

**Department of State Health Services  
Agenda Item for State Health Services Council  
October 5, 2006**

**Agenda Item Title:** Amend 25 TAC §97.91 and Repeal §97.92, Rules Relating to Informed Consent, Amend 25 TAC §§97.151-97.153 and §§97.155-97.156 and New §97.154, Rules Relating to Vaccination Stamps

**Agenda Number:** 3a

**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 vaccine-preventable diseases in children and adults.

*The Immunization Branch proposes amendments to 25 TAC, Part 1, Chapter 97, Communicable Diseases, Subchapter C, §97.91, regarding Delegation of Authority to Give Informed Consent for Immunizations of a Minor, Subchapter G, §97.151, §97.152, §97.153, §97.155, §97.156, regarding Vaccination Stamps, new §97.154 regarding Vaccination Stamps, repeal §97.92 regarding Informed Consent.*

**Amendment §97.91 and Repeal §97.92:**

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. Sections 97.91-97.92 have been reviewed and the department has determined that reasons for adopting continue to exist because rules on this subject are needed. However, §97.92 is proposed for repeal due to redundant language.

**Amendments §§97.151-97.153; 97.155-97.156**

**New §97.154**

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. Sections 97.151-97.153 and 97.155-97.156 have been reviewed and the department has determined that reasons for adopting continue to exist because rules on this subject are needed.

The U.S. Public Health Service has designated the Department of State Health Services as the governmental entity which is responsible for determining which physicians in Texas are authorized to administer yellow fever vaccine for persons who travel outside the United States. The department provides this authorization by issuing Uniform Stamps to designated physicians. Physicians are authorized to use the Uniform Stamp for validating administration of yellow fever vaccine on vaccination certificates issued at approved vaccination centers.

- Amendments to §97.151 update the agency, division, section, and branch names, plus, provide consistency in terminologies.
- Amendments to §97.152 update agency names and terminologies.
- Amendments to §97.153 simplify the process by deleting current language which requires administration of 20 or more doses of yellow fever vaccine annually for Uniform Stamp eligibility, plus, clarify language for the Uniform Stamp's issuance and responsibilities. New language that physicians are encouraged, but not required, to report cases of febrile illness potentially caused by yellow fever vaccination to the CDC/FDA Vaccine Adverse Events reporting System (VAERS) is added. These

amendments more closely follow federal guidelines, which are referenced in the section. Also, the Uniform Stamp application, renewal, and replacement processes and fees are updated.

- New §97.154 reorders the criteria for operating a vaccination center into one section and clarifies those requirements.
- Amendments to §97.155 update language for consistent terminology.
- Amendments to §97.156 update division, branch and department names, clarifies that renewals are also encompassed in subsection (a), plus, subsection (b) is clarified to state that hearings, when available, occur if they are requested.

**Summary:**

In the 4 year review of these rules, the amendments update the agency, division, section, and branch names. The amendments clarify language, simplify processes, reorder text, and more closely follow federal guidelines:

**Amendment §97.91:**

Section 97.91 provides that certain information must be obtained prior to immunizations of a minor when the parent/legal guardian is not present and another adult purports to have consent of that parent/legal guardian. In addition, the proposed amendment provides that immunizations may also be administered as provided in Family Code, §32.101. The proposed amendments clarify these requirements, and include a cross-reference to the Family Code. There is no anticipated fiscal impact to state and/or local government. There is no anticipated non-fiscal impact to local government.

There is no anticipated fiscal or non-fiscal impact to small or micro-businesses as a result of administering or enforcing the amendments as proposed.

**Repeal §97.92**

Since Family Code, §32.101 provides requirements related to who shall be allowed to grant consent to immunize a child (i.e., parent/legal guardian) and who shall be allowed to grant consent in the event that parent/legal guardian is not available, the agency proposes that section §97.92 be repealed in its entirety in order to provide clarity to the public concerning who may provide consent to immunize a child under various circumstances. The Family Code provision speaks to the scenarios which §97.92 attempts to address; therefore, the agency proposes repealing §97.92 as redundant. There is no anticipated fiscal impact to state and/or local government.

There is no anticipated non-fiscal impact to local government. There is no anticipated fiscal or non-fiscal impact to small or micro-businesses as a result of repealing this rule.

**Amendments §§97.151-97.153; 97.155-97.156**

**New §97.154**

After conducting a cost analysis, the branch determined that the existing \$25 fees for Uniform Stamp application, renewal, and replacement were not sufficient for the department to recover its' costs. The increased fees are not expected to have a significant impact, and are necessary to cover state costs; the simplified procedures are expected to have a positive impact because they're streamlined and therefore more efficient. The Uniform Stamp application, renewal, and replacement fees are increased for a reasonable recovery of the department's costs. However, all fees remain waived for public health departments, public health districts, and public health regions.

- New Applications: Increased from \$25.00 to \$68.00.
- Renewals: Increased from \$25.00 to \$38.00. This is an annual expense.
- Replacements: Increased from \$25.00 to \$50.00. This expense is incurred when the provider requests DSHS to order a replacement stamp, usually when the provider moves or loses a stamp.

There is no anticipated non-fiscal impact to local government.

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

**Amendment §97.91 and Repeal §97.92:**

In May 2006, the Immunization Branch consulted with internal stakeholders to explore impacts, define stakeholders, and determine communication methods. In June 2006, the Immunization Branch will solicit preliminary comments and input from stakeholders using email. The initial stakeholder list includes the following: Department of Family and Protective Services, Disease Prevention and Intervention Section, Health Promotion Unit, Chronic Disease Prevention Branch, and Youth-Focused Group (DSHS). Email notifications and the DSHS Immunization website (www.ImmunizeTexas.com) will keep stakeholders up to date on the rule's status and provide comment opportunities. Stakeholder comments are archived.

**Amendments §§97.151-97.153; 97.155-97.156**

**New §97.154**

In May 2006, the Immunization Branch consulted with internal stakeholders to explore impacts, define stakeholders, and determine communication methods. In June 2006, the Immunization Branch solicited preliminary comments and input from stakeholders using e-mail. The initial stakeholder list includes the following: the Health Service Regions, Texas Association of Local Health Officials, DSHS Infectious Disease Control Unit, Texas Academy of Family Physicians, Texas Medical Association, and the current directory of authorized yellow fever vaccine providers. Email notifications and the DSHS Immunization website (www.ImmunizeTexas.com) will keep stakeholders up to date on the rule's status and provide comment opportunities. Stakeholder comments are archived.

**Proposed Motion:**

Motion to recommend HHSC approval for publication of rules contained in agenda item 3a.

**Approved by:** \_\_\_\_\_  
Assistant Commissioner, Division for Prevention and Preparedness Services

**Presented by:** Mr. Jack Sims      **Title:** Branch Manager  
**Program/Division:** Disease Prevention and Intervention Section, Immunization Branch

**Contact:** Ms. Victoria Brice x6658 regarding §§97.151-97.156  
Mr. Tim Hawkins x3394 regarding §§97.91—97.92

**Date Submitted**

7/13/2006

Title 25. HEALTH SERVICES  
Part 1. DEPARTMENT OF STATE HEALTH SERVICES  
Chapter 97. Communicable Diseases  
Subchapter C. Consent for Immunization  
Amendment §97.91; Repeal §97.92  
Subchapter G. Vaccination Stamps  
Amendments §§97.151-97.153 and 97.155-97.156  
New §97.154

### Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission on behalf of the Department of State Health Services (department) proposes an amendment to §97.91, concerning the delegation of authority to give informed consent for immunizations of a minor, and repeal of §97.92, concerning recommendations for documentation of reason(s) parent, managing conservator, guardian, or other person could not be contacted; and proposed amendments to §§97.151-97.153 and 97.155-97.156 and new 97.154, concerning the process by which physicians in the state are authorized to administer yellow fever vaccine for persons who travel outside the United States.

### 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 97.91-97.92 have been reviewed and the department has determined that reasons for adopting §97.91 continue to exist because a rule on this subject is needed. However, §97.92 is proposed for repeal due to redundant language.

Section 97.91 provides that certain information must be obtained prior to immunizations of a minor when the parent/legal guardian is not present and another adult purports to have consent of that parent/legal guardian. In addition, the proposed amendment provides that immunizations may also be administered as provided in Family Code, §32.101. The proposed amendments clarify these requirements, and include a cross-reference to the Family Code.

Since Family Code, §32.101, provides requirements related to who shall be allowed to grant consent to immunize a child (i.e., parent/legal guardian) and who shall be allowed to grant consent in the event that parent/legal guardian is not available, the agency proposes that §97.92 be repealed in its entirety in order to provide clarity to the public concerning who may provide consent to immunize a child under various circumstances. The Family Code provision speaks to the scenarios which §97.92 attempts to address; therefore, the department proposes repealing §97.92 as redundant.

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 97.151-97.153 and 97.155-97.156 have been reviewed and the department has determined that reasons for adopting the sections continue to exist because rules on this subject are needed. However, new §97.154 is proposed so that there is a section which consolidates the criteria for operating as a vaccination center, and clarifies those criteria.

Proposed amendments to §§97.151-97.153 and 97.155-97.156 and new 97.154, concern the process by which physicians in the state are authorized to administer yellow fever vaccine for persons who travel outside the United States. The department provides this authorization by issuing Uniform Stamps to designated physicians.

Sections 97.151 - 97.156 cover the criteria by which the department issues the Uniform Stamps to physicians, and processes for denial, revocation, suspension, or non-renewal.

In the 4-year review of these rules, the amendments to §§97.151-97.153 and 97.155-97.156 update the agency, division, section, and branch names, plus, clarify language, simplify processes, reorder text, and more closely follow federal guidelines. After conducting a cost analysis, the branch determined that the existing \$25 fees for Uniform Stamp application, renewal, and replacement were not sufficient for the department to recover its' costs. The Uniform Stamp application, renewal, and replacement fees are increased for a reasonable recovery of the department's costs. However, all fees remain waived for public health departments, public health districts, and public health regions.

The department consulted with the Health Service Regions, Texas Association of Local Health Officials, DSHS Infectious Disease Control Unit, Texas Academy of Family Physicians, Texas Medical Association, and the current directory of authorized yellow fever vaccine providers during the rule development process.

#### SECTION-BY-SECTION SUMMARY

Section 97.91(a) is amended to include the phrase “parent/legal guardian is not present and another adult purports to have consent of that parent/legal guardian” as clarifying language. Language concerning contacting a “parent/guardian” is proposed to be deleted because it causes confusion and is not necessary.

In §97.91, subsections (b) and (c)(1) are amended to include “parent/legal guardian” as clarifying language.

Section 97.91(e) is added to include “immunizations may also be administered as provided in Family Code, §32.101” as a cross-reference to an existing statutory provision which speaks to the situations that §97.92 attempts to address. Section 97.92 is therefore proposed to be repealed as redundant language.

Amendments to §97.151 update the agency, division, section, and branch names, plus, provide consistency in terminologies. The amendments to §97.152 update agency names and terminologies. Amendments to §97.153 simplify the process by deleting current language which requires administration of 20 or more doses of yellow fever vaccine annually for Uniform Stamp eligibility, plus, clarify language for the Uniform Stamp's issuance and responsibilities. New language that physicians are encouraged, but not required, to report cases of febrile illness potentially caused by yellow fever vaccination to the CDC/FDA Vaccine Adverse Events reporting System (VAERS) is added. These amendments more closely follow federal guidelines, which are referenced in the section. Also, the Uniform Stamp application, renewal, and replacement processes and fees are updated. New §97.154 reorders the criteria for operating a vaccination center into one section and clarifies those requirements. The amendments to §97.155 update language for consistent terminology. The amendments to §97.156 update division, branch and department names, clarifies that renewals are also encompassed in subsection (a), plus, subsection (b) is clarified to state that hearings, when available, occur if they are requested.

#### FISCAL NOTE

Casey S. Blass, Section Director, Disease Prevention and Intervention Section, has determined that for each year of the first five years that §97.91 will be in effect, if future funds are appropriated at current levels, there will be no additional costs to state or local government as a result of enforcing and administering the section as proposed.

Mr. Blass has also determined that for each year of the first five years that §97.92 will no longer be in effect, there will be no additional costs to state or local government as a result of repeal of the section.

Casey Blass, Section Director, Disease Prevention and Intervention Section, has determined that for each calendar year of the first five years that §§97.151-97.156 are in effect, there will be fiscal implications to the state as a result of administering the sections as proposed. The effect on state government will be an increase in revenue due to the increased Uniform Stamp fees. The Uniform Stamp application, renewal, and replacement fees are increased for a reasonable recovery of the department's costs. There will be no fiscal implications to local governments as a result of enforcing and administering the sections as proposed. The fees will remain waived for public health departments, public health districts, and public health regions.

#### 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 §97.91 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. 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.

Mr. Blass has also has also determined that there are no anticipated economic costs to small businesses, micro-businesses or persons because §97.92 is no longer necessary, and business practices will not be altered in order to comply with the proposed repeal of the section. There will be no impact on local employment.

Mr. Blass has determined that the price increase of the stamp is not expected to have a significant impact on small and micro-businesses that comply with §§97.151-97.156 as proposed, and is necessary to cover the costs incurred by the department; furthermore, the possible alteration of small and micro-business procedures should have a positive impact on those small and micro-businesses as a result of improved efficiency. 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.

#### PUBLIC BENEFIT

Mr. Blass has determined that for each year of the first five years that the amendments to §97.91 and the repeal of §97.92 is 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 provide clarity concerning the delegation of authority to give informed consent for immunizations of a minor when a parent/legal guardian is not present and another adult purports to have consent of that parent/legal guardian.

In addition, Mr. Blass has also determined that for each year of the first five years that §§97.151-97.156 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 is to generate funding to operate the program to ensure the safety of the public, and to simplify and 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 §§97.91 - 97.92 may be submitted to Tim Hawkins, Disease Prevention and Intervention Section, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756, (512) 458-7111 extension 3394, or (800) 252-9152. Comments will be accepted for 30 days following publication of this proposal in the *Texas Register*.

Comments on amendments to §§97.151-97.153 and 97.155-97.156 and new 97.154, 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

Sections 97.91 and 97.92 are authorized by Health and Safety Code, §81.023, which requires the department to develop immunization requirements for children; §§97.151-97.156 are authorized by Health and Safety Code, §81.021; 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 and 1001; Government Code, Chapter 531; Education Code, §§38.001 and 51.933; and Human Resource Code, §42.043.

Section for repeal.

§97.92. Recommendations for Documentation of Reason(s) Parent, Managing Conservator, Guardian, or Other Person Could Not Be Contacted.

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

### Subchapter C. Consent for Immunization.

#### §97.91. Delegation of Authority to Give Informed Consent for Immunizations of a Minor.

(a) Certain information must be obtained prior to immunizations of a minor when the parent/legal guardian is not present and another adult purports to have consent of that parent/legal guardian.

**[parent/guardian can be contacted but another adult is giving consent.]**

(b) The information may be hand written or typed and should be completed on each minor for each clinic visit when an adult other than the parent/legal guardian **[parent/guardian]** is providing consent for the immunizations.

(c) The delegation of authority to consent for immunization of a minor shall include the following information:

(1) the signature of parent, managing conservator, legal guardian, or other person authorized to give consent;

(2) the name and birthdate of minor;

(3) the name of the adult giving consent for immunizations of the minor; and

(4) the relationship of the adult to the minor for whom they are giving consent.

(d) The delegation of authority statement must contain the information in subsection (c) of this section and could resemble the following.

Figure: 25 TAC §97.91(d)

**[Figure: 25 TAC §97.91(d)]**

(e) Immunizations may also be administered as provided in Family Code, §32.101.

### ~~Subchapter C. Consent for Immunization.~~

#### ~~§97.92. Recommendations for Documentation of Reason(s) Parent, Managing Conservator, Guardian, or Other Person Could Not Be Contacted~~

~~(a) The immunization clinic staff should ascertain the reason the parent, managing conservator, guardian, or other authorized person cannot be contacted. The clinic staff should interview the consenting adult and document the reason in writing. The documentation should remain on file with the consent form(s).~~

~~(b) The reason the parent, managing conservator, guardian, or other authorized person cannot be contacted should contain the name of the consenting adult, name of the minor child, the relationship of the consenting adult to the minor child, the date of the interview, the initials of the clinician conducting the interview of the consenting adult, and the reason the parent, managing conservator, guardian, or other authorized person could not be contacted.~~

~~(c) A person cannot be contacted if:~~

~~(1) the location of the person is unknown;~~

~~(2) a reasonable effort was made by a grandparent, adult brother or sister, or other adult listed in the law to locate and communicate with the person for the purpose of obtaining the consent has failed and not more than 90 days have passed since the date that the effort was made; or~~

~~(3) the person who may consent has been contacted and the person:~~

~~(A) refuses to consent or fails to carry out consent for the minor or refuses to carry out a delegation under the Family Code, §35.012; and~~

~~(B) does not expressly deny authority to the grandparent, adult brother or sister, or another person listed in the Family Code, §35.011(a).~~

~~(d) The documentation of failure to contact the parent, managing conservator, guardian, or other authorized person should contain at least the information in subsections (b) and (c) of this section and could resemble the following.~~

Figure: ~~25 TAC §97.92(d)~~

#### Subchapter G. Vaccination Stamps. §97.151. Purpose and Scope.

The U.S. Public Health Service has designated the Department of State Health Services [**Texas Department of Health**] as the governmental entity in the State of Texas which is responsible for determining which physicians in the state are authorized to administer yellow fever vaccine for persons who travel outside the United States. The department provides this authorization by issuing Uniform Stamps [**vaccination stamps**] to designated physicians. These sections cover the criteria by which the department issues the Uniform Stamp and the criteria for designating and operating a Vaccination Center [**yellow fever vaccination stamp to physicians**].

#### §97.152. Definitions.

The following words and terms, when used in these sections, shall have the following meanings, unless the context clearly indicates otherwise:

(1) Department--The Department of State Health Services [**Texas Department of Health**], 1100 West 49th Street, Austin, Texas 78756.

(2) Branch [Division]--The Immunization Branch, Disease Prevention and Intervention Section, Department of State Health Services [Division, Bureau of Immunization and Pharmacy Support, Texas Department of Health].

(3) Physician--A physician licensed to practice medicine in the State of Texas.

(4) Vaccination Center [Site]--The location where a physician is authorized to administer yellow fever vaccine.

(5) Uniform Stamp [Yellow fever vaccination stamp]--A [vaccination] stamp issued by the branch [department] to a physician for use in validating certificates of yellow fever vaccination [authorizing him or her to purchase and administer yellow fever vaccine] for persons who travel outside the United States.

§97.153. Criteria for Issuing Uniform [Yellow Fever] Stamps to Physicians.

Uniform Stamps may be issued to physicians holding a current Texas medical license, for use only at the specific vaccination center designated on the application. If a physician practices at more than one vaccination center, a separate application for each is required.

(1) Physicians may apply for the Uniform Stamp by sending an application form to the branch. Application forms may be obtained from the branch or online at [www.immunizetexas.com](http://www.immunizetexas.com).

(2) Physicians are authorized to use the Uniform Stamp solely for the purpose of validating administration of yellow fever vaccine on vaccination certificates issued at the approved vaccination center indicated on their application.

(3) Physicians are authorized to use only the Uniform Stamp assigned to them. Uniform Stamps may not be assigned, loaned, or given to another person or physician except those working under supervision of the physician holding the stamp. The physician will at all times be responsible for the Uniform Stamp.

(4) A physician shall report immediately to the branch any loss or theft of the Uniform Stamp.

(5) Physicians are encouraged to report cases of febrile illness potentially caused by yellow fever vaccination to the CDC/FDA Vaccine Adverse Events Reporting System (VAERS <<http://www.vaers.org/>>).

(6) U.S. Public Health Services (PHS) requirements. The PHS requirements are found, as follows:

(A) Code of Federal Regulations, Title 42-Public Health, Part 71-Foreign Quarantine, §71.3, Designation of Yellow Fever Vaccination Centers; Validation Stamps; and

(B) PHS publications entitled, Division or Quarantine Circular No.106; Advisory Memorandum No.66; and Advisory Memorandum No.72.

(C) The department adopts the PHS requirements listed in subparagraphs (A) and (B) of this paragraph by reference. Physicians shall administer yellow fever vaccines in accordance with PHS requirements as incorporated. Copies of the requirements are available upon request from the Immunization Branch, Department of State Health Services, 1100 West 49th Street, Austin, Texas.

**[(a) Previous stamp holders.]**

**[(1) Physicians who have administered 20 or more doses of yellow fever vaccine for one year prior to the effective date of this section are authorized to receive a new yellow fever vaccination stamp. Physicians may apply for the stamp by sending an application form to the division in accordance with the requirements of subsection (d) of this section. Physicians shall return their old stamps to the division upon receipt of the new stamp.]**

**[(2) Physicians who have administered less than 20 doses of yellow fever vaccine for one year preceding the effective date of this section are required to return their old stamps to the division within 60 days after the effective date of this section. These physicians may be authorized to receive new stamps only for valid cause. The division will determine valid cause on an individual basis. The criteria which the division will use to determine valid cause are as follows.]**

**[(A) The number of doses of yellow fever vaccine administered on an annual basis. Physicians who administer less than 20 doses of yellow fever vaccine will be requested to relinquish their yellow fever vaccination stamp.]**

**[(B) The requirement to administer 20 doses of yellow fever on an annual basis may be waived if the stamp is issued to a physician who provides the vaccine in an underserved geographical area.]**

**[(b) Authorized use of a yellow fever vaccination stamp. Physicians may use the stamp only for the purposes of administering vaccines and validating immunization certificates.]**

**[(c) U.S. Public Health Services (PHS) requirements. Physicians shall administer yellow fever vaccines in accordance with the vaccine manufacturer and PHS requirements.]**

**[(1) The PHS requirements are found, as follows:]**

**[(A) 42 Code of Federal Regulations, Part 71, Foreign Quarantine, §71.3, Designation of Yellow Fever Vaccination Centers; Validation Stamps, issued on January 11, 1985; and]**

**[(B) PHS publications entitled, "Division of Quarantine Circular No. 106," revised on January 7, 1983; Advisory Memorandum No. 66, issued on January 7, 1983; and Advisory Memorandum No. 72, issued on October 5, 1984.]**

**[(2) The department adopts the PHS requirements listed in paragraph (1) (A) and (B) of this subsection by reference. Copies of the requirements may be reviewed during regular working hours at the Immunization Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas.]**

**[(d) Application for yellow fever vaccination stamp. In order to receive a yellow fever vaccination stamp, a physician shall submit a completed application form to the division. Copies of the application forms may be obtained from the division.]**

**[(e) Site for use of the yellow fever vaccination stamp. A physician shall use the yellow fever vaccination stamp only at the site where the yellow fever vaccine is delivered. If the physician chooses to administer the vaccine at a site other than that designated on the current application request, prior approval must be obtained from the division stating the reason for vaccine administration at a non-designated site and the means for ensuring that appropriate temperatures are maintained and**

documented during transit of the vaccine. If a physician chooses to administer yellow fever vaccine at a non-designated site more than twice in a 12-month period, an application for permission to administer the vaccine at that site shall be filed with the division. The physician to whom the yellow fever vaccination stamp has been issued is not authorized to administer yellow fever vaccine on board ship or aircraft.]

**[(f)Physician record keeping. The physician to whom the yellow fever stamp is issued is responsible for maintaining the following information:**

**[(1) name, address, birthdate, sex, race, and occupation of the vaccine recipient;]**

**[(2) reason for vaccinating the vaccine recipient;]**

**[(3)destinations of the vaccine recipient;]**

**[(4) time, date, and address of vaccine administration; and]**

**[(5) lot number and expiration date of the vaccine.]**

**(7) [(g)] Charges for the Uniform Stamp [stamp].**

**(A) New Applicant Fee. Each new applicant is required to submit a fee of \$68 by personal check, cashier's check, or money order along with the completed application. If the branch denies the application, the branch will return the \$68 to the physician.**

**(B) Annual Renewal Fee. In January of each year, each physician holding a Uniform Stamp is required to pay an annual fee of \$38. The physician shall submit the \$38 by personal check, cashier's check, or money order to the branch with the agency's Annual Renewal Form. If the branch denies the renewal, the branch will return the \$38 to the physician.**

**(C) Stamp Replacement Fee. A fee of \$50 will be required for issuing replacement Uniform Stamps in the event the original is lost or stolen.**

**(D) All fees will be waived for public health departments, public health districts, and public health regions.**

**[(1) In January of each year, each physician is required to pay an annual charge of \$25 to cover the cost to the department in issuing and renewing stamps. The physician shall submit the \$25 by personal check, cashier's check, or money order to the division with the application form. If the division denies the application, the division will return the \$25 to the physician.]**

**[(2) The \$25 charge will be waived for public health departments, public health districts, and public health regions.]**

**[(h) Non-assignability of stamps. A physician may not assign, loan, or give the stamp to another person.]**

**[(i) Loss or theft of stamps. A physician shall report immediately to the division any loss or theft of the stamp.]**

**[(j) Annual report. In January of each year, a physician shall report to the division the number of doses of yellow fever vaccine administered during the preceding year. Reporting forms are available from the division.]**

**[(k) Local health requirements. Local health departments and public health districts may choose to require additional measures for yellow fever vaccinations occurring within their jurisdictions.]**

Legend: (Proposed New Rule)  
Regular Print = Current language

#### §97.154 Criteria for Operating as a Vaccination Center

Designation as a vaccination center is made upon completion of an application and presentation of evidence satisfactory to the Branch that the applicant has adequate facilities and professionally trained personnel for the handling, storage, and administration of safe and effective yellow fever vaccine.

(1) A physician shall use the Uniform Stamp only at the vaccination center where the yellow fever vaccine is delivered and the vaccine may not be redistributed. The physician to whom the Uniform Stamp has been issued is not authorized to administer yellow fever vaccine on board ship or aircraft.

(2) Physicians shall administer yellow fever vaccine in accordance with the vaccine manufacturers' recommendations for safe and effective use of yellow fever vaccine, as long as such recommendations do not conflict with §97.153(6)(C) of this title (relating Criteria for Issuing Uniform Stamps to Physicians) or other requirements of §§97.151-97.156 of this title.

(3) Annual report. Each physician holding a Uniform Stamp shall establish the need for continuing possession of the Uniform Stamp by completing and returning an annual renewal form along with the annual renewal fee. The annual renewal form is available from the Branch or on line at [www.immunizetexas.com](http://www.immunizetexas.com).

(A) If the annual renewal form is not received by the Branch within the timeframe stated on the form, designation as an authorized vaccination center may be removed and the physician will be required to return their Uniform Stamp.

(B) If the physician no longer wishes to retain their Uniform Stamp, the stamp must be returned to the Branch.

(4) Local health requirements. Local health departments and public health districts may choose to require additional measures for yellow fever vaccinations occurring within their jurisdictions.

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

§97.155. Format of the Uniform Stamp **[Yellow Fever Vaccination Stamp]**.

The format of the Uniform Stamps [yellow fever vaccination stamps] will be according to federal guidelines Division of Quarantine Circular No. 106, which is adopted by reference in §97.153 of this title (relating to Criteria for Issuing Uniform Stamps [Yellow Fever Stamps] to Physicians).

§97.156. Denial, Suspension, or Revocation of Stamp.

(a) The branch [division] may deny an application for a stamp or suspend or revoke an existing stamp or not renew a stamp if the applicant or holder fails to comply with the requirements of these sections. The applicant or holder has the opportunity to request a hearing on any of these actions in accordance with department fair hearing rules, §§1.51 - 1.55 of this title (relating to Fair Hearing Procedures).

(b) The branch [department] will not suspend or revoke a stamp without a prior hearing, except if the branch [division] determines that immediate suspension or revocation is necessary because of imminent threat to public health. **[; the division may suspend or revoke the stamp and offer the holder the opportunity for a post-action hearing.]**