## CHAPTER 15 FORMERLY HOUSE BILL NO. 47 AS AMENDED BY HOUSE AMENDMENT NO. 1 AS AMENDED BY HOUSE AMENDMENT NO. 1 & HOUSE AMENDMENT NO. 2 TO HOUSE AMENDMENT NO. 1 AND SENATE AMENDMENT NO. 1

AN ACT TO AMEND TITLES 16 AND 24 OF THE DELAWARE CODE RELATING TO THE REGULATION, INVESTIGATION AND INSPECTION OF UNSANITARY OR UNSAFE CONDITIONS IN FACILITIES WHERE INVASIVE MEDICAL PROCEDURES ARE PERFORMED.

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

Section 1. Amend §122(3), Title 16 of the Delaware Code by adding a new paragraph y as follows:

"y. Establish standards with respect to safety and sanitary conditions of any facility defined in subparagraph 3.C. and investigate and inspect any such facility for unsafe or unsanitary conditions upon receipt of a complaint by a patient 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 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 16 *Del.C.* §1001(2), or any freestanding birthing center, freestanding surgical center or freestanding emergency center, as such terms are defined in §122(3)p. of this Title.

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, as well as any parent, legal guardian or legal custodian of such person who is under eighteen years of age or any legal guardian or legal custodian of such person who is an adult.".

Section 2. Amend Chapter 17, Title 24 of the Delaware Code by adding a new §1741 as follows:

"§ 1741 Complaints of unsanitary or unsafe conditions.

(a) A person certified or licensed under this chapter may be disciplined by the Board for maintaining a facility in an unsanitary or unsafe condition, by means of levying a fine, or by the restriction, suspension, or revocation, either permanent or temporary, of that person's certificate or license, or by other appropriate action, which may include a requirement that a person who is disciplined must complete specified continuing education courses. For purposes of this section, 'facility' shall have the same meaning as defined in §122(3)y.3.C. of Title 16.

(b) The Division shall have the authority to conduct inspections upon receipt of any complaint in connection with subsection (a) or upon the occurrence of an adverse event as defined in §122(3)y.3.A. of Title 16 and, as applicable, to refer such information to the Department of Health and Social Services pursuant to §122(3)y. of Title 16. In connection herewith, the Division may share information with the Department of Health and Social Services in accordance with applicable law."

Section 6. Amend §1127, Title 24 of the Delaware Code by adding a new subsection (c) as follows:

"(c) The Division shall have the authority to conduct inspections upon receipt of any complaint in connection with \$1128(12) of this title or upon the occurrence of an adverse event as defined in \$122(3)y.3.A. of Title 16 and, as applicable, refer such information to the Department of Health and Social Services pursuant to 16 Del.C. \$122(3)y. In connection herewith, the Division may share information with the Department of Health and Social Services in accordance with applicable law."

Section 7. Amend §1128, Title 24 of the Delaware Code by adding a new subsection (12) to read as follows:

"(12) Has maintained a facility in an unsanitary or unsafe condition. For purposes of this section, 'facility' shall have the same meaning as defined in §122(3)y.3.C. of Title 16."

Section 8. Amend §514, Title 24 of the Delaware Code by adding a new subsection (c) to read as follows:

"(c) The Division shall have the authority to conduct inspections upon receipt of any complaint in connection with \$515(a)(8) of this title or upon the occurrence of an adverse event as defined in \$122(3)y.3.A. of Title 16 and, as applicable, to refer such information to the Department of Health and Social Services pursuant to \$122(3)y. of Title 16. In connection herewith, the Division may share information with the Department of Health and Social Services in accordance with applicable law."

Section 9. Amend §515(a), Title 24 of the Delaware Code by renumbering paragraphs (8) and (9) as paragraphs (9) and (10) respectively and inserting a new paragraph (8) to read as follows:

"(8) Has maintained a facility in an unsanitary or unsafe condition. For purposes of this section, 'facility' shall have the same meaning as defined in §122(3)y.3.C. of Title 16."

Section 10. Amend §515, Title 24 of the Delaware Code by adding a new subsection (c) as follows:

"(c) The Division shall have the authority to conduct inspections upon receipt of any complaint in connection with paragraph (a)(8) or upon the occurrence of an adverse event as defined in §122(3)y.3.A. of Title 16 and, as applicable, refer such information to the Department of Health and Social Services pursuant to 16 Del. C. §122(3)y., In connection herewith, the Division may share information with the Department of Health and Social Services in accordance with applicable law."

Approved May 04, 2011