[First Reprint]

SENATE, No. 515

STATE OF NEW JERSEY

219th LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2020 SESSION

Sponsored by:
Senator JOSEPH F. VITALE
District 19 (Middlesex)
Senator VIN GOPAL
District 11 (Monmouth)
Senator PAUL A. SARLO
District 36 (Bergen and Passaic)

Co-Sponsored by:
Senators Doherty and Bateman

SYNOPSIS

Requires DOH to license certain qualifying hospitals to provide full service adult diagnostic cardiac catheterization, primary angioplasty, and elective angioplasty services.

CURRENT VERSION OF TEXT

As reported by the Senate Health, Human Services and Senior Citizens Committee on December 7, 2020, with amendments.

AN ACT concerning hospital licensure to perform certain cardiac procedures, amending P.L.1992, c.160, and supplementing Title 26 of the Revised Statutes.

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

1. (New section) As used in [1]**[**this act**]** P.L. , c. (C.) (pending before the Legislature as this bill)[1] :

"Angioplasty" or "percutaneous coronary intervention" means the mechanical reopening of an occluded vessel in the heart or corona using a balloon-tipped catheter.

"Applicant hospital" means a general hospital that has entered into a collaboration agreement with a cardiac surgery center licensed in New Jersey.

"Application" means all information required by the commissioner of an applicant hospital to determine compliance with [1]**[**this act**]** P.L. , c. (C.) (pending before the Legislature as this bill)[1] .

"C-PORT-E study" means the Atlantic Cardiovascular Patient Outcomes Research Team Elective Angioplasty Study clinical trial.

"Collaboration agreement" means an agreement between a licensed cardiac surgery center and a general hospital that includes:

(1) written protocols for enrolled patients who require transfer to, and receipt at, a cardiac surgery center's operating room within one hour of the determination of the need for such transfer, including the emergency transfer of patients who require an intra-aortic balloon pump;

(2) regular consultation between the two hospitals on individual cases, including use of technology to share case information in a rapid manner; and

(3) evidence of adequate cardiac surgery on-call backup.

"Commissioner" means the Commissioner of Health.

"Department" means the Department of Health.

"Elective angioplasty" means an angioplasty or percutaneous coronary intervention performed on a non-emergent basis.

"Full service adult diagnostic cardiac catheterization facility" means an acute care general hospital that provides invasive cardiac diagnostic services to adult patients without cardiac surgery backup, is equipped with laboratories, and performs at least 250 cardiac catheterizations each year.

"Primary angioplasty" means an angioplasty or percutaneous coronary intervention performed on an acute or emergent basis.

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.
Matter enclosed in superscript numerals has been adopted as follows:
[1]Senate SHH committee amendments adopted December 7, 2020.

2. (New section) a. An applicant hospital may apply to the commissioner for a license to provide full service adult diagnostic cardiac catheterization services. The commissioner shall issue a license pursuant to such application to any hospital that:

(1) is not licensed as a cardiac surgery center;

(2) demonstrates the ability to provide full service adult diagnostic catheterization services consistent with national standards of care and current best practices;

(3) commencing in the second year of licensure pursuant to this subsection, and in each year thereafter, performs at least 250 catheterizations per year, with each interventional cardiologist performing at least 50 catheterizations per year; and

(4) meets such other requirements as the commissioner may establish by regulation including, but not limited to, [1][participating] participation[1] in the department's data collection programs and in national registries such as the National Cardiovascular Data Registry to monitor quality, outcomes, and compliance with State regulations.

b. An applicant hospital may apply to the commissioner for a license to provide primary angioplasty services. The commissioner shall issue a license pursuant to such application to any hospital that:

(1) is not licensed as a cardiac surgery center;

(2) has been licensed for at least six months pursuant to subsection a. of this section to provide full service adult diagnostic catheterization services;

(3) demonstrates the ability to consistently provide primary angioplasty services 24 hour per day and seven days per week, consistent with national standards of care and current best practices; and

(4) meets such other requirements as the commissioner may establish by regulation.

c. An applicant hospital may apply to the commissioner for a license to provide elective angioplasty services. The commissioner shall issue a license pursuant to such application to any hospital that:

(1) is not licensed as a cardiac surgery center;

(2) holds licensure to participate in the C-PORT-E study or the Elective Angioplasty Demonstration Project, or is an applicant hospital licensed by the department to provide primary angioplasty services pursuant to subsection b. of this section;

(3) demonstrates the ability to provide elective angioplasty services consistent with the provisions of N.J.A.C.8:33-3.11 or any successor regulation, as well as national standards of care and current best practices, including ensuring that all patients

considered for elective angioplasty undergo careful selection, screening, and risk stratification pursuant to requirements promulgated by the department by regulation, and ensuring that patients who do not meet such screening criteria are transferred to an appropriate [1]cardiac[1] surgery facility for elective angioplasty;

(4) commencing in the second year of licensure pursuant to this subsection, and in each year thereafter, performs a minimum of 200 angioplasty procedures per year, with each interventional cardiologist performing at least 50 angioplasty procedures per year; and

(5) meets such other requirements as the commissioner may establish by regulation.

d. (1) A hospital issued a license pursuant to subsection a. or b. of this section that fails to meet the qualification requirements for that license shall be subject to corrective administrative action or other remedial action as the commissioner may establish by regulation, including, but not limited to, [1]**[**submitted**]** submitting[1] a corrective action plan to the department for approval and meeting any benchmarks or deadlines for compliance as may be required by the department.

(2) A hospital issued a license pursuant to subsection c. of this section shall have two years to meet the volume requirements set forth in paragraph (4) of subsection c. of this section. A hospital that fails to meet or maintain the qualification requirements for that license, including the volume requirements set forth in paragraph (4) of subsection c. of this section, shall be subject to corrective administrative action or other remedial action as the commissioner may establish by regulation, including, but not limited to, submitting a corrective action plan to the department for approval and meeting any benchmarks or deadlines for compliance as may be required by the department. If a hospital that has entered into a corrective action plan pursuant to this subsection fails to meet and maintain the qualification requirements for a license issued pursuant to subsection c. of this section, including attaining the volume requirements set forth in paragraph (4) of subsection c. of this subsection, within two years after the hospital enters into a corrective action plan, the hospital's license issued pursuant to subsection c. of this section shall be revoked.

e. The department may impose fines, suspend or revoke a license, [1]require corrective administrative action or other remedial action, including requiring submission of a corrective action plan,[1] or impose other lawful remedies against any entity issued a license pursuant to this section that violates any of the requirements of this section. Subject to the provisions of subsection d. of this section, the department may revoke the license of a hospital authorized to

provide any cardiac service, including elective angioplasty, which fails to comply with the licensing requirements set forth in this section related to that license, including facility volume requirements, within two years after the date of licensure.

f. (1) Diagnostic cardiac catheterization and angioplasty programs in all cardiac surgery facilities shall meet such other requirements as the commissioner may establish by regulation including, but not limited to, participation in [1]**[**department**]** the department's[1] data collection programs and in national registries such as the National Cardiovascular Data Registry to monitor quality, outcomes, and compliance with State regulations.

(2) A licensed cardiac surgery facility may request a waiver based on documented and continued accreditation by the Accreditation for Cardiovascular Excellence or by a national organization or association that meets similar standards specific to cardiac catheterization and percutaneous coronary intervention. Licensed facilities that seek accreditation shall provide the department with access to reports, site visits, site visit reviews, any notice related to compliance standards and notices related to change of accreditation status.

g. The commissioner shall establish by regulation the application and renewal fees for licenses issued pursuant to this section, including a nonrefundable fee for initial licensure in the amount of at least $5,000.

3. (New section) Prior to performing any procedure authorized under a license issued pursuant to section 2 of P.L. , c. (C.) (pending before the Legislature as this bill), the applicant hospital shall furnish the following information to the patient and afford the patient the opportunity to review and consider such information before being asked to consent in writing to the procedure:

a. notice included with the informed consent form that the procedure is not being performed at a licensed cardiac surgery center, and in the event that the patient requires emergency cardiac surgery, the patient will be transferred to a licensed cardiac surgery center; and

b. details concerning the applicant hospital's plan and protocols for transferring patients who require emergency cardiac surgery, including the name and location of the cardiac surgery center with which the applicant hospital has entered into a collaboration agreement.

The applicant hospital shall, upon request, furnish the patient with a written copy of the hospital's transfer protocols, including transportation and associated charges for transportation, and a summary of the collaboration agreement.

4. Section 19 of P.L.1992, c.160 (C.26:2H-7a) is amended to read as follows:

19. Notwithstanding the provisions of section 7 of P.L.1971, c.136 (C.26:2H-7) to the contrary, the following are exempt from the certificate of need requirement:

Community-based primary care centers;

Outpatient drug and alcohol services;

Hospital-based medical detoxification for drugs and alcohol;

Ambulance and invalid coach services;

Mental health services which are non-bed related outpatient services;

Full service diagnostic catheterization services, primary angioplasty services, and elective angioplasty services in accordance with a license issued under section 2 of P.L. , c. (C.) (pending before the Legislature as this bill);

Residential health care facility services;

Dementia care homes;

Capital improvements and renovations to health care facilities;

Additions of medical/surgical, adult intensive care and adult critical care beds in hospitals;

Inpatient special psychiatric beds used solely for services for patients with co-occurring mental health and substance use disorders;

Replacement of existing major moveable equipment;

Inpatient operating rooms;

Alternate family care programs;

Hospital-based subacute care;

Ambulatory care facilities;

Comprehensive outpatient rehabilitation services;

Special child health clinics;

New technology in accordance with the provisions of section 18 of P.L.1998, c.43 (C.26:2H-7d);

Transfer of ownership interest except in the case of an acute care hospital;

Change of site for approved certificate of need within the same county;

Additions to vehicles or hours of operation of a mobile intensive care unit;

Relocation or replacement of a health care facility within the same county, except for an acute care hospital;

Continuing care retirement communities authorized pursuant to P.L.1986, c.103 (C.52:27D-330 et seq.);

Magnetic resonance imaging;

Adult day health care facilities;

Pediatric day health care facilities;

Chronic or acute renal dialysis facilities; and

Transfer of ownership of a hospital to an authority in accordance with P.L.2006, c.46 (C.30:9-23.15 et al.).
(cf: P.L.2017, c.94, s.1)

5. The Commissioner of Health may, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), adopt such rules and regulations as shall be necessary to implement the provisions of this act.

6. This act shall take effect on the 90th day after the date of enactment, except that the Commissioner of Health may take anticipatory administrative action in advance as shall be necessary for the implementation of the provisions of this act.