

Significant Legislative Rule Analysis (SA)
WAC 246-105-040,
A Rule Concerning
School and Child Care Center Immunization Requirements
Based on National Immunization Guidelines

Section 1. What is the scope of the rule?

This proposed rule change will update the reference to the Advisory Committee on Immunization Practices' (ACIP) Recommended Childhood and Adolescent Immunization Schedule from the 2008 version to the 2010 version. The ACIP has made changes to its recommended immunization schedule to improve the efficacy of the polio vaccine to reduce the chance that a United States citizen will contract polio, a potentially deadly disease. The proposed effective date of the revised schedule is July 1, 2011. This rule revision is necessary to maintain consistency between the national immunization standards as set by the ACIP and Washington State school and child care immunization entry requirements. The ACIP is the federal entity responsible for providing guidance and advice on immunization practices (e.g., ages and intervals) to the Secretary of the U.S. Department of Health and Human Services, the Assistant Secretary for Health, and the Centers for Disease Control and Prevention (CDC).

With this change, schools and child care centers will be required to follow the 2010 recommendations in order for children to be allowed entry for the 2011 - 2012 school year. Parents would still, however, have the option to exempt their children from any required vaccine due to religious, personal or medical reasons. The only change to vaccine requirements for schools and child care centers relate to minor adjustments and clarifications for polio vaccine (IPV). These are:

- The minimum interval between the third and final fourth dose, known as the “booster” dose, is being changed to 6 months (previously 4 weeks).
- It is being clarified that the fourth booster dose must be given on or after the child’s 4th birthday to be valid. If a child receives a fourth dose of IPV vaccine before 4 years of age, he or she must receive an additional dose at the recommended 4 through 6 years of age.

Section 2. What are the general goals and specific objectives of the proposed rule’s authorizing statute?

The general goal of RCW 28A.210.060 through RCW 28A.210.170 is to protect the public’s health by preventing outbreaks of vaccine-preventable disease in schools and child care centers. This is achieved by assuring children have received the required vaccinations before being

allowed to attend school or child care centers. The State Board of Health (board) is given authority to examine and decide which diseases are required for vaccination.

The rule implements the statute's objectives for the board to establish requirements for children to be fully immunized, consistent with the referenced national guidelines for ages and intervals of certain immunizations.

Section 3. What is the justification for the proposed rule package?

Individual states determine immunization requirements for schools and child care centers. The proposed rule will achieve the authorizing statute's goals and objectives by ensuring clear guidance regarding the ages and intervals of vaccines required for attending schools and child care centers.

Because federal guidelines are updated annually, this rule revision is necessary to maintain consistency between the national immunization standards as set by the ACIP and Washington State school and child care immunization entry requirements. To be enforceable the federal guidelines must be adopted into rule.

If this rule is not adopted, immunization requirements in our state would remain based upon outdated federal recommendations that do not reflect current best practices.

Section 4. What are the costs and benefits of each rule included in the rules package? What is the total probable cost and total probable benefit of the rule package?

Significant Rule Analysis

WAC 246-105-040

Rule Overview

For school and child care entry, the board establishes which diseases children must be immunized against and how to show proof of immunization status through chapter 246-105 WAC. To establish the ages and intervals of a vaccine required by this chapter, the board adopts a specific immunization schedule established by the national Advisory Committee on Immunization Practices (ACIP) in WAC 246-105-040.

The ACIP publishes updated schedules every year in the *Morbidity and Mortality Weekly Report*. As the federal schedule is continually updated, the board reviews and updates as appropriate its reference in WAC 246-105-040 to the most current federal schedule possible to maintain consistency and current best practices. Currently the WAC 246-105-040 references the 2008 ACIP schedule. The proposed rule would update that reference to the 2010 ACIP schedule. Except for the vaccination against polio (IPV), the 2010 ACIP schedule imposes no changes

from the 2008 ACIP schedule for school and child care centers to implement. In the case of IPV, the changes are minor and will have a minimal impact, as described below.

For several decades the standard federal recommended series for IPV is a total of 4 doses at ages 2 months, 4 months, 6-18 months, and a final booster dose at 4-6 years. The 2010 ACIP schedule does not change this. The two minor changes are relate to the fourth dose in the series and are as follows:

1. The minimum interval between the third and fourth dose is lengthened. Whereas the 2008 scheduled required a minimum of 4 weeks between the third and fourth dose, the 2010 schedule lengthens the required timeframe to 6 months. The ACIP's reasoning is that a longer interval is optimal for immunity response to the booster dose. Physicians began implementing this change for the administration of recommended vaccines in August 2009, when the change was published. Further, the routinely recommended vaccination schedule for all children currently in child care or grades K-12 stipulates an interval already exceeding 6 months between the third and fourth dose. The board assumes that the rule may have a nominal impact due to a small percentage of children that receive their fourth dose with a gap of less than six months.
2. The recommended age for the fourth dose of IPV is clarified to be on or after the child's fourth birthday (between 4-6 years of age). This clarification was needed due to conflicting schedules created by the new IPV-containing combination vaccine Pentacel®. The Pentacel vaccine is a five dose series with the fourth recommended dose at age 15-18 months, not at the usually recommended age of 4-6 years for IPV. The 2010 ACIP schedule is clarifying that in order for the fourth IPV booster dose to be valid, it must be after the child's fourth birthday. If a child received four IPV doses via Pentacel by his or her 18 month of age, that child would need an additional IPV dose at age 4-6 years to be fully immunized against polio. The ACIP's reasoning for this age range for a fourth (booster) dose is that polio may still be imported into the country, and there is not sufficient data on the duration of polio immunity into adulthood if the child receives their fourth dose at age 15-18 months. The department assumes that a small percentage of children may need to receive an additional dose. This does is needed to fully protect the child from polio. Vaccines are free in Washington State; however parents may still be required to pay nominal administrative costs.

Rule Cost/Benefit Analysis –

The ACIP has updated the recommended immunization schedule to make vaccination more effective. Ultimately, the benefit of this proposed rule is the reduction in the probability of Washington State resident contracting polio, which could cause serious illness, paralysis or death. Parents of children who may be required to get an additional dose of IPV may have to pay nominal administrative costs. The change in the immunization schedule, as described above, will have a minor impact for schools and child care centers. Through the department's normal course of business, it will create notices and learning tools to make sure schools and child care centers are aware of these minor changes. Because children are routinely vaccinated against

polio during the ages when they attend child care centers, these establishments will be primarily responsible for implementing during the screening process. Child care centers are already screening for immunization status as a normal course of business, so the proposed rule change does not require any additional work or pose additional costs for them. Therefore, the benefits of assuring children in Washington State are current with the national immunization standards, as set by the ACIP and Washington State school and child care immunization entry requirements, outweigh the nominal cost of implementing the rule.

Section 5. What alternative versions of the rule did we consider? Is the proposed rule the least burdensome approach?

Individual states determine immunization requirements for schools and child care centers. Washington State directly references national guidelines rather than reiterate each requirement in WAC. One alternative would be to not update the rule to reflect the 2010 schedule, however immunization requirements in our state would remain based upon outdated federal recommendations that do not reflect current best practices.

Section 6. Did you determine that the rule does not require anyone to take an action that violates another federal or state law?

The rule does not require those to whom it applies to take an action that violates requirements of federal or state law.

Section 7. Did we determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless the difference is required in federal or state law?

The Department of Health determined that the rule does not impose more stringent performance requirements on private entities than on public entities.

Section 8. Did you determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, did we determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary?

The rule does not differ from any applicable federal regulation or statute.

Section 9. Did we demonstrate that the rule has been coordinated, to the maximum extent possible, with other federal, state, and local laws applicable to the same activity or subject matter?

There are no other applicable laws.