WASHINGTON STATE BOARD OF HEALTH

Date: April 13, 2022

To: Washington State Board of Health Members

From: Keith Grellner, Board Chair

Subject: Rulemaking Petitions – 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 March 18, 2022 the Board received a petition for rulemaking from Julie Barrett and Emily Linh on behalf of Conservative Ladies of Washington 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, unless certain criteria are met. 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 unless pediatric hospital capacity is below 50% and the pediatric death rate for the condition being considered is greater than 1%. The Board received additional petitions on March 31 and April 1, 2022 from Jenn Slater and Dr. AnneRené Joseph, requesting the same rule changes.

The Board received a subsequent petition for rulemaking from Emily Ling on March 21, 2022 requesting new rules that would prohibit the Board from amending chapter 246-105 WAC to include any product or disease requiring immunization that does not comply with the criteria specified in chapter 246-105 WAC. The petition further states that COVID-19 is not a vaccine preventable disease.

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. These rules are set forth in chapter 246-105 WAC, which defines the diseases that children must be protected against and the means of meeting these requirements. Beginning in 2004, the Board established a set of nine criteria that are used to assess candidate antigens for inclusion in the rules

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A technical advisory group (TAG) first reviews the candidate antigen and develops recommendations for the full Board. When the review is complete, the TAG's recommendation is considered by the full Board at a regularly scheduled meeting.

The Board previously received similar petitions for rulemaking on December 28, 2021 and February 22, 2022 from other petitioners. Those petitions 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 considered those requests at their January 12, 2022 and March 9, 2022 meetings respectively.

The Board voted to deny the previous requests after discussing the inability to fully know what type of emergencies might exist in the future and what kind of response future emergencies 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, and amend if necessary, one of the following motions:

The Board declines the petition to initiate rulemaking to amend chapter 246-105 WAC for the reasons articulated by Board members and directs staff to notify the requestors of the Board's decision.

OR

The Board accepts the petition for rulemaking to amend chapter 246-105 WAC. The Board directs staff to notify the requestors 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 <u>kelie.kahler@sboh.wa.gov.</u> TTY users can dial 711.

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