



**TO:** Health and Human Services Commission  
Executive Council

**DATE:** February 22, 2018

**FROM:** Janna Zumbrun, Laboratory and Infectious  
Disease Services Division

**AGENDA ITEM: 2.d**

**SUBJECT:** Prophylaxis against Ophthalmia Neonatorum

**BACKGROUND:**  Federal  Legislative  Other: Program Initiative

The purpose of the amendment to §97.136 in Texas Administrative Code, Title 25, is to comply with House Bill (HB) 2886, 85th Legislature, Regular Session, 2017, which amended Health and Safety Code §81.091.

Health and Safety Code, §81.091 requires a physician, nurse, midwife, or other person in attendance at childbirth to apply prophylaxis or an antibiotic ointment to the newborn's eyes 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 gonorrhoea*) 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.

HB 2886 provides an exception for certain health care providers who are unable to apply prophylaxis to a newborn due to the objection of a parent, managing conservator, or guardian of the newborn infant. Under this exception, the health care provider does not commit an offense and is not subject to criminal, civil, or administrative liability or any professional disciplinary action for failure to administer the prophylaxis.

HB 2886 also requires that the physician, nurse, midwife, or person in attendance shall ensure that the objection of the parent, managing conservator, or guardian is entered into the medical record of the infant.

**ISSUES AND ALTERNATIVES:**

No issues anticipated.

**STAKEHOLDER INVOLVEMENT:**

The proposed amendment was sent to stakeholders via email on September 15, 2017. Comments received from stakeholders were reviewed by Department of State Health Services staff and taken into consideration.

External stakeholders included:

- Association of Texas Midwives
- Consortium of Texas Certified Nurse-Midwives
- Texas Association of Obstetricians and Gynecologists
- Texas Health Resources
- Texas Hospital Association
- Texas Medical Association
- Texas Nurses Association
- Texas Pediatric Society

Comments received from the Texas Hospital Association suggested addressing policies and procedures for clinicians who did not document a parent, managing conservator, or guardian’s objection to prophylaxis in the infant's medical record. This change was not made as these policy decisions should be made by each individual entity.

**FISCAL IMPACT:**

None

**SERVICES IMPACT STATEMENT:**

None anticipated.

**RULE DEVELOPMENT SCHEDULE:**

February 22, 2018	Present to HHSC Executive Council
March 2018	Publish proposed rules in <i>Texas Register</i>
July 2018	Publish adopted rules in <i>Texas Register</i>
July 2018	Effective date

## PROPOSED PREAMBLE

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (DSHS), proposes an amendment to §97.136, concerning Prophylaxis against Ophthalmia Neonatorum.

## BACKGROUND AND PURPOSE

The purpose of the amendment is to comply with House Bill (HB) 2886, 85th Legislature, Regular Session, 2017, which amended Texas Health and Safety Code, §81.091.

Texas Health and Safety Code, §81.091 requires a physician, nurse, midwife, or other person in attendance at childbirth to apply prophylaxis or an antibiotic ointment to the newborn's eyes 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 gonorrhoea*) 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.

HB 2886 provides an exception for certain health care providers who are unable to apply prophylaxis to a newborn due to the objection of a parent, managing conservator, or guardian of the newborn infant. Under this exception, the health care provider does not commit an offense and is not subject to criminal, civil, or administrative liability or any professional disciplinary action for failure to administer the prophylaxis.

HB 2886 also requires that the physician, nurse, midwife, or person in attendance shall ensure that the objection of the parent, managing conservator, or guardian is entered into the medical record of the infant.

## SECTION-BY-SECTION SUMMARY

Proposed amendment to §97.136(b) references an exception in subsection (c) that health care providers are protected from civil or criminal liability if they are unable to apply prophylaxis on an infant due to the objection of the parent, managing conservator, or guardian and is consistent with Texas Health and Safety Code, §81.091(g), as amended by HB 2886.

Proposed amendment to §97.136(c) adds the protection granted to health care providers in attendance at birth who are unable to apply prophylaxis to

a newborn infant to prevent ophthalmia neonatorum. Also, a statement is added that the health care provider is required to document the refusal of the parent, managing conservator, or guardian in the infant's medical record. The changes are consistent with Texas Health and Safety Code, §81.091(g-1), as amended by HB 2886. Subsections (c) and (d) were renumbered to subsections (d) and (e) due to the addition of new subsection (c).

#### FISCAL NOTE

Donna Sheppard, Chief Financial Officer, has determined that for each year of the first five years 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.

#### GOVERNMENT GROWTH IMPACT STATEMENT

DSHS has determined that during the first five years that the section will be in effect:

- (1) the proposed rule will not create or eliminate a government program;
- (2) implementation of the proposed rule will not affect the number of employee positions;
- (3) implementation of the proposed rule will not require an increase or decrease in future legislative appropriations to the agency;
- (4) the proposed rule will not affect fees paid to the agency;
- (5) the proposed rule will not create a new rule;
- (6) the proposed rule will expand an existing rule;
- (7) the proposed rule will not change the number of individuals subject to the rule; and
- (8) the proposed rule will not affect the state's economy.

#### SMALL BUSINESS, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT ANALYSIS

Ms. Shepard has also determined that there will be no adverse economic effect on small businesses, micro-businesses or rural communities required to comply with the section as proposed. Small businesses or micro-businesses, or rural communities will not be required to change their business practices as a result of this rule.

#### 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 negative impact on local employment.

#### COSTS TO REGULATED PERSONS

Texas Government Code, §2001.0045 does not apply to this rule because the rule is necessary to implement legislation that does not specifically state that §2001.0045 applies to the rule.

#### PUBLIC BENEFIT

Felipe Rocha, Director, TB/HIV/STD Section, has determined that for each year of the first five years that the section will be in effect, the public will benefit from adoption of the section as it will provide continued disease prevention in newborns.

#### TAKINGS IMPACT ASSESSMENT

DSHS has determined that the proposal 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 Texas Government Code, §2007.043.

#### PUBLIC COMMENT

Written comments on the proposal may be submitted Tammy Foskey, Manager, HIV/STD Public Health Follow Up Team, P.O. Box 149347, Mail Code 1873, Austin, Texas 78714-9347; by fax to 512-533-3177; or by email to [HHSRulesCoordinationOffice@hhsc.state.tx.us](mailto:HHSRulesCoordinationOffice@hhsc.state.tx.us) within 30 days of publication of this proposal in the *Texas Register*. When faxing or emailing comments, please indicate "Comments on Proposed Rule 25R068" in the subject line.

To be considered, comments must be submitted no later than 30 days after the date of this issue of the *Texas Register*. The last day to submit comments falls on a Sunday; however, comments postmarked, shipped, faxed or emailed before midnight on the following Monday will be accepted.

#### STATUTORY AUTHORITY

The amendment is authorized by Texas Health and Safety Code, §81.091 which requires the Executive Commissioner of HHSC to approve prophylaxes for ophthalmic neonatorum prevention; Texas Health and Safety Code,

Chapter 81; and Texas Government Code, §531.0055, and Texas 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 DSHS and for the administration of Texas Health and Safety Code, Chapter 1001.

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

The agency certifies that legal counsel has reviewed the proposal and found it to be within the agency's legal authority to adopt.

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)

**§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.

(b) Except as provided by subsection (c) of this section, a person commits an offense if the person is a physician, nurse, midwife, or other person in attendance with a pregnant woman either during pregnancy or at delivery and fails to perform a duty required by subsection (a) of this section. An offense under this section [Failure to perform] is a Class B misdemeanor under the Texas Health and Safety Code, §81.091(g).

(c) A physician, nurse, midwife, or other person in attendance at childbirth who is unable to apply the prophylaxis as required by this section due to the objection of a parent, managing conservator, or guardian of the newborn infant does not commit an offense under this section and is not subject to criminal, civil, or administrative liability or any professional disciplinary action for failure to administer the prophylaxis. The physician, nurse, midwife, or person shall ensure that the objection of the parent, managing conservator, or guardian is entered into the medical record of the infant.

(d) ~~(c)~~ The 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.

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