

WASHINGTON STATE BOARD OF HEALTH

Date: January 12, 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 December 28, 2021 the Board received a petition for rulemaking from Xavier Figueroa, Ph.D. on behalf of Informed Choice 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. The petition specifically requests that the Board adopt 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 petition states that the Board has convened a technical advisory group (TAG) to examine adding COVID-19 vaccine to WAC 246-105-030 despite the absence of a Food and Drug Administration (FDA) licensed COVID-19 vaccine with phase three clinical studies in children. The petition further states that the Board is convening this TAG despite CDC-acknowledged risks of myocarditis and blood clots.

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 TAG first reviews the candidate immunization and develops recommendations for the full Board. At its October 2021 meeting, the Board directed staff to begin the process of convening a TAG for purposes of reviewing the COVID-19 vaccine for inclusion in the rule.

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

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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.

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. TTY users can dial 711.

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