



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

HOUSE OF REPRESENTATIVES
149th GENERAL ASSEMBLY

HOUSE BILL NO. 219

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

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

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

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

4 The Department shall have the following general powers and duties:

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

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

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

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

21 3. For purposes of this paragraph (3)y. of this section:

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

52 accrediting organization approved by the Department. For an accrediting organization to be approved
53 it must be entirely independent from the facility and there shall be no conflict of interest. For
54 purposes of this section, ~~the terms paragraph (3)z. of this section, "facility" and "invasive medical~~
55 ~~procedure" shall have the meanings set forth~~ "office-based surgery" mean as defined in paragraph
56 (3)y. of this section. All such offices or facilities must register with the Department utilizing a form
57 created for this purpose by the Department.

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

60 I. Findings of surveys.

61 II. Findings of complaint and incident investigations.

62 III. Data for all facilities that perform office-based surgery.

63 2. All facilities in operation as of July 5, 2011, where invasive medical procedures are performed
64 shall submit proof of the facility's accreditation, or application for same, to the Department within 6
65 months of the adoption of regulations by the Department hereunder. Any facility where invasive
66 medical procedures are performed which shall become operational following July 5, 2011, shall
67 submit proof of the facility's accreditation to the Department within 12 months of first day of
68 operation of such facility. All facilities where office-based surgery is performed shall submit proof of
69 the facility's accreditation, as required, to the Department. Any newly opened facility where office-
70 based surgery is performed shall submit proof of the facility's accreditation to the Department within
71 12 months of the first day of operation of such facility.

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

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

75 No person licensed under this chapter shall perform any ~~invasive procedure,~~ office-based surgery, as defined in §
76 122(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
77 of this section, ~~the terms "facility" and "invasive medical procedure" shall have the meanings set forth~~ "office-based
78 surgery" mean as defined in § 122(3)y. of Title 16.

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

81 § 1138. Accreditation of facilities where invasive procedures are performed.

82 No person licensed under this chapter shall perform any ~~invasive procedure~~, office-based surgery, as defined in §
83 122(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
84 purposes of this section, ~~the terms "facility" and "invasive medical procedure" shall have the meanings set forth~~ "office-
85 based surgery" mean as defined in § 122(3)y. of Title 16.

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

88 § 1705. Accreditation of facilities where invasive procedures are performed.

89 No person licensed under this chapter shall perform any ~~invasive medical procedure~~, office-based surgery, as
90 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
91 Title 16. For purposes of this section, ~~the terms "facility" and "invasive medical procedure" shall have the meanings set~~
92 ~~forth~~ "office-based surgery" mean as defined in § 122(3)y. of Title 16.

SYNOPSIS

The 146th General Assembly gave the Department of Health and Social Services the authority to promulgate regulations and require accreditation for facilities that perform invasive medical procedures. The current terminology and definition of an "invasive medical procedure" has been frequently misinterpreted and caused a great deal of confusion in the medical community. This Act revises the current language to be consistent with terminology used by accreditation organizations and other states, replacing the term "invasive medical procedure" with the term "office-based surgery". In addition, this Act clarifies the definition to ensure that all facilities that perform such procedures do so in a safe and sanitary environment. Finally, this Act adds a requirement that the approved accreditation organizations shall report, at a minimum, findings of surveys and complaint and incident investigations, and data for all office-based surgical facilities to the Department.

This Act also updates Title 24 where the term "invasive medical procedure" is used and § 122(3) of Title 16 is referenced.