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

CURRENT VERSION OF TEXT
As reported by the Assembly Appropriations Committee on May 20, 2019, with amendments.

(Sponsorship Updated As Of: 5/24/2019)
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 this act:
   “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 this act.
   “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 providing invasive cardiac diagnostic services to adult patients, without cardiac surgery backup, equipped with laboratories, and performing at least 250 cardiac catheterizations annually.
   “Primary angioplasty” means an angioplasty or percutaneous coronary intervention performed on an acute or emergent basis.

2. (New section) a. An applicant hospital may apply to the commissioner for a license to provide full service diagnostic cardiac

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:
1Assembly AAP committee amendments adopted May 20, 2019.
catheterization services. The commissioner shall issue a license pursuant to such application to any hospital that is compliant with the following provisions:

(1) is not licensed as a cardiac surgery center;
(2) is licensed by the department to provide low-risk catheterization services;
(3) demonstrates the ability to provide full service diagnostic catheterization services consistent with national standards of care and current best practices;
(4) 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
(5) meets such other requirements as the commissioner may establish by regulation, including, but not limited to, participation in the Department of Health’s data collection programs and national registries to monitor quality and outcomes.

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 is compliant with the following provisions:

(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 diagnostic catheterization services;
(3) demonstrates the ability to provide primary angioplasty services 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 is compliant with the following provisions:

(1) is not licensed as a cardiac surgery center;
(2) holds licensure to participate in the C-PORTE 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 national standards of care and current best practices, including ensuring that all patients considered for elective angioplasty undergo careful selection, screening, and risk stratification as promulgated by the Department of Health, and ensuring that patients who do not meet such screening criteria are transferred to an appropriate cardiac 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 elective angioplasty procedures per year, with each interventional cardiologist performing at least 75 elective angioplasty procedures per year; and

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

d. The commissioner may waive any requirement for licensure established pursuant to this section based on the applicant hospital’s request to waive specific rule provisions based on the applicant hospital’s special need or the applicant hospital’s special experience with cardiac and endovascular catheterizations.

(1) An application shall state specific circumstances that support the need for a waiver including, but not limited to, circumstances that support the need for a waiver; information and data sufficient to support a waiver; the duration of the requested waiver; and, the ability to comply with the Department of Health’s requirement to provide access to the highest quality health care services.

(2) An applicant hospital may request a waiver based on documented and continued accreditation such as the Accreditation for Cardiovascular Excellence Standards Platinum level or by a national organization or association that meet similar standards specific to cardiac catheterization and percutaneous coronary intervention. Licensed facilities that seek accreditation shall provide the Department of Health with access to reports, site visits, site visit reviews, any notice related to compliance standards and notices related to change of accreditation status.

e. Unlawful acts committed by a recipient of a license issued in accordance with the provisions of this act may result in fines imposed by the Department of Health, the revocation or suspension of the license, or other lawful remedies. The Department of Health may revoke the license of a hospital authorized to provide any cardiac service, including elective angioplasty, which fails to comply with licensing requirements and facility volume requirements, within two years of licensing.

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 Department of Health’s data collection programs and 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 such as the Accreditation for Cardiovascular Excellence or by a national organization or association that meet similar standards specific to cardiac catheterization and percutaneous coronary intervention.
Licensed facilities that seek accreditation shall provide the Department of Health 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 impose a nonrefundable application fee in the amount of $5,000. The commissioner shall from time to time fix application fees and license fees imposed under the provisions of this act.¹

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 ¹included with the informed consent form¹ 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 ¹including transportation and associated charges for transportation,¹ 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.).

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 [immediately] on the 60th 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.