



Washington State Board of Health

Petition for Rulemaking: Chapter 246-105 WAC

June 8, 2022

Outline

- Review of Board authority and rule
- Review of petition for rulemaking
- Additional considerations



Board Authority and Current Rules

RCW 28A.210

Child care and school entry requires one of the following:

Proof of full
immunization

Initiation of and
compliance with
schedule

Applicable
Exemption

Board Rule – chapter 246-105 WAC

- RCW 28A.210.140 requires the Board to adopt rules which establish the procedural and substantive requirements for full immunization.
- These rules establish the requirements for immunization status for child care and school entry, including a list of vaccine preventable diseases a child is required to provide documentation for.
- The rules further establish certain duties for schools and child care centers and health care providers.
- The rules establish criteria for exclusion of children who have not provided required documentation during an outbreak of a vaccine preventable disease.



Petition for Rulemaking

Petition for Rulemaking – WAC 246-105-070

- The Board received a petition for rulemaking from Kenneth Harp on May 16, 2022, requesting amendment to WAC 246-105-070.
- The petition requests specific changes to WAC 246-105-070 to require providers immunizing patients to ensure informed consent is obtained when administering vaccines with an Emergency Use Authorization or product that has not completed Stage III Clinical Trials.
- The petition requests specific language be adopted that details what informed consent must contained [see next slide].

Petition for Rulemaking – WAC 246-105-070 (cont'd)

- The petition requests that informed consent for these products include:
 - (1) The regulatory status of the *specific immunization lot number* they are receiving, including:
 - (a) Approval status (Emergency Use Authorized, fully FDA approved, other)
 - (2) Clinical trial status. The current status of clinical trials for the immunization, including whether the clinical trial has been properly blinded or unblinded. If clinical trials are incomplete and/or being performed in parallel with deployment a notice shall be provided that clearly communicates this to the person immunized.
 - (3) Whether or not the immunization prevents infection and transmission.
 - (4) All known potential side effects, both short term and long term.
 - (5) Clearly identification of the party(s) financially responsible for any adverse health impacts that may occur as a result of the immunization, including legal and lawful recourse for injuries sustained from any adverse events associated with the immunization and any legal indemnification afforded to the product manufacturer, the health care provider administering the immunization, or the organization he or she works for, either public or private.

Additional Background Information

- Informed consent is not within the scope of chapter 246-105 WAC. The intent of the chapter and authorizing statute is to establish documentation requirements for fulfilling full immunization for school entry and does not extend to the practice of medicine.
- Rules regarding how providers practice medicine are more appropriately governed by the health professions' respective board or commission.
- Federal and state requirements already address consent for medical intervention.

Board Discussion

**Would the Board consider accepting or denying this petition?
Why or why not?**

Discussion and justification for the Board's decision will be included in the Board's determination letter to the petitioner.

| THANK YOU