

Significant Analysis
Eye Prophylaxis for Newborns
Revising WAC 246-100-202 (e)

Section 1- Scope of proposed rule package

The proposed rules amends Washington Administrative Code (WAC) 246-100-202 (1)(e) that instructs providers to put a prophylactic agent into the newborn's eyes in order to prevent Ophthalmia Neonatorum caused by a gonococcal infection.

The proposed rule will:

- A. Incorporate the list of approved prophylactic agents to treat newborns' eyes into Washington Administrative Code (WAC) 246-100-202(1)(e). Currently this list is identified in the WAC by referencing an outdated Department of Social and Health Services (DSHS) policy¹.
- B. Remove silver nitrate solution from the list of approved agents. The Centers for Disease Control and Prevention (CDC) removed silver nitrate solution from their list of recommended agents in 2006 because of eye irritation.
- C. Instruct health care providers to document in the medical records if parents or legal guardians refuse the treatment.

2. Why we are proposing the rule(s)?

The Department of Health (department) and the State Board of Health (board) believe that amending this rule is in the best interest of public health because the new rule incorporates the most current standard of care, which removes silver nitrate from the list of approved prophylactic medications.

The silver nitrate solution, which is currently listed as an approved treatment option, is an outdated standard of practice. This treatment was removed from CDC recommendations in 2006 due to the irritation it causes in the newborn's eyes following administration.

The current medications administered to newborns, Tetracycline and Erythromycin, are endorsed by the CDC. The cost of these medications is similar to the cost of silver nitrate, and their effectiveness in preventing Gonococcal Ophthalmia Neonatorum is comparable. In addition, these medications do not have any documented adverse effects on the newborn, making them more favorable than silver nitrate.

¹ The Department of Social and Health Services policy for ophthalmic agents approved for the prevention of ophthalmia neonatorum in the newborn was established when the Department of Health was a division within the Department of Social and Health Services.

Over the past four years, Maternal and Infant Health at the Department of Health has received numerous complaints from parents and providers because silver nitrate is still on the list of approved agents. Parents have also indicated that they want the ability to decline the procedure without referral to child protective services by hospital staff

In consultation with, the Department of Health, State Board of Health and an assistant attorney general, we propose rule language that requires health care providers to document if a parent or guardian refuses the eye prophylaxis for the newborn. This language was first requested by the public and providers who sought answers as to what to do about parents/guardians who refused the treatment.

Section 2- General goals and specific objectives of the proposed rule's authorizing statute

This rule implements the authority given to the board in RCW 70.24.130. The statutory purpose of this law is to allow the board to adopt rules that protect the public's health and welfare and meet the emerging needs of reducing the incidence of sexually transmitted diseases.

When adopting the authorizing statute the Legislature found that the incidence of sexually transmitted diseases may result in significant social, health and economic costs including infant and maternal mortality, temporary and lifelong disability and premature death. Medical knowledge and information about sexually transmitted diseases are rapidly changing (RCW 70.24.015). The goal of this rule is to reduce the morbidity and mortality of infants and women due to sexually transmitted diseases.

Section 3- Proposed rule justification

1. How will the proposed rule achieve the authorizing statute's goals and objectives?

The proposed rule updates existing rule it to reflect the current standard of care. This will protect newborns from Gonococcal eye infections and help reduce the incidence of newborn blindness associated with sexually transmitted diseases.

The proposed rule will also instruct health care providers to document, in the medical records, if parents or legal guardians refuse the required treatment.

2. Describe why we need the rule versus pursuing an alternative to rulemaking (e.g., could we create a best management practice recommendation or a guidance document that would also achieve the statute's goals and objectives?)

Currently there are existing rules setting standards for health care providers to prevent Ophthalmia Neonatorum in newborns. Timely treatment is necessary to prevent irreversible blindness. The current rule needs to be amended to incorporate the most current standard of care to continue to enforce the reduction of newborn blindness associated with sexually transmitted diseases. This includes removing silver nitrate from

the list of approved prophylactic medications. In addition, this will keep Washington State's standards consistent with other states; most states have a rule addressing Gonorrhea induced eye infections (Gonococcal Ophthalmia Neonatorum).

3. What would happen if we do not adopt this rule (i.e., consequences)? If the board repealed the standard there may be fewer newborns getting the prophylaxis treatment because not all health care providers may follow the practices endorsed by the CDC and the American Academy of Pediatrics. This may result in higher occurrence in newborn blindness due to Gonococcal infections.

Section 4- Sectional cost/benefit analysis

As described above, the rule revision amends three subjects in the rule.

1. This rule package amends WAC 246-100-202(1)(e).

The first item incorporates the list of approved prophylactic agents to treat newborns' eyes directly into WAC 246-100-202(1)(e). Currently this list is identified in the WAC by referencing an outdated DSHS policy. There is no fiscal impact from placing the list of approved agents into rule.

2. Removal of silver nitrate from list of approved medications.

The second item removes silver nitrate from the list of approved medications to be administered to newborns. Silver nitrate was included on the list provided in the original DSHS policy. Health care providers and medical institutions have requested the department to change this rule to reflect current practice. Institutions and health care providers have indicated that the antibiotic prophylaxis treatment is easier to administer, does not cause burning in the eyes of the newborn, is cost equivalent and equally effective. Based upon this and recommendations from the CDC and American Academy of Pediatrics (AAP), most providers stopped using the 1% silver nitrate solution. Instead, they have been administering the other two remaining recommended agents, Tetracycline and Erythromycin antibiotics, for the last few years. There is no anticipated cost impact of removing silver nitrate from the list of approved agents.

3. Addressing refusal of treatment.

The third item adds language that instructs healthcare providers to document when parents/ legal guardians refuse the treatment. For this purpose providers will have to do some minor record keeping which we believe is already being done in an attempt by providers to legally protect themselves. In instances where this record keeping function is not currently being done, it is estimated to be a minor cost for the provider or institution.

Cost Benefit Comparison

This rule will not impose a cost on those that administer prophylactic eye treatment for newborns. Moving the list of approved agents from policy to rule will not impose a cost. Furthermore, removing silver nitrate from the list of approved agents will also not impose a cost because health care providers are already treating newborns' eyes with the

approved antibiotic prophylactic treatments, Tetracycline and Erythromycin. The cost of these medications is comparable to silver nitrate.

Lastly, establishing a process for providers to document if parents or guardians refuse treatment in the newborns' chart is a nominal cost but will ensure that providers offer the treatment and document if it is refused. Therefore the total probable benefits of this rule (i.e., putting requirement for treatment in rule instead of policy, removing outdated medication from list of approved agents, establishing a process to document if parents or guardians refuse the treatment) exceed the total probable costs.

Section 5- Description of alternative considered and least burdensome determination

1. Determine, after considering alternative versions of the rule, that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives stated previously.

For the purpose of this rule revision we have worked closely with stakeholders including providers, parents, DSHS, various sections at the Department of Health, and the State Board of Health. In the course of these efforts, we assessed but are not proposing the following alternative version(s):

Alternative version: An alternative version would be to update the rule to reflect current medications being used, and incorporates treatment options within sub-section (1)(e) of WAC 246-100-202 so that no additional reference material is necessary. However, it would not include a process for health care providers to document if parents or guardians of the newborn refuse the treatment.

Compared to this alternative version, the proposed rule is less burdensome for those required to comply with it because it includes the process for health care practitioners to document if the parents or guardians refuse the required treatment.,

In the proposed rule answering the question sought by the public and providers as to what to do about parents and guardians who refused the treatment.

Section 6- Determine that the rule does not require those to whom it applies to take an action that violates requirements of 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- Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

The rule does not impose more stringent performance requirements on private entities than on public entities. All individuals partaking in the delivery of newborns must adhere to the rule, regardless of the location (home, state institution, and/or private facilities). The rule consistently applies to public and private entities.

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

The rule does not deviate from any applicable federal regulation, statute or guideline.

Section 9- Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

There are no other applicable laws.

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