

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

Agenda Item Title: Amendments to rules concerning the surveillance and control of birth defects

Agenda Number: 4e

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background:

The Birth Defects Epidemiology and Surveillance Branch (branch) is located in the Environmental Epidemiology and Disease Registries Section in the Division of Prevention and Preparedness.

The branch promotes public health through the surveillance and control of birth defects and their possible causes. The branch collects data on 17,000 infants and fetuses with birth defects per year from a catchment of 400,000 births annually, and identifies and describes the patterns for structural malformations and chromosomal anomalies among infants in Texas. Children identified through the Texas Birth Defects Registry (Registry) are referred to appropriate medical and community services. The branch collaborates with others to find the causes of birth defects and work toward their prevention.

The Registry employs an active surveillance approach, which entails staff routinely visiting all hospitals and birthing centers where affected children are delivered or treated. Staff review logs to find potential cases, and medical records to identify those indicating one or more birth defects. Information is abstracted from medical records on pregnancies with birth defects delivered to residents of Texas and includes birth defect diagnoses; medical tests and procedures; gestational age; delivery information; illnesses, complications, and maternal exposures; and demographic information. All information is held in strict confidence in accordance with state and federal privacy laws.

The branch also collaborates with researchers in finding causes of birth defects, working towards prevention and linking families with services. The Research Center funded by the Centers for Disease Control and Prevention uses Registry data to conduct epidemiologic studies to find the preventable causes of birth defects in Texas.

Funding for the branch is approximately \$2.8 million, which includes approximately 56% in general revenue and 44% in Title V federal funds.

Summary:

The purpose of the amendments is to allow DSHS to collect data in a more efficient and convenient manner. The amendments will also clarify that active surveillance may be conducted through in-person visits by DSHS staff or through remote access to electronic medical records. (The current rules discuss visits by DSHS staff to review records, but do not mention remote access.) Additionally, the amendments will bring DSHS rules up to date with current medical records systems, which are moving away from paper records and toward electronic records. The amendments add clinical and medical laboratories to the type of health facility included in definitions. The amendments also clarify DSHS's policies and procedures regarding access to data and the allowed research use of the data.

The review of the rules complies with the four-year agency review required by Government Code, Section 2001.039.

The rules allow DSHS to consider the known incidence and prevalence rates of birth defects in the state; the known incidence and prevalence rates of particular birth defects in specific population groups who live in the state or portions of the state; the morbidity and mortality resulting from these birth defects; and the existence, cost, and availability of a strategy to prevent and treat these birth defects.

Summary of Input from Stakeholder Groups:

The draft rules were developed through a cross functional effort between Birth Defects Epidemiology and Surveillance staff. Stakeholder input for these rules was obtained through phone calls and emails with Texas residents in contact with the Registry, the Texas Hospital Association, Texas Health Information Management Association, Texas Association for Clinical Laboratory Services, Southwest Association for Clinical Microbiology, Texas Medical Association, March of Dimes Public Affairs, clinical reviewers for the Branch, and collaborators of the Texas Center for Birth Defects Research and Prevention.

Stakeholder response was favorable and no revisions were suggested.

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

Approved by Assistant Commissioner/Director: Adolfo Valadez, M.D., M.P.H. **Date:** 5/19/2009

Presenter: Mark Canfield **Program:** Birth Defects Epidemiology and Surveillance Branch **Phone No.:** 512/458-7111, ext 6158

Approved by CPCPI: Carolyn Bivens **Date:** 5/15/2009

Title 25. HEALTH SERVICES
Part 1. DEPARTMENT OF STATE HEALTH SERVICES
Chapter 37. Maternal and Infant Health Services
Subchapter P. Surveillance and Control of Birth Defects
Amendments §§37.301 - 37.306

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 §§37.301 - 37.306, concerning the surveillance and control of birth defects.

BACKGROUND AND PURPOSE

The birth defects program was established by Health and Safety Code, Chapter 87, to monitor birth defects; to collect reports of and maintain a registry of birth defects; and to conduct "investigations to determine the nature and extent of the disease, or the known or suspected cause of the birth defect and to formulate and evaluate control measures to protect the public health."

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). Sections 37.301 - 37.306 have been reviewed and the department has determined that reasons for adopting the sections continue to exist because rules on this subject are needed.

SECTION-BY-SECTION SUMMARY

Amendments to §§37.301, 37.302, 37.304, and 37.306 clarify and improve the rule language in order to strengthen the requirements of the program. The amendment to §37.303(10)(I) adds "a clinical or medical laboratory" to the types of health facility definitions. Amendments to §37.303(14) and §37.305(d) add new language to provide guidance for remote electronic access active data collection.

FISCAL NOTE

Lucina Suarez, Ph.D., Director, Environmental Epidemiology and Disease Registries Section, has determined that for the first five-year period the sections are in effect, there will be no fiscal implications to state or local government as a result of enforcing or administering the sections as proposed, because there is no cost impact to state or local government.

ECONOMIC IMPACT STATEMENT AND REGULATORY FLEXIBILITY ANALYSIS FOR SMALL AND MICRO-BUSINESSES

Dr. Suarez has also determined that there will be no adverse economic impact on small businesses or micro-businesses required to comply with the sections as proposed. This was determined by interpretation of the rules that small businesses and micro-businesses will not be

required to alter their business practices in order to comply with the sections. An economic impact statement and regulatory flexibility analysis are not required.

ECONOMIC IMPACT TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

There are no anticipated economic costs to persons who are required to comply with the sections as proposed. There is no anticipated impact on local employment.

PUBLIC BENEFIT

In addition, Dr. Suarez has also determined that for each year of the first five years the sections are in effect, the public will benefit by added clarity to the definitions. The amendments allow the department to collect data in a more efficient and convenient manner. The amendments clarify the department's policies and procedures regarding access to data and the allowed research use of the data.

In adopting the rules which cover this program, the department has considered the known incidence and prevalence rates of birth defects in the state; the known incidence and prevalence rates of particular birth defects in specific population groups who live in the state or portions of the state; the morbidity and mortality resulting from these birth defects; and the existence, cost, and availability of a strategy to prevent and treat these birth defects.

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 environment 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 environment 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 COMMENT

Comments on the proposal may be submitted to Mark Canfield, Ph.D., Department of State Health Services, MC 1964, P.O. Box 149347, 1100 West 49th Street, Austin, Texas 78714-9347, telephone (512) 458-7232, fax (512) 458-7330. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The proposed amendments are authorized by Health and Safety Code, §87.001, which allows the department to specify which health facilities are required to report information on birth defects; §87.021(d), which requires the department to adopt rules to govern the operation of the program and carry out the intent of the statute; §87.022(b) and (c), which requires the department to adopt rules on how information is made available to the department; §87.063(a), which requires the department to adopt rules to establish criteria to be used in deciding if research which proposes to use birth defect data should be approved; and 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. Review of the rules implements Government Code, §2001.039.

The proposed amendments affect Health and Safety Code, Chapters 87 and 1001; and Government Code, Chapter 531.

Legend: (Proposed Amendments)

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

§37.301. Purpose.

These sections implement the provisions of Health and Safety Code, Chapter 87, **[to the Health and Safety Code. Chapter 87]** that provides **[the Texas Board of Health with]** the authority to adopt rules relating to the surveillance and control of birth defects. The legislation directs the Texas Department of Health to develop a statewide surveillance program. The Texas Department of Health and the Texas Board of Health were abolished by Chapter 198, §§1.18 and 1.26, 78th Legislature, Regular Session, 2003. Health and Safety Code, Chapter 1001, establishes the Department of State Health Services (department), which now administers these programs. Government Code, §531.0055, provides authority to the Executive Commissioner of the Health and Human Services Commission to adopt rules for the department.

§37.302. Policy.

(a) The department, recognizing the sensitive and confidential nature of information collected regarding birth defects and their possible causes, expects **[shall expect]** all staff to carry out all duties in a professional, compassionate, and culturally sensitive manner.

(b) The department shall **[It is the policy of the program to]** limit medical researcher contact with individuals and families identified by the central registry to only those studies with high scientific merit with no feasible alternate means of conducting the study.

(c) The department shall **[It is also the policy of the program to]** protect patient information from disclosure through the legal process and Government Code, Chapter 552.

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

(1) - (9) (No change.)

(10) Health facility--Any of the following types of facility:

(A) - (F) (No change.)

(G) a physician peer review organization; **[or]**

(H) a birthing center; or **[.]**

(I) a clinical or medical laboratory.

(11) - (13) (No change.)

(14) Surveillance--The systematic collection, analysis, interpretation, and dissemination of health data on an ongoing basis.

(A) Active surveillance--program staff regularly contact or visit data sources, or use remote electronic access, to find and collect data on cases.

(B) (No change.)

(15) (No change.)

§37.304. Confidentiality of Information Provided to the Department.

(a) (No change.)

(b) The department may release demographic, medical, epidemiological, or toxicological information:

(1) (No change.)

[(2) to the case management program of the department for guidance in applying for financial or medical assistance available through existing state and federal programs, if appropriate;]

(2) [(3)] with the consent of each person identified in the information or, if the person is unable to consent or is a minor, the minor's parents, managing conservator, guardian, or other person who is legally authorized to consent;

(3) [(4)] to medical personnel, appropriate state agencies, health authorities, regional directors, and public officers of counties and municipalities relating to the identification, monitoring, and referral of children with birth defects;

(4) [(5)] to appropriate federal agencies such as the Centers for Disease Control and Prevention of the United States Public Health Service;

(5) [(6)] to medical personnel to the extent necessary to protect the health or life of the child identified in the information; or

(6) [(7)] to medical researchers conducting bona fide medical research under the conditions described in §37.306 of this title (relating to Access to Information in the Central Registry), and Health and Safety Code, §87.063.

§37.305. Surveillance of Birth Defects: Central Registry.

(a) - (c) (No change.)

(d) Interaction between department staff and health facility staff [**at facilities**] is detailed below:

(1) The chief operating officer, administrator, manager, director, and/or person in charge of each facility or office or center shall appoint one staff member as the contact person for the central registry surveillance activities. That staff member will coordinate scheduled visits and/or remote electronic access by central registry staff to review logs, discharge indices and other case-finding sources, and will be responsible for arranging visits and/or remote electronic access for medical records review [**visits**] and providing the needed records at the time [**of the**] scheduled [**visit**].

(2) (No change.)

(3) Central registry staff and the contact individual shall establish a general schedule of visits and/or remote electronic access for case-finding and record review [**visits**]. This schedule shall take into account the capabilities of the health care facility in responding to requests, as well as the expected needs of the central registry workload.

(e) (No change.)

§37.306. Access to Information in the Central Registry.

(a) (No change.)

(b) After the program manager receives the completed request for information, the protocol will be reviewed by a program review panel. The panel shall consist of the program manager, the unit manager, and a departmental epidemiologist. Upon approval by the program panel, the protocol shall be evaluated and judged by the department's institutional review board. Final approval of the protocol shall require the approval of both the program panel and the institutional review board and shall be based on an evaluation of the criteria listed in subsection (c) of this section. The department's institutional review board shall evaluate the research based on federal regulations found in Title 45, Code of Federal Regulations, Chapter 46.

(c) - (i) (No change.)