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District 1 (Cape May, Atlantic and Cumberland)
Assemblywoman VALERIE VAINIERI HUTTLE
District 37 (Bergen)

Co-Sponsored by:
Senator Van Drew, Assemblywoman Greenstein, and Assemblyman Conners

SYNOPSIS
Requires single operating-room facilities to register with DHSS, permits practitioners to refer patients to ambulatory surgery facilities in which practitioners have financial interest under certain circumstances.

CURRENT VERSION OF TEXT
Substitute as adopted by the Senate.

(Sponsorship Updated As Of: 2/6/2009)

BE IT ENACTED by the Senate and General Assembly of the State of New Jersey:

1. Section 12 of P.L.1971, c.136 (C.26:2H-12) is amended to read as follows:

12. a. No health care service or health care facility shall be operated unless it shall: (1) possess a valid license issued pursuant to this act, which license shall specify the kind or kinds of health care services the facility is authorized to provide; (2) establish and maintain a uniform system of cost accounting approved by the commissioner; (3) establish and maintain a uniform system of reports and audits meeting the requirements of the commissioner; (4) prepare and review annually a long range plan for the provision of health care services; and (5) establish and maintain a centralized, coordinated system of discharge planning which assures every patient a planned program of continuing care and which meets the requirements of the commissioner which requirements shall, where feasible, equal or exceed those standards and regulations established by the federal government for all federally-funded health care facilities but shall not require any person who is not in receipt of State or federal assistance to be discharged against his will.

b. (1) Application for a license for a health care service or health care facility shall be made upon forms prescribed by the department. The department shall charge a single, nonrefundable fee for the filing of an application for and issuance of a license and a single, nonrefundable fee for any renewal thereof, and a single, nonrefundable fee for a biennial inspection of the facility, as it shall from time to time fix in rules or regulations; provided, however, that no such licensing fee shall exceed $10,000 in the case of a hospital and $4,000 in the case of any other health care facility for all services provided by the hospital or other health care facility, and no such inspection fee shall exceed $5,000 in the case of a hospital and $2,000 in the case of any other health care facility for all services provided by the hospital or other health care facility.

No inspection fee shall be charged for inspections other than biennial inspections. The application shall contain the name of the health care facility, the kind or kinds of health care service to be provided, the location and physical description of the institution, and such other information as the department may require. (2) A license shall be issued by the department upon its findings that the

EXPLANATION – Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.

Matter underlined thus is new matter.
premises, equipment, personnel, including principals and management, finances, rules and bylaws, and standards of health care service are fit and adequate and there is reasonable assurance the health care facility will be operated in the manner required by this act and rules and regulations thereunder.

c. (Deleted by amendment, P.L.1998, c.43).

d. The commissioner may amend a facility's license to reduce that facility's licensed bed capacity to reflect actual utilization at the facility if the commissioner determines that 10 or more licensed beds in the health care facility have not been used for at least the last two succeeding years. For the purposes of this subsection, the commissioner may retroactively review utilization at a facility for a two-year period beginning on January 1, 1990.

e. If a prospective applicant for licensure for a health care service or facility that is not subject to certificate of need review pursuant to P.L.1971, c.136 (C.26:2H-1 et seq.) so requests, the department shall provide the prospective applicant with a pre-licensure consultation. The purpose of the consultation is to provide the prospective applicant with information and guidance on rules, regulations, standards and procedures appropriate and applicable to the licensure process. The department shall conduct the consultation within 60 days of the request of the prospective applicant.

f. Notwithstanding the provisions of any other law to the contrary, an entity that provides magnetic resonance imaging or computerized axial tomography services shall be required to obtain a license from the department to operate those services prior to commencement of services, except that a physician who is operating such services on the effective date of P.L.2004, c.54 shall have one year from the effective date of P.L.2004, c.54 to obtain the license.

g. (1) Notwithstanding the provisions of any other law to the contrary, an entity that operates a surgical practice on the effective date of this section of P.L. , c. (pending before the Legislature as this bill), as defined in this subsection, shall be required to register with the department within one year of the effective date of P.L. , c.

(2) An entity that has not commenced operation as a surgical practice on the effective date of this section of P.L. , c. (pending before the Legislature as this bill), but has filed or files before the 180th day after the effective date of this section of P.L. , c. its plans, specifications, and required documents with the municipality in which the surgical practice will be located, shall register with the department prior to the commencement of services.

(3) As a condition of registration with the department, a surgical practice shall be required to obtain certification by the Centers for Medicare and Medicaid Services as an ambulatory surgery center
provider or obtain ambulatory care accreditation from an
accrediting body recognized by the Centers for Medicare and
Medicaid Services.

(4) As a condition of registration with the department, a surgical
practice shall be required to report the following information
annually: the number of patients served by payment source,
including the number of Medicaid-eligible and medically indigent
persons served; the number of new patients accepted; and the
number of physicians, physician assistants, and advance practice
nurses providing professional services at the surgical practice.

(5) As used in this subsection and subsection i. of this section,
“surgical practice” means a structure or suite of rooms that has the
following characteristics:

(a) has no more than one room dedicated for use as an operating
room which is specifically equipped to perform surgery, and is
designed and constructed to accommodate invasive diagnostic and
surgical procedures;

(b) has one or more post-anesthesia care units or a dedicated
recovery area where the patient may be closely monitored and
observed until discharged; and

(c) is established by a physician, physician professional
association surgical practice, or other professional practice form
specified by the State Board of Medical Examiners pursuant to
regulation solely for the physician’s, association’s or other
professional entity’s private medical practice.

“Surgical practice” includes an unlicensed entity that is certified
by the Centers for Medicare and Medicaid Services as an
ambulatory surgery center provider.

(6) Nothing in this subsection shall be construed to limit the
State Board of Medical Examiners from establishing standards of
care with respect to the practice of medicine.

h. An ambulatory care facility licensed to provide surgical and
related services shall be required to obtain ambulatory care
accreditation from an accrediting body recognized by the Centers
for Medicare and Medicaid Services as a condition of licensure by
the department.

An ambulatory care facility that is licensed to provide surgical
and related services on the effective date of this section of P.L. , c.
(pending before the Legislature as this bill) shall have one year
from the effective date of this section of P.L. , c. to obtain
ambulatory care accreditation.

i. Beginning on the effective date of this section of P.L. , c.
(pending before the Legislature as this bill), the department shall
not issue a new registration to a surgical practice or a new license to
an ambulatory care facility to provide surgical and related services
unless:
(1) in the case of a registered surgical practice or licensed facility in which a transfer of ownership of the practice or facility is proposed, the commissioner reviews the qualifications of the new owner or owners and approves the transfer;

(2) (a) except as provided in subparagraph (b) of this paragraph, in the case of a registered surgical practice or licensed facility for which a relocation of the practice or facility is proposed, the relocation is within 20 miles of the practice’s or facility’s current location or the relocation is to a “Health Enterprise Zone” designated pursuant to section 1 of P.L. 2004, c.139 (C.54A:3-7), there is no expansion in the scope of services provided at the new location from that of the current location, and the commissioner reviews and approves the relocation; or

(b) in the case of a licensed facility described in paragraphs (5) or (6) of this subsection for which a relocation of the facility is proposed, the commissioner reviews and approves the relocation;

(3) the entity is a surgical practice required to be registered pursuant to paragraph (1) of subsection g. of this section and meets the requirements of that subsection;

(4) the entity has filed its plans, specifications, and required documents with the Health Care Plan Review Unit of the Department of Community Affairs or the municipality in which the surgical practice or facility will be located, as applicable, on or before the 180th day following the effective date of this section of P.L. , c. ;

(5) the facility is owned jointly by a general hospital in this State and one or more other parties; or

(6) the facility is owned by a hospital or medical school.

(j) (1) The department shall require an applicant for registration as a surgical practice, as provided in subsection g. of this section, to submit an application for registration in a form and manner prescribed by the department. The applicant shall submit the name and address of the surgical practice that is to be registered, the name of the chief administrator or designated agent of the practice, the names and addresses of all owners of the practice, the scope of services provided at the practice, proof of certification by the Centers for Medicare and Medicaid Services or accreditation from an accrediting body recognized by the Centers for Medicare and Medicaid Services, and such other information as the commissioner deems necessary and as provided by regulation.

(2) The registration shall be valid for a one-year period and may be renewed upon submission to the department of an application for renewal.

(3) The commissioner may suspend, revoke, or deny a registration if the registrant or applicant, as applicable, is not in compliance with the requirements of this section.
(4) No registered surgical practice shall be owned, managed, or operated by any person convicted of a crime relating adversely to the person's capability of owning, managing, or operating the practice.

(5) The department may charge a reasonable fee for filing an application for registration and for each renewal thereof.

(cf: P.L. 2004, c.54, s.4)

2. Section 2 of P.L.1989, c.19 (C.45:9-22.5) is amended to read as follows:

a. A practitioner shall not refer a patient or direct an employee of the practitioner to refer a patient to a health care service in which the practitioner, or the practitioner's immediate family, or the practitioner in combination with the practitioner's immediate family has a significant beneficial interest; except that, in the case of a practitioner, a practitioner's immediate family or a practitioner in combination with the practitioner's immediate family who had the significant beneficial interest prior to the effective date of P.L.1991, c.187 (C.26:2H-18.24 et al.), and in the case of a significant beneficial interest in a health care service that provides lithotripsy or radiation therapy pursuant to an oncological protocol that was held prior to the effective date of this section of P.L. , , c. (pending before the Legislature as this bill), the practitioner may continue to refer a patient or direct an employee to do so if that practitioner discloses the significant beneficial interest to the patient.

b. If a practitioner is permitted to refer a patient to a health care service pursuant to [subsection a. of] this section, the practitioner shall provide the patient with a written disclosure form, prepared pursuant to section 3 of P.L.1989, c.19 (C.45:9-22.6), and post a copy of this disclosure form in a conspicuous public place in the practitioner's office.

c. The restrictions on referral of patients established in this section shall not apply to:

(1) [a health care service that is provided at the practitioner's medical office and for which the patient is billed directly by the practitioner; and] medical treatment or a procedure that is provided at the practitioner’s medical office and for which a bill is issued directly in the name of the practitioner or the practitioner’s medical office;

(2) [radiation therapy pursuant to an oncological protocol, lithotripsy and] renal dialysis; and

(3) ambulatory surgery or procedures requiring anesthesia performed at a surgical practice registered with the Department of Health and Senior Services pursuant to subsection g. of section 12 of P.L.1971, c.136 (C.26:2H-12) or at an ambulatory care facility licensed by the Department of Health and Senior Services to
perform surgical and related services, if the following conditions are met:

(a) the practitioner who provided the referral personally performs the procedure;
(b) the practitioner’s remuneration as an owner of or investor in the practice or facility is directly proportional to his ownership interest and not to the volume of patients the practitioner refers to the practice or facility;
(c) all clinically-related decisions at a facility owned in part by non-practitioners are made by practitioners and are in the best interests of the patient; and
(d) disclosure of the referring practitioner’s significant beneficial interest in the practice or facility is made to the patient in writing, at or prior to the time that the referral is made, consistent with the provisions of section 3 of P.L.1989, c.19 (C.45:9-22.6).

3.  Section 3 of P.L.1989, c.19 (C.45:9-22.6) is amended to read as follows:

3.  The written disclosure form required pursuant to section 2 of this act P.L.1989, c.19 (C.45:9-22.5) shall be in the following form:

Public law of the State of New Jersey mandates that a physician, chiropractor or podiatrist inform his patients of any significant financial interest he may have in a health care service. Accordingly, I wish to inform you that I do have a financial interest in the following health care service(s) to which I refer my patients:

(list applicable health care services)

You may, of course, seek treatment at a health care service provider of your own choice. A listing of alternative health care service providers can be found in the classified section of your telephone directory under the appropriate heading prescribed by regulation of the State Board of Medical Examiners. In addition to such other information as the board determines necessary, the disclosure shall inform the patient whether any services or facility fees associated with the referral will be considered to be, and reimbursed at, an “out-of-network” level by the patient’s insurance carrier or other third party payer.

(cf: P.L. 1989, c.19, s. 3)

4.  (New Section) a.  A referral for ambulatory surgery or a procedure requiring anesthesia made prior to the effective date of this section of P.L. , c. (pending before the Legislature as this bill) by a practitioner to a surgical practice or ambulatory care facility licensed by the Department of Health and Senior Services to perform surgical and related services shall be deemed to comply
with the provisions of section 2 of P.L.1989, c.19 (C.45:9-22.5) if
the practitioner personally performed the procedure that is the
subject of the referral.

b. As used in this section, “surgical practice” means a structure
or suite of rooms that has the following characteristics:
   (1) has no more than one room dedicated for use as an operating
   room which is specifically equipped to perform surgery, and is
designed and constructed to accommodate invasive diagnostic and
surgical procedures;
   (2) has one or more post-anesthesia care units or a dedicated
recovery area where the patient may be closely monitored and
observed until discharged; and
   (3) is established by a physician, physician professional
association surgical practice, or other professional practice form
specified by the State Board of Medical Examiners pursuant to
N.J.A.C.13:35-6.16(f) solely for the physician’s, association’s or
other professional entity’s private medical practice.

“Surgical practice” includes an unlicensed entity that is certified
by the Centers for Medicare and Medicaid Services as an
ambulatory surgery center provider.

5. (New section) a. A referral made during the first 12 months
after the effective date of this section of P.L. , c. (pending before
the Legislature as this bill) to a surgical practice or an ambulatory
care facility licensed by the Department of Health and Senior
Services to perform surgical and related services, shall be deemed
to comply with the provisions of section 2 of P.L.1989, c.19
(C.45:9-22.5) if:
   (1) the practitioner who makes the referral also personally
performs the procedure; and
   (2) disclosure of the referring practitioner’s significant beneficial
interest in the surgical practice or licensed ambulatory care facility
is made to the patient in writing, at or prior to the time that the
referral is made, consistent with the provisions of section 3 of

b. As used in this section, “surgical practice” means a structure
or suite of rooms that has the following characteristics:
   (1) has no more than one room dedicated for use as an operating
room which is specifically equipped to perform surgery, and is
designed and constructed to accommodate invasive diagnostic and
surgical procedures;
   (2) has one or more post-anesthesia care units or a dedicated
recovery area where the patient may be closely monitored and
observed until discharged; and
   (3) is established by a physician, physician professional
association surgical practice, or other professional practice form
specified by the State Board of Medical Examiners pursuant to
N.J.A.C.13:35-6.16(f) solely for the physician’s, association’s or other professional entity’s private medical practice.

“Surgical practice” includes an unlicensed entity that is certified by the Centers for Medicare and Medicaid Services as an ambulatory surgery center provider.

6. The Commissioner of Health and Senior Services shall adopt rules and regulations, pursuant to the “Administrative Procedure Act,” P.L.1968, c.410 (C.52:14B-1 et seq.), to carry out the provisions of section 1 of this act, including prescribing the application form and process to register with the department as a surgical practice and the information that shall be reported to the department pursuant to paragraph (4) of subsection g. of section 12 of P.L.1971, c.136 (C.26:2H-12).

7. This act shall take effect immediately, except that section 2 shall take effect on the first day of the 12th month after the date of enactment, and section 5 shall expire on the first day of the 12th month after the date of enactment.

STATEMENT

This substitute seeks to establish standardized requirements for health care facilities in the State that provide ambulatory surgery and related procedures, to enhance quality of care and patient safety, to address the economic disadvantage that hospitals face with the proliferation of free-standing ambulatory surgical facilities throughout the State, and to ensure that patients receiving care at such facilities are adequately informed as to whether they will be responsible for out-of-network cost sharing. Accordingly, the substitute: (1) requires that single operating-room surgical facilities register with the Department of Health and Senior Services (DHSS) and report certain information to DHSS; (2) limits the issuance of new registrations for surgical practices and licenses for ambulatory care facilities in the State; and (3) revises the law pertaining to patient referrals to health care services in which health care practitioners or their immediate families have a significant beneficial interest.

Specifically, the substitute provides as follows:

- A surgical practice operating on the effective date of the substitute shall register annually with DHSS. The initial registration shall be within one year of the date of enactment of the substitute. In addition, as a condition of registration with DHSS, surgical practices shall obtain certification by the Centers for Medicare and Medicaid Services (CMS) or accreditation from an accrediting body recognized by CMS,
and comply with certain annual reporting requirements concerning utilization and staffing. The substitute also specifies the information that shall be submitted to the department by an applicant for registration. The substitute provides that its provisions shall not be construed to limit the State Board of Medical Examiners from establishing standards of care with respect to the practice of medicine.

- A surgical practice is defined as a structure or suite of rooms that:
  -- has no more than one room dedicated for use as an operating room which is specifically equipped to perform surgery, and is designed and constructed to accommodate invasive diagnostic and surgical procedures;
  -- has one or more post-anesthesia care units or a dedicated recovery area where the patient may be closely monitored and observed until discharged; and
  -- is established by a physician, physician professional association surgical practice, or other professional practice form specified by the State Board of Medical Examiners solely for the physician’s, association’s, or other professional entity’s private medical practice.

- As a condition of DHSS licensure, ambulatory care facilities shall obtain ambulatory care accreditation from an accrediting body recognized by CMS. Facilities shall have one year from the date of enactment of the substitute to comply with the requirement to obtain accreditation.

- As of the date of enactment of the substitute, DHSS shall not issue a new registration to a surgical practice or a new license to an ambulatory care facility to provide surgical and related services unless:
  -- in the case of a registered surgical practice or licensed facility in which a transfer of ownership of the practice or facility is proposed, the commissioner reviews the qualifications of the new owner or owners and approves the transfer;
  -- except as provided below, in the case of a registered surgical practice or licensed facility for which a relocation of the practice or facility is proposed, the relocation is within 20 miles of the practice’s or facility’s current location or is to a State-designated “Health Enterprise Zone,” there is no expansion in the scope of services provided at the new location from that of the current location, and the commissioner reviews and approves the relocation. In the case of a licensed facility owned jointly by a general hospital in the State and other parties, or owned by a hospital or medical school for which a relocation of the facility is
proposed, the commissioner reviews and approves the relocation;
-- the entity is a surgical practice required to be registered, and otherwise meets the requirements of the substitute;
-- the entity has filed, on or before the 180th day following the effective date of the substitute, its plans, specifications, and required documents with the Health Care Plan Review Unit of the Department of Community Affairs or the municipality in which the facility or surgical practice will be located, as applicable;
-- the facility is owned jointly by a general hospital in this State and one or more other parties; or
-- the facility is owned by a hospital or medical school.

• Effective one year after the date of enactment of the substitute, practitioner self-referrals to a health care service that provides lithotripsy or radiation therapy pursuant to an oncological protocol in which the practitioner, the practitioner's immediate family, or the practitioner in combination with practitioner's immediate family has a significant beneficial interest for health care services will be prohibited; however, practitioners who held significant beneficial interests in such health care services before the effective date are permitted to continue referring patients to those services, provided they comply with the substitute’s disclosure requirements.

• The substitute provides an exemption for referrals for ambulatory surgery and procedures requiring anesthesia performed at a registered surgical practice or at a licensed ambulatory care facility if the following conditions are met:
-- the practitioner who provides the referral also personally performs the procedure;
-- the practitioner’s remuneration as an owner of or investor in the practice or facility is directly proportional to his ownership interest and not to the volume of patients the practitioner refers to the practice or facility;
-- all clinically-related decisions at a facility owned in part by non-practitioners are made by practitioners and are in the best interests of the patient; and
-- disclosure of the referring practitioner’s significant beneficial interest in the practice or facility is made to the patient in writing, at or prior to the time that the referral is made.

• The provisions of this substitute concerning patient referrals for ambulatory surgery performed in a facility in which a practitioner or a member of the practitioner’s immediate family has a significant beneficial interest are not intended to limit referrals between practitioners of a medical office
that are made for the benefit and in the best interests of the
patient.

- The substitute amends section 3 of P.L.1989, c.19 (C.45:9-
22.6) to provide that the State Board of Medical Examiners
shall prescribe the information which must be disclosed to
patients (rather than specifying in the statute the exact
language of the disclosure), although the substitute specifies
that the disclosure must include whether any services or
facility fees associated with a referral will be considered to
be, and reimbursed at, an “out-of-network” level by the
patient’s insurance carrier or other third party payer.

- The substitute takes effect immediately, but provides a 12-
month transition period for: (1) surgical practices to meet the
requirements for DHSS registration, including obtaining
CMS certification or accreditation from an accrediting body
recognized by CMS, and (2) licensed facilities to obtain
accreditation from an accrediting body recognized by CMS.
Referrals for health care services in which a practitioner has
a beneficial interest made before and during the 12 months
after the date of enactment of the substitute shall be deemed
to comply with the substitute if the referring practitioner also
performs the procedure, and for referrals made during the
one-year period after the date of enactment of the substitute,
if the practitioner also discloses any significant beneficial
interest he may have in the health care service.