Variances

• Updated: Language—no substantive changes

### WAC 246-370-170 Severability

• **Updated**: Language—no substantive changes

### WAC 246-370-180 Appeals

• Updated: Language—no substantive changes



### WAC 246-370 School Environmental Health and Safety

#### School Environmental Health and Safety Rule Project 2024 - 2025

#### WAC 246-370-001 Purpose

(1) The purpose of this chapter is to set minimum environmental health and safety standards for school facilities operated for the primary purpose of providing education.

#### WAC 246-370-005 Definitions

- (1) "**Air cleaning technologies**" means technologies used to reduce the levels of air contaminants in indoor air.
- (2) **"Air contaminant"** means pollutants in the air that could, depending on dose and circumstances, cause adverse health impacts.
- (3) **"Carbon Filter**" means a type of filter that uses activated carbon or charcoal to absorb air contaminants.
- (4) "Decibel (dB)" means a standard unit of measurement of sound pressure.
- (5) **"Decibel, A-weighted (dBA)"** means a decibel measure that has been weighted in accordance with the A-weighting scale. The A-weighting adjusts sound level as a function of frequency to correspond approximately to the sensitivity of human hearing.
- (6) "Department" refers to the Washington State Department of Health.
- (7) **"Emergency washing facilities**" means emergency washing facilities such as emergency showers, eyewashes, eye/face washes, hand-held drench hoses, or other similar units.
- (8) **"Emissions**" mean substances released into the air, including gases and particles, from various sources.
- (9) **"Equivalent Continuous Sound Level" or "Leq"** means the sound pressure level of a noise fluctuating over a period of time, expressed as the amount of average energy.
- (10) **"Foot candle"** means a unit of measure of the intensity of light falling on a surface, equal to one lumen per square foot.
- (11) **"HEPA filter**" means a high-efficiency particulate air filter, a type of pleated mechanical air filter that can theoretically remove 99.97% of particles with a size of 0.3 microns.
- (12) "**Imminent health hazard**" means a significant threat or significant danger to health or safety that requires immediate action to prevent serious illness, injury, or death.
- (13) **"Integrated pest management"** means a program that reduces sources of food, water, and shelter for pests by using the least toxic pest controls when necessary.
- (14) **"Local board of health"** means the county or district board of health as defined in RCW 70.05.010(3).
- (15) **"Local health officer"** means legally qualified physician who has been appointed as the health officer for the city, town, county, or district public health department as defined in RCW 70.05.010(2) or their authorized representative.

- (16) **"New construction**" means new buildings or structures, including construction of additions to existing school facilities and reconstruction or retrofitting of an existing building not originally intended for use as a school facility. New construction does not include reconstruction of an existing school facility.<sup>1</sup>
- (17) "Noise abatement" means measures taken to reduce unacceptable sounds or vibrations.
- (18) **"Noise criterion"** means a single number for rating the sound quality of a room by comparing actual or calculated sound level spectra with a series of established octave band spectra.
- (19) **"Noise criterion 35 (NC35)"** means the curve for specifying the maximum permissible sound pressure level for each frequency band.
- (20) "**Portable**" means any school building with a prefabricated structure that can be transported and installed on-site to provide additional educational space.
- (21) **"Preschool**" means an educational establishment or learning space offering early childhood education to children not old enough to attend kindergarten.
- (22) "**Readiness Plan**" means a written guide to ensure the health and safety of the occupants of a school facility in the event of a particular hazard, such as extreme heat or wildfire smoke.
- (23) **"School**" means any public institution of learning where the primary purpose is educational instruction for children in any grade from kindergarten through grade twelve and related activities by the public school as defined in RCW 28A.150.010 and any private school or private institution regulated by chapter 28A.195 RCW.
- (24) **"School facility**" means all buildings and land intended primarily for student use including, but not limited to portables, sports fields, playgrounds, classrooms, and common areas.
- (25) **"School official**" means a member of the district or school staff who has the authority to make decisions on behalf of the district or school to maintain and improve environmental health and safety within the limitations of this rule.<sup>1</sup>
- (26) **"Source capture system**" means a mechanical exhaust system designed and constructed to capture air contaminants at their source and release air contaminants to the outdoor atmosphere.
- (27) **"Specialized room**" means a space or room that has a specific function that utilizes equipment, furniture, or supplies not found in a standard room. This may include but is not limited to, a career and technical education room, laboratory, art room, or health room.
- (28) **"Stationary machinery**" means equipment that is designed to be installed in a fixed location and does not require intermittent movement to service different needs. <sup>2</sup>
- (29) **"Total ventilation**" means the portion of air that is supplied to a designated zone from the outdoors, plus any filtered and recirculated air.

<sup>&</sup>lt;sup>1</sup> The committee will review and vote on this definition on December 16, 2024.

<sup>&</sup>lt;sup>2</sup> The committee will review and vote on this definition on December 16, 2024.

#### School Environmental Health and Safety Rule Project 2024 - 2025

#### WAC 246-370-010 Applicability

- (1) Chapter 246-370 WAC applies to all facilities operated for the primary purpose of providing education, including those primary and secondary school facilities that offer preschool education or transition services except:
  - (a) Any facility or part of a facility that is licensed by the department of children, youth, and families under Title 110 WAC;
  - (b) Private residences used for home-based instruction as defined by RCW 28A.225.010(4);
  - (c) Facilities hosting educational programs where educational instruction is not a primary purpose, including, but not limited to, detention centers, jails, hospitals, mental health units, or long-term care facilities;
  - (d) Private facilities where tutoring is the primary purpose;
  - (e) Public or private postsecondary education facilities providing instruction to students enrolled in secondary school; and
  - (f) State-tribal education compact schools established under chapter 28A.715 RCW.
- (2) Additional environmental health and safety rules that apply to school facilities include, but are not limited to:
  - (a) Facility and equipment sanitation, food preparation, food storage, and food temperature control must follow the requirements of chapter 246-215 WAC;
  - (b) Food service workers, including contracted staff and volunteers, must maintain a current food worker card per chapter 246-217 WAC;
  - (c) Water Recreation Facilities or aquatic venues must follow the requirements of chapters 246-260 and 246-262 WAC, as applicable;
  - (d) Supply sewer and liquid waste disposal supplied to the school facility that:
    - (i) Is connected to a municipal sewage disposal system according to chapter 173-240 WAC, if available; or
  - (e) Is connected to an on-site sewage disposal system designed, constructed, and maintained as required by chapters 246-272A or 246-272B WAC, and local ordinances;
  - (f) The installation and maintenance of carbon monoxide detection and alarms in mechanical rooms and occupied zones as set forth in chapter 51-54A-0915 WAC;
  - (g) Potable water supplied to the school facility that:
    - (i) Meets the provisions of chapters 246-290 or 246-291 WAC;
    - (ii) Meets the requirements of the uniform plumbing code set forth in chapter 51-56 WAC; and
    - (iii) Follow the requirements for lead in drinking water set forth in RCW 43.70.830 through 43.70.845 if the facility was built or the plumbing was replaced before 2016.

- (3) These rules are not intended to replace or supersede the department of labor and industries' authority and jurisdiction under Title 296 WAC over employee safety and health.
- (4) These rules are not intended to replace building code council requirements under Title 51 WAC. In the event this chapter is more stringent to protect health and safety it may supersede Title 51 WAC.
- (5) If the local permitting jurisdiction received a complete building permit application for school construction before the effective date of this chapter, the construction-related requirements of chapter 246-366 WAC apply.

#### WAC 246-370-015 Guidance

- (1) The department, in cooperation with the state superintendent of public instruction, shall review potentially hazardous conditions in schools which are in violation of good safety practices and jointly prepare a guide for use during routine school inspections that:
  - (a) Recommends corrective action to remediate violations of good safety practices;
  - (b) Includes recommendations for safe facilities and safety practices; and
  - (c) Is reviewed and updated every five years.

#### WAC 246-370-020 Site Assessment

- (1) A local health officer shall conduct or require a site assessment when a school district is planning:
  - (a) To construct a new school facility on a site that was previously undeveloped or developed for other purposes; or
  - (b) To convert an existing structure for primary use as a school facility.
- (2) A local health officer may conduct or require a site assessment when a school district is planning to construct:
  - (a) A new school facility on an existing school site; or
  - (b) An addition to an existing school facility.
- (3) A site assessment must include:
  - (a) A Phase 1 Environmental Site Assessment (ESA) that meets the requirements of the American Society for Testing and Materials (ASTM) Standard #1527-21 (published December 2021);
  - (b) Sampling and analysis of potential contaminants if the Phase 1 ESA indicates that hazardous materials may be present. Sampling and analysis must comply with the applicable rules of the Washington state department of ecology, chapter 173-303-110 WAC; and

- (c) A noise assessment that measures noise from all sources during the hours that school is normally in session.
  - (i) The noise must not exceed:
    - (A) An hourly average of 55 dBA or the mean sound energy level for a specified time in Leq 60 minutes; and
    - (B) A maximum sound level, recorded during a specified time measured as Lmax, of 75 dBA during the time of day the school is in session.
- (4) A school official shall:
  - (a) Notify the local health officer within 90 days of starting:
    - (i) The preliminary planning for school construction that requires a review and approval of a site assessment by a local health officer under subsection (1) of this section, or
    - (ii) The preliminary planning for school construction under subsection (2) of this section to determine if a site assessment is required.
  - (b) Consult with the local health officer throughout the plan development phase regarding the scope of the site assessment and the timeline for completion of the site assessment.
  - (c) Submit the written report to the local health officer assessing the potential impact of health and safety risks presented by the proposed site, including, but not limited to the following:
    - (i) The findings and results obtained under subsection (3) of this section;
    - (ii) An analysis of the findings;
    - (iii) If a site exceeds sound levels under subsection (3)(c)(i), the school official must include a plan for noise reduction in the new construction proposal;
    - (iv) A description of any mitigation proposed to address identified health and safety risks present at the site; and
    - (v) Any site assessment-related information requested by the local health officer to complete the site assessment review and approval process.
  - (d) Obtain the site review and written site approval from the local health officer when required under subsection (1) or (2) of this section.
- (5) The local health officer shall:
  - (a) When notified by a school official, conduct an inspection of the proposed site;
  - (b) Review the site assessment for environmental health and safety risk;
  - (c) For site assessments according to subsection (1) of this section, provide written approval, describe site deficiencies needing mitigation to obtain approval, or deny use of the proposed school facility site within 60 days of receiving a complete request unless a school official and the local health officer agree to a different timeline; and

- (d) For site assessments according to subsection (2) of this section, provide written approval or describe site deficiencies needing mitigation to obtain approval of the proposed school facility site within 60 days of receiving a complete request unless the school officials and the local health officer agree to a different timeline.
- (6) If a written site assessment request from a school official is received by the local health officer before the effective date of this section, the site assessment requirements of chapter 246-366 WAC apply unless otherwise specified in this chapter.

#### WAC 246-370-030 Construction Plan Review New, Alterations, and Portables

- (1) The following school construction projects must be reviewed and approved by the local health officer:
  - (a) Construction of a new school facility, playground, or specialized room;
  - (b) Establishment of a school in all or part of any existing structure previously used for another purpose;
  - (c) Additions or alterations consisting of more than 5,000 square feet of floor area or more than 20 percent of the total square feet of an existing school facility, whichever is less;
  - (d) Alteration of a playground or specialized room; and
  - (e) Installation or construction of a portable classroom.
- (2) A school official shall:
  - (a) Consult with the local health officer at the 50 percent design development stage for school construction projects plans to determine if the project requires construction review.
    - (i) Provide additional documents requested by the local health officer, which may include, but are not limited to, written statements signed by the project's licensed professional engineer verifying that design elements comply with requirements specified by these rules; and
    - (ii) Consult with the local health officer to determine whether additional construction project review is required to ensure that the project meets the requirements of these rules;
  - (b) Obtain written approval from the local health officer for the construction project before starting construction.
    - (i) If the school official meets the requirements of subsection (2)(a) but the local health officer does not meet the requirements of subsection (3), the school official may proceed with their scheduled construction timeline.
  - (c) Request a preoccupancy inspection by the local health officer to ensure the correction of any imminent health hazards before allowing occupancy at the school facilities; and
  - (d) Notify the local health officer at least five business days before a desired preoccupancy inspection.

#### School Environmental Health and Safety Rule Project 2024 - 2025

- (3) The local health officer shall:
  - (a) Respond to a request to consult with a school official within 15 business days of receipt;
  - (b) Consult with a school official to determine what is required for plan review and approval;
  - (c) Review construction project plans at the 50 percent design development stage to confirm if a construction review and approval is needed to meet the health and safety requirements of this chapter;
  - (d) Consult with a school official when additional reviews are required;
  - (e) Identify and request any additional documents required to determine compliance with requirements outlined in this chapter, if construction review is necessary;
  - (f) Provide written approval within 60 days of receiving the 100 percent design development for the construction design plans or provide a written statement describing construction project plan deficiencies that need to change to obtain approval. This timeline may be altered if mutually agreed upon by the school official and the local health officer; and
  - (g) Conduct inspections:
    - (i) In a coordinated effort with the on-site project manager or other appropriate person identified by a school official;
    - (ii) At any point during the construction period to verify compliance with the requirements of this chapter;
    - (iii) Before the completed construction project is occupied and not more than five business days after the date requested by a school official or as otherwise agreed to by the school official and the local health officer;
      - (A) If an imminent health hazard is identified, a solution must be identified and agreed to by the school official, the local health officer, and the local building official and implemented by school officials before the affected portion of the building is occupied.
      - (B) If other conditions of noncompliance with this chapter are identified, provide the school official with a written list of items and consult in developing a correction schedule based on the level of risk to health and safety.
    - (iv) To confirm satisfactory correction of the items identified under (iii) of this subsection.

#### WAC 246-370-040 Routine Inspection

- (1) The local health officer shall:
  - (a) Conduct an environmental health and safety inspection of each school facility within their jurisdiction every three years, prioritizing areas for emphasis based on risk.
  - (b) Notify school officials at the time of discovery, or immediately following the inspection, if conditions that pose an imminent health hazard are identified and follow the imminent health hazard requirements set forth in WAC 246-370-130.

27

#### School Environmental Health and Safety Rule Project 2024 - 2025

- (c) Consult with school officials upon completion of the inspection about findings and recommended follow-up actions and, if necessary, collaborate with school officials to develop a remediation schedule.
- (d) Issue a final inspection report, within 60 days following an inspection. The local health officer may establish an alternate timeline for issuing the final inspection report when agreed upon in consultation with school officials. The report must include inspection findings related to this chapter and any required remediation.
- (e) Confirm, as needed, that corrections are accomplished.
- (2) The local health officer may:
  - (a) Adjust the inspection interval of the schools within their jurisdiction if:
    - (i) The local health officer develops a written risk-based inspection schedule, that is uniformly applied throughout the jurisdiction based on credible data or local risk factors.
      - (A) The time between routine inspections may not exceed five years.
      - (B) The time between routine inspections may not be more frequent than one year.
  - (b) A school official or qualified designee may conduct the required additional inspections under a program approved by the local health officer, if the program includes provisions for:
    - (i) Assuring that the school official or designee conducting the inspection has attended training in the standards, techniques, and methods used to conduct an environmental health and safety inspection;
    - (ii) Completing a standardized checklist at each inspection; and
    - (iii) Providing a written report to the local health officer detailing the findings of the inspection, within 60 days of completing the inspection.

#### WAC 246-370-050 General Building Requirements

A school official shall ensure that school facilities:

- (1) Are clean and in good repair;
- (2) Do not attract, shelter, or promote the propagation of insects, rodents, bats, birds, and other pests of public health significance;
- (3) Have floors that suit the intended use, allow easy cleaning, and dry easily to inhibit mold growth and mitigate fall risks;
- (4) Has vacuum breakers or backflow prevention devices installed on hose bibs and supply nozzles used to connect hoses or tubing to housekeeping sinks;
- (5) Provide proper storage for student jackets or backpacks, play equipment, and instructional equipment to mitigate trip, pest, or other public health hazards; and

#### School Environmental Health and Safety Rule Project 2024 - 2025

- (6) Provide toilet and handwashing facilities accessible for use during school hours and scheduled events that:
  - (a) Provide handwashing facilities with access to:
    - (i) Soap;
    - (ii) Fixtures that maintain water temperatures between 85- and 120-degrees Fahrenheit;
    - (iii) With single-use or disposable towels or blower or equivalent hand-drying device; and
  - (b) Provide toilet paper.

#### WAC 246-370-060 Showers and Restrooms

- (1) When new installation or renovation of an existing shower or restroom facility is planned, school officials shall:
  - (a) Consult with the local health officer to determine if a construction review and plan approval is required.
  - (b) Shower facilities must:
    - (i) Automatically maintain hot water between 100° F and 120° F;
    - (ii) Meet the requirements of the uniform plumbing code set forth in chapter 51-56 WAC;
    - (iii) Contain floor surfaces in shower areas that are water-impervious, slip-resistant, and sloped to floor drains. Walls must be water-impervious up to showerhead height. Upper walls and ceilings must have an easily cleanable surface;
  - (c) Provide shower facilities for grades nine and above for classes in physical education and for team sports that:
    - (i) Meet a ratio of one shower per 15 individuals of each gender participating in physical education classes or team sports;<sup>3</sup>
    - (ii) If provided, have drying areas adjacent to showers and locker or dressing rooms. Walls and ceilings must have an easily cleanable surface and floor surfaces must be water impervious, slip-resistant, and sloped to floor drains;
    - (iii) When drying areas are not provided, locker or dressing room floor surfaces must be waterimpervious, slip-resistant, and sloped to floor drains; and
    - (iv) Provide locker or dressing rooms adjacent to showers or drying rooms. Walls and ceilings must have an easily cleanable surface. When drying areas are provided, floor surfaces in locker or dressing rooms must be appropriate for the intended use, easily cleanable and dryable to effectively inhibit mold growth.

<sup>&</sup>lt;sup>3</sup> Per L&I shower requirements for employees <u>WAC 296-800-23065</u> is 10 showers per gender. 1:15 is per the building code of 1 fixture per every 15 people.

#### School Environmental Health and Safety Rule Project 2024 - 2025

- (d) Provide restrooms:
  - (i) With handwashing fixtures that automatically maintain water between 85° F and 120° F;
  - (ii) At a ratio of one toilet per 15 individuals with up to 10 percent of the toilet fixtures being substituted with urinals;<sup>4</sup>
  - (iii) Meet the requirements of the uniform plumbing code set forth in chapter 51-56 WAC
  - (iv) That contain water-impervious floor surfaces that are slip-resistant and sloped to floor drains;
  - (v) With walls that are water-impervious up to water splash height. Upper walls and ceilings must have an easily cleanable surface; and
  - (vi) With soap and single-use or disposable towels or blower or equivalent hand-drying device.
- (2) If a new installation or renovation of an existing shower or restroom facility requires local health officer review and approval, the local health officer shall follow the construction plan review requirements for new construction or alterations set forth in WAC 246-370-030.

#### WAC 246-370-080 Indoor Air Quality and Ventilation

A school official shall:

- (1) Ensure the implementation of a written indoor air quality plan within five years of the effective date of this section that includes:
  - (a) Identified areas of indoor air quality concerns and develop preventative measures to address the concerns;
  - (b) A schedule to perform routine inspections of heating, ventilation, and cooling systems;
  - (c) An integrated pest management plan; and
  - (d) A plan for monitoring carbon dioxide levels if required by subsection (7) of this section.
- (2) Control sources of air contaminants by:
  - (a) Excluding sources of potential air contaminants from a school facility; or
  - (b) Providing a space with appropriately used and maintained ventilation to minimize student exposure to potential air contaminants.
- (3) Develop and implement a plan to test for radon every five years in regularly occupied areas on or below ground level.
- (4) Prohibit the use of air fresheners, candles, or other products that contain fragrances.
- (5) Physically contain construction activities that generate emissions or conduct construction at times that minimize student exposure.
- (6) Promptly control sources of moisture and remediate mold using measures to minimize occupant exposure to mold and chemicals used during the remediation process.

10

<sup>&</sup>lt;sup>4</sup> Per L&I specs for # of toilets in <u>WAC 296-800-23020</u>.

#### School Environmental Health and Safety Rule Project 2024 - 2025

- (7) Provide adequate ventilation by:
  - (a) Ensuring direct mechanical exhaust for specialized rooms as set forth in WAC 246-370-150.
  - (b) Providing ongoing carbon dioxide concentration monitoring if the school facility does not have a mechanical outdoor air ventilation system or the outdoor air flow rate cannot be determined.
  - (c) Ensuring all student-occupied instruction and gathering spaces during hours of occupation provide outdoor air ventilation flow rates as set forth in chapter 51-52 WAC at the time the ventilation system was permitted.
    - (i) If outdoor air ventilation flow rates were not established at the time of the original building construction, ventilation airflow rates must be operated to meet chapter 51-52 WAC or maximum outdoor air ventilation flow rates achievable within existing system capacity.
    - (ii) Compliance is determined based on variables including but not limited to:
      - (A) The type and area of the space;
      - (B) The planned number of occupants; and
      - (C) The type of ventilation system;
  - (d) Ensuring particulate matter filtration as set forth in chapter 51-52 WAC at the time the heating, ventilation, and air conditioning systems were permitted, including in facilities that have small, ducted air handlers and ventilation systems.
    - (i) If particulate matter filtration requirements were not established at the time of the original installation of the system, the system must meet chapter 51-52 WAC or the maximum particulate matter filtration achievable within existing system capacity.
  - (e) Ensuring new ventilation systems that are permitted after the effective date of this section shall be designed and constructed to be capable of the maximum outdoor air ventilation rates as set forth in chapter 51-11C WAC to be used as needed for periods of increased health risk.
  - (f) Performing routine maintenance of the mechanical ventilation system that includes:
    - (i) Testing and balancing for heating, ventilation, and air conditioning systems every ten years;
    - (ii) Performing routine inspections of heating, ventilation, and cooling systems to ensure systems are operating within intended parameters of this rule;
    - (iii) Replacing filters as needed to achieve required filtration and air flow rates; and
    - (iv) Maintaining records of these activities for review on site.

#### WAC 246-370-090 Temperature

- (1) A school official shall ensure the development and implementation of an extreme temperature readiness plan for non-specialized rooms when:
  - (a) A school facility is occupied by students and:
    - (i) Classroom temperatures are outside of the range of 65 degrees 79 degrees Fahrenheit; or
    - (ii) Hallways and common area temperatures are outside of the range of 60 degrees 79 degrees Fahrenheit.
- (2) A school official may consult with a local health officer to develop an extreme temperature readiness plan.

#### School Environmental Health and Safety Rule Project 2024 - 2025

#### WAC 246-370-100 Noise

A school official shall ensure:

- (1) In new construction:
  - (a) Construction plans that include designs for ventilation equipment or other equipment that will contribute to mechanical noise sources in a classroom must include designs that ensures that the background sounds conform to a noise criterion curve or equivalent not to exceed NC-35. The school official shall certify equipment and features are installed according to the approved plans.
  - (b) The actual background noise at any student location within a newly constructed classroom does not exceed 45 dBA (Leqx) and 70 dB(Leqx) (unweighted scale) where x is thirty seconds or more. The health officer shall determine compliance with this section when the ventilation system and the ventilation system's noise generating components, e.g., condenser, heat pump, etc., are in operation.
  - (c) The maximum ambient noise level in specialized rooms shall not exceed 65 dBA when all fume and dust exhaust systems are operating.
- (2) Portable classrooms constructed before January 1, 1990, moved within the same school property or the same school district, are exempt from the requirements of this section if the portable classrooms:
  - (a) Do not alter the noise abatement features;
  - (b) Do not increase noise-generating features;
  - (c) Were previously used for classroom instruction;
  - (d) Do not change ownership; and
  - (e) Are located on a site that meets the noise assessment requirements set forth in WAC 246-370-020(3)(c).
- (3) The maximum noise exposure for students in classroom shall not exceed the levels specified in Table 1.
- (4) That activities that expose students to sound levels equal to or greater than 115 dBA are prohibited.
- (5) That students are provided and required to use personal protective equipment where noise levels exceed those specified in Table 1. Personal protective equipment must reduce student noise exposure to comply with the levels specified in Table 1.

| Table 1<br>Maximum noise exposures permissible |                      |  |
|--|----------------------|--|
| Duration per day<br>(hours)                    | Sound Level<br>(dBA) |  |
| 8  | 85                   |  |
| 6  | 87                   |  |
| 4  | 90                   |  |
| 3  | 92                   |  |
| 2  | 95                   |  |
| 1-1/2  | 97                   |  |
| 1  | 100                  |  |
| 1/2  | 105                  |  |
| 1/4  | 110                  |  |

#### WAC 246-370-110 Lighting

A school official shall:

- (1) Provide light intensities that meet or exceed those specified in Table 2.
  - (a) Natural lighting, energy-efficient lighting systems, lighting fixtures, or bulbs may be used to maintain the minimum lighting intensities.

| Table 2   |                               |  |
|---|-------------------------------|--|
| Lighting intensities measured 30 inches above the floor or on working or teaching surfaces. Some lighting fixtures may require a start-up period before reaching maximum light output.  |                               |  |
| Task  | Min. Foot Candle<br>Intensity |  |
| Specialized rooms where safety is of prime consideration<br>or fine detail work is done, for example, family and<br>consumer science laboratories, science laboratories<br>(including chemical storage areas), shops, drafting rooms,<br>and art and craft rooms. | 50                            |  |
| Kitchen areas including food storage and preparation areas.   | 50                            |  |
| General instructional areas, for example, study halls, lecture rooms, and libraries.  | 30                            |  |
| Gymnasiums: main and auxiliary spaces, shower rooms and locker rooms.   | 20                            |  |
| Noninstructional areas including auditoriums, lunchrooms, assembly rooms, corridors, stairs, storerooms, and restrooms.   | 10                            |  |

(2) Control excessive brightness and glare in all instructional areas. Surface contrasts and direct or indirect glare must not cause excessive eye accommodation or eye strain problems.

- (3) Provide sun control to exclude direct sunlight from window areas and skylights of instructional areas, assembly rooms, and meeting rooms during at least 80 percent of the normal school hours. Sun control is not required for sun angles less than 42 degrees up from the horizontal. Sun control is not required if air conditioning is provided, or special glass is installed having a total solar energy transmission factor less than 60 percent.
- (4) Provide lighting in a manner that minimizes shadows and other lighting deficiencies on work and teaching surfaces.
- (5) Provide windows in sufficient number, size, and location to enable students to see outside at least 50 percent of the school day. Windows are optional in specialized rooms.

#### WAC 246-370-120 Injury Prevention

A school official shall:

- (1) Mitigate potential slip and fall hazards by, but not limited to:
  - (a) Providing stairwells and ramps with handrails and stairs with surfaces that reduce the risk of injury;
  - (b) Providing protection or barriers for areas that have fall risks such as balconies and orchestra pits;
  - (c) Storing unsecured equipment in a manner that prevents unauthorized use or injury;
- (2) Ensure chemical and cleaning supply storage that includes:
  - (a) Manufacturer use instructions, warning labels, and Safety Data Sheets for proper storage of the supplies;
  - (b) Labels on supplies that are diluted from bulk chemical or cleaning agents with the accurate agent name and dilution rates;
  - (c) The original bulk or concentrated containers of cleaning and disinfectant agents for reference to labels and instructions until diluted contents are exhausted;
  - (d) Separation of incompatible substances; and
  - (e) Access that is limited to authorized users.
- (3) Provide fragrance-free and low-hazard cleaning and sanitation supplies when available or ensure cleaning at a time and manner that would limit exposure to students; and
- (4) Provide a written policy to mitigate injury and the spread of diseases if the school allows animals other than service animals in a school facility.

#### School Environmental Health and Safety Rule Project 2024 - 2025

#### WAC 246-370-130 Imminent Health Hazard Procedure

- (1) If a school official identifies a condition that could pose an imminent health hazard, a school official shall:
  - (a) Immediately consult with the local health officer to investigate the suspected hazard;
  - (b) Take immediate action to mitigate hazards and prevent exposure if an imminent health hazard is confirmed; and
  - (c) A school may consult with the local health officer in developing appropriate health and safety messages for school staff, students, and parents.
- (2) If a local health officer identifies a condition that is an imminent health hazard at a school, the local health officer shall:
  - (a) Immediately inform school officials of the imminent health hazard;
  - (b) Consult with school officials to mitigate hazards and prevent exposure; and
  - (c) If requested, assist school officials in developing health and safety messages for school staff, students, and parents.

#### WAC 246-370-140 Playgrounds

- (1) A school official shall:
  - (a) Consult with the local health officer regarding playground review and approval requirements prior to:
    - (i) Installing new playground equipment or fall protection surfaces;
    - (ii) Adding new playground features or equipment to an existing playground; or
    - (iii) Modifying existing playground equipment, features, or fall protection surfaces;
  - (b) Install, maintain, and operate playground equipment, including used equipment, and fall protection surfaces:
    - (i) In a manner consistent with the ASTM F 1487-21: Standard Consumer Safety Performance Specification for Playground Equipment for Public Use; and
    - (ii) In a manner consistent with the manufacturer's instructions and *Consumer Product Safety Commission Handbook for Public Playground Safety*, 2010;
  - (c) Provide playground plans and equipment specifications and any additional information the local health officer requests;
  - (d) Obtain plan review and written approval from the local health officer before installing, adding, or modifying playground equipment or fall protection surfaces; and

#### School Environmental Health and Safety Rule Project 2024 - 2025

- (2) The local health officer shall:
  - (a) Consult with a school official to determine requirements for playground plan review and approval consistent with the scope of the project;
  - (b) Review playground plans and equipment specifications to confirm that the requirements of these rules are addressed;
  - (c) Identify and request any additional documents required to complete the review;
  - (d) Provide written approval or denial of the playground plans and equipment specifications within 30 days of receiving all documents needed to complete the review unless the school officials and the local health officer agree to a different timeline;
  - (e) Verify that playground installation complies with the requirements of this section; and
  - (f) Coordinate all playground-related inspections with the school official.
- (3) The use of chromated copper arsenate or creosote-treated wood to construct or install playground equipment, landscape structures, or other structures on which students may play is prohibited.

#### WAC 246-370-150 Specialized Rooms

A school official shall ensure specialized rooms that are part of a school facility include, if applicable:

- (1) Single-use soap and single-use towels at handwashing sinks.
- (2) Emergency washing facilities:
  - (a) An emergency shower must be provided:
    - (i) When there is potential for major portions of a person's body to contact corrosives, strong irritants, or toxic chemicals; and
    - (ii) That delivers water to cascade over the user's entire body at a minimum rate of 20 gallons (75 liters) per minute for fifteen minutes or more.
  - (b) An emergency eyewash fountain must be provided:
    - (i) When there is potential for a person's eyes to be exposed to corrosives, strong irritants, or toxic chemicals;
    - (ii) That irrigates and flushes both eyes simultaneously while the user holds their eyes open;
    - (iii) With an on-off valve that activates in one second or less and remains on without user assistance until intentionally turned off; and
    - (iv) That delivers at least 0.4 gallons (1.5 liters) of water per minute for fifteen minutes or more.

#### School Environmental Health and Safety Rule Project 2024 - 2025

- (c) Emergency washing facilities must:
  - (i) Be located so that it takes no more than 10 seconds to reach and no more than 50 feet;
  - (ii) Be kept free of obstacles blocking their use;
  - (iii) Function correctly; and
  - (iv) Provide the quality and quantity of water that is satisfactory for the emergency washing purposes.
- (d) The design, installation, and maintenance of emergency washing facilities must meet the American National Standards Institute (ANSI) publication Z358.1 - 2014, American National Standard for *Emergency Eyewash and Shower Equipment*.
- (3) A prohibition of use and storage of compounds that are:
  - (a) Considered shock-sensitive explosives, for example, picric acid, dinitro-organics, isopropyl ether, ethyl ether, tetrahydrofuran, dioxane; or
  - (b) Lethal at low concentrations when inhaled or in contact with skin, for example, pure cyanides, hydrofluoric acid, toxic compressed gases, mercury liquid and mercury compounds, and chemicals identified as the P-list under WAC 173-303-9903.
- (4) Safety procedures and process for instructing students regarding the proper use of hazardous materials or equipment.
- (5) Appropriate personal protective equipment when exposure to potential hazards might occur.
- (6) Appropriate situation-specific emergency equipment is available when exposure to potential hazards might occur.
- (7) Appropriate ventilation, source capture system, or other equipment approved by the local health officer to prevent the recirculation of air into the room or transfer of airflow into other parts of the school facility and to prevent contaminant from entering the students breathing zone.
- (8) If a school facility includes a designated health room, a school official shall ensure that the health room includes:
  - (a) The means to visually supervise and provide privacy for room occupants;
  - (b) Surfaces that staff can easily clean and sanitize;
  - (c) A handwashing sink in the room;
  - (d) An adjoining restroom; and
  - (e) Mechanical exhaust ventilation that ensures that air does not flow from the health room to other parts of the school facility.

#### 

#### School Environmental Health and Safety Rule Project 2024 - 2025

- (9) Emergency shut-off valves or switches for gas and electricity connected to stationary machinery are installed during **new construction**. Valves or switches must:
  - (a) Be located close to the room exit door;
  - (b) Have unobstructed access; and
  - (c) Have signage posted adjacent to the valve that room occupants can easily read and understand from the opposite side of the room during an emergency.

#### WAC 246-370-160 Variances and Emergency Waivers

- (1) School officials may:
  - (a) Submit a written variance request to the local health officer if there is an alternative that meets the intent of chapter 246-370 WAC. The variance request must include:
    - (i) The specific rule section or sections that the variance would replace;
    - (ii) The alternative that is proposed to replace the required rule;
    - (iii) A description of how the variance will provide a comparable level of protection as the rule that it will replace;
    - (iv) Any clarifying documentation needed to support the request including but not limited to engineering reports, scientific data, or photos.
  - (b) Implement a variance only after obtaining approval from the local health officer.
- (2) The local health officer shall:
  - (a) Provide written approval or denial of a request for a variance to the school applicant and the department within 60 days of receiving a complete written variance request, unless the school official and the local health officer agree to a different timeline.
- (3) The local health officer may grant a school official an emergency waiver from some or all of the requirements in these rules:
  - (a) For the use of a temporary facility if the facility normally used by the school is not safe to be occupied; or
  - (b) If a school can safely remain in operation during an imminent health hazard.

#### WAC 246-370-170 Severability

If any provision of this chapter or its application to any person or circumstance is held invalid, the remainder of the chapter or the application of the provision to other persons or circumstances is not affected.

#### School Environmental Health and Safety Rule Project 2024 - 2025

#### WAC 246-370-180 Appeals

- (1) Environmental health and safety decisions or actions of the local health officer may be appealed to the local board of health.
- (2) Environmental health and safety appeals will be conducted in a manner consistent with the written procedure within each office.



## **Project Update**

Andrew Kamali, School Rule Project Manager Nina Helpling, Policy Analyst

March 12, 2025

## WASHINGTON STATE **BOARD**OF**HEALTH**

## Overview

- Proviso
- Process
- Community Engagement
- Summary of Changes

1

## Proviso

## Funding & Purpose

- \$750,000 allocated for FY 2025 to update school health & safety rules.
- Goal: Establish minimum statewide
   health & safety standards for schools.

### **Key Considerations**

- School district size & regional cost differences.
- Age of schools & feasibility of phased implementation.
- Other variables impacting rule implementation.

## Proviso

## **Advisory Committee Composition**

- Office of Superintendent of Public Instruction (OSPI)
- Small & large school districts
- WA Association of School Administrators
- WA State School Directors' Association
- WA Association of Maintenance & **Operations Administrators**
- WA Association of School Business Officials

## **Process & Collaboration**

- committee input.
- considering:
  - District size
  - cost differences
  - school age  $\bullet$
  - implementation costs ullet

1. Develop draft rules with advisory

2. Review draft rules with advisory committee and gather feedback.

3. Conduct fiscal analysis with OSPI,

4. Perform environmental justice assessments on proposed rules.

## Proviso

### **Final Report**

- Due June 30, 2025
- Sections prioritized with the greatest student health & safety benefits
- Recommended implementation order
- Additional recommendations for rule implementation

### Collaboration

- OSPI
- State Board of Health Department of Health Advisory committee

- Local health jurisdictions

## **Process - Representation**

### Associations

- Association of Washington School Principals
- School OPS
- The Rural Alliance
- Washington Association of Maintenance & Operations Administrators (WAMOA)
- Washington Association of School Administrators (WASA)
- Washington Association of School Business Officials (WASBO)
- Washington Education Association
- Washington State Association of Local Public Health Officials (WSALPHO)
- Washington State Parent Teacher Association (PTA)

### **Public School Districts**

- Auburn
- Bellingham Public Schools\
- Evergreen (Clark County)
- Inchelum
- Lake Washington
- Richland
- South Kitsap
- Spokane

### **Private Schools**

- Washington Federation of Independent Schools
- Washington State Catholic Conference/Catholic Schools

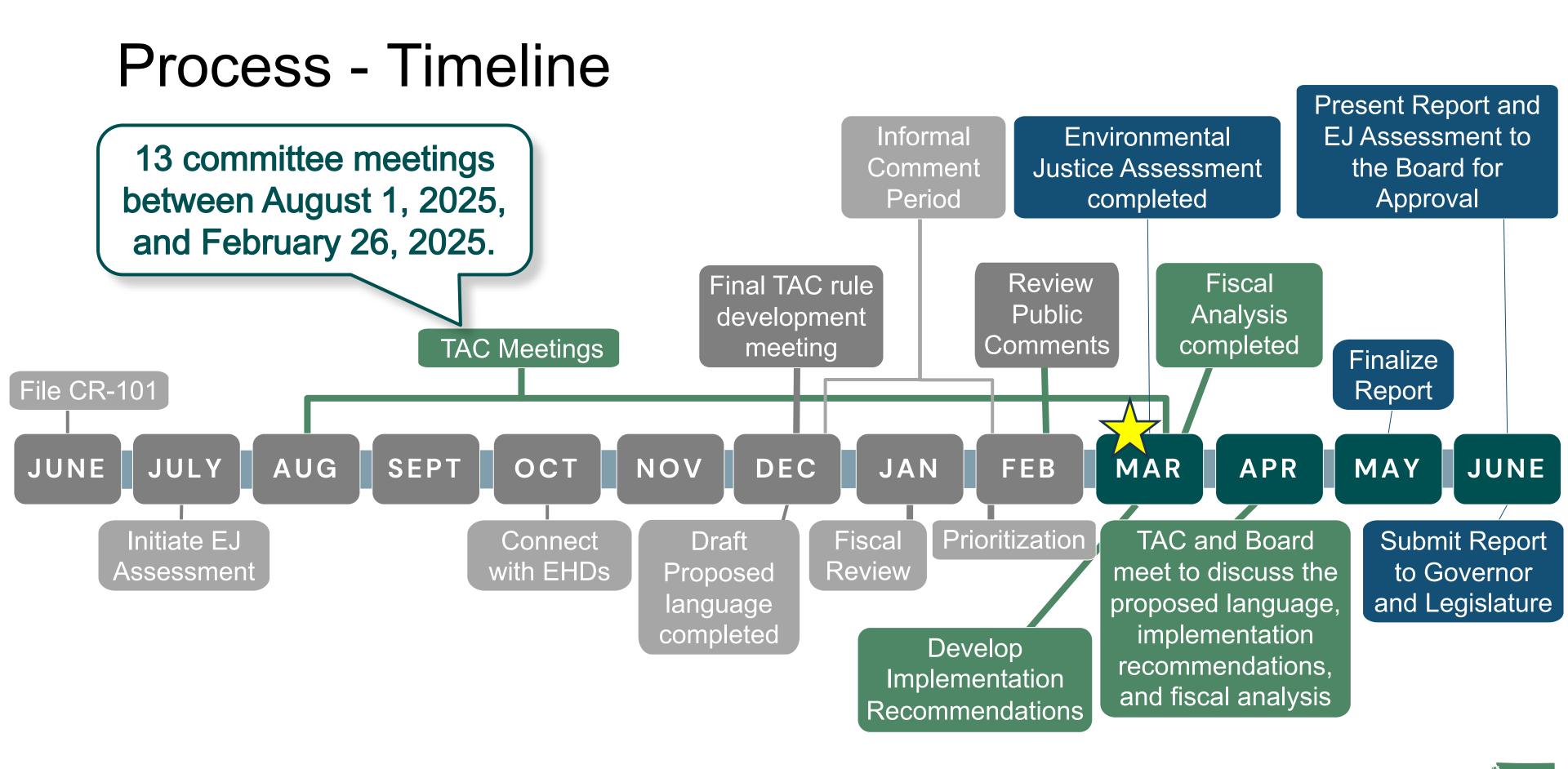
### **Health Districts**

- Spokane
- Benton-Franklin
- Whatcom

### State Agencies

- Office of Superintendent of Public Instruction (OSPI)
- Washington State Department of Health (Department)
- Washington State Board of Health (Board)

5



## **Community Engagement**

- In-Person Listening Sessions held throughout WA State, 2024 – 2025
  - Yakima
  - Olympia
  - Spokane
  - Tri-Cities
  - Vancouver
  - Auburn
- 3 Online Listening Sessions
  - 1 daytime and 2 evening sessions
- Tribal outreach:
  - 29 Tribes with a Tribal Listening Session
  - 12 Tribal educational or community organizations

- - 24 school districts
- - Latino
  - **BIPOC**
  - -LGBTQ
  - Disability

## 9 Educational School Districts – Flyers to families of 198,232 students - 364 schools contacted

## • Community outreach:

– Other community-based organizations

WAC 246-370-001 Purpose **Combined**: Introduction statement with Purpose statement

WAC 246-370-005 Definitions Added: 24 New definitions **Removed**: 5 Obsolete definitions **Modernized**: 3 Existing definitions **No Change:** 2 Existing definitions

### WAC 246-370-010 Applicability **Referenced**: Existing regulations:

- Food handling and preparation
- Water recreation
- Sewer and liquid waste disposal
- Carbon monoxide detection
- Drinking water
- **Referenced**: Exceptions to chapter 246-370 WAC including:
- Facilities licensed under Title 110 WAC
  - Department of Children, Youth, and Families
- Home-based instruction
- Locations that provide education services, but education is not the primary function of the facility
- Private tutoring Post secondary schools
- State-tribal education compact schools

WAC 246-370-015 Guidance Updated: Language—no substantive changes

- WAC 246-370-020 Site Assessment Added: Local Health Officer (LHO) may require a site assessment for construction projects on existing school facilities. Added: School officials must:
  - Have a Phase 1 Site Assessment
  - Notify LHO at least 90 days prior to planning new construction
  - Submit site assessments to LHOs
  - Added: LHOs must:
  - Review site assessments
  - Provide written approval within 60 days of receiving a completed site assessment

WAC 246-370-030 Construction Plan Review New, Alterations, and Portable Added: Specifications for types of construction that might require plan review Added: Set timelines for school officials and LHOs to review construction plans

WAC 246-370-040 Routine Inspection Added: Routine inspection frequency Added: Allow a trained LHO designee to perform additional inspections

WAC 246-370-050 General Building Requirements

Added: Backflow devices on housekeeping sinks.

Added: Bathrooms and handwashing facilities are available during school hours and scheduled events.

### WAC 246-370-060 Showers and Restrooms\*

Added: At new construction or renovation

- Must have 1 shower per 15 individuals per each gender participating in physical education or sports teams.
- Must have 1 toilet per 15 individuals with up to 10% of the fixtures being urinals.
- Section subject to change pending TAC review

WAC 246-370-080 Indoor Air Quality **New Section**: Sets prescribed indoor air quality requirements like radon testing and pest management planning. **New Section**: Sets prescribed ventilation requirements like outdoor air intake rates.

WAC 246-370-090 Temperature Added: Maximum and minimum temperature requirements. **Added**: Requirement for the implementation of an extreme temperature readiness plan.

changes

### WAC 246-370-100 Noise

**Updated**: Language—no substantive

WAC 246-370-110 Lighting

– **Updated**: Language—no substantive changes.

WAC 246-370-120 Injury Prevention

- Added: Fall protection from balconies or orchestra pits and storage of unsecured equipment.
- Added: Updated language for chemical storage.
- Added: Fragrance-free and low-hazard cleaning requirements.
- Added: Injury and communicable disease prevention planning when animals are allowed in school.

- Hazard

  - sewage spillage.
- - playgrounds.

## WAC 246-370-130 Imminent Health

– **New Section**: Sets prescribed imminent health hazard requirements for hazards like

WAC 246-370-140 Playgrounds - New Section: Sets prescribed installation and maintenance requirements for

WAC 246-370-150 Specialized Rooms – **New Section**: Sets prescribed requirements for specialized rooms like health rooms, laboratories, and wood shops.



WAC 246-370-160 Variances

- Updated: Language—no substantive changes
- WAC 246-370-170 Severability
  - Updated: Language—no substantive changes
- WAC 246-370-180 Appeals
  - Updated: Language—no substantive changes

12



# THANK YOU

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- 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.



## WASHINGTON STATE BOARD OF HEALTH

Date: March 12, 2025

To: Washington State Board of Health Members

From: Patty Hayes, Board Chair

**Subject:** Request for Delegated Rulemaking, chapter 246-290 WAC, Miscellaneous Sections, Group A Public Water Systems, and chapter 246-390 WAC, Drinking Water Laboratory Certification and Data Reporting to adopt by reference the new, federal National Primary Drinking Water Regulation related to per- and polyfluoroalkyl substances

#### Background and Summary:

In October 2021 the Board adopted drinking water state action levels (SALs) for perand polyfluoroalkyl substances (PFAS) in <u>chapter 246-290 WAC</u>, Group A Public Water Supplies and related provisions in <u>chapter 246-390 WAC</u>, Drinking Water Laboratory Certification and Data Reporting.

On April 26, 2024, the Environmental Protection Agency (EPA) published the first-ever national drinking water <u>standard</u> (federal standard) to protect communities from exposure to PFAS. The federal standard establishes federal maximum contaminant levels (MCLs), requirements for monitoring, reporting, public notification, treatment, and violations.

Across almost all the contaminants, MCLs in the federal standard are more stringent than the SALs the Board adopted in 2021. The EPA also included a hazard index for certain chemicals to account for additive effects of some combinations of PFAS.

The Department of Health (Department) is requesting the Board delegate rulemaking authority to allow the Department to adopt by reference the new federal standards, without change. This action is necessary for the Department to maintain primacy and aligns with the Board's delegation criteria, provided in your packets.

This rulemaking is separate from the standard rulemaking being conducted by the Board to consider adopting the stricter MCL values as SALs, and the emergency rules adopted by the Board to correct WAC 246-290-315 in response to the new federal standard. Today, the Department is requesting delegation to incorporate relevant references into the rule, and updating tables to reflect the new values directly outlined in the federal standard.

Your packet includes the delegation request from the Department, which outlines how this request conforms with the Board's delegation criteria and the need for the rule

Washington State Board of Health March 12, 2025, Meeting Memo Page 2 change. Mike Means with the Office of Drinking Water will present the Department's request for Board Members to consider.

#### **Recommended Board Actions:**

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

The Board moves to delegate rulemaking authority to the Department of Health to adopt by reference new, federal National Primary Drinking Water Regulations related to PFAS into chapter 246-290 WAC and chapter 246-390 WAC.

OR

The Board declines to delegate rulemaking authority to the Department of Health.

Staff Ash Noble, Policy Advisor

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February 25, 2025

| TO: | Michelle Davis, Executive Director |
|-----|------------------------------------|
|     | Washington State Board of Health   |

- FROM: Lauren Jenks, Assistant Secretary Division of Environmental Public Health
- SUBJECT: State Board of Health Rule Making Authority Delegation Request- Aligning chapters 246-290 and 246-390 WAC with the changes to the National Primary Drinking Water Regulation regarding PFAS.

The Department of Health (department) is requesting delegation of rule-making authority from the State Board of Health (board) to conduct exception rulemaking to align chapter 246-290 WAC, Group A Public Water Supplies, and chapter 246-390 WAC, Drinking Water and Laboratory Certification and Data Reporting, with the recent changes to the National Primary Drinking Water Regulation (40 CFR Part 141) regarding PFAS. Changes to the rule under this delegation request, if approved, will be limited to:

- Citing the federal rule in numerous sections within chapters 246-290 and 246-390 WAC to add by reference the requirements for monitoring, reporting, public notification, treatment, and violations.
- Incorporating the federal PFAS maximum contaminant levels (MCLs) into the appropriate contaminant tables.
- Consideration of minor editorial changes and updates to definitions to ensure consistency of terms between federal and state rules in chapters 246-290 and 246-390 WAC.

On April 26, 2024, the EPA published the first-ever national drinking water standard (federal standard) to protect communities from exposure to PFAS. The federal standard used new science to establish federal MCLs, requirements for monitoring, reporting, public notification, treatment, and violations. Across almost all the contaminants, the MCLs in the federal standard are more stringent than the state action levels (SALs) the Board adopted in 2021. The EPA also included a hazard index for certain chemicals to account for additive effects of some combinations of PFAS. However, certain aspects of the federal standard are not effective until 2027 and 2029, including 30-day public notification.

The Board adopted an emergency rule, WSR 24-14-016 on June 24, 2024, to amend WAC 246-290-315 and is currently working on permanent rulemaking to keep state protections for drinking water in place until the EPA's new federal standards take effect. This exception rulemaking is necessary to adopt by reference the federal PFAS requirements for monitoring, reporting, public notification, treatment, and violations.

#### Conformance with the State Board of Health Delegation Criteria:

The board's policy (Policy Number 2000-001) for Considering Delegation of Rule to the Department of Health provides the following elements for consideration:

## The extent to which the proposed rule revision is expected to include editorial and/or grammatical changes that do not change the substance of the rule:

• Editorial changes and technical corrections may be necessary to improve clarity and align the federal requirements with the structure and organization of the chapter. None of these changes will affect the substance of the language being incorporated into the chapter.

The extent to which the proposed rule may make significant changes to a policy or regulatory program.

• The scope of the proposed rule will be limited to adding by reference the federal PFAS requirements for monitoring, reporting, public notification, treatment, and violations, adding PFAS federal levels into the applicable contaminants tables, and making minor editorial changes and updates to definitions to ensure consistency of terms between federal and state rules.

The extent to which the proposed rule seeks to adopt federal requirements in which the state has little or no discretion.

• The scope of the proposed rule will be limited to adding by reference the federal PFAS requirements for monitoring, reporting, public notification, treatment, and violations, adding PFAS federal levels into the applicable contaminants tables, and making minor editorial changes and updates to definitions to ensure consistency of terms between federal and state rules.

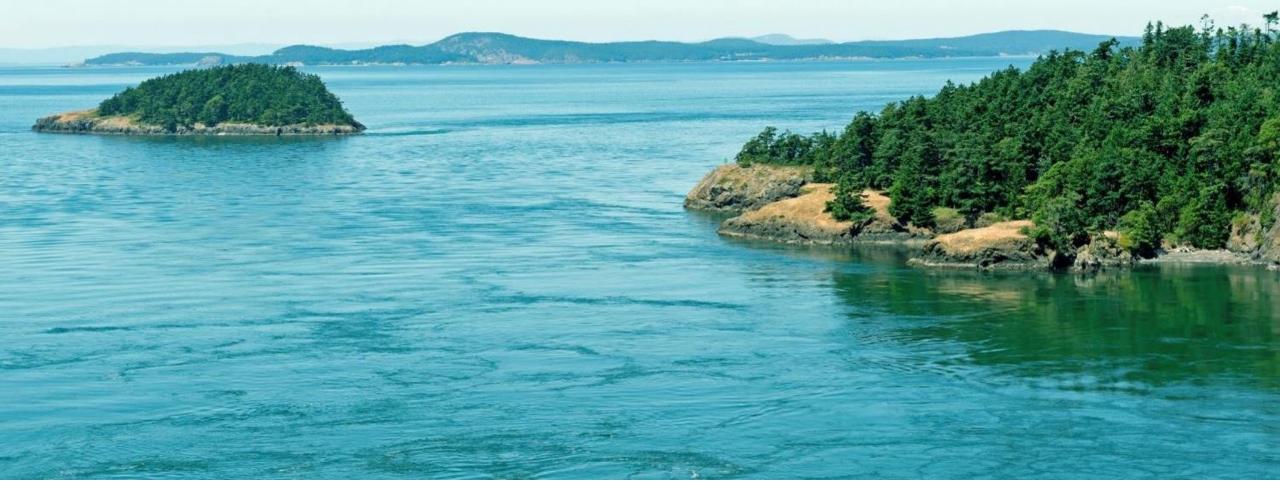
## The extent to which the substance and direction of the proposed rule is expected to have broad public and professional consensus.

• The department does not anticipate any controversy or opposition to this rule change.

## The extent to which the rule revision process would benefit from the board's role as a convener of interested parties.

• The department will keep interested parties engaged and informed throughout rule-making process via an up-to-date webpage and GovDelivery notifications that will be distributed using existing listservs. The department will have a formal comment period, as well as hold a public hearing.

For additional information, please contact Mike Means, Capacity Development and Policy Manager for the Office of Drinking Water, at <u>mike.means@doh.wa.gov</u>.





REQUEST FOR DELEGATED RULEMAKING FOR WAC 246-290 and WAC 246-390 PFAS Exception Rulemaking

State Board of Health Meeting March 12, 2025

## Presenter

#### **Mike Means**

Capacity Development and Policy Manager

Office of Drinking Water Division of Environmental Public Health

mike.means@doh.wa.gov



@WADeptHealth

#### Background Information

- Per- and Polyfluoroalkyl Substances (PFAS) are a group of manufactured chemicals that can be found in public drinking water systems and private drinking water wells.
- Chapter 246-290 WAC sets basic regulatory requirements to protect the health of consumers using public drinking water supplies.
- Chapter 246-390 WAC sets minimum certification and data reporting requirements for environmental laboratories that analyze drinking water samples.
- The EPA recently adopted the first national regulations related to PFAS, including federal maximum containment levels (MCLs). The federal rules include PFAS requirements for monitoring, reporting, public notification, treatment, and violations. Across almost all contaminants, the federal MCLs are stricter than the SALs currently in rule.

## Background Information Cont.

- The Board adopted an emergency rule, WSR 24-14-016 on June 24, 2024, and is currently working on permanent rulemaking to amend WAC 246-290-315 to keep state protections in place until the EPA's new federal standards take effect.
- The final federal rule requires:
  - By April 2027, water systems have three years to complete initial monitoring for PFAS and provide the public with information on the levels of PFAS in their drinking water.
  - By April 2029, public water systems have five years to implement solutions that reduce PFAS if monitoring shows that drinking water levels exceed the MCLs, must take action to reduce levels of PFAS, and notify the public of violations.

## Potential Changes to Rule

- Add the federal rule by reference in numerous sections within chapters 246-290 and 246-390 WAC to incorporate federal PFAS requirements for monitoring, reporting, public notification, treatment, and violations.
- Add federal PFAS levels to the appropriate contaminant tables in chapters 246-290 and 246-390 WAC.
- Minor editorial changes and updates to definitions may be considered to ensure consistency
  of terms between federal and state rules.

#### SBOH Delegation Considerations

- The scope of the rulemaking will be limited to incorporating the federal PFAS requirements and adding federal PFAS levels into the appropriate contaminant tables.
- The changes are exempt from significant rulemaking under RCW 34.05310(4) because incorporating federal regulations by reference without material change.
- The changes do not impact the Board's permanent rulemaking for PFAS.
- The department does not anticipate any controversy or opposition to this rule change.
- The department will use an exception rulemaking process.
- The department will keep interested parties engaged and informed via an up-to-date webpage and GovDelivery notifications that will be distributed using existing listservs. The department will have a formal comment period, as well as hold a public hearing.

Questions?



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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.

#### Washington State Board of Health Policy & Procedure

| Policy Number: | 2000-001  |
|----------------|---|
| Subject:       | Considering Delegation of Rules to Department of Health |
| Approved Date: | November 8, 2000 (Revised June 13, 2012)                |

#### Policy Statement

In some instances, the Washington State Board of Health may determine it is appropriate to delegate its authority for rulemaking to the Department of Health (RCW 43.20.050). The Board and the Department recognize the need to balance both broad constituent participation and administrative efficiency when making decisions about any rule delegation. For this reason, the Board and the Department have agreed upon a set of criteria to assist Board members in their decisions related to rule delegation.

The Board's decision to delegate a specific rule will be made on a case-by-case basis. The Board will determine the breadth of the delegation, which may range from specific aspects of a single rule section to a broader body of regulatory authority, such as an entire chapter of rules. Each Board delegation is for a single rulemaking process unless specified in an approved motion to be a continuing delegation until rescinded. Once a rule has been delegated, the Department will keep the Board informed about the rule making process through periodic progress reports. The Board may rescind its delegation at any time.

When considering delegation of authority to modify or adopt a rule, the Board may consider the following criteria:

- The extent to which the proposed rule revision is expected to include editorial and/or grammatical changes that do not change the substance of the rule;
- The extent to which the proposed rule seeks to adopt federal requirements in which the state has little or no discretion;
- The extent to which the substance and direction of the proposed rule is expected to have broad public and professional consensus;
- The extent to which the proposed rule may make significant changes to a policy or regulatory program; and
- The extent to which the rule revision process would benefit from the Board's role as a convener of interested parties.

#### **Procedure**

When the Board receives a request from the Department to delegate authority for rulemaking, the Executive Director will review the request compared with the above policy criteria. The Executive Director will prepare or direct staff to prepare a recommendation for the Board to consider at its next most convenient meeting. The Executive Director will consult with the Board Chair and members of any appropriate policy committee to formulate the recommendation. The Board may take action to delegate authority to the Department as requested or may otherwise specify rulemaking authority it delegates.

If the Board is not scheduled to meet again within two months and the Department justifies a pressing need to begin rulemaking, the Board's Chair may delegate the Board's rulemaking authority to the Department without a vote of the Board. The Board's Chair will consider recent actions of the Board that inform the collective philosophy of the Board, along with recommendations from the Executive Director and an appropriate policy committee of the Board. The Board before deciding to delegate authority to the Department without a vote of the Board. The Chair will limit any such delegation to a single rulemaking process. The Chair or Executive Director shall notify Board members of the delegation.

## WASHINGTON STATE BOARD OF HEALTH



# Planning for the 2026 State Heath Report

Core Team process
Scoping and landscape analysis
Community partner engagement strategy



## STATE OF WASHINGTON WASHINGTON STATE BOARD OF HEALTH

PO Box 47990 • Olympia, Washington 98504-7990

#### Resolution 2025-01

WHEREAS the State Constitution established the Washington State Board of Health in 1889;

**WHEREAS** the Board provides a forum for developing public health policy in Washington State and is empowered to hold hearings and explore ways to improve the health status of the citizenry;

**WHEREAS** Governor Jay Inslee appointed Dimyana Abdelmalek, MD, MPH, to the Board in October 2022 to represent local health officers in Washington, and subsequently reappointed her in September 2023;

**WHERAS** Member Abdelmalek's interest and passion for health is reflected by her bachelor's degree in biology and advanced degrees in emergency medicine and global health, and has taken her from Berkeley, California, to the Bronx, New York, and from Cleveland, Ohio, to Cairo, Egypt, where she has dedicated herself to emergency medicine and improving access to health services for those in need;

**WHEREAS** Member Abdelmalek has demonstrated a profound commitment to serving others and advancing community health, particularly in institutionally underserved communities in the U.S. and abroad;

**WHEREAS** Member Abdelmalek has exemplified extraordinary leadership in public health by serving in the critical role of Health Officer for Thurston County amid the COVID-19 pandemic, demonstrating grace, compassion, and unwavering dedication and leadership during unprecedented times;

**WHEREAS** Member Abdelmalek has served as Chair of the Board's Health Promotion Subcommittee since September 2023, providing leadership and guidance on critical health promotion topics, including newborn screening, communicable disease prevention, maternal health, oral health equity, and more;

**WHEREAS** Member Abdelmalek has provided invaluable expertise to the Board on critical issues, including clandestine drug labs, notifiable condition reporting requirements, and school environmental safety;.

**WHEREAS** Member Abdelmalek enhanced engagement and communication between the Board and Washington's Local Health Officers, and is highly regarded by her colleagues and Board staff for her thoughtful questions and valuable insights;

**WHEREAS** Member Abdelmalek has accomplished this and more demonstrating fairness, kindness, good humor and an unfaltering graciousness;

**THERFORE BE IT RESOLVED** that the Board formally recognizes and expresses deep gratitude to Member Abdelmalek for her exceptional leadership, dedication to public health, tireless service to communities worldwide, and outstanding contributions to the people of Washington State as a member of the Board.