



STATE OF HAWAII
DEPARTMENT OF HEALTH
P.O. Box 3378
HONOLULU, HAWAII 96801-3378

In reply, please refer to:
File:

September 17, 2009

Waiver of Hawai'i Administrative Rules Section 11-156-4.4(b)

Permitting Alternative Treatment Regimen for Ophthalmia Neonatorum or Neonatal Conjunctivitis During Erythromycin Ophthalmic Ointment Shortage

Hawai'i Administrative Rules (HAR) Section 11-156-4.4(b), contains a requirement for either: 1) one percent silver nitrate; or 2) ophthalmic ointments containing tetracycline or erythromycin to be administered to newborns within one hour after birth as prophylaxis for acute infectious conjunctivitis of the newborn. The recent shortage of erythromycin ophthalmic ointment has resulted in some practitioners, hospitals and birthing facilities depleting their supplies of this product and others having only a limited supply. Additionally, tetracycline ophthalmic ointment and silver nitrate solution are no longer manufactured or available for purchase in the United States.

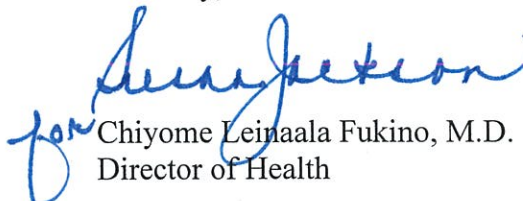
A waiver is hereby granted to HAR §11-16-4.4(b) to allow for use of alternative regimens recommended by the Centers for Disease Control and Prevention (CDC) [authorized ONLY where erythromycin ophthalmic ointment is unavailable]:

Currently recommended alternatives if erythromycin (0.5 percent) ophthalmic ointment is unavailable:

1. AzaSite® (azithromycin ophthalmic solution, one percent, Inspire Pharmaceuticals) is the CDC-recommended substitute. The Department of Health has confirmed that this is currently in stock.
2. Acceptable alternatives, according to the CDC, when erythromycin ophthalmic ointment and azithromycin ophthalmic solution are not available include: Gentak® Gentamicin ophthalmic ointment, 0.3 percent, Akorn) or Tobrex® (tobramycin ophthalmic ointment 0.3 percent, Alcon Laboratories).
3. If none of the above-referenced alternatives are available, the CDC lists a third alternative approach for mothers to be tested for chlamydia and gonorrhea prior to delivery, and results obtained as soon as possible. The 2006 STD Treatment Guidelines (<http://www.cdc.gov/std/treatment/2006/rr5511.pdf>) outlines recommended prophylactic treatment for infants whose mothers have gonococcal infection and for management of infants born to mothers who have untreated chlamydia. Empiric treatment is recommended for infants exposed to gonorrhea, while monitoring for development of symptoms prior to initiating treatment is recommended for infants exposed to Chlamydia.

Health care providers are advised to monitor CDC's website, <http://www.cdc.gov/std/treatment/>, for up-to-date information and alternatives caused by this temporary shortage of erythromycin (0.5%) ophthalmic ointment.

Sincerely,


for Chiyome Leinaala Fukino, M.D.
Director of Health