

# WASHINGTON STATE BOARD OF HEALTH

**Date:** March 9, 2022

**To:** Washington State Board of Health Members

**From:** Tom Pendergrass, Board Vice Chair

**Subject:** Rulemaking Petition – Chapter 246-105 WAC, Immunization of Child Care and School Children for Vaccine Preventable Diseases

## Background and Summary:

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

On February 22, 2022 the Board received a petition for rulemaking from Kersandra Puderbaugh requesting new rules prohibiting the Board from including certain products in chapter 246-105 WAC, Immunization of Child Care and School Children for Vaccine Preventable Diseases. The petition specifically requests that the Board adopt permanent rules that would prohibit any product with an Emergency Use Authorization (EUA) or any licensed product formulation which has not yet completed Phase 3 clinical trials from inclusion in the rule.

The Board's authority under RCW 28A.210.140 requires the Board to adopt rules to establish the procedural and substantive requirements for full immunization. The Board has adopted such rules in chapter 246-105 WAC. Beginning in 2004, the Board established a set of nine criteria that are used to assess candidate immunizations for inclusion in chapter 246-105 WAC. A technical advisory group (TAG) first reviews the candidate immunization and develops recommendations for the full Board. When the review is complete, the TAG's recommendation is considered by the full Board at regularly scheduled meeting.

For vaccines, the FDA has issued an EUA for three COVID-19 vaccine products: the Moderna COVID-19 vaccine for those ages eighteen years and older, the Janssen COVID-19 vaccine for those ages eighteen years and older, and the Pfizer-BioNTech COVID-19 vaccine as a two-dose primary series for those ages five to fifteen, as a three-dose primary series for those immunocompromised individuals ages twelve and older, and as a single dose booster for those ages sixteen and older. The FDA has also approved the Pfizer-BioNTech COVID-19 vaccine, known as Comirnaty, for those ages sixteen years and older as a two-dose primary series.

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The Board received a similar petition for rulemaking on December 28, 2021 from Xavier Figueroa, Ph. D. on behalf of Informed Choice Washington. That petition also requested new rules that would prohibit the Board from including any product with an EUA or any licensed product formulation which has not yet completed Phase 3 clinical trials in chapter 246-105 WAC. The Board voted to deny the request at its January 12, 2022 meeting. The Board concluded that rules prohibiting certain categories of products could reduce its ability to respond to future emergencies. The Board discussed the inability to fully know what type of emergencies might exist in the future and what kind of response they that might require. The Board also referred to the fact that it uses a rigorous, evidence-based TAG process to consider adding new immunization requirements in chapter 246-105 WAC and noted that the TAG process allows the Board to make a decision about whether or not to include a particular vaccine in the rules based on evidence-based information and expert input.

### Recommended Board Actions

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

The Board declines the petition to initiate rulemaking to prohibit certain products from inclusion in chapter 246-105 WAC for the reasons articulated by Board members and directs staff to notify the requestor of the Board's decision.

OR

The Board accepts the petition for rulemaking to prohibit certain products from inclusion in chapter 246-105 WAC. The Board directs staff to notify the requestor of its decision and to file a CR-101, Preproposal of Inquiry, under its authority in RCW 28A.210.140.

### Staff

Samantha Pskowski

To request this document in an alternate format or a different language, please contact Kelie Kahler, Washington State Board of Health Communication Manager, at 360-236-4102 or by email at [kelie.kahler@sboh.wa.gov](mailto:kelie.kahler@sboh.wa.gov). TTY users can dial 711.

PO Box 47990 • Olympia, WA 98504-7990  
360-236-4110 • [wsboh@sboh.wa.gov](mailto:wsboh@sboh.wa.gov) • [sboh.wa.gov](http://sboh.wa.gov)

