

DATE: October 14, 2009

TO: Washington State Board of Health Members

FROM: Dr. Patricia Ortiz, SBOH Member

SUBJECT: **WAC 246-100-202(1)(E), OPHTHALMIC AGENTS FOR NEWBORNS, RECONSIDERATION OF FINAL RULE LANGUAGE IN RESPONSE TO NATIONAL ERYTHROMYCIN SHORTAGE**

Background and Summary:

WAC 246-100-202 lists the duties of health care providers related to sexually transmitted diseases. On July 8, 2009, the Board held a public hearing and passed a motion to adopt revisions to WAC 246-100-202(1)(e) as published in WSR 09-11-110. The new rule language would require health care providers to use either erythromycin or tetracycline for prophylaxis against ophthalmia neonatorum. This is in line with Centers for Disease Control and Prevention (CDC) guidelines.

In August 2009, the U.S. Food and Drug Administration (FDA) declared a national shortage of erythromycin (0.50%) ophthalmic ointment. Shortly thereafter, the CDC issued guidance on the shortage of erythromycin. After the FDA declared the shortage, the Department of Health learned that though tetracycline is listed on CDC guidelines, it has been in short supply since 2007.

The CR-102 has not been filed. I am therefore recommending the Board rescind its July 8 adoption without amendment of the language as published in WSR 09-11-110, and then readopt the proposed rule with the addition of a new sentence specifying that in the event that the U.S. FDA declares a shortage of these prophylactic ophthalmic agents, health care providers may substitute alternative prophylactic ophthalmic agents recommended by the CDC. Another minor technical change to the published proposal would substitute the word *agents* for *regimens*. Proposed rule language with the suggested amendments is included in Tab 10 and identified as OTS-2335.2

The Department sent this language to its interested parties list and did not receive any comments opposing the change.

Bat-Sheva Stein from the Maternal Child Health program at the Department of Health is here today to provide more detail on the shortage and answer questions.

Recommended Board Action:

The Board may choose to consider, amend if necessary, and adopt the following motions:

Motion 1: *The Board rescinds its July 8, 2009 adoption of revised WAC 246-100-202(1)(e) as published in WSR 09-11-110.*

Motion 2: *The Board adopts revised WAC 246-100-202(1)(e) as published in WSR 09-11-110 with the amendatory language reflected in OTS-2335.2.*