SPONSOR: Sen. Venables & Sen. Marshall & Rep. Brady & Rep. Hudson
Sens. Blevins, Hocker, Pettyjohn, Simpson;
Reps. Briggs King, Dukes, Kenton, Miro, Mitchell, D. Short, Wilson

DELAWARE STATE SENATE
147th GENERAL ASSEMBLY

SENATE BILL NO. 140

AN ACT TO AMEND TITLE 16 OF THE DELAWARE CODE RELATING TO INVASIVE MEDICAL PROCEDURE FACILITIES.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

Section 1. Amend Chapter 1, Title 16 of the Delaware Code by making insertions as shown by underlining and deletions as shown by strike through as follows:

§ 122. Powers and duties of the Department of Health and Social Services.

The Department shall have the following general powers and duties:

(1) Supervision of all matters relating to the preservation of the life and health of the people of the State.

(2) Supreme authority in matters of quarantine; it may declare and enforce such quarantine, when necessary and where no quarantine exists, and may modify, relax or abolish it, where it has been established.

(3) Adopt, promulgate, amend, and repeal regulations consistent with law, which regulations shall not extend, modify or conflict with any law of this State or the reasonable implications thereof, and which shall be enforced by all state and local public health officials, to:

y. Establish standards with respect to safety and sanitary conditions of any facility defined in paragraph 3 ~~e~~ C. of this section and investigate and inspect any such facility for unsafe or unsanitary conditions upon receipt of a complaint by a patient or facility employee in accordance with this paragraph, or upon the occurrence of any adverse event in connection with any such facility. The Department may share information hereunder with the Department of State, Division of Professional Regulation in accordance with applicable law.

1. The Department may make and enforce such orders as it deems necessary to protect the health and safety of the public hereunder. Without limitation of the foregoing, if the Department determines during the course of any investigation or inspection that any facility hereunder poses a substantial risk to the health or safety of any person, the Department may order that such facility be closed until such time as it no longer poses a substantial risk.

2. No later than March 31, 2012, the Department shall adopt regulations to strengthen the oversight of facilities hereunder.

3. For purposes of this paragraph:

A. "Adverse event" means: I. The death or serious injury of any patient at a facility; II. A reasonable determination by the Department that death or serious injury may result from any unsafe or unsanitary condition at a facility; or III. The initiation of any criminal investigation arising out of or relating to any diagnosis, treatment or other medical care at a facility.

B. "Complaint" means a complaint filed by a patient or facility employee in writing, in such format as the Department shall require.

C. "Facility" means a location at which any invasive medical procedure is performed, but shall not include any hospital, as defined in § 1001(2) of this title, or any freestanding birthing center, freestanding surgical center or freestanding emergency center, as such terms are defined in paragraph (3)p. of this section.

D. "Invasive medical procedure" means any medical procedure in which the accepted standard of care requires anesthesia, major conduction anesthesia or sedation. Without limitation of the foregoing, the term "medical procedure" shall include dental and podiatric procedures.

E. "Patient" means a person who has received diagnosis, treatment or other medical care at a facility hereunder, or such person's spouse, as well as any parent, legal guardian or legal custodian of such person who is under 18 years of age or any legal guardian or legal custodian of such person who is an adult.

When deemed necessary by the Department, such regulations may provide for the issuance of permits to persons engaged in the occupations or businesses so regulated and the revocation for cause of the permits.

z. Establish standards for a facility accreditation program. --

1. To operate in this State, any facility not licensed by the Department where invasive medical procedures are performed must maintain accreditation by an accrediting organization approved by the Department. For an accrediting organization to be approved it must be entirely independent from the facility and there shall be no conflict of interest. For purposes of this section, the terms "facility" and "invasive medical procedure" shall have the meanings set forth in paragraph (3)y. of this section. All such offices or facilities must register with the Department utilizing a form created for this purpose by the Department.

Section 2. Department of Health and Social Services shall promulgate final rules and regulations in response to this Act with six month after enactment.

SYNOPSIS

Recently the Department of Health and Social Services promulgated rules for the regulation and accreditation of medical facilities that perform invasive medical procedures. This bill builds on that effort by allowing a complaint from an employee of the facility. Facilities must be accredited by independent agencies. Finally, the bill requires the Department to promulgate rules and regulation based on this statute within 6 months of enactment.

Author: Senator Venables