

**Department of State Health Services**  
**Agenda Item for State Health Services Council**  
**April 12, 2007**

**Agenda Item Title:** Amend 25 TAC, §97.121 and §§97.123-97.125, Rules Relating to the Provision of Anti-Rabies Biologicals.

**Agenda Number:** 5c

**Recommended Council Action:**

For Discussion Only

For Discussion and Action by the Council

**Background:** The Disease Prevention and Intervention Section, Immunization Branch, provides services to prevent, control, reduce, and eliminate diseases in children and adults.

Government Code, §2001.039, requires that each state agency review and consider for re-adoption every 4 years each rule adopted by that agency pursuant to the Government Code, Chapter 2001.

In the 4-year review of these rules, the amendments to §97.121 and §§97.123-97.125 update the agency, division, section, and branch names, update language for consistent terminology, reorganize text to simplify processes, clarify the department's policies for storage, distribution, loss due to negligence, and reporting requirements of anti-rabies biologicals, and provide the Advisory Committee on Immunization Practices (ACIP) as a reference for assessing rabies exposure and treatment recommendations.

**Summary:** The amendments establish that the provision of anti-rabies biologicals be in accordance with recent recommendations of the ACIP, and clarify payment responsibilities, including the clarification that issuance of anti-rabies biologicals will not be withheld due to a patient's inability to pay. In addition, the amendments clarify that department-owned anti-rabies biologicals may be dispensed from depots at the price the department procures the vaccine under the current state contract, plus, the depot's responsibilities for anti-rabies biologicals stocking, issuing, returning, and loss due to negligence.

**Summary of Stakeholder Input to Date (including advisory committees):**

In November and December of 2006, the Immunization Branch consulted with the Health Service Regions, the Zoonosis Control Program, and the regional doctors of veterinarian medicine. Stakeholder input was solicited through verbal and written communication about the up-coming four-year review of the rule. Stakeholder comments are archived.

**Proposed Motion:** Motion to recommend HHSC approval for publication of rules contained in agenda item #6c.

**Agenda Item Approved by:** \_\_\_\_\_  
Debra Stabeno, Assistant Commissioner, Prevention and Preparedness

**Date Submitted**  
January 22, 2007

**Presented by:** Jack Sims                      **Title:** Immunization Branch Manager  
**Program/Division:** Immunization Branch, Disease Prevention & Intervention Section,  
Prevention & Preparedness Division

**Contact Name/Phone:** Victoria Brice, 512-458-7111x6658

Title 25. HEALTH SERVICES  
Part 1. DEPARTMENT OF STATE HEALTH SERVICES  
Chapter 97. Communicable Diseases  
Subchapter E. Provision of Anti-Rabies Biologicals  
Amendment §97.121, §§97.123-97.125

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission on behalf of the Department of State Health Services (department) proposes amendments to §97.121 and §§97.123-97.125, concerning the provision of anti-rabies biologicals (vaccines and hyper-immune sera) by the department in accordance with recommendations of the Advisory Committee on Immunization Practices (ACIP).

BACKGROUND AND PURPOSE

Government Code, §2001.039, requires that each state agency review and consider for readoption every 4 years each rule adopted by that agency pursuant to the Government Code, Chapter 2001. Sections 97.121 and 97.123-97.125 have been reviewed and the department has determined that reasons for adopting the sections continue to exist because rules on this subject are needed.

In the 4-year review of these rules, the amendments to §97.121 and §§97.123-97.125 update the agency, division, section, and branch names, plus, reorder text to simplify processes. In addition, the amendments clarify the department's policies for storage, distribution, loss due to negligence, and reporting requirements of anti-rabies biologicals, plus, provide the ACIP as a reference for assessing rabies exposure and treatment recommendations.

The department consulted with the Health Service Regions, the Zoonosis Control Program, and the regional doctors of veterinarian medicine during the rule development process.

SECTION-BY-SECTION SUMMARY

Amendments to §97.121 and §§97.123-97.125 update the agency, division, section, and branch names and update language for consistent terminology. Amendments to §97.121 establishes that the provision of anti-rabies biologicals be in accordance with recent recommendations of the ACIP. Amendments to §97.123 reorder the text, and clarify procedures for stocking, issuing, and returning anti-rabies biologicals. Amendments to §97.124 provide clarification of payment responsibilities, including the clarification that issuance of anti-rabies biologicals will not be withheld due to a patient's inability to pay. Amendments to §97.125 clarifies that department-owned anti-rabies biologicals may be dispensed from depots at the price the department procures the vaccine under the current state contract, plus, explains the depot's responsibilities when vaccine is lost due to negligence.

## FISCAL NOTE

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

## SMALL AND MICRO-BUSINESS IMPACT

Mr. Blass has also determined that there will be no effect on small businesses or micro-businesses required to comply with the sections as proposed. This was determined by interpretation of the rules that small businesses and micro-businesses will not be required to alter their business practices in order to comply with the sections. There are no anticipated economic costs to persons who are required to comply with the sections as proposed. There is no anticipated negative impact on local employment.

## PUBLIC BENEFIT

Mr. Blass has determined that for each year of the first five years that the sections are in effect, the public will benefit from adoption of the sections. The public benefit anticipated as a result of enforcing or administering the sections as proposed is to operate the program to ensure the safety of the public, and to clarify processes.

## 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 rules do 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, do not constitute a taking under Government Code, §2007.043.

## PUBLIC COMMENT

Comments on the proposed rules may be submitted to Victoria Brice, Disease Prevention and Intervention Section, Division of Prevention and Preparedness, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756, 512-458-7111, extension 6658, or by email to Victoria.Brice@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, Cathy Campbell, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

## STATUTORY AUTHORITY

The proposed rules are authorized by Health and Safety Code, §81.021, which requires the department to protect the public from communicable disease; and §81.004 which allows the department to adopt rules for the effective administration of the Communicable Disease Act; §826.025 which allows the department to adopt rules to provide, and obtain payment for anti-rabies biologicals; §826.011 which allows the department to adopt rules necessary to administer the Rabies Control Act; 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 rules affect Health and Safety Code, Chapters 81, 826 and 1001; and Government Code, Chapter 531. Review of the sections implements Government Code, §2001.039.

Legend: (Proposed Amendment(s))

Single Underline = Proposed new language

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

Regular Print = Current language

(No change.) = No changes are being considered for the designated subdivision

§97.121. Purpose.

The purpose of these sections is to provide anti-rabies biologicals (vaccines and hyper-immune sera) in accordance with the recent “ Human Rabies Prevention, United States, Recommendations of the Advisory Committee on Immunization Practices (ACIP)” of the U.S. Health Services **[for the use and benefit of persons exposed, or suspected of having been exposed, to rabies]**.

§97.123. Stocking, **[and]** Issuing, and Returns.

(a) Stocking. Anti-rabies biologicals may be procured and distributed by the Department of State Health Services **[Texas Department of Health]** (department). The department may enroll off-site depots for the storage and distribution of department-owned anti-rabies biologicals. **[Anti-rabies biologicals may be stocked in depots located throughout the state.]** The depot will be licensed as defined by the Texas Board of Pharmacy that allows for the storage and distribution of anti-rabies biologicals to individuals presenting a signed order from a medical practitioner licensed to practice in Texas. The products in each depot will remain under the ownership **[control]** of the **[appropriate regional director of this]** department until issued.

(b) Issuing.

(1) Anti-rabies biologicals may only be issued **[for post-exposure treatment for any person]** upon receipt of a **[the]** signed order from **[of]** a medical practitioner **[professional]** licensed to practice in Texas.

(2) The department has the right to refuse to provide anti-rabies biologicals if the incident in question does not warrant rabies post-exposure prophylaxis according to the recent ACIP’s recommendations on human rabies prevention. **[The guidelines established by the Advisory Committee on Immunization Practices of the U.S. Public Health Service will be used as guidelines for assessing rabies exposure. In event the department elects not to supply biologicals for post-exposure prophylaxis, the department will provide the medical professional the name of a source from which anti-rabies biologicals may be purchased.]**

(3) Partial issuance. Issues may be less than the full regimen of treatment when:

(A) there is reason to believe that the treatment may be terminated before completion; or

(B) in the event of a biological shortage.

**[(3) The following will be accomplished at time of issue.]**

**[(A) A department-prepared human rabies prophylaxis surveillance report will be completed by the person issuing the anti-rabies biologicals and sent to the Texas Department of Health.]**

**[(B) An information sheet about rabies and rabies biologicals will be provided by the department to the attending medical professional for informing the patient of the risks and benefits of the anti-rabies treatment.]**

**[(C) The most recent guidelines for treatment for the prevention of rabies as recommended by the Advisory Committee on Immunization Practices of the U.S. Public Health Service will be provided by the department to the attending medical professional.]**

(4) For individuals who are declined anti-rabies biologicals, the department will provide a source from which biologicals may be purchased.

(5) At the time of issuance.

(A) A human rabies prophylaxis surveillance report will be completed by the person issuing the anti-rabies biologicals and forwarded to the appropriate health service region.

(B) An information sheet about rabies and rabies biologicals will be provided by the department for use by the attending medical practitioner to inform the patient of the risks and benefits of the anti-rabies treatment.

(C) The recent ACIP's recommendations on human rabies prevention will be provided to the attending medical practitioner.

(D) An information sheet will be provided to the patient or the patient's agent on the proper transport of the biologicals.

(E) The patient or patient's agent will receive and sign an information sheet pertaining to payment responsibilities.

(F) Anti-rabies materials may be obtained from the Department of State Health Services, Immunization Branch, 1100 W. 49th Street, Austin, Texas 78765-3199, or by request by phoning, 1-800-252-9152.

**[(c) Partial issue. Issues may be made of less than the full regimen of treatment whenever less than the full regimen is necessary, or when there is reason to believe that treatment may be terminated before completion of the full course for any reason. After a partial issue is made, the remaining doses needed may be issued later if laboratory tests or other evidence confirm the need for continuing the treatment.]**

**[(d) Administration of anti-rabies biologicals. Anti-rabies biologicals issued by the Texas Department of Health may be administered to humans only by or under the supervision of a medical professional licensed to practice in Texas. Anti-rabies biologicals may be issued at the depot to the bearer of the medical professional's order for transport to a medical professional and subsequent administration to the patient by or under the supervision of a medical professional.]**

**(c) [(e)] Return of anti-rabies biologicals. Once issued to a patient or patient's agent and removed from the depot storage area, no anti-rabies biologicals may be returned for credit or reimbursement [ , nor may any returned anti-rabies biologicals be reissued for use of any kind].**

§97.124. Payment for Anti-Rabies Biologicals.

The department is specifically authorized by law to distribute anti-rabies biologicals and to receive reimbursement based on the department's current contract **[for the cost of the biologicals].**

(1) Options for reimbursement will be in accordance with policies set by the department **[Immunizations Division, Texas Department of Health]**, and are as follows:

(A) The patient or patient's agent will provide the department proof of viable insurance coverage. If the insurance does not pay or does not pay the entire amount, the patient or patient's agent may be responsible for any outstanding balance.

**[(A) Payment at time of issue. Arrangements for payment must be complete at the time of issuance of the anti-rabies biologicals, including options for monthly payments and/or third party coverage, or payment in full at the time of receipt. The regional director is responsible for ensuring that payment arrangements are made.]**

(B) Proof of inability to pay. If a patient is unable to pay, the patient will be required to sign a statement that he/she will provide the department with financial information to pursue a reduced amount charged.

**[(B) Inability to pay. The regional director will accept, in lieu of payment, a statement signed by the patient that the patient is unable to pay in whole or part the cost of the biologicals and has no third party or other alternate source to provide payment.]**

(2) Refusal to pay. The department shall have the right to seek reimbursement in the event of a refusal to pay by a patient, or by his or her third-party coverage or other legally obligated source. A county or district attorney or the Texas Attorney General **[attorney general]**, upon request of the **[a]** department, may initiate suit or other proceeding in the county of the recipient's residence**[against the recipient, the parent, guardian, or other person or persons legally responsible for the support of the recipient or against responsible third parties].**

(3) The issuance of anti-rabies biologicals will not be withheld due a patient's inability to pay.

§97.125. Designation of Depots for Anti-Rabies Biologicals.

The department may enroll [procure] off-site depots [facilities] for the storage and dispensing of department-owned anti-rabies biologicals.

(1) The [These] depots will be licensed as defined by the Texas Board of Pharmacy that allows for the storage and distribution of anti-rabies biological to individuals presenting a signed order from a medical practitioner licensed to practice in Texas [comply with the department's policy regarding storage, dispensing and reporting requirements].

(2) The depot's designee will enroll as a depot with the department and comply with the department's policy regarding storage, distribution, and reporting requirements [depots will dispense the vaccine at the price designated by the department].

(3) Anti-rabies biologicals will be dispensed at the price the department procures the vaccine under the current state contract.

(4) Loss due to negligence.

(A) The department will require a letter outlining the reason for the loss and the corrective action to prevent recurrence.

(B) The department will review the letter and determine if billing is appropriate.

(C) If found to be at fault and reimbursement does not occur, the department may pursue legal action.

(D) Failure to reimburse the department within the specified time frame may result in revocation of the authority to dispense anti-rabies biologicals.