

**Department of State Health Services
Council Agenda Memo for State Health Services Council
November 4, 2009**

Agenda Item Title: Amendment to a rule concerning prophylaxis against ophthalmia neonatorum

Agenda Number: 7h

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background: The HIV/STD Prevention and Care Branch of the TB/HIV/STD Unit is responsible for the treatment and prevention of HIV and STD in Texas. The Branch implements HIV/STD disease intervention, treatment and service programs through contracts and relationships with local city and county health departments, private physicians, area hospitals and community clinics. The Branch also implements HIV/STD prevention programs through contracts and relationships with local community organizations.

Funding for the program is through the Centers for Disease Control and Prevention (CDC), Health Resources Services Administration, Housing and Urban Development and State Services funds.

Summary: The purpose of the amendment is to provide treatment alternatives to allow continued disease prevention in newborns. An emergency rule was put in place to incorporate alternate medications described in guidance issued by the CDC to respond to a shortage of 0.5% ophthalmic erythromycin ointment; this rule became effective September 15, 2009, and will expire January 12, 2010, with a possibility of extension until March 13, 2010. The proposed amendment will replace the emergency rule. The amendment will update the list of available and recommended medications for prophylaxis, eliminating the references to the two drugs no longer available, and will direct those affected by the rule to guidance by the Department of State Health Services or the CDC for alternate regimens in case of a future shortage of erythromycin, which will become the sole required prophylaxis.

Health and Safety Code, Section 81.091, requires a physician, nurse, midwife, or other person in attendance at childbirth to use or cause to be used prophylaxis approved by the Texas Board of Health (now the Executive Commissioner of the Health and Human Services Commission) to prevent ophthalmia neonatorum. This law provides for medical care for newborns to prevent neonatal conjunctivitis and complications such as blindness that may arise in the newborn through birth to a mother with untreated gonorrhea (neisseria gonorrhea) or chlamydia (chlamydia trachomatis) infection. The law provides that it is a criminal offense, a Class B misdemeanor, for a person to fail to perform a duty required under this law.

Section 97.136 lists the approved prophylaxes in rule. This rule instructs persons attending the childbirth to administer 1.0% ophthalmic tetracycline solution or ointment, a 0.5% ophthalmic erythromycin solution or ointment, or two drops of 1.0% silver nitrate solution in each eye within two hours of birth. The rule does not allow for any alternates to these prophylaxes. Two of these medications, the 1.0% ophthalmic tetracycline and the 1.0% silver nitrate, are no longer available in the United States.

The third prophylactic medication is 0.5% ophthalmic erythromycin. There is a nation-wide shortage of this prophylaxis. On August 31, 2009, the CDC issued a "Dear Colleague" letter identifying the reason for the shortage as change in manufacturers. The CDC states that a new manufacturer recently acquired the rights to the ointment and is actively working to make the ointment available and that a second manufacturer is working to increase production during this time of shortage. The CDC and the United States Food and Drug Administration expect the shortage to be fully resolved by the end of 2009.

Summary of Input from Stakeholder Groups: The HIV/STD Comprehensive Services Branch worked with the Centers for Disease Control and Prevention as well as the Texas Pediatric Society to determine appropriate treatment regimens for infants that are currently available in the United States and Texas. Stakeholder response was favorable and no revisions were suggested.

Proposed Motion: Motion to recommend HHSC approval for publication of rule contained in agenda item #7h

Approved by Assistant Commissioner/Director: Adolfo Valadez, M.D., M.P.H. **Date:** 10/06/09

Presenter: Ann Robbins **Program:** Manager, HIV/STD **Phone No.:** 533-3099
Prevention and Care Branch

Approved by CPCPI: Carolyn Bivens **Date:** 10/06/09

Title 25. HEALTH SERVICES

Part 1. DEPARTMENT OF STATE HEALTH SERVICES

Chapter 97. Communicable Diseases

Subchapter F. Sexually Transmitted Diseases Including Acquired Immunodeficiency Syndrome (AIDS) and Human Immunodeficiency Virus (HIV)

Amendment §97.136

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission (HHSC) on behalf of the Department of State Health Services (department) proposes an amendment to §97.136 relating to Prophylaxis Against Ophthalmia Neonatorum.

BACKGROUND AND PURPOSE

Health and Safety Code, §81.091, requires a physician, nurse, midwife, or other person in attendance at childbirth to use or cause to be used prophylaxis approved by the Texas Board of Health (now the Executive Commissioner of HHSC) to prevent ophthalmia neonatorum. This law provides for medical care for newborns to prevent neonatal conjunctivitis and complications such as blindness that may arise in the newborn through birth to a mother with untreated gonorrhea (neisseria gonorrhea) or chlamydia (chlamydia trachomatis) infection. The law provides that it is a criminal offense, a Class B misdemeanor, for a person to fail to perform a duty required under this law.

The approved prophylaxes are listed in the rule of the department at §97.136. Section 97.136 instructs persons attending the childbirth to administer 1.0% ophthalmic tetracycline solution or ointment, a 0.5% ophthalmic erythromycin solution or ointment, or two drops of 1.0% silver nitrate solution in each eye within two hours of birth. The rule does not allow for any alternates to these prophylaxes. Two of these medications, the 1.0% ophthalmic tetracycline and the 1.0% silver nitrate, are no longer available in the United States.

The third prophylactic medication is 0.5% ophthalmic erythromycin ointment. There is a nationwide shortage of this prophylaxis. On August 31, 2009, the Centers for Disease Control and Prevention (CDC) issued a "Dear Colleague" letter identifying the reason for the shortage as a change in manufacturers. The new manufacturer is actively working to make the ointment available and that a second manufacturer is working to increase production during this time of shortage. The CDC and the United States Food and Drug Administration indicate that the shortage is expected to be resolved by the end of 2009.

An emergency rule was put in place to incorporate alternate medications described in guidance issued by the CDC to respond to shortage of 0.5% ophthalmic erythromycin ointment; this rule became effective September 15, 2009, and will expire on January 12, 2010, with a possibility of extension until March 13, 2010.

This rule change will update the list of available and recommended medications for prophylaxis, eliminating the two drugs no longer available in the United States, leaving 0.5% ophthalmic

erythromycin ointment as the sole required treatment. It will direct those affected by the rule to guidance by the department or the CDC for alternate regimens in case of a future shortage of erythromycin ointment. It requires no practice changes, as it requires only continued use of erythromycin ointment, which is expected to have unrestricted availability at the time this revised rule is enacted.

SECTION-BY-SECTION SUMMARY

Proposed amendments to §97.136(a) delete the two prophylaxes not available in the United States, and directs those affected to guidance by the department or the CDC in the event of a manufacturing or distribution shortfall of 0.5% ophthalmic erythromycin ointment. No other subsections have substantive changes.

FISCAL NOTE

Casey Blass, Director, Disease Intervention and Prevention Section, has determined that for each year of the first five-year period that the section will be in effect, there will be no fiscal implications to state or local governments as a result of enforcing and administering the section as proposed.

MICRO-BUSINESSES AND SMALL BUSINESSES ECONOMIC IMPACT STATEMENT AND REGULATORY ANALYSIS

Mr. Blass has also determined that there will be no adverse economic impact on small businesses or micro-businesses required to comply with the section as proposed. This was determined by interpretation of the rule that small businesses and micro-businesses will not be required to alter their business practices in order to comply with the section, and an economic impact statement and regulatory flexibility analysis are not required.

ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

There are no anticipated economic costs to persons who are required to comply with the section as proposed. There is no anticipated impact on local employment.

PUBLIC BENEFIT

In addition, Mr. Blass has also determined that for each year of the first five years the section is in effect, the public will benefit from adoption of the section, as it will provide treatment alternatives to allow continued disease prevention in newborns.

REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector

of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposed amendment does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to Todd Logan, HIV/STD Prevention and Care Branch, TB/HIV/STD Unit, Department of State Health Services, P.O. Box 149347, Austin, Texas 78714-9347, (512) 533-3098 or by e-mail to todd.logan@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rule has been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The proposed amendment is authorized by Health and Safety Code, Chapter 81; and Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001.

The proposed amendment affects Health and Safety Code, Chapters 81 and 1001; and Government Code, Chapter 531.

Legend: (Proposed Amendment(s))

Single Underline = Proposed new language

[Bold, Print, and Brackets] = Current language proposed for deletion

Regular Print = Current language

§97.136. Prophylaxis against Ophthalmia Neonatorum.

(a) A physician, nurse, midwife, or other person in attendance at childbirth shall apply, or cause to be applied, to the child's eyes a 0.5% ophthalmic erythromycin ointment in each eye within two hours after birth. If this ointment is not available due to a disruption in distribution or manufacturing, a physician, nurse, midwife, or other person subject to this section shall apply or cause to be applied to the child's eyes an alternative treatment included in guidance issued by the Department of State Health Services (department) or the Centers for Disease Control and Prevention. **[one of the following:]**

[(1) a 1.0% ophthalmic tetracycline solution (drops) or ointment in each eye within two hours after birth;]

[(2) a 0.5% ophthalmic erythromycin solution (drops) or ointment in each eye within two hours after birth; or]

(3) two drops of 1.0% silver nitrate solution in each eye within two hours after birth.]

(b) Failure to perform is a Class B misdemeanor under the Texas Health and Safety Code, §81.091(g).

(c) The department **[Department of State Health Services (department)]** may provide an approved prophylaxis without charge to health-care providers if the newborn's financially responsible adult is unable to pay. The health-care provider shall not charge for the prophylaxis that is received free of charge from the department.

(d) Midwives shall follow the additional requirements in Texas Health and Safety Code, §81.091.