

**Department of State Health Services
Council Agenda Memo for State Health Services Council
June 25, 2009**

Agenda Item Title: Amendments to rules concerning the reporting of Sexually Transmitted Diseases (STD), including Acquired Immunodeficiency Syndrome (AIDS) and Human Immunodeficiency Virus (HIV)

Agenda Number: 4d

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background:

The TB/HIV/STD Epidemiology and Surveillance Branch, within the DSHS TB/HIV/STD Unit in the Prevention and Preparedness Services Division, is responsible for conducting disease surveillance, monitoring the burden of disease and disease trends, conducting epidemiologic studies, and analyzing and disseminating data for tuberculosis (TB), HIV/AIDS and STD in Texas.

HIV and STD surveillance is conducted through a statewide system of surveillance staff at local health departments, DSHS health service regions, and DSHS central office in Austin. These staff access HARS (HIV/AIDS Reporting System) and STD*MIS (STD Management Information System Sites), which are the disease registries at local and regional health departments. Mandated HIV and STD disease reporting from healthcare providers and laboratories is a key component of surveillance. Data from the surveillance systems are used extensively to monitor these diseases, allocate State and federal resources, target prevention and treatment programs, and conduct program evaluation. Surveillance reports are used to trigger public health follow-up and disease intervention activities at local and regional health departments. Complete and timely disease reporting is critical to intervening in the transmission of HIV/AIDS and STD in Texas.

Funding for HIV/AIDS surveillance comes from the HIV/AIDS Surveillance Cooperative Agreement and Enhanced Perinatal Surveillance Grant from the Centers for Disease Control and Prevention (CDC) and general revenue. Funding for STD surveillance and disease intervention activities come from the Comprehensive STD Prevention System Cooperative Agreement from the CDC and general revenue.

Summary:

The purpose of the amendments is to improve the completeness and timeliness of STD reporting, resulting in increased case ascertainment and earlier public health interventions to control the spread of STD in Texas. Enhanced HIV/AIDS and STD data will allow public health officials to better target prevention and treatment programs for individuals and groups at risk for or infected with HIV and other STD.

The amendments update and clarify the disease reporting for STD, including HIV and AIDS, in accordance with Health and Safety Code, Chapter 81, amended by the 80th Legislature, 2007. The rules comply with the four-year review of agency rules required by Government Code, Section 2001.039.

The proposed amendments update legacy agency references; add definitions related to new reporting requirements; and reflect Texas-specific reporting forms for adult and pediatric HIV/AIDS cases. The amendments would require the reporting of additional types of STD laboratory tests: negative confirmatory tests for syphilis; non-detectable HIV viral loads; negative HIV Polymerase Chain Reaction tests for infants up to three years of age; and HIV genotype resistance tests. The amendments would change the level of the reporting of CD4-T-Lymphocyte (CD4) counts from the current level of <200 cells/microliter or less than 14% to all CD4 counts, regardless of level for adults and adolescents over the age of 12.

The proposed amendments revise the time frame and method for healthcare providers to report primary and secondary syphilis from seven days to within one working day and revise the time frame for laboratories to report syphilis test results from weekly to within three working days. The changes will primarily affect the Branch, local and regional health department HIV/STD surveillance programs, public and private laboratories, and healthcare providers who diagnose, treat and report HIV and STD.

There are objectives in the federal grants for both HIV/AIDS and STD reporting, which include timeliness and completeness of reporting. The TB/HIV/STD Epidemiology and Surveillance Branch runs these measures on a regular basis for both laboratories and health care providers to conduct quality assurance on the surveillance system. DSHS reports these objectives in its annual reports to the CDC.

Summary of Input from Stakeholder Groups:

The Branch solicited stakeholder input by:

- holding face-to-face regional stakeholder meetings in Austin, Houston, Dallas, and San Antonio in conjunction with the local and regional health departments in those areas;
- inviting key healthcare providers, hospitals, laboratories, community planning group members, and HIV/STD public health staff from local health departments to participate in the regional stakeholder meetings;
- presenting the rules at a Texas Association of Local Health Officials meeting;
- sending the rules to appropriate professional organizations (e.g. Texas Hospital Association, Texas Medical Association, and Texas Association for Clinical Laboratory Science);
- posting the rules on the HIV/STD program website at <http://www.dshs.state.tx.us/hivstd/default.shtm> and providing a response link for comments;
- sending letters to major stakeholders in areas of the state where an in-person meeting was not held; and
- consulting other areas within DSHS who may be affected by the rule changes.

DSHS has received stakeholder feedback on the time frame for reporting syphilis results and diagnoses by laboratories and providers, which was originally within one working day, and has been modified for laboratories to within three working days. There may be continued comments on the primary and secondary syphilis reporting time frame for healthcare providers and laboratories. However, DSHS has deemed the three working days for laboratories and the one working day for healthcare providers to be protective of the health, safety, and environmental and economic welfare of the state. Primary and secondary syphilis is increasing in Texas with case numbers tripling over the last eight years, and keeping these reporting requirements will aid in the public health effort to quickly intervene in disease transmission and prevent new syphilis cases.

DSHS received feedback on the reporting of all CD4 counts in children, specifically the lack of usefulness of the CD4 counts in children and the burden it would put on pediatric providers to report all levels of CD4s. DSHS revised the proposed amendment to only include CD4 counts for adults and adolescents over the age of twelve. Additional input was received from physician stakeholders concerned about reporting of all CD4 counts because it would result in persons without HIV/AIDS being reported and in the DSHS database. The concern was about the uncompensated burden of work by physicians to explain to public health surveillance personnel that these patients do not have HIV. A suggestion was to require laboratories to report CD4s only when they are ordered with an HIV viral load test. DSHS plans to match the CD4 counts received to viral loads received and only send those cases with both a CD4 and a viral load to the local or regional HIV/AIDS surveillance sites for case investigation. This will decrease the number of CD4 counts from non-HIV/AIDS cases that will require a phone call to a physician or other healthcare provider for case investigation. However, DSHS would prefer to do this as a procedure and not have it written into the rules. Matching the CD4s and viral loads would put an additional burden on the laboratories and some laboratories do not conduct both tests resulting in missing many CD4 counts on HIV positive patients.

DSHS has received some objections to reporting of electronic nucleotide sequences from HIV resistance testing from some laboratories due to the need to reconfigure their data reporting systems to report a new test result. However, only a very few large commercial laboratories currently conduct this type of testing. Most large commercial laboratories already conduct electronic disease reporting and would have the information technology infrastructure to make these changes without a large input of resources, and some already report HIV genotype electronic data to other states. One stakeholder also raised concerns that HIV genotype data from HIV resistance testing linked to an individual could be used in a criminal HIV transmission prosecution. Texas has very stringent confidentiality laws for HIV test results and disease reporting and surveillance data; HIV genetic sequences are confidential and cannot be subpoenaed in a criminal case. The Branch implements strict security and confidentiality standards for HIV/AIDS and STD data. DSHS has decided to keep the proposed reporting requirement because of the public health benefit accrued from the enhanced monitoring of HIV resistance patterns and the quality of treatment for HIV infection.

Proposed Motion: Motion to recommend HHSC approval for publication of rules contained in agenda item #4d

Approved by Assistant Commissioner/Director:	Adolfo Valadez, M.D., M.P.H.	Date:	May 19, 2009		
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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

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, concerning the reporting of sexually transmitted diseases (STD), 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 STD, including HIV and AIDS and to make the STD reporting process more efficient and effective in Texas in accordance with Health and Safety Code, Chapter 81, amended by the 80th Legislature, 2007. The proposed amendments would require the reporting of additional types of STD laboratory tests: negative confirmatory tests for syphilis; non-detectable HIV viral loads; negative HIV Polymerase Chain Reaction (PCR) tests for infants up to three years of age; and HIV genotype resistance tests. The proposed amendments would also change the level of the reporting of CD4-T-Lymphocyte (CD4) counts from the current level of <200 cells/microliter or less than 14% to all CD4 counts, regardless of level for adults and adolescents over the age of 12. The proposed amendments would also change the timeframes for reporting certain STD diagnoses and tests. The proposed amendments would have great public health benefit by improving the completeness and timeliness of STD reporting, resulting in increased number of cases of STD being identified and earlier public health interventions to control the spread of STD 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 readoption each rule adopted by that agency pursuant to the Government Code, Chapter 2001 (Administrative Procedure Act), according to the schedule in the statute. Sections 97.131 – 97.134 have been reviewed and the department has determined that reasons for adopting the sections continue to exist because rules on this subject are needed. Revisions are proposed to clarify the rules, improve readability and better reflect the rules' statutory authority.

SECTION-BY-SECTION SUMMARY

Section 97.131.

Proposed amendments to §97.131(1) would add the acronym for the Centers for Disease Control and Prevention (CDC), update the agency and branch name, and update the mailing address for requesting publications from the department.

Existing §97.131(2) is proposed to be deleted, and existing §97.131(3) renumbered paragraph (7) with changes, because the STD defined here would instead be defined by inserting a cross-reference to the federal CDC definitions of those diseases. The acronym for Sexually Transmitted Diseases is also proposed to be added.

New definitions are proposed in §97.131 as these new terms are used in subsequent sections of rule text. The proposed new definitions are as follows:

(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).

(4) HIV-Exposed Infant--Any infant born to an HIV-infected woman.

(5) Point of Care Tests--Diagnostic tests performed at or near the site of patient care 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.

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

Section 97.132.

Proposed changes to the introductory paragraph for §97.132 would clarify language by using the standard term “report.” The amendments would also add “HIV-exposed infants” to the list of what triggers reporting because infants born to HIV-infected mothers are suspected to have HIV infection and must be reported according to Health and Safety Code, §81.042(b), which requires reporting of a patient that has or is suspected of having a reportable disease. Proposed amendments would also provide a cross-reference to §97.133 (relating to Reporting Information for Sexually Transmitted Diseases) regarding what must be reported, and would improve readability by using the term STD instead of listing each reportable disease separately (this tracks changes proposed for the definitions section of the rules).

Proposed amendments to §97.132(1) would better reflect the requirements of Health and Safety Code, §81.042 regarding reporting triggers as well as where the ultimate legal responsibility for reporting lies, and would improve readability by using the acronym STD.

Proposed amendments to §97.132(2) would better reflect the requirements of Health and Safety Code, §81.042, particularly subsection (e). Proposed amendments would also change the word

“patient” to “person” because some of the persons reported will not be patients of the reporting person.

Proposed amendments to §97.132(3) would add language to include hospital laboratories as an entity required to report cases of STD, to track corresponding language in Health and Safety Code, §81.042(d), and would add the acronym for sexually transmitted diseases instead of listing each reportable STD separately. Proposed amendments would delete language about the type of tests and test results required to be reported because that information is provided in more detail in §97.133 and a cross-reference to §97.133 is already provided in this section.

Proposed amendments to §97.132(4) would replace the terminology “counseling and testing site or a community-based organization” with the term “testing program”, to make the language consistent with Health and Safety Code, §85.002, and would add a reference to that section in the rule text. Proposed amendments also clarify the reason for the medical director or other physician to report cases of STD and would use the acronym STD instead of listing each reportable STD separately. Language regarding delegation of reporting duties would be deleted so that the rule doesn’t improperly imply that the statutorily-designated persons can legally avoid their reporting responsibilities under the statute.

Proposed amendments to §97.132(5) would add language requiring local school authorities to report a child attending school who is suspected of having a STD, based on medical evidence. The amendments would also add a cross-reference to Health and Safety Code, §81.003, where the term “school authority” is defined. The proposed changes to this section (along with the existing rule text in the department's rule, §97.7) are necessary to be consistent with the requirements of Health and Safety Code, §81.042(c).

Section 97.133.

The introductory paragraph for §97.133 is proposed to be amended to remove an inappropriate qualifier statement, to add language that clarifies the reporting “trigger” to reflect Health and Safety Code, Chapter 81, and to use the acronym STD for sexually transmitted disease instead of listing each reportable STD separately and to delete language about the type of tests and test results required to be reported because this information is provided in §97.133(2) and (3).

Proposed amendments to §97.133(1) would improve readability and clarity by replacing language about how to report with a cross-reference to §97.133(2) which contains the most recent information on that subject.

The text in existing §97.133(2) is proposed to be moved to §97.133(1) as part of the reorganization of this section to improve flow and readability.

Existing subparagraph in §97.133(1)(A)-(G) are proposed to be deleted because the STD listed and the most current forms used to report them will be in proposed new language in §97.133(2).

New language proposed for §97.133(2) would clearly state that the referenced persons have to report as described in the subsequent list in subparagraphs (A) - (E). The proposed amendments

change the reporting forms for adult and adolescent HIV/AIDS and pediatric HIV/AIDS from CDC forms to department-specific forms (the department's Texas HIV/AIDS Adult/Adolescent case report form and the department's Texas HIV/AIDS pediatric case report form), and add the entire name of the department's forms in addition to the number of the form for the reporting forms that are not being changed. The proposed new language separates reporting requirements for physicians and other persons specified in amended §97.132(1) - (2), (4), and (5) and laboratories as specified in §97.133(3) into two different subsections to improve clarity in the differences in reporting requirements for physicians and laboratories. The proposed amendments to §97.133(2) will also clarify that results from point of care tests must be reported.

Existing language at §97.133(3) is proposed to be replaced with language requiring persons in charge of a laboratory or any other facility described in §97.132(3) to report results, as described, for each person who has or is suspected of having an STD and/or is an HIV-exposed infant. The existing language in this section is proposed to be deleted as unnecessary, since §97.134 specifies how reporting should be done. The proposed new language in §97.133(3) lists the specific types of tests and test results required to be reported. The proposed new §97.133(3) would add language that clarifies that positive or reactive STD test results, including screening tests, are required to be reported. The proposed amendment changes the current requirement that only detectable HIV viral loads are reported, making both detectable and non-detectable HIV viral loads required to be reported. The proposed new §97.133(3) changes the reporting of CD4+T-lymphocytes (CD4s) from counts below 200 cells/microliter or less than 14% to all CD4 counts, regardless of level for adults and adolescents over 12 years of age. The proposed new §97.133(3) revises the requirement to report PCR tests for HIV (DNA or RNA) on all infants to include both positive and negative results for infants from birth to three years of age, instead of the existing requirement to report only positive PCR results. Adding a requirement to report negative PCR results for infants will enable the State to determine perinatal HIV transmission rates for Texas with more accuracy and will also decrease the amount of time public health workers spend on contacting health care providers to obtain negative PCR results on HIV-exposed infants. Overall, these changes to reporting requirements for HIV test results by laboratories and other listed entities will greatly enhance completeness of reporting for HIV and increase the number of new HIV cases reported, resulting in better data to target prevention interventions and allocate scarce resources. These changes will also result in better monitoring of severity of HIV disease and the quality of HIV care in Texas. These changes will allow a more accurate determination of the unmet needs for HIV care in Texas. The proposed new §97.133(3) changes the required reporting of confirmatory tests for syphilis from the existing requirement to only report positive (reactive) results to the requirement to report both reactive and non-reactive tests. This will allow public health personnel to spend less time investigating positive screening tests with missing confirmatory test results and decrease calls to physicians and laboratories to provide this information. The proposed new §97.133(3) also adds the requirement to report nucleotide sequences of HIV from resistance testing, e.g. FASTA files, so that the State can obtain more complete information for its HIV resistance surveillance activities, including monitoring the level and types of HIV medication resistance in Texas.

Section 97.134.

Proposed amendments to §97.134(a) would add clarifying language that specifies that case reports are confidential as provided by law, and would remove vague language.

Proposed amendments to §97.134(b) would delete the word “region” and replace it with “departmental regional office which covers the area” for clarity on who should receive case reports in the absence of a local health department director.

Proposed amendments to §97.134(c) would update the agency, branch name and the mailing address for sending reports of STD. A reference to the HIV/STD program website for obtaining additional reporting information is proposed to be added, and the statement about obtaining postage paid envelopes from the HIV/STD program is proposed to be deleted because there have been no requests for such envelopes for the past five years and the department is discontinuing that service.

Proposed amendments to §97.134(d) would specify data elements required to be reported for cases of STD and HIV infection or AIDS, to be consistent with amendments made to Health and Safety Code, §81.043 and §81.044 during the 80th Legislature, 2007. Text is proposed to be added that updates the reference to the department's health service regions, and text is proposed to be deleted that states forms can be obtained from the department's HIV/STD program and the related address since this entity does not provide reporting forms. Proposed amendments add a reference to the HIV/STD program website for a list of local health departments and the department's health service region offices where reporting forms can be obtained.

Proposed amendments to §97.134(e) would require a shorter reporting period for physicians and other referenced persons to submit reports of primary or secondary syphilis by telephone (i.e., within one working day of determining the diagnosis). Other STD retain the existing requirement that reporting be made within calendar seven days. The proposed amendment for reporting syphilis test results within one working day will allow public health authorities to respond more quickly to reported cases and interrupt the chain of transmission earlier, thereby reducing the spread of the disease. Primary and secondary (P&S) syphilis are the stages of syphilis where the disease is most transmissible. In Texas, cases of P&S syphilis have steadily increased from 398 in 2000 to 1,172 in 2007 indicating a need for more aggressive intervention measures for syphilis, including earlier disease reporting. The proposed amendment for reporting primary and secondary syphilis would also put Texas in compliance with the CDC syphilis surveillance recommendations. Currently Texas is one of only seven states that have a syphilis reporting timeframe of seven calendar days; 29 states have syphilis reporting within one working day.

Proposed amendments to §97.134(f) would require any person in charge of a clinical laboratory or other entity as specified by §97.132(3) to submit syphilis test results within three working days of obtaining the test result, which is a change from the existing rule that requires weekly submission. Other STD retain the existing requirement that test results be reported within seven calendar days in §97.134(f). Syphilis is proposed to be treated separately for the same reasons previously stated in this preamble regarding proposed changes to §97.134(e). Laboratory reporting of syphilis tests is proposed to be within three working days of obtaining the test result compared to within one working day for physicians and other non-laboratory reporters. This timeframe is proposed based on feedback from stakeholders that were concerned that “within

one day” reporting from laboratories could result in a laboratory triggering a disease intervention specialist (DIS) contacting a patient before the physician received the laboratory report. Feedback from laboratory stakeholders was that a “within one day” reporting time frame would be overly burdensome. A “within three-day” timeframe for reporting syphilis is recommended because it shortens the reporting timeframe but also allows a short time-lag for physicians to receive results before a DIS contacts the patient. Laboratory stakeholders also indicated that this timeframe would not be as overly burdensome as a “within one-day” timeframe. Proposed amendments to §97.134(f) would add clarifying language that the requirement for laboratories to report quarterly if they have no positive test results for that calendar quarter is an additional requirement and does not replace other reporting requirements.

Existing language at §97.134(g) is proposed to be deleted in its entirety because a rule on the subject is not needed. New language is proposed for subsection (g), which would require health authorities to report each week to the department, using electronic or paper reports, all STD cases, including HIV infection and AIDS, to be consistent with amendments made to Health and Safety Code, §81.043, during the 80th Legislature, 2007. The proposed new language will also include the address for mailing paper reports and an email address to request information on how to file electronic reports.

FISCAL NOTE – STATE GOVERNMENT

Casey S. Blass, Director, Infectious Disease Prevention Section, has determined that for each of the first five years the sections are in effect, there will be no fiscal implications to state government. The proposed rule amendments will result in an increase in the volume and type of STD reports received by the department, however, other provisions in the proposed amendments would offset those resource demands by decreasing the amount of time which needs to be spent on case follow-up by department STD surveillance personnel. No new personnel are anticipated to be needed under the proposed rules.

FISCAL NOTE – LOCAL GOVERNMENT

Mr. Blass has also determined that for each of the first five years the sections are in effect, there will be no fiscal implications to local government. The proposed rule amendments will result in an increase in the volume and type of STD reports received by local health departments and may increase the number of new cases needing disease intervention services; however, other provisions in the proposed amendments should offset those resource demands by decreasing the amount of time needed for follow-up on preliminary positive STD results with a missing confirmatory test and follow-up on HIV-exposed infants without test results indicating final HIV status.

MICRO-BUSINESS AND SMALL BUSINESS IMPACT ANALYSIS

Once a person/entity is within the scope of these rule amendments, then the proposed rules would provide for certain things that must be done such that the impacts are definite (e.g. small business must devote resources necessary to file reports). Since these impacts will happen, the

department analysis under Economic Impact Statement as follows will also serve to satisfy the Small Business Impact Analysis required by Government Code, §2006.002(a).

The Economic Impact Statement does not explicitly cover “micro-businesses,” but Government Code, §2006.002(a) requires an analysis of the impacts on such businesses. The department could not discern any difference in the impact of these rules on small businesses versus micro-business as defined in the statute, so the analysis will consider them both together and refer to them collectively only as “small businesses.”

There is no anticipated negative impact on local employment.

The definition of a “small business” for purposes of this requirement was codified at Sec. of the Government Code, §2006.001(2). Under this definition, a “small business” is an entity that is: for profit, independently owned and operated; and has fewer than 100 employees or less than \$6 million in annual gross receipts. Independently owned and operated businesses are self-controlling entities that are not subsidiaries of other entities or otherwise subject to control by other entities (and are not publicly traded).

Mr. Blass has determined that there may be an adverse economic effect on those small businesses directly regulated by the proposed rules. Therefore, the following two analyses have been performed:

--ECONOMIC IMPACT STATEMENT

The areas of possible impacts to small businesses regarding the proposed rules involve reporting and the frequency of reporting. Possible impacts are discussed on a section-by-section basis, below.

The proposed amendments to §97.132 do not add persons to the list of those who must report beyond those mandated by existing statutory language (see discussion in the Section-By-Section Summary of this preamble). Because statutory provisions already require these persons to report as indicated, there is no new legal burden created by more clearly expressing at fact in §97.132.

The proposed amendments to §97.133 requiring the use of Texas specific forms to report adult/adolescent and pediatric HIV/AIDS cases will have no adverse effect on small businesses in Texas. The HIV/AIDS case report forms are primarily used by the HIV/AIDS reporting sites, which are all local or regional health departments, the Texas Department of Criminal Justice, or by a limited number of larger volume HIV testing sites and hospitals, all of which would be categorized as either nonprofit organizations or large businesses. The Texas-specific case report forms should be available free of charge from local and regional health departments.

The proposed amendments to §97.133 requiring laboratories that conduct HIV drug resistance testing to submit reports containing the nucleotide sequence (e.g., FASTA file) to the department will have no adverse effect on small business in Texas. HIV drug resistance testing is a highly specialized laboratory procedure that appears to be limited to a handful of large reference labs across the country. In a telephone survey of select laboratories doing business in Texas

completed in March of 2009, only eight labs were identified that do this type of testing, none of which would be classified as a small business.

The proposed amendments to §97.133 requiring laboratories to report all PCR test results for children less than three years of age will have no adverse effect on small businesses in Texas. As with HIV drug resistance testing, HIV PCR testing appears to be a specialized test only performed in very large reference laboratories. In March of 2009, an informal survey of HIV/AIDS reporting sites was conducted to determine which labs reported positive PCR results, and only four very large laboratories were named. This was further confirmed through laboratory report information contained in STD*Management Information System (STD*MIS), the state STD data reporting system in Texas. None of the 107 positive PCR tests that were reported in 2007 through STD*MIS were from laboratories that would be classified as a small business.

The proposed amendments to §97.133 requiring the reporting of all levels of CD4 counts and percentages for adults and adolescents, and all detectable and non-detectable HIV viral load tests, will not have an effect on small businesses in Texas. STD*MIS laboratory report data was used to determine how many labs conduct CD4 and HIV viral load tests. In the first six months of 2008, 63 laboratories were listed as having performed either CD4 or viral load tests, and none of these would be classified as a small business.

The proposed amendments to §97.133 requiring laboratories to report all confirmatory syphilis test results will have an overall negligible effect on small business in Texas. To estimate the number of laboratories performing syphilis tests that might be affected, all syphilis lab reports from the first six months of 2008 were pulled from STD*MIS. In that period, 265 facilities were listed as the laboratory that performed any type of syphilis 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 24 organizations were left that might qualify as small business. Even if that number were doubled to account for small private facilities that may not have had a syphilis test reported in STD*MIS in the six month period, this rule change should affect no more than 50 small businesses. If one assumes that the difference between the number of positive screening tests reported in STD*MIS from these 24 small labs and the number of positive confirmatory tests reported were all negative confirmatory tests, which are not currently reportable, the total additional volume to be reported per year is estimated to be 60 to 120 negative confirmatory test results. Since this total number of tests is spread across 50 estimated small laboratories, an average small lab will only be reporting two or three negative syphilis confirmatory results per year. Any extra costs associated with printing and mailing in these extra syphilis test results is mitigated by the fact that under the current reporting rule, local STD reporting sites are calling labs to follow-up on positive screening tests that were received without an accompanying confirmatory test result. For small laboratories, having employees field calls from the health department and look up negative confirmatory results is presumed to be equally if not more costly to the business than just routinely submitting the negative confirmatory test result along with the positive screening test.

The proposed amendments to §97.134 revising the timeframe for laboratories to report syphilis test results within three working days of obtaining a result will have a nominal effect on small

business in Texas. As described previously, the number of small business laboratories conducting syphilis tests in Texas is estimated at no more than 50. Requiring small labs to report syphilis results in three days as opposed to the current weekly rule will not have an effect on the number of tests reported, only the frequency with which these results are submitted to the health department. According to 2008 STD*MIS data, the average small laboratory reports eight syphilis lab tests per year, so even if each one of those tests required an individual transmittal to the health department, the cost would be quite low per year, per lab. One small business laboratory in Texas was consulted and they estimated that it takes a lab technician no more than ten minutes to print and mail out a test result. Lab technicians earn approximately \$20 per hour. Reporting a single test result might cost a lab a maximum of \$5, including man-hours, paper, envelope and postage. The total extra cost per year for the average small lab should be no more than \$40.

The proposed amendments to §97.134 revising the timeframe and method for healthcare providers to report P&S syphilis diagnoses would have a negligible effect on small business in Texas. According to STD*MIS data, approximately 300 different healthcare providers diagnosed P&S syphilis cases in the first six months of 2008. Of that total about half would clearly be classified as government, nonprofit, or large business providers. Factoring in some extra providers for a full year timeframe, the department estimates that 200 small business providers may be impacted by this rule change. The total number of P&S syphilis cases to be reported among these 200 healthcare providers is estimated at 400 cases per year, for an average of two cases per provider per year. While changing the timing of the case report from within seven days to within one working 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 proposed rule amendment also requiring diagnosing facilities to report P&S syphilis 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 complete all of their P&S case reports for a year with two five-minute phone calls.

The proposed amendments to §97.134 deleting the portion stating that in addition to report forms, postage paid envelopes may be obtained from the HIV/STD Epidemiology Division without charge will not have an adverse effect on small business. The department has not provided any postage paid envelopes to any individual or organization wishing to report HIV/STD in the past five years or more. Making this change in the reporting rules will have no adverse effect on small business in Texas because no business is currently taking advantage of this offer and hasn't for many years.

--REGULATORY FLEXIBILITY ANALYSIS

The department considered several alternative methods to achieve the purpose of the rule change proposed for §97.134(e) - (f). Initially the proposal was to make all syphilis test results reportable by laboratories within one day rather than three days. However, the early feedback received from meetings with key HIV/STD laboratory stakeholders in early 2009, was that one-day reporting would be excessively burdensome to lab workflow. Another concern expressed by stakeholders was that within one day reporting from laboratories could result in a laboratory

report triggering a DIS contacting a patient before the physician received the laboratory report. The three working day time period for laboratory reporting for syphilis is being proposed as a compromise. Another alternative considered was to proscribe electronic lab reporting. The department may provide limited technical assistance to any laboratory that may be interested in moving towards the reporting of lab test results through secure electronic file transfers. After the initial set up, electronic reporting would reduce costs by eliminating the paper and postage from the equation and reducing the time spent by staff to complete the reporting process. However, it was determined that department does not have the statutory authority to mandate electronic reporting from laboratories, and there are also technical issues regarding compatibility of different electronic data systems. Finally, the department also considered implementing a different timetable for syphilis reporting among small laboratories (as opposed to those that are not small businesses); however this was not deemed to be adequately protective of public health and safety. P&S syphilis is increasing in Texas with case numbers tripling over the last eight years. Moving to within three-day reporting of syphilis for all laboratories will shorten the timeframe from its current reporting requirement, which will in turn allow earlier public health intervention but not be overly burdensome to laboratories.

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, 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 amendments 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 BENEFIT

In addition, Mr. Blass has 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 will benefit from adoption of the proposed amendments because more complete and timely STD reporting will result in enhanced STD data, increased identification of new cases of STD and earlier public health interventions to control the spread of STD in Texas. The enhanced data will allow public health officials to better target prevention and treatment programs for individuals at risk for HIV and other STD and will enable public health officials to identify disease outbreaks in specific geographical areas or in specific populations more quickly.

PUBLIC COMMENT

Comments on the proposal may be submitted to Nicole Hawkins, Department of State Health Services, HIV/AIDS Epidemiology and Surveillance Branch, MC 1873, P.O. Box 149347, Austin, TX 78714-9347, or by email to Nicole.Hawkins@dshs.state.tx.us. Comments will be accepted for 30 days following publication of this 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' legal authority to adopt.

STATUTORY AUTHORITY

The proposed 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 proposed 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 proposed 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

§97.131. Definitions.

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

(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 [HIV/STD] Epidemiology and Surveillance Branch [Division], P.O. Box 149347, [1100 West 49th Street] Austin, Texas 78714-9347 [78756-3199].

(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.

[(2) Chancroid, *Chlamydia trachomatis* infection, gonorrhea and syphilis--These diseases are as defined by the Centers for Disease Control and Prevention. The publication designating the most current definition may be requested from: Texas Department of Health , HIV/STD Epidemiology Division, 1100 West 49th Street, Austin, Texas 78756-3199.]

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

(4) HIV-Exposed Infant--Any infant born to an HIV-infected woman.

(5) Point of Care Tests--Diagnostic tests performed at or near the site of patient care 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.

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

(7) **[(3)] 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. Acquired Immune Deficiency Syndrome (AIDS), chancroid, Chlamydia trachomatis infection, gonorrhea, HIV infection, and syphilis are sexually transmitted diseases reportable under these rules, and each are as defined by CDC (see http://www.cdc.gov/ncphi/diss/nndss/casedef/case_definitions.htm).

§97.132. Who Shall Report Sexually Transmitted Diseases.

The following shall report **[provide information on]** cases of STD and HIV-exposed infants, as detailed in §97.133 of this title (relating to Reporting Information for Sexually Transmitted Diseases) **[AIDS, chancroid, Chlamydia trachomatis infection, gonorrhea, HIV infection, or syphilis]**:

(1) A physician or dentist shall report each patient who has or is suspected of having an STD and/or is an HIV-exposed infant **[that is diagnosed or treated for AIDS, chancroid, Chlamydia trachomatis infection, gonorrhea, HIV infection, or syphilis]**. 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 [A] physician or dentist to ensure **[who can assure]** that **[a designated or appointed person in]** the required reporting **[clinic or office]** is submitted **[regularly reporting every occurrence of these diseases does not have to submit a duplicate report.]**

(2) The following persons **[chief administrative officer of a hospital, medical facility, or penal institution]** shall report each person **[patient]** who has or is suspected of having **[is medically attended at the facility and is diagnosed with]** 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: **[AIDS, chancroid, Chlamydia trachomatis infection, gonorrhea, HIV infection, or syphilis. The chief administrative officer may designate an employee of the institution to serve as the reporting officer. A chief administrative officer who can assure that a designated or appointed person in the institution is regularly reporting every occurrence of these diseases does not have to submit a duplicate report. Hospital laboratories may report through the reporting officer or independently in accordance with the hospital's policies and procedures.]**

(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;

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

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

(3) Any person in charge of a clinical laboratory, hospital laboratory, blood bank, mobile unit, or other facility in which a laboratory examination of a blood specimen, or any specimen derived from a human body, [that] yields microscopic, cultural, serological or any other evidence of **an STD [AIDS, chancroid, Chlamydia trachomatis infection, gonorrhea, HIV infection, or syphilis, including a CD4+ T lymphocyte cell count below 200 cells/microliter or a CD4+ T lymphocyte percentage of less than 14%,]** shall report according to §97.133 of this title (relating to Reporting Information for Sexually Transmitted Diseases).

(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, [counseling and testing site or a community-based organization] shall report each patient who has or is suspected of having an STD and/or is an HIV-exposed infant. [that is diagnosed with AIDS, chancroid, Chlamydia trachomatis infection, gonorrhea, HIV infection, or syphilis. The medical director or clinic physician may designate an employee of the counseling and testing site or community-based organization to serve as the reporting officer. A medical director or

clinic physician who can assure that the designated reporting officer is regularly reporting every occurrence of these diseases, in accordance with §97.133 of this title, does not have to submit a duplicate report.]

(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-infected infant [School administrators, as defined in §97.1 of this title (relating to Definitions), who are not medical directors meeting the criteria described in this section, are exempt from reporting AIDS, chancroid, Chlamydia trachomatis infection, gonorrhea, HIV infection or syphilis].

(6) (No change.)

§97.133. Reporting Information for Sexually Transmitted Diseases.

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 who has or is suspected of having an STD and/or is an HIV-exposed infant and [, to the extent that the information is collected by the reporting entity,] for any specimen derived from a human body that yields microscopic, cultural, serological or any other evidence of STD. [AIDS, chancroid, *chlamydia trachomatis* infection, gonorrhea, HIV infection or syphilis, including a CD4+ T lymphocyte cell count below 200 cells/microliter or a CD4+ T lymphocyte percentage of less than 14%.]

(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 **[which may be in writing, by telephone, by electronic data transmission, or by other means]**. Completed written reports, electronic reports, and telephone reports shall be made in accordance with §97.134 of this title (relating to How to Report Sexually Transmitted Diseases).

[(A) Reports of AIDS, HIV infection, CD4+ T Lymphocyte cell count below 200 cells/microliter, or CD4+ T lymphocyte percentage of less than 14% shall be made using all of the information collected by the reporting entity found in the most current version of forms CDC 50.42B, CDC 50.42C, or STD-28.]

[(B) Reports of chancroid shall be made using all of the information collected by the reporting entity found in the most current version of form STD-27 or STD-28.]

[(C) Reports of *chlamydia trachomatis* infection shall be made using all of the information collected by the reporting entity found in the most current version of form STD-27 or STD-28.]

[(D) Reports of gonorrhea shall be made using all of the information collected by the reporting entity found in the most current version of form STD-27 or STD-28.]

[(E) Reports of syphilis shall be made using all of the information collected by the reporting entity found in the most current version of form STD-27 or STD-28.]

[(F) Reports pertaining to congenital syphilis shall be made using all of the elements found in the most current version of the form adopted by the Bureau of HIV and STD Prevention.]

[(G) Reports pertaining to enhanced perinatal HIV surveillance shall be made using all of the elements found in the most current version of the form adopted by the Bureau of HIV and STD Prevention.]

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

(A) All diagnoses of adult or adolescent HIV infection and AIDS using all of the information found in 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) and all diagnoses of pediatric HIV infection and AIDS using all of the information from the most current version of the department's Texas HIV/AIDS pediatric case report form (available as specified in §97.134 of this title).

(B) Information on all HIV positive women giving birth and HIV exposed infants using all of the elements from the most current version of the department's Enhanced Perinatal HIV Surveillance form adopted by the department (available as specified in §97.134 of this title).

(C) All chancroid, *Chlamydia trachomatis*, gonorrhea, and syphilis infections using all of the information found in 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).

(D) All congenital syphilis infections using all of the information found in the most current version of the department's Confidential Report of Sexually Transmitted Diseases form (STD-27).

(E) 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 the most current version of the department's Confidential Report of Sexually Transmitted Diseases form (STD-27).

[(2) Completed written reports, electronic reports, and telephone reports shall be made in accordance with §97.134 of this title (relating to How to Report Sexually Transmitted Diseases).]

(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.

(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 for adults and adolescents over 12 years of age.

(B) Polymerase Chain Reaction tests (PCR) for HIV (DNA or RNA) on all infants from birth to three years of age, regardless of the test findings (e.g., negative or positive).

(C) All confirmatory tests for syphilis, regardless of result (e.g., reactive or non-reactive).

(D) HIV drug resistance testing that contains the resulting nucleotide sequences of the HIV (e.g., FASTA file).

[(3) Electronic reports shall be made in accordance with §97.134(i) of this title.]

§97.134. How to Report Sexually Transmitted Diseases.

(a) All case reports received by the health authority or the department are confidential as provided by law. [records and not public records.]

(b) Reporting forms and/or information from all entities required to report should be sent to the local health department director where the physician's office, hospital, laboratory or medical facility is located or, if there is no such facility, the reports should be forwarded to the regional director in the department's health service region office which covers the area [region] where the physician's office, hospital, laboratory, or medical facility is located.

(c) If any individual or entity is unsure where to report any of the diseases mentioned in this title, the reports shall be placed in a sealed envelope addressed as follows: Texas Department of State Health Services, TB/HIV/STD [HIV/STD] Epidemiology and Surveillance Branch [Division], MC 1873, P.O. Box 149347 [1100 West 49th Street], Austin, Texas 78714-9347 [78756-3199] and the envelope shall be marked "Confidential." The envelope shall be delivered with the seal unbroken to the TB/HIV/STD [HIV/STD] Epidemiology and Surveillance Branch [Division] 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>. [Postage paid envelopes may be obtained by contacting the HIV/STD Epidemiology Division and are provided without charge.]

(d) Reports of STD and/or HIV-exposed infants shall contain all of the information found on the reporting forms specified in §97.133(2) of this title (relating to Reporting Information for Sexually Transmitted Diseases) including, but not limited to (reporting [Reporting] forms can be obtained from local health departments and department health service regions; [, regional offices, and the Texas Department of Health, HIV/STD Epidemiology Division, 1100 West

49th Street, Austin, Texas 78756-3199.] forms [Forms] shall be provided without charge to individuals required to report; [.] a list of local health departments and the department's health service region offices that can provide reporting forms is available at <http://www.dshs.state.tx.us/hivstd/healthcare/reporting/shtm>):

(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.

(e) Physicians and other persons as specified by §97.132(1) - (2), (4), and (5) of this title must submit reports of primary or secondary syphilis by telephone within one working day of determining the diagnosis. All other reports [Reports] of STD [confirmed or suspected sexually transmitted diseases] including AIDS and HIV from physicians and other persons as specified by §97.132 of this title [infection] must be submitted within seven calendar days of the determination of the existence of a reportable condition.

(f) Any person in charge of a clinical laboratory or other entity as specified by §97.132(3) of this title shall submit syphilis test results within three working days of obtaining the test result and shall submit all other test results within seven calendar days. [Laboratories shall submit information weekly.] In addition to required reporting, if [If], during any calendar quarter, tests for chancroid, Chlamydia trachomatis infection, gonorrhea, HIV infection and syphilis are performed and all test results are 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.

(g) A health authority shall report each week to the department all cases reported to the authority during the previous week of STD, including HIV infection and AIDS, 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.

[(g) A local health director or regional director may authorize one or more employees under his/her supervision to receive the report from the physician by telephone and to physically complete the form; use of this alternative, if authorized, is at the option of the reporting physician. The local health department director or regional director shall implement a method for verifying the identity of the telephone caller when that person is unfamiliar to the employee.]

(h)-(i) (No change.)