

**Department of State Health Services
Council Agenda Memo for State Health Services Council
November 4, 2009**

Agenda Item Title: New rule concerning the establishment of a diabetes pilot project that will create an electronic registry to track glycosylated hemoglobin levels and to govern the format and method of collecting glycosylated hemoglobin data

Agenda Number: 7f

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background: The Diabetes Program, located in the Division for Prevention and Preparedness Services, oversees 17 contracts with local health departments, community health centers, and grassroots organizations providing services in each Health and Human Services region in Texas. These programs have demonstrated success in establishing effective programs for promoting wellness, physical activity, weight and blood pressure control, and smoking cessation for people with diabetes. All of these community-based organizations, which are found in both rural and urban settings, target racial and ethnic minorities that have disproportionately high rates of diabetes and have limited access to health services. The Diabetic Eye Disease Program provides clinical eye examinations to identify diabetic retinopathy and related conditions at no cost for eligible residents who have no other source to pay for such exams.

The program is funded with both state and federal funds - approximately \$5,900,000 in state funds and \$945,620 in federal funds from the Centers for Disease Control and Prevention. In fiscal year 2008, the Diabetes Program funded activities have resulted in the following outcomes:

- provided nearly 6,000 persons with diabetes eye exams;
- 11,806 people with diabetes, 62% of whom are female, were enrolled in diabetes registries in 12 Community Health Centers across the state; and
- 103,508 persons received diabetes education and disease management support through community based programs.

In addition to programmatic responsibilities, staff provide support to the initiatives of the Texas Diabetes Council.

Summary:

The purpose of the new rule is to establish a diabetes mellitus registry pilot program. Institutions and individuals responsible for reporting the glycosylated hemoglobin tests will have clear guidance on what is reportable; the public health community will be able to assess methods to promote the prevention and improve control of diabetes; and the general public will be better served by DSHS as it fulfills its responsibility to monitor, track, and assess the trends and economic burden of diabetes.

New Section 61.91 that was originally proposed to comply with Chapter 706, uncodified, House Bill (HB) 2132, 80th Legislature, Regular Session, 2007, required DSHS to establish a diabetes mellitus registry pilot program. The proposed section was published in the January 30, 2009, issue of the *Texas Register* and was withdrawn in the July 31, 2009, issue, because of new legislation in 2009.

The proposed rule is necessary to comply with Chapter 262, uncodified, HB 1363, 81st Legislature, Regular Session, 2009, which modifies the original 2007 legislation. The rule requires a clinical laboratory located in the participating public health district to submit to the district and DSHS the results of each glycosylated hemoglobin test along with the diagnosis codes that the laboratory performs in which the patient has given prior consent. The

rule also requires physicians who order a glycosylated hemoglobin test for a patient, provide the patient with a form developed by DSHS that allows the patient to opt out of having the patient's information included in the registry and requires physicians to report patient diagnosis codes to the laboratory with the test orders. New Section 61.91(c) provides language stating that the pilot program will be conducted by the San Antonio Metropolitan Health District.

Not later than December 1, 2010, DSHS shall submit a report to the Legislature concerning the effectiveness and recommendations for the program. This rule and the statute that supports it expire in September 2011.

Summary of Input from Stakeholder Groups: Staff from the San Antonio Metropolitan Health District participated in conference calls and other discussions on development of the rule and on aspects of implementing and managing the program. A draft of the proposed rule was presented to the Texas Diabetes Council on August 6, 2009. Preliminary feedback from the Texas Diabetes Council and the San Antonio Metropolitan Health District has been favorable. There were no changes to the rule based on feedback.

Proposed Motion: Motion to recommend HHSC approval for publication of rule contained in agenda item #7f

Approved by Assistant Commissioner/Director: Adolfo Valadez, M.D., M.P.H. **Date:** 9/23/09

Presenter: Cassandra DeLeon **Program:** Diabetes Program **Phone No.:** 458-7111 x 3549

Approved by CPCPI: Carolyn Bivens **Date:** 9/23/2009

Title 25. HEALTH SERVICES
Part 1. DEPARTMENT OF STATE HEALTH SERVICES
Chapter 61. Chronic Diseases
Subchapter F. Diabetes Registry
New §61.91

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes new §61.91 concerning the establishment of a diabetes pilot project that will create an electronic registry to track glycosylated hemoglobin levels and to govern the format and method of collecting glycosylated hemoglobin data.

BACKGROUND AND PURPOSE

New §61.91 that was originally proposed to comply with Chapter 706, uncodified, House Bill (HB) 2132, 80th Legislature, Regular Session, 2007, required the department to establish a diabetes mellitus registry pilot program. The amendment to §61.91 was previously proposed in the January 30, 2009 issue of the *Texas Register* and was withdrawn on July 31, 2009, because of new legislation in 2009.

The proposed rule is necessary to comply with Chapter 262, uncodified, HB 1363, 81st Legislature, Regular Session, 2009, which modifies the original 2007 legislation. The rule requires a clinical laboratory located in the participating public health district to submit to the district and the department the results of each glycosylated hemoglobin test along with the diagnosis codes that the laboratory performs in which the patient has given prior consent. The rule also requires physicians who order a glycosylated hemoglobin test for a patient, provide the patient with a form developed by the department that allows the patient to opt out of having the patient's information included in the registry and requires physicians to report patient diagnosis codes to the laboratory with the test orders. New §61.91(c) provides language stating that the pilot program will be conducted by the San Antonio Metropolitan Health District.

Not later than December 1, 2010, the department shall submit a report to the Legislature concerning the effectiveness and recommendations for the program. This rule and the statute that supports it expire in September 2011.

SECTION-BY-SECTION SUMMARY

New §61.91(a) describes the purpose of the Diabetes Mellitus Registry Pilot Program. New §61.91(b) defines the terms "Diabetes Mellitus" and "Glycosylated hemoglobin test." New §61.91(c) provides language stating that the pilot program will be conducted by the San Antonio Metropolitan Health District, and provides language informing the clinical or hospital laboratory staff where to report glycosylated hemoglobin test results. New §61.91(d) provides language stating what information shall be reported for each glycosylated hemoglobin test result and describes the protocol to ensure confidentiality. New §61.91(e) and §61.91(f) state when

reporting of glycosylated hemoglobin test results shall begin and the date when reporting will end.

FISCAL NOTE

Cassandra DeLeon, Diabetes Prevention and Control Branch Manager, Health Promotion and Chronic Disease Prevention Section, has determined that for each year of the first five years that the section will be in effect, there will not be fiscal implications to state government as a result of enforcing or administering the section as proposed because the legislation states that “the participating public health district is solely responsible for the costs of establishing and administering the pilot program.” as stated in Chapter 262, uncodified, HB 1363, 81st Legislature, 2009. There are fiscal implications for the San Antonio Metropolitan Health District, who will administer this program. These implications apply only in the next two years of the program because the legislation expires in September 2011 as stated in Chapter 262, uncodified, HB 1363, 81st Legislature, 2009. During this period the estimated cost to the district shall be approximately one full time staff person to administer and implement this program and a contractor to collect and analyze the data, an annual cost of approximately \$200,000.

SMALL AND MICRO-BUSINESS ECONOMIC IMPACT STATEMENT

Ms. DeLeon has also determined that there will an effect on small businesses or micro-businesses required to comply with the section as proposed. These small businesses would consist of single physician offices or physician group practices that would be required to obtain and maintain patient consent and "opt out" forms and report patient diagnosis codes to the laboratory with the test orders. The physicians primarily would be physicians in the following practices: family practice, general practice, internal medicine, endocrinology, geriatrics and pediatrics. From data provided by the Texas Medical Board, 942 physicians in these practices are licensed in the county. Neither the Texas Medical Association nor the Texas Workforce Commission have data to estimate the number of small or micro-businesses that would consist of these 942 physicians in the county comprising the health district, but some of these physicians are in large group practices whose income would disqualify them under the definition of “small business” used in the Government Code, §2006.001.

The number of small businesses subject to the proposed rule can only be estimated. Assuming four physicians comprise a single group practice, approximately 236 group medical practices would be located within the health district. Each would be considered a small business.

Health district staff estimate that a person takes approximately five minutes to make a disease report. From their experiences, health district staff believe nurses in medical offices are the primary reporters. Nurses earn an average of \$25 per hour. A single report would cost a business the amount of \$2.08. The estimated total cost to make 418,478 lab reports based on the prevalence of diabetes in and estimating that each individual would have at least 2 glycosylated hemoglobin tests per year would be \$870,434.

According to the San Antonio Metropolitan Health District, the 2007 diabetes prevalence is estimated to at 10.3% for the San Antonio Metropolitan Statistical Area (MSA). The United

States Census population estimates for the San Antonio MSA as of July 2008 is 2,031,441, the population estimated to be diagnosed with diabetes is 209,239. Assuming each of the possible 236 group medical practices 1773 glycosylated hemoglobin tests to report, the possible cost per practice would be approximately \$3,688.

All glycosylated hemoglobin tests that have patient consent and the patient diagnosis codes will be reported by clinical laboratories, which are not small businesses or micro-businesses.

Requiring reporting from clinical and hospital laboratories is the only way to accomplish the important public health purpose of Chapter 262, uncodified, HB 1363, 81st Legislature, 2009. The department chose the San Antonio Metropolitan Health District because it was the only district that met the requirements set in §1(c) of the Chapter.

ECONOMIC COSTS TO PERSONS

There is a cost per report for the clinical laboratory. A major laboratory informed the department that the anticipated economic cost to comply with the section as proposed is up to \$25,000.

LOCAL EMPLOYMENT IMPACT

There is no anticipated impact on local employment.

PUBLIC BENEFIT

In addition, Ms. DeLeon has also determined that for each year of the first five years that the section is in effect, the public will benefit from adoption of the section. The institutions and individuals responsible for reporting the glycosylated hemoglobin tests will have clear guidance on what is reportable; the public health community will be able to assess methods to promote the prevention and improve control of diabetes; and the general public will be better served by the department as it fulfills its responsibility to monitor, track, and assess the trends and economic burden of diabetes.

REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposed rule 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 Cassandra DeLeon, Director, Texas Diabetes Council/Program, Department of State Health Services, P. O. Box 149347, Austin, Texas 78714-9347, (512) 458-7111 ext. 3549 or by email to Cassandra.deleon@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 rule has been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The proposed new section is authorized by Chapter 262, uncodified, (HB) 1363, 81st Legislature, 2009, which requires the Executive Commissioner of the Health and Human Services Commission to adopt rules necessary to implement and govern the format and method of collecting glycosylated hemoglobin data; and Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of the health and human services by the department and for the administration of Health and Safety Code, Chapter 1001.

The proposed new section affects Chapter 262, uncodified, (HB 1363), 81st Legislature, 2009; Health and Safety Code, Chapter 1001; and Government Code, Chapter 531.

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

§61.91. Diabetes Mellitus Glycosylated Hemoglobin Test Registry Pilot.

(a) Purpose. The Diabetes Mellitus Registry Pilot Program, Statute Chapter 262, uncodified, House Bill 1363, 81st Texas Legislature, 2009 requires the establishment of a pilot program for the reporting of glycosylated hemoglobin tests.

(b) Definitions. The following words and terms when used in this subchapter shall have the following meanings unless the context clearly states otherwise.

(1) Diabetes Mellitus--A syndrome characterized by disordered metabolism and abnormally high blood sugar (hyperglycemia) resulting from insufficient levels of the hormone insulin or reduced insulin sensitivity.

(2) Glycosylated hemoglobin test--A measurement of a form of hemoglobin used primarily to identify the average plasma glucose concentration over prolonged periods of time.

(c) Where to report. The pilot program is being conducted in Bexar County. This jurisdiction meets the requirements of the statute. A clinical laboratory located in the participating public health district shall submit to the district and the department the results of each glycosylated hemoglobin test that the laboratory performs for each patient that has not chosen to opt out of having their information included in the registry.

(d) Reportable information requirements.

(1) The physician who orders a glycosylated hemoglobin test on or after November 1, 2009 shall submit to the clinical laboratory the patient diagnosis codes along with the patient's sample.

(2) A physician, who orders a glycosylated hemoglobin test for a patient, shall provide the patient with a form, developed by the department, that allows the patient to opt out of having the patient's information included in the registry. If the patient opts out by signing the form, the physician shall keep the form in the patient's medical records; and may not submit to the clinical laboratory the patient's diagnosis codes along with the patient's sample.

(3) The test result information that shall be reported for each glycosylated hemoglobin test performed within the San Antonio Metropolitan Health District service area is as follows: glycosylated hemoglobin value; patient name, address, telephone number, age, date of birth, sex, race and ethnicity; date of test, location of test site, patient diagnosis codes; and physician name, address, and telephone number.

(4) Additional information necessary to determine the trends and public health costs of diabetes control shall also be reported if requested.

(5) Reports, records, and information are confidential and are not subject to disclosure under Government Code, Chapter 552, are not subject to subpoena, and may not otherwise be released. The reports, records, and information obtained are for the confidential use of the department and the persons or public or private entities that the department determines are necessary to carry out the intent of this pilot program.

(e) When to report. Reporting shall begin on the effective date of this rule. Glycosylated hemoglobin test results shall be reported within 5 calendar days.

(f) This rule expires September 1, 2011.