



Diabetes Mellitus / Hemoglobin A1c Registry Program

**As Required by
Health and Safety Code
Chapter 95. Diabetes
Subchapter B. Diabetes Mellitus Registry**



**Department of State Health Services
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Executive Summary

SB 510, 82nd Regular Session, 2011, relating to a voluntary statewide diabetes mellitus registry, modified and permanently extended an existing pilot program in Bexar County created by HB 2132, 80th Legislature, Regular Session, 2007 and revised by HB 1363, 81st Regular Session, 2009. SB 510 codified the original 2007 and 2009 legislation as Health and Safety Code, Chapter 95, Subchapter B, “Diabetes Mellitus Registry.” The legislation also requires that not later than December 1 of each even-numbered year, the department shall submit a report to the Legislature concerning the effectiveness of the registry and number of public health districts voluntarily participating in the registry.

In the pilot program, the Department of State Health Services (DSHS) coordinated with the San Antonio Metropolitan Health District (SAMHD) to create and maintain an electronic diabetes mellitus registry to track the glycosylated hemoglobin (A1c) level of each person who has a laboratory test to determine that level at a clinical laboratory in the participating district. SAMHD operated the registry from 2007 to 2010, collecting and analyzing patient A1c data from the four labs operating in the San Antonio area.

While the data gave broad insight into geographic areas with poor A1c control, analysis remained limited without additional patient data showing whether there was a diabetes diagnosis. The A1c test is provided to persons with diabetes to determine their levels of blood glucose control over a three-month period. It is also used to diagnose diabetes in persons who may or may not have the disease. As a result, A1c data collected by the registry included persons with diabetes as well as persons who did not have diabetes, which was problematic for what was intended to be a diabetes registry.

HB 1363, 81st Regular Session, 2009, addressed this situation by requiring that physicians provide diabetes diagnosis information when ordering an A1c exam. The bill also included a provision allowing patients to opt out of having their information included in the registry.

No data were collected from 2011-2012. This was due in part to challenges created by the additional reporting requirements and the opt-out provision for patients. In addition, no funds were specifically allocated to the diabetes registry project in 2011-2012.

In 2012, SAMHD created a new Chief Epidemiologist position to oversee all public health data monitoring and analysis, including oversight of the diabetes registry program. SAMHD reinitiated the registry during the summer of 2012 with the capacity to collect a limited amount of data. SAMHD continues to explore options for establishing a local data platform capable of supporting expanded, ongoing registry operations. SAMHD is researching the anticipated costs of operating the expanded registry, since the public health district that participates in the registry is solely responsible for the costs of establishing and administering the program in that district.

DSHS proposed a new rule, presented to the DSHS Council on November 20, 2014, which was necessary to comply with legislation that changed the status of the registry from a pilot project to a permanent registry codified in Health and Safety Code, Chapter 95, Subchapter B. This rule maintains registry procedures for receiving diabetes diagnosis information established under the

pilot program, which allow for better assessment of prediabetes and diabetes prevalence at the community level, as well as using standard lab test results to target and evaluate local diabetes prevention and control interventions.

Introduction

Chapter 95, Subchapter B of the Health and Safety Code applies only to a public health district that serves a county that has a population of more than 1.5 million and in which more than 75 percent of the population lives in a single municipality.

Diabetes Mellitus Registry

DSHS, in coordination with participating public health districts, shall create and maintain an electronic diabetes mellitus registry to track the A1c level of each person who has a laboratory test to determine that level performed at a clinical laboratory in the participating district.

A public health district may participate in the diabetes mellitus registry. A public health district that participates in the registry is solely responsible for the costs of establishing and administering the program in that district.

A physician practicing in a participating public health district who, on or after November 1, 2011, orders an A1c test for a patient shall submit to a clinical laboratory located in the participating public health district the diagnosis codes of a patient along with the patient's sample. The clinical laboratory shall submit to the district for a patient whose diagnosis codes were submitted with the patient's sample the results of the patient's A1c test along with the diagnosis codes provided by the physician for that patient.

A physician who orders an A1c test for a patient must 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.

The participating public health districts shall compile results submitted in order to track:

- the prevalence of diabetes mellitus among people tested in the district;
- the level of diabetic control for the patients with diabetes mellitus in each demographic group;
- the trends of new diagnoses of diabetes mellitus in the district; and
- the health care costs associated with diabetes mellitus and A1c testing.

The district must provide the department with de-identified aggregate data.

DSHS and participating public health districts shall promote discussion and public information programs regarding diabetes mellitus.

Confidentiality

Reports, records, and information obtained under this subchapter are not public information under Chapter 552, Government Code, and are subject to the confidentiality requirements described by Section 81.046.

Rules

The executive commissioner shall adopt rules to implement this subchapter, including rules to govern the format and method of collecting A1c data.

Report

Not later than December 1 of each even-numbered year, DSHS shall submit to the governor, lieutenant governor, speaker of the House of Representatives, and appropriate standing committees of the legislature a report regarding the diabetes mellitus registry that includes an evaluation of the effectiveness of the registry and the number of public health districts voluntarily participating in the registry.

Background

Diabetes Mellitus/Hemoglobin A1c Registry Implementation: 2007-2010

In 2007, the San Antonio City Council authorized SAMHD to seek legislation to make diabetes mellitus a reportable disease. In response to this request, the Texas Diabetes Council (TDC) recommended a pilot project to serve as a potential model for future statewide application. HB 2132, 80th Legislature, Regular Session, 2007, authorized the collection and study of A1c test results from labs in order to create and maintain a diabetes mellitus registry. A Memorandum of Agreement (MOA) was established between DSHS and SAMHD to designate Bexar County as the location for the fulfillment of this statutory directive.

In order to implement the pilot program, the San Antonio City Council approved the MOA with DSHS and funded two full time equivalents, as well as an appropriation to contract with Vermont Clinical Decisions Support (VCDS). VCDS is a Vermont-based clinical software company, hired to assist SAMHD in gathering, storing, and analyzing the A1c Registry data from Bexar County. VCDS deliverables included the following: connection to four main labs in San Antonio (University Health System, Quest Diagnostics, Lab Corporation of America, Clinical Pathology Labs); enrollment of all Bexar County residents tested by those labs (with no upper numeric limit); maintenance of the registry including any new patients through September 2009; and, when available, addition of retrospective A1c data. In addition, VCDS produced quarterly reports for SAMHD containing enrolled patients by sex, age group, testing lab and zip code as well as several patient-level analyses of the data. VCDS also provided raw data to SAMHD for further analysis.

By September 30, 2009, the San Antonio Diabetes Registry contained over 652,000 A1c test results/values for 236,170 unique individuals, including retrospective data representing a period of approximately four years and nine months. While the data gave broad insight into geographic areas with poor A1c control, analysis remained limited without additional patient data showing whether there was a diabetes diagnosis. The A1c test is provided to persons with diabetes to

determine their levels of blood glucose control over a three-month period. It is also used to diagnose diabetes in persons who may or may not have the disease. As a result, A1c data collected by the registry included persons with diabetes as well as persons who did not have diabetes, which was problematic for what was intended to be a diabetes registry.

In 2009, the Legislature approved the extension of the Diabetes Registry pilot program through September 1, 2011, and included a provision for the collection of diabetes diagnostic codes. HB 1363, 81st Regular Session, 2009, authorized the extension of the electronic diabetes mellitus registry pilot program for two additional years and expanded the data collection to require that any physician practicing in Bexar County who ordered an A1c test for a patient shall submit to the clinical laboratory, along with the patient's sample, the diagnostic codes of each individual receiving the test. In addition, the bill stated that clinical laboratories shall submit to SAMHD the results of the diagnostic codes provided by the physician for that patient. Further, the new bill required that a physician provide the patient with a form developed by DSHS that would allow the patient to opt out of having the patient's information included in the registry. The rules, based on this new legislation, essentially made participation in the registry voluntary.

The additional logistical challenges of collecting diagnosis codes and tracking patients who choose to opt out of the registry came at a time when funds from the City of San Antonio General Fund to continue to contract with VCDS were significantly reduced. Due to these funding limitations, SAMHD began investigating an internal strategy to transfer the existing data and potential future data onto a server hosted by the City of San Antonio. Though discussions progressed, momentum stalled on determining how to address the physician involvement in securing patient consent. Also of concern was whether physicians, even if they were willing, could provide diagnostic codes directly to the laboratories for reporting purposes. Another internal challenge to the sustainability of the pilot included a lack of internal staff capacity for sufficient data analysis.

Diabetes Mellitus / Hemoglobin A1c Registry Implementation 2011-2012

Due to funding limitations and the logistical challenges previously described, the diabetes registry program stalled between January 2011 and April 2012. In April 2012, SAMHD created a new Chief Epidemiologist position and hired Dr. Anil T. Mangla, PhD., MPH, to oversee all public health data monitoring and analysis, including oversight of the diabetes registry program. Dr. Mangla resumed progress on the diabetes registry program, and in October 2012, SAMHD initiated a partnership with University Health System to request a data set including all of the A1c test results from 2011. With the exception of the Chief Epidemiologist position, there are no funds specifically allocated to the diabetes registry project.

SAMHD reinitiated the registry during the summer of 2012. The data collected contained 34,649 A1c test results / values for 18,501 unique individuals tested during January 2011 through December 2011. The test results were only available from one of the four reporting laboratories for 2011. All results were confirmed by their internal laboratories and stored in a secure system.

Diabetes Mellitus / Hemoglobin A1c Registry Report for 2013-14

SAMHD continues to maintain capacity to collect data from one of the four labs (University Health System) contributing to the original registry for purposes of diabetes surveillance and potential program planning. In order to establish a local data platform capable of supporting expanded, ongoing registry operation, SAMHD has solicited assistance of Healthcare Access San Antonio (HASA), which supports health information exchange for Bexar and surrounding counties. For providers with electronic medical records HASA delivers a secure, single point of access to a patient's community health record and maintains sophisticated security protocols to ensure that no unauthorized individual can access a patient's record. HASA's data platform allows patient opt-in or opt-out of data collection. SAMHD has determined initial and ongoing costs to support the registry using HASA's data platform; however, implementation remains dependent on securing a funding source.