



**OFFICE OF GENERAL COUNSEL
LEGAL OPINION**

**TO: Dr. Adolfo Valadez, MD, MPH, Assistant Commissioner
Division of Prevention and Preparedness**

**CC: Dr. Lauri Kalanges, Director
Health Promotion and Chronic Disease Section**

FROM: Office of General Counsel

DATE: March 21, 2011

RE: Establishment of a Stroke Registry

BACKGROUND

In 1999 the Texas Legislature established the Council on Cardiovascular Disease and Stroke (council), the voting members of which are appointed by the governor.¹ Nonvoting members are appointed by the state agencies represented on the council. The council has a number of functions assigned by the statute, including the development of a “plan to reduce the morbidity, mortality, and economic burden of cardiovascular disease and stroke in this state”, and advising the Department of State Health Services (department) and legislature.² The department, which is represented by a nonvoting member on the council, is to provide administrative support.³

QUESTION

In pursuit of its statutory duties, the council has considered the establishment of a stroke registry. Members of the council have asked the department to determine if the department currently has the authority to establish a stroke registry in this state.

ANSWER

Neither the department nor the council has the authority, under existing statutes, to establish a stroke registry.

¹ Health and Safety Code Chapter 93, “Prevention of Cardiovascular Disease and Stroke”. This Chapter 93 should not be confused with another chapter assigned the same chapter number by the legislature, “Education and Prevention Program for Hepatitis C.”

² Health and Safety Code § 93.051(a), (b) & (c).

³ Each agency represented on the council is to provide such support, (Health and Safety Code §93.010), but the council has always been administratively attached to the department.

DISCUSSION

Each state agency, including the department, has only those powers delegated to it by the legislature. For several types of health conditions, the legislature has authorized the department to collect health information about identifiable patients. Examples include communicable disease⁴; cancer⁵; birth defects⁶; elevated childhood lead levels.⁷ The department also has broad authority to collect data needed to conduct specific “epidemiologic or toxicologic investigations”⁸.

In all cases, the specific legal requirement to release otherwise confidential medical information to a government agency is necessary because release in the absence of such authority may violate state and federal laws on the confidentiality of medical information.⁹ The laws authorizing the collection of data go back many years and were enacted for a number of different reasons,¹⁰ and have a number of different features, but all include specific authority to collect patient information from specified providers, as well as provisions insure the confidentiality of data in the possession of the agency.

There is a section of Chapter 93 that authorizes the council to “collect and analyze information related to cardiovascular disease and stroke at the state and regional level, and to the extent feasible, at the local level.”¹¹ The legislature contemplated that such information might contain patient identifiers, and imposed confidentiality protections on the data.¹² But these provisions do not authorize collection of patient-level data directly from providers (as in other statutes that have served as the basis for creating registries). The data mentioned in the statute are all from existing sources:

The council shall obtain the information from federal and state agencies and from private and public organizations.

[T]he council may use information available from other sources, such as the Behavioral Risk Factor Surveillance System established by the Centers for Disease Control and Prevention, reports of hospital discharge data, and information included in death certificates.¹³

⁴ Health and Safety Code Chapter 81.

⁵ Health and Safety Code Chapter 82.

⁶ Health and Safety Code Chapter 87.

⁷ Health and Safety Code Chapter 88.

⁸ Health and Safety Code Chapter 161, Subchapter C. This provision has been used to support investigations of specific health conditions, but has never been used to support ongoing disease reporting or any type of registry.

⁹ The authority to release confidential data without patient consent is limited to instances where release is “required or authorized by law” in the Medical Practice Act, Occupations Code §159.004(1) and the HIPAA privacy regulations, 45 C.F.R. §164.512(a).

¹⁰ Fairchild, Amy L., *et.al.*, *Searching Eyes: Privacy, the State, and Disease Surveillance in America*, 2007.

¹¹ Health and Safety Code §93.053(a).

¹² Health and Safety Code §94.054.

¹³ Health and Safety Code §93.053(a)&(c).

This language authorizes the collection of some data, but not with sufficient specificity to constitute a “registry” as the legislature has done for the creation of other registries.¹⁴ Also compare the language in other statutes, which requires physicians and other providers to report the diagnoses of specified diseases or health conditions.¹⁵ No such requirement or authorization exists in the statutory provisions governing the department or the council as it relates to stroke data.

As an example of how the legislature has authorized registries, the statute governing the Cancer registry states that the department “shall maintain a cancer registry for the state” which “must include” specific types of information with the department authorized to establish detailed reporting procedures by rule.¹⁶

In the alternative statutes may require health professionals to report conditions:

A dentist or veterinarian licensed to practice in this state or a physician shall report, after the first professional encounter, a patient or animal examined that has or is suspected of having a reportable disease.¹⁷

Many other examples could be cited, but all issue a clear directive to the agency.

The legislature has enacted a legislative goal and framework to “. . . construct an emergency treatment system in this state so that stroke victims may be quickly identified and transported to and treated in appropriate stroke treatment facilities.”¹⁸ The department, in its rules for stroke facilities, has required that they submit “. . . data to the department as requested.”¹⁹ However, this is a reference to information needed by the department in its regulatory capacity to determine how or whether a facility should be licensed. Neither the statute nor the rules authorize the collection of information that would be necessary to support a stroke registry.

The closest thing to a stroke registry currently operated by the department is the trauma registry. Trauma registry rules used two different statutes as authority (25 TAC §103.1(a)):

- Health and Safety Code Chapter 92, “Injury Prevention and Control” requires the department to make certain types of injury as reportable, “Spinal cord injuries, traumatic brain injuries and submersion injuries” (§92.002(a)), and it allows us to “adopt rules that require other injuries to be reported.” (§92.002(b))

¹⁴ Health and Safety Code §82.004 (Cancer Registry), Health and Safety Code §§87.021 (Birth Defects Registry), Health and Safety Code §§88.003 (Childhood Lead Registry).

¹⁵ Health and Safety Code §§ 81.042, 82.008, 87.022, 88.004, 161.0211 are provisions which require health care providers to provide data to support the programs mentioned in the text and footnotes above. Other examples could be cited.

¹⁶ Health and Safety Code §§82.004, 82.005.

¹⁷ Health and Safety Code §81.042(b).

¹⁸ Health and Safety Code §773.201.

¹⁹ 25 TAC §157.133(a).

- Health and Safety Code Chapter 773 requires us to establish a trauma care system. §773.112(c)(6) require those rules to contain requirements for data collection, including trauma incidence reporting . . .” §773.113(a)(3) requires us to “develop and maintain a trauma reporting and analysis system to identify severely injured trauma patients at each health care facility in this state.”

The language in the cardiovascular disease statute is not as specific as either of these statutes nor does it provide sufficient implied authority to create a registry. Each of the statutes above provides independent support for the reporting of trauma injuries but the definition of “injury” in §92.001 would exclude most, if not all strokes, so this statute would not support stroke reporting. Chapter 773 has no definition of “trauma” or “injury” but by common understanding of the definition, “stroke” would not be included.

The council is an independent government body, with membership appointed by the governor. As an independent “department of state government”, it may request an opinion of the attorney general through its chair.²⁰

If the council believes that the legislature should authorize and fund a stroke registry it is authorized to advise the legislature on this need,²¹ though care should be exercised to avoid using appropriated funds for this purpose unless authorized by law.²²

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²⁰ Government Code §402.042(b)(2).

²¹ Health and Safety Code §93.051(b)&(c).

²² Government Code §556.006(a).