SPONSOR: Rep. Bentz & Sen. Townsend
Reps. Baumbach, Viola

HOUSE OF REPRESENTATIVES
149th GENERAL ASSEMBLY

HOUSE BILL NO. 219
AS AMENDED BY
HOUSE AMENDMENT NO. 1

AN ACT TO AMEND TITLE 16 AND TITLE 24 OF THE DELAWARE CODE RELATING TO INVASIVE MEDICAL PROCEDURES.

Section 1. Amend § 122, Title 16 of the Delaware Code by making deletions as shown by strikethrough and insertions as shown by underline as follows:

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

The Department shall have the following general powers and duties:

(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)y.3.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 <u>(3)y. of this section</u>:

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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~~ office-based surgery is performed, but ~~shall~~ does not include any hospital, as defined in § 1001(3) of this title, or any freestanding birthing center, freestanding surgical ~~center~~ 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.~~

"Office-based surgery" means any medical procedure, including dental and podiatric procedures, including any of the following:

I. Surgical abortions.

II. Procedures in which the facility utilizes anesthesia, major conduction anesthesia, or sedation.

III. Procedures in which the spine (i.e. epidural, facet joint) is the target of an injection.

IV. Procedures in which the accepted standard of care requires anesthesia, major conduction anesthesia, or sedation.

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~~ 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.A. To operate in this State, any facility not licensed by the Department where ~~invasive medical procedures are~~ office-based surgery is 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~~ paragraph (3)z. of this section, "facility" and ~~"invasive medical procedure" shall have the meanings set forth~~ "office-based surgery" mean as defined 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.

B.I. An Accrediting organization shall report to the Department, at a minimum, all of the following regarding facilities the organization has accredited under this paragraph:

(A) Findings of surveys.

(B) Findings of complaint and incident investigations.

(C) Data for all facilities that perform office-based surgery.

II. Documents provided under this paragraph (3)z.1.B. are not public records under the Freedom of Information Act, Chapter 100 of Title 29.

2. ~~All facilities in operation as of July 5, 2011, where invasive medical procedures are performed shall submit proof of the facility's accreditation, or application for same, to the Department within 6 months of the adoption of regulations by the Department hereunder. Any facility where invasive medical procedures are performed which shall become operational following July 5, 2011, shall submit proof of the facility's accreditation to the Department within 12 months of first day of operation of such facility.~~ All facilities where office-based surgery is performed shall submit proof of the facility's accreditation, as required, to the Department. Any newly opened facility where office-based surgery is performed shall submit proof of the facility's accreditation to the Department within 12 months of the first day of operation of such facility.

Section 2. Amend § 521 of Title 24 of the Delaware Code by making deletions as shown by strikethrough and insertions as shown by underline as follows:

§ 521. Accreditation of facilities where invasive procedures are performed.

No person licensed under this chapter shall perform any ~~invasive procedure,~~ office-based surgery, as defined in § 122(3)y. of Title 16, in a facility unless it is accredited or licensed in accordance with § 122(3)z. of Title 16. For purposes of this section, ~~the terms~~ "facility" and ~~"invasive medical procedure" shall have the meanings set forth~~ "office-based surgery" mean as defined in § 122(3)y. of Title 16.

Section 3. Amend § 1138 of Title 24 of the Delaware Code by making deletions as shown by strikethrough and insertions as shown by underline as follows:

§ 1138. Accreditation of facilities where invasive procedures are performed.

No person licensed under this chapter shall perform any ~~invasive procedure,~~ office-based surgery, as defined in § 122(3)y. of Title 16, in a facility unless such facility is accredited or licensed in accordance with § 122(3)z. of Title 16. For purposes of this section, ~~the terms~~ "facility" and ~~"invasive medical procedure" shall have the meanings set forth~~ "office-based surgery" mean as defined in § 122(3)y. of Title 16.

Section 4. Amend § 1705 of Title 24 of the Delaware Code by making deletions as shown by strikethrough and insertions as shown by underline as follows:

§ 1705. Accreditation of facilities where invasive procedures are performed.

No person licensed under this chapter shall perform any ~~invasive medical procedure,~~ office-based surgery, as defined in § 122(3)y. of Title 16, in a facility unless such facility is accredited or licensed in accordance with § 122(3)z. of Title 16. For purposes of this section, ~~the terms~~ "facility" and ~~"invasive medical procedure" shall have the meanings set forth~~ "office-based surgery" mean as defined in § 122(3)y. of Title 16.