

**Department of State Health Services
Council Agenda Memo for State Health Services Council
February 26, 2015**

Agenda Item Title: Amendments to rules concerning the reporting of sexually transmitted diseases (STDs), including Acquired Immunodeficiency Syndrome (AIDS) and Human Immunodeficiency Virus (HIV)

Agenda Number: 3.b

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background:

The HIV/STD Program, within the TB/HIV/STD/Viral Hepatitis Unit, has the duty to identify, report, prevent, and control HIV, AIDS, and STDs in the State of Texas. The HIV/STD Program is divided into two branches: the Epidemiology and Surveillance Branch, which is responsible for surveillance, epidemiologic assessment, research and evaluation, planning, and data management; and the HIV/STD Prevention and Care Branch, which is responsible for HIV/STD policy development, field operations, monitoring, training and technical assistance, grants, contract development, and clinical resources. The proposed amendments primarily affect the operations of the HIV/STD Epidemiology and Surveillance Branch. The Unit is a part of the Infectious Disease Prevention Section within the Division for Disease Control and Prevention Services.

The transmission of HIV and STDs in Texas continues to be an issue of extreme importance with more than 100,000 cases of these conditions being reported through the HIV/STD surveillance system each year. The HIV/STD Program is dedicated to preventing the spread of HIV and other STDs while minimizing complications and costs. This is achieved primarily through education, prevention counseling, screening and testing, partner elicitation and notification, and the provision of medical and social services. While some of these services are directly provided, most are provided through contracts with community-based agencies. Funding for the program is through the Centers for Disease Control and Prevention (CDC).

Summary:

The purpose of the amendments is to clarify reporting language, align the reporting rules with recent changes to the CDC's HIV surveillance case definition, and update language to reflect advancements in HIV testing technology. The rules also comply with the four-year review of agency rules required by Government Code, Section 2001.039.

The public will benefit from the proposed amendments by improving the completeness and timeliness of STD reporting that will result in enhanced STD data, increased identification of acute HIV, and earlier public health interventions to control the spread of STDs in Texas. The enhanced data will allow public health officials to better target prevention and treatment programs for individuals at risk for or infected with HIV and other STDs.

Key Health Measures:

The proposed changes affect the reporting of STDs by health care providers and laboratories and the impact of the rule changes will be measured through:

- increased and earlier identification of pediatric AIDS cases;
- increased and earlier identification of acute HIV cases; and
- overall improved compliance with the reporting rules through better understanding of reporting requirements.

Possible unintended consequences of the rule changes could be the non-compliance by reporting entities, particularly laboratories, if they do not understand the new reporting requirements for supplemental tests. DSHS will monitor the test volume and type of laboratory reports by reporting entities on a daily basis and at least quarterly will assess a number of standard laboratory reporting metrics.

DSHS collects and enters all provider and laboratory reports into standardized databases from which information can be easily extracted and analyzed. As part of the program's routine practice, laboratory reports are monitored daily, quarterly, and annually and provider reports are monitored monthly and annually. The two primary sources of information will be from the enhanced HIV/AIDS Reporting System database and the electronic laboratory reporting database.

The measurements that will be used are complete CD4 reporting/Identification of AIDS cases:

- Compare the number of laboratories reporting CD4 values for persons <13 years of age before and after the rule change; and
- Compare the number of percent of pediatric (<13 years of age) AIDS cases identified before and after the rule change.

Baseline measurements that will be used include:

- Number of laboratories that report CD4 lab results for persons under age 13;
- Number of laboratories that report all HIV supplemental lab test results; and
- Timeframe in which acute HIV cases are reported by providers.

Summary of Input from Stakeholder Groups:

Unit staff engaged community stakeholders through a series of webinars for an opportunity to review proposed amendments and provide feedback. Stakeholders were alerted to the webinars through the publication of the HIV/STD Insider, an electronic newsletter distributed regularly to over 6,000 HIV/STD stakeholders and through emailed invitations for high volume organizations/providers. Three webinars held in September 2014 included local and regional health jurisdictions, health care providers, and laboratories. Over 130 stakeholders participated in the webinars. The stakeholder response was generally positive and no controversial comments are expected through the public comment period.

Proposed Motion:

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

Approved by Assistant Commissioner/Director: Janna Zumbrun **Date:** 02/10/2015

Presenter: Rebecca Filipowicz **Program:** HIV/STD EPI & Surveillance **Phone No.:** 512-533-3101
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Approved by CPEA: Carolyn Bivens **Date:** 2/9/2015

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)
Amendments §§97.131 - 97.134 and §97.139

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 §§97.131 - 97.134, and §97.139, concerning the reporting of sexually transmitted diseases (STDs), including Acquired Immunodeficiency Syndrome (AIDS) and Human Immunodeficiency Virus (HIV).

BACKGROUND AND PURPOSE

The amendments are proposed to update and clarify the disease reporting rules for STDs, including HIV and AIDS and to make the disease reporting process more efficient in Texas. The proposed amendments will clarify reporting language, align the reporting rules with recent changes to the Centers for Disease Control and Prevention's (CDC) HIV surveillance case definition, and update language to reflect advancements in HIV testing technology. The proposed amendments, if enacted, will have great public health benefit by improving the completeness and timeliness of STD reporting resulting in increased case ascertainment and earlier public health interventions to control the spread of STDs in Texas. The proposed amendments will also allow for better monitoring of the care and treatment given for HIV infection.

Government Code, §2001.039, requires that each state agency review and consider for reoption each rule adopted by that agency pursuant to the Government Code, Chapter 2001 (Administrative Procedure Act). Sections 97.131 - 97.134 and 97.139 have been reviewed and the department has determined that reasons for adopting the sections continue to exist because rules on this subject are needed.

SECTION-BY-SECTION SUMMARY

Amendments to §97.131, Definitions, would add new definitions numbered as paragraphs (1) Acute HIV Infection, (3) Contract Research Organization, (4) Drug Resistance Testing, (5) Health Professional, (7) Nucleotide Sequence, (11) Stage of HIV Infection, and (12) Supplemental test. These new terms are proposed to reflect new language found in the CDC's new case surveillance definition as well as to reflect advancements in diagnostic testing technologies and are also used in subsequent sections of rule text.

Existing §97.131(1), is proposed to be renumbered as §97.131(2) to reflect the addition of new terms. Proposed amendments to §97.131(2) would delete the last sentence in the paragraph (regarding how to request the most current definition of AIDS and HIV infection from the department) as the department has not received any requests for the definition of HIV or AIDS

under this rule in the last several years. In addition, when a current definition is needed, the department routinely references the current CDC definitions.

Existing §97.131(2), Confirmatory Test, is proposed to be deleted because advances in diagnostic testing technology have changed the terms associated with HIV and AIDS diagnostic testing, rendering this definition outdated.

Existing §97.131(3), FASTA File, is proposed to be deleted as the data format defined here is no longer the exclusive format for submitting sequence data to the department. Laboratories can use any electronic format for submitting sequence data.

Proposed amendments to existing §97.131(4) - (7) would renumber the terms as paragraphs (6) HIV-Exposed Infant, (8) Point of Care Tests, (9) Screening Test, and (10) Sexually Transmitted Disease (STD) to reflect the addition of new terms; reflect changes in testing practice settings and diagnostic testing technologies; and align terms with the CDC's new case surveillance definition.

Proposed amendments to the introductory paragraph for §97.132 would renumber it as subsection (a) and add language to cross-reference the general reporting requirements found in §97.1 in Subchapter A of Chapter 97, applicable to all communicable diseases. This ensures that all general reporting requirements are met in addition to the more specific reporting requirements pertaining to STD, including HIV and AIDS, addressed in Subchapter F.

Proposed amendments to §97.132(1) would replace the language "physician or dentist" with "health professional" which is a new term added under §97.131(5), Definitions. This proposed change would reflect a more inclusive term for all health professionals and would allow for the proposed deletion of all the different health professions listed in existing §97.132(2) as all the professions are already listed under Health and Safety Code (HSC) §81.042 (relating to Persons Required to Report).

Proposed amendments to existing §97.132(3) would renumber this subsection as (a)(2) to reflect section reorganization; and add language "contract research organization laboratory" as an example of other facilities that are required to report to the department. This amendment is proposed to reflect new facilities where testing is now taking place and to clarify that these facilities are required to report to the department.

Proposed amendments to existing §97.132(4) would renumber this subsection as (a)(3) to reflect section reorganization and delete the last sentence of this subsection as it is duplicative concerning reporting of patients who have an STD.

Existing §97.132(5) is proposed to be deleted as this type of facility is already listed in the enabling statute, HSC, §81.042.

Proposed amendments to existing §97.132(6) would renumber this subsection as (b) to reflect section reorganization and to clarify that failure to report is considered a crime under the HSC, §81.049.

Proposed amendments would include new §97.132(c) which specifies that reporting to the department without authorization is allowed under the Health Insurance Portability and Accountability Act (HIPAA) for public health purposes and where required by law and list the enabling federal regulations.

Proposed amendments to the introductory paragraph of §97.133 and §97.133(1) would renumber the paragraphs as subsections (a) and (b) respectively and make minor changes to improve readability and clarity.

Proposed amendments to existing §97.133(2) would renumber this subsection as (c) and substitute new language to clarify that all persons required to report under §97.132 must report all data elements (listed subsequently as paragraphs (1) - (7)) and that the data elements must be reported either using the department's form or a substitute form as long as it captures all the data elements in the department's form.

Proposed amendments to existing §97.133(2)(A) would renumber the subsection as (c)(1) to reflect section reorganization; clarify that adolescent means anyone 13 years of age or older; and reflect new language found in the CDC's new case surveillance definition. In addition, existing §97.133(2)(A) would be divided into two paragraphs (1) and (2). The newly renumbered subsection (c)(2) would add clarity for reporting requirements for pediatric HIV infections and include the CDC's new case surveillance definition which now identifies AIDS as stage 3 of HIV infection.

Proposed amendments to existing §97.133(2)(B) would renumber the subsection as (c)(3) to reflect section reorganization; and to delete the language "women giving birth" and replace it with "all HIV-positive pregnant women" as all these infections are reportable as well. Also, a reference to an outdated form, (Enhanced Perinatal HIV Surveillance form), would be deleted and the currently used Texas HIV/AIDS Adult/Adolescent case report form was added.

The new §97.133(c)(4) would add clarity by listing HIV-exposed infants in its own section.

Proposed amendments to existing §97.133(2)(C) would renumber the subsection as (c)(5) to reflect section reorganization; add the complete name of the disease Neisseria gonorrhoea; and delete the language "for adults and adolescents" as the form's title no longer includes these terms.

Proposed amendments to existing §97.133(2)(D) would renumber the subsection as (c)(6) to reflect section reorganization; delete the reference to the department's reporting form listed; and substitute it with the CDC's Congenital Syphilis Case Investigation and Report form that the department is now utilizing; and add a reference to §97.134 to be consistent with earlier paragraphs.

Proposed amendments to existing §97.133(2)(E) would renumber the subsection as (c)(7) to reflect section reorganization; insert the word "All" to clarify that all positive or reactive results

need to be reported; delete language that references adults, adolescents or infants as the form does not differentiate between these.

New §97.133(d) adds new language that reflects advances in diagnostic testing, align descriptions with the new CDC case surveillance definition; and deletes existing language in existing §97.133(3) and replaces it with current terminology to improve readability and clarity.

Proposed amendments to existing §97.133(3)(A) would renumber the subsection as (d)(1) to reflect section reorganization; add a reference to the current version of the department's form used for reporting purposes; and delete language that limits reporting of CD4 results from adults and adolescents only as the CDC HIV surveillance case definition now uses CD4 results to stage HIV infections in children.

Proposed amendments to existing §97.133(3)(B) would renumber the subsection as (d)(2) to reflect section reorganization; add "suspected of HIV exposure" as a descriptor to the tests conducted on infants to clarify reporting of these infants' results; and add a reference to §97.134 to be consistent with earlier paragraphs.

Proposed amendments to existing §97.133(3)(C) would renumber the subsection as (d)(3) to reflect section reorganization; replace the text "confirmatory" with "supplemental" to reflect advances in testing technology and the new terms associated with those advancements; require that all HIV supplemental test results are reported so that acute HIV infections can be identified according to the new CDC HIV Surveillance case definition; and add a reference to §97.134 to be consistent with earlier paragraphs.

Proposed amendments to existing §97.133(3)(D) would renumber the subsection as (d)(4) to reflect section reorganization; add "All" to clarify that all nucleotide sequence testing is to be reported; reorganize existing language to improve readability and clarity; and add a reference to §97.134 to be consistent with earlier paragraphs.

Proposed amendments to §97.134(a) would delete the language "case reports" and add "reportable information" to clarify that all information reported, not just case reports, is confidential; and add a reference to the state law that protects the confidentiality of the reported information.

Proposed amendments to §97.134(b) would reorganize existing language to improve readability and clarity; replace the language "physician's" with "health professional's" to reflect new terms proposed for amendment in the definition section (§97.131); and add a website as a resource tool for further clarification on identifying the proper reporting location if needed.

Existing §97.134(c) is proposed to be deleted as proposed amendments to §97.134(b) would clarify how to identify the appropriate reporting location.

Proposed amendments to existing §97.134(d) would renumber the subsection as (c) to reflect section reorganization; add language to improve readability and clarity and reflect currently used terms; add a revised website as a resource tool for further clarification on identifying the proper

reporting location if needed; and delete language to remove duplicative information and reflect current practices.

Proposed amendments to existing §97.134(e) would renumber the subsection as (d) to reflect section reorganization; replace text “Physicians” with “Health Professionals” to reflect new terms proposed for amendment in the definition section (§97.131); update references to newly proposed sections within these rules; change the reporting requirement from seven calendar days to one day when reporting acute HIV infections by health professionals to allow the department to take appropriate public health action as early as possible as acute infections are the most infectious; and reorganize language to improve readability and clarity.

Proposed amendments to existing §97.134(f) would renumber the subsection as (e) to reflect section reorganization; update references to newly proposed sections within these rules; add language to differentiate between reportable and non-reportable test results; and add language to improve readability and clarity and reflect currently used terms.

Proposed amendments to existing §97.134(g) would renumber the subsection as (f) to reflect section reorganization; add language to improve readability and clarity; add language to clarify that local health authorities will forward all STD test results (including AIDS) received by them to the department each week; and delete language that describes reporting processes no longer used by the department such as reporting information or are covered in another section.

Existing §97.134(h) is proposed to be deleted as these processes concerning reporting are no longer used by the department.

New §97.134(g) adds new language to reflect department security and confidentiality requirements for reportable information and reflect current practices for submitting electronic and paper reports.

Existing §97.134(i) is proposed to be deleted to remove language that describes processes concerning reporting of information that are no longer used by the department.

Proposed amendments to §97.139 would reflect recent changes in the name of the department and the branch, reflect changes to the program’s mailing address, and add a reference to the enabling statute in the Texas Insurance Code, §545.055

FISCAL NOTE

Ms. Imelda Garcia, Director, Infectious Disease Prevention 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 governments as a result of enforcing and administering the sections as proposed.

The proposed rule amendments will result in an increase in the volume and type of STD laboratory reports received by local health departments. These additional laboratory reports will be used to identify if cases have progressed to AIDS or are in the acute HIV infection phase. The increase in volume should not increase the number of new cases needing surveillance

investigation and disease intervention services. Rather, these additional laboratory reports should help supplement information on existing cases eliminating the need for local health departments to follow-up with providers to gather the additional information. The proposed amendments will also change the timeframe in which acute HIV cases must be reported by healthcare providers. This change in timeframe should not have an impact on local governments since it only changes the timeframe not the volume of reports or the action that must be taken on the reports.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Ms. Garcia has also determined that there will be no adverse impact on small businesses or micro-businesses required to comply with the sections as proposed. The amendments to §97.133 requiring the reporting of all CD4 T-lymphocyte (CD4) counts and percentages for children will not have an effect on small businesses in Texas. The Enhanced HIV/AIDS Reporting System (eHARS) laboratory report data was used to determine which laboratories conduct CD4 testing. In 2013, 38 laboratories were listed as having performed a CD4 test of which only one would be classified as a small business. Also, laboratories are already required to report CD4 test results for adults and adolescents and in doing this many already report CD4 tests for persons of all ages. In 2013, the one small business laboratory reported an average of three CD4 reports per month, with the addition of pediatric reporting it is anticipated that there would only be one additional report per month.

The amendment to §97.133 requiring laboratories to report all supplemental test results for HIV will have an overall negligible effect on small business in Texas. To estimate the number of laboratories performing supplemental tests that might be impacted by the amendment, all HIV lab reports from 2013 were drawn from eHARS. In that period, 54 facilities were listed as the laboratory that performed a supplemental test with any result. After removing laboratories from the list that would be classified as government or nonprofit, and researching the size of the remaining businesses, only three organizations were left that might qualify as small business. These three laboratories reported 94 HIV positive laboratory results in 2013. So, even if these three laboratories reported the same number of negative test results as positive test results, these three laboratories would on average each report an additional 31 lab reports per year.

The amendment to §97.134 revising the timeframe and method for healthcare providers to report acute HIV diagnoses will have a negligible effect on small businesses in Texas. Healthcare providers are already required to report primary and secondary syphilis. While changing the timing of the case report from within seven days to within one day for a provider may be slightly less convenient, the overall time and effort required to make the report will not change for these small businesses. In fact, with this rule amendment also requiring diagnosing facilities to report acute HIV cases by telephone, these small businesses may incur less expense compared to the resources required to report cases on paper. Under this rule amendment, the average small business healthcare provider should be able to report an acute HIV case with a five-minute phone call.

ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

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

In addition, Ms. Garcia has also determined that for each year of the first five years 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 will be more complete and timely STD reporting which will result in enhanced STD data, increased identification of new cases of STDs and earlier public health interventions to control the spread of STDs in Texas. The enhanced data will allow public health officials to better target prevention and treatment programs for individuals at risk for or infected with HIV and other STDs.

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 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 Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to Juanita Salinas, Department of State Health Services, TB/HIV/STD/VH Unit, MC 7909, P.O. Box 149347, Austin, TX 78714-9347, or by email to juanita.salinas@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 rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The amendments are authorized by the Health and Safety Code, Subtitle D, Chapter 81, Subchapter C, §§81.041 - 81.044, which grants the Texas Board of Health authority to identify

each communicable disease or health condition that shall be reported under Chapter 81, authority to maintain and revise as necessary the list of reportable diseases, and authority to require reporting of HIV and AIDS. The proposed amendments are also authorized by the other statutory citations listed in the individual sections herein. The amendments are also authorized by the 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 review of the rules implements Government Code, §2001.039.

The amendments affect 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

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

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

§97.131. Definitions.

The following words and terms when used in this subchapter **[chapter]** shall have the following meanings unless the context clearly indicates otherwise.

(1) Acute HIV Infection--The stage immediately following HIV infection, as identified by clinical symptoms, history of exposure, and/or specific laboratory results. This includes, but is not limited to, a case that has a documented negative or indeterminate HIV test result that occurred no more than 180 days prior to the initial positive HIV test result.

(2) [(1)] AIDS and HIV Infection--Acquired Immune Deficiency Syndrome (AIDS) and Human Immunodeficiency Virus (HIV) infection are as defined by the Centers for Disease Control and Prevention (CDC) and in accordance with the Health and Safety Code, §81.101. [The publication designating the most current definition may be requested from: Texas Department of State Health Services, TB/HIV/STD Epidemiology and Surveillance Branch, P.O. Box 149347, Austin, Texas 78714-9347.]

(3) Contract Research Organization (CRO)--An organization that is contracted by pharmaceutical, biotechnology, or medical device industries to provide various aspects of the clinical research process. A CRO may provide such services as clinical trials management and laboratory testing.

(4) Drug Resistance Testing--Genotypic testing that identifies the nucleotide sequence and uses the resulting sequence to identify strains resistant to specific types of drug therapies.

(5) Health professional--An individual whose:

(A) vocation or profession is directly or indirectly related to the maintenance of the health of another individual or of an animal; and

(B) duties require a specified amount of formal education and may require a special examination, certificate or license, or membership in a regional or national association.

[(2) Confirmatory Test--A second analytical test that is done to detect disease, when an initial or screening test yields a preliminary positive result, which is independent of the initial test and uses a different technique and chemical principle in order to ensure reliability and accuracy.]

[(3) FASTA File--An electronic data format used to store nucleotide sequences of the Human Immunodeficiency Virus (HIV).]

(6) [(4)] HIV-Exposed Infant--Any infant suspected of HIV exposure through mother to child transmission [born to an HIV-infected woman].

(7) Nucleotide Sequence--The relative order of base pairs in a fragment of deoxyribonucleic acid (DNA) or ribonucleic acid (RNA), a gene, a chromosome, or an entire genome.

(8) [(5)] Point of Care Tests--Analytic [Diagnostic] tests performed at or near the site of patient care outside of a laboratory setting [that increase the likelihood of the patient receiving the results as well as referrals for treatment and support services in a timely manner. These tests are usually performed in emergency rooms, outpatient clinics and physician offices].

(9) [(6)] Screening Test--The initial [An] analytical test used to preliminarily detect the presence of disease. Positive screening test results should be followed by a supplemental [confirmatory] test to verify the presence of that disease.

(10) [(7)] Sexually transmitted disease (STD)--An infection, with or without symptoms or clinical manifestations, that is or may be transmitted from one person to another during or as a result of sexual relations, and that produces or might produce a disease in, or otherwise impair, the health of either person, or might cause an infection or disease in a fetus in utero or a newborn. For purposes of this subchapter, the term “STD” refers to the following reportable conditions: HIV (including AIDS); [Acquired Immune Deficiency Syndrome (AIDS),] chancroid; [,] Chlamydia trachomatis [infection,]; Neisseria gonorrhoea; [,] [HIV infection,] and syphilis infections. [are sexually transmitted diseases reportable under these rules, and each are] Each of these conditions is as defined by CDC [(see http://www.cdc.gov/ncphi/diss/nndss/casedef/case_definitions.htm)]].

(11) Stages of HIV Infection--For purposes of this subchapter, HIV infection is classified into four stages (stage 0, 1, 2 or 3). The CDC definition of each stage is incorporated here by reference (see http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6303a1.htm?s_cid=rr6303a1_e).

(12) Supplemental test--The subsequent test or tests in a diagnostic testing algorithm that are performed following a preliminary positive on the initial/screening test. Positive or reactive results on supplemental tests, when performed in a specific sequence as part of a diagnostic algorithm, confirm disease infection. However, supplemental tests, when run outside of a testing algorithm, are not necessarily sufficient to diagnose infection.

§97.132 Who Shall Report Sexually Transmitted Diseases.

(a) In addition to the reporting requirements for communicable diseases found in §97.1 of this title, the [The] following shall report cases and suspected cases of STD(s), which includes [of STD and] HIV-exposed infants, in the manner described [as detailed] in §97.133 of this title (relating to Reporting Information for Sexually Transmitted Diseases):

(1) A health professional, and any other person mandated to report under Texas Health and Safety Code, §81.042; [physician or dentist shall report each patient who has or is suspected of having an STD and/or is an HIV-exposed infant. A physician or dentist may designate an employee of the clinic, including a school based clinic or physician's/dentist's office, to serve as the reporting officer. However, it is ultimately the responsibility of the physician or dentist to ensure that the required reporting is submitted.]

[(2) The following persons shall report each person who has or is suspected of having an STD and/or is an HIV-exposed infant, if a report is not made as required by persons specified in paragraphs (1), and (3) - (5) of this section:]

[(A) a professional registered nurse;]

[(B) an administrator or director of a public or private temporary or permanent child-care facility (as defined in Title 40, Texas Administrative Code, Part 19, Chapter 746, Subchapter A, §746.105);]

[(C) an administrator or director of a nursing facility (as defined in Title 40, Texas Administrative Code, Part 1, Chapter 18, Subchapter A, §18.2);]

[(D) an administrator or director of a personal care facility (as defined in Title 40, Texas Administrative Code, Part 19, Chapter 705, Subchapter A, §705.1001);]

[(E) an administrator or director of an adult day-care facility (as defined in Title 40, Texas Administrative Code, Part 1, Chapter 98, Subchapter A, §98.2(3));]

[(F) an administrator or director of a maternity home (as defined in Texas Health and Safety Code, §249.001(3));]

[(G) an administrator or director of an adult respite care center (as defined in Texas Health and Safety Code, §242.181(3));]

[(H) an administrator of a home health agency (as defined in Texas Insurance Code, §1351.001(2));]

[(I) an administrator or health official of a public or private institution of higher education;]

[(J) an owner or manager of a restaurant, dairy, or other food handling or processing establishment or outlet;]

[(K) a superintendent, manager, or health official of a public or private camp, home, or institution;]

[(L) a parent, guardian, or householder;]

[(M) a health professional;]

or] [(N) an administrator or health official of a penal or correctional institution;

[(O) emergency medical service personnel, a peace officer, or a firefighter.]

(2) [(3)] Any person in charge of a clinical laboratory, hospital laboratory, blood bank, mobile unit, or other facility (such as a contract research organization laboratory) in which a laboratory examination of a blood specimen, or any specimen derived from a human body, yields microscopic, cultural, serological or any other evidence of a suspected [an] STD; [shall report according to §97.133 of this title.]

(3) [(4)] The medical director or other physician responsible for the medical oversight of a testing program, as defined in Texas Health and Safety Code, §85.002; [, shall report each patient who has or is suspected of having an STD and/or is an HIV-exposed infant.]

(5) A local school authority, as defined at Texas Health and Safety Code, §81.003, shall report a child attending school who is suspected, based on medical evidence, of having an STD and/or is an HIV-exposed infant.]

(b) [(6)] Failure to report as required under this subchapter is a crime in Texas, as described in [a reportable disease is a Class B misdemeanor under the] Texas Health and Safety Code, §81.049.

(c) The Health Insurance Portability and Accountability Act (HIPAA) allows covered entities to disclose otherwise protected health information, without either obtaining the written authorization of the individual whose information is at issue or giving that individual the opportunity to agree or object, for purposes of public health communicable disease reporting requirements (see Title 45 Code of Federal Regulations §164.512(a) and (b)).

§97.133. Reporting Information for Sexually Transmitted Diseases.

(a) Reporting entities described in §97.132 of this title (relating to Who Shall Report Sexually Transmitted Diseases) shall report all information required by the department for each person (which includes an HIV-exposed infant) who has or is suspected of having an STD, as well as [and/or is an HIV-exposed infant and] for any specimen derived from a human body that yields microscopic, cultural, serological or any other evidence of a suspected STD.

(b) [(1)] The department has established the reporting procedures required under Texas Health and Safety Code, §81.044, including the designation of specific forms and methods of reporting. The required [Completed] written reports, electronic reports, and telephone reports shall be made in a complete, accurate and timely manner, all in accordance with §97.134 of this title (relating to How to Report Sexually Transmitted Diseases).

(c) All persons required to report under §97.132 of this title, must report the following (each report must either use the department's form specified in this subsection, or a substitute form which captures all the data elements of the specified department form):

[(2) Physicians and other persons as specified by §97.132(1), (2), (4), and (5) of this title are required to report.]

(1) [(A)] All [diagnoses of] adult or adolescent (13 years of age or older) HIV infections [infection] and AIDS (stage 3 of HIV infection) diagnoses [using all of the information found in] (see the most current version of the department's Texas HIV/AIDS Adult/Adolescent case report form (available as specified in §97.134 of this title [(relating to How to Report Sexually Transmitted Diseases)]).

(2) All [and all diagnoses of] pediatric HIV infections [infection] and AIDS (stage 3 of HIV infection) diagnoses [using all of the information from] (see the most current version of the department's Texas HIV/AIDS pediatric case report form (available as specified in §97.134 of this title)).

(3) [(B)] All [Information on all] HIV-positive pregnant women. [women giving birth and HIV-exposed infants using all of the elements from] (see the most current version of the department's Texas HIV/AIDS Adult/Adolescent case report form [Enhanced Perinatal HIV Surveillance from adopted by the department] (available as specified in §97.134 of this title)).

(4) All HIV-exposed infants (see the most current version of the department's Texas HIV/AIDS Pediatric case report form (available as specified in §97.134 of this title)).

(5) [(C)] All chancroid, Chlamydia trachomatis, Neisseria gonorrhoea, and syphilis infections [using all of the information found in] (see the most current version of the department's Confidential Report of Sexually Transmitted Diseases form (STD-27) [for adults and adolescents] (available as specified in §97.134 of this title)).

(6) [(D)] All congenital syphilis infections [using all of the information found in] (see the most current version of the CDC's Congenital Syphilis Case Investigation and Report form (available as specified in §97.134 of this title)) [department's Confidential Report of Sexually Transmitted Diseases form (STD-27)].

(7) [E] All positive [Positive] or reactive results from point of care testing for STDs [(including HIV) for adults, adolescents and HIV-exposed infants using all of the information found in] (see the most current version of the department's Confidential Report of Sexually Transmitted Diseases form (STD-27) (available as specified in §97.134 of this title)).

(d) Persons described in §97.132(a)(2) of this title must report the following regarding any specimen derived from a human body that yields microscopic, cultural, serological or any other evidence of a suspected STD (each report must either use the department's form specified in this subsection, or a substitute form which captures all the data elements of the specified department form):

[(3) Any person in charge of a laboratory or other facility as specified by §97.132(3) of this title is required to report the results for each person who has or is

suspected of having an STD and/or is an HIV-exposed infant by providing all of the information sought in the most current version of the department's Notification of Laboratory Test Findings Indicating Presence of Chlamydia trachomatis, Gonorrhea, Syphilis, Chancroid, HIV Infections or CD4 Counts form (STD-28) (available as specified in §97.134 of this title), including the following:]

(1) [(A)] All positive or reactive STD test results, including screening tests; [,] all HIV viral loads (detectable and non-detectable); [,] and all CD4+T-lymphocyte cell counts and percentages (see the most current version of the department's Notification of Laboratory Test Findings Indicating Presence of Chlamydia trachomatis, Gonorrhea, Syphilis, Chancroid, HIV Infections or CD4 Counts form (STD-28) (available as specified in §97.134 of this title))[**for adults and adolescents over 12 years of age**].

(2) [(B)] HIV DNA or RNA virologic tests on all infants suspected of HIV exposure from birth to three years of age, regardless of the test findings (e.g., negative or positive) (see the most current version of the department's STD-28 form (available as specified in §97.134 of this title)).

(3) [(C)] All supplemental [confirmatory] tests for syphilis and HIV that result from an initial positive screening test, regardless of result (e.g., reactive or non-reactive) (see the most current version of the department's STD-28 form (available as specified in §97.134 of this title)).

(4) [(D)] All HIV nucleotide sequences that are resultant of genotypic testing, including HIV drug resistance testing (see the most current version of the department's STD-28 form (available as specified in §97.134 of this title)) [that contains the resulting nucleotide sequences of the HIV (e.g., FASTA file)].

§97.134. How to Report Sexually Transmitted Diseases.

(a) All reportable information [case reports] received by the health authority or the department is [are] confidential as provided by law, including (but not limited to) Texas Health and Safety Code, §81.046 and §81.103.

(b) Reporting forms and/or information from all entities required to report should be sent to the local health authority [**department director**] where the health professional's [physician's] office, hospital, laboratory or medical facility is located or, if there is no local health authority in that jurisdiction [such facility], the reports should be forwarded to the regional director in the department's health service region office which covers the area where the health professional's [physician's] office, hospital, laboratory, or medical facility is located. A department resource to help determine the proper reporting location can be found at <http://www.dshs.state.tx.us/hivstd/healthcare/reporting/regions.shtm>.

[(c) If any individual or entity is unsure where to report any of the diseases mentioned in this subchapter, the reports shall be placed in a sealed envelope addressed as follows: Texas Department of State Health Services, TB/HIV/STD Epidemiology and Surveillance Branch, MC 1873, P.O. Box 149347, Austin, Texas 78714-9347 and the envelope shall be marked "Confidential." The envelope shall be delivered with the seal unbroken to the

TB/HIV/STD Epidemiology and Surveillance Branch office for opening and processing of the contents. Additional reporting information can be obtained from the HIV/STD Program website at <http://www.dshs.state.tx.us/hivstd/default.shtm>.]

(c) [(d)] Reports of STD cases (including HIV) as well as [and/or] HIV-exposed infants shall contain all of the information required [found] on the reporting forms specified in §97.133(2) of this title (relating to Reporting Information for Sexually Transmitted Diseases). Forms can be obtained from local health departments and department health service regions; forms shall be provided without charge to individuals required to report. A list of local health departments and department health service region offices that can provide reporting forms is currently available at <http://www.dshs.state.tx.us/hivstd/healthcare/reporting/regions.shtm>. [<http://www.dshs.state.tx.us/hivstd/healthcare/reporting/shtm>. Information required on the reporting form shall include (but is not limited to) the following:]

[(1) the patient's name, address, age, sex, race, and occupation; the date of onset of the disease or condition; the probable source of infection and the name of the attending physician or dentist; and]

[(2) reports of HIV infection or AIDS shall also contain the patient's ethnicity, national origin, and city and county of residence.]

(d) [(e)] Health professionals [Physicians**] and other persons as specified by §97.132(a)(1) - (3) [**§97.132(1), (2), (4), and (5)**] of this title must submit reports of suspected primary or secondary syphilis and acute HIV infection by telephone within one working day of a suspected diagnosis. [determining the diagnosis.] All other reports of suspected STD cases and HIV-exposed infants [including AIDS and HIV] from health professionals [physicians] and other persons as specified by §97.132 of this title must be submitted within seven calendar days of that determination [the determination of the existence of a reportable condition].**

(e) [(f)] Any person in charge of a clinical laboratory or other entity as specified by §97.132(a)(2) [§97.132(3)**] of this title shall submit reportable syphilis test results within three working days of obtaining the test result and shall submit all other reportable STD (including HIV) test results within seven calendar days of obtaining the test results. In addition to required reporting, if, during any calendar quarter, tests for chancroid, Chlamydia trachomatis [**infection**], Neisseria gonorrhoea, HIV and/or [infection and] syphilis are performed and all test results are non-reportable [negative], the person in charge of reporting for the laboratory shall submit a statement to this effect on or before January 5, April 5, July 5, and October 5 following that calendar quarter.**

(f) [(g)] A local health authority shall forward [report] each week to the department all cases and STD test results [reported to the authority during the previous week of STD], including HIV infection and AIDS (stage 3 of HIV infection) reported to that health authority during the previous week. [, using electronic or paper reports. Information on how to submit electronic reports can be obtained from the TB/HIV/STD Epidemiology and Surveillance Branch through an email request to HIVSTDreporting@dshs.state.tx.us. Paper reports should be mailed to the Texas Department of State Health Services, TB/HIV/STD

Epidemiology and Surveillance Branch, MC 1873, P.O. Box 149347, Austin, TX, 78714-9347.]

[(h) A local health department director or regional director shall forward to the department at least weekly all reports of cases received by him/her. Transmittal may be by mail, courier or electronic transmission.]

(g) All reporting of personal health information to the department shall be submitted in accordance with department's security and confidentiality requirements, currently found at <https://www.dshs.state.tx.us/hivstd/policy/security.shtm>.

(1) Information on how to submit electronic reports can be obtained from the Epidemiology and Surveillance Branch through an email request (current e-mail address is HIVSTDreporting@dshs.state.tx.us).

(2) Paper reports should be mailed to the Texas Department of State Health Services, Epidemiology and Surveillance Branch, MC 1873, P.O. Box 149347, Austin, TX 78714-9347.

[(i) If reporting by electronic transmission, including facsimile transmission by telephone, the same degree of protection of the information against unauthorized disclosure shall be provided as those of reporting by mail or courier transmittal. The department shall, before authorizing such transmittal, establish guidelines for establishing and conducting such transmission.]

§97.139. Fee for Providing Written Notice of a Positive Human Immunodeficiency Virus (HIV)-Related Test Result to an Applicant for Insurance.

An applicant for insurance must be given written notice of a positive HIV-related test result by a physician designated by the applicant, or in the absence of that designation, by the **[Texas Department of Health (] department [)]**. When the department is requested to make this notification:

(1) the form designated by the department for this purpose must be used. Copies of the form and other information concerning notification by the department may be requested from: Texas Department of State Health Services, Epidemiology and Surveillance Branch, MC 1873, P.O. Box 149347, Austin, TX, 78714-9347 [Bureau of HIV and STD Prevention, 1100 West 49th Street, Austin, Texas 78756-3199]; and

(2) the insurer shall pay the department a fee of \$25 to cover the cost of the department providing the written notice to the applicant for insurance, pursuant to Texas Insurance Code, §545.055.