

[First Reprint]

SENATE, No. 2427

STATE OF NEW JERSEY
218th LEGISLATURE

INTRODUCED APRIL 5, 2018

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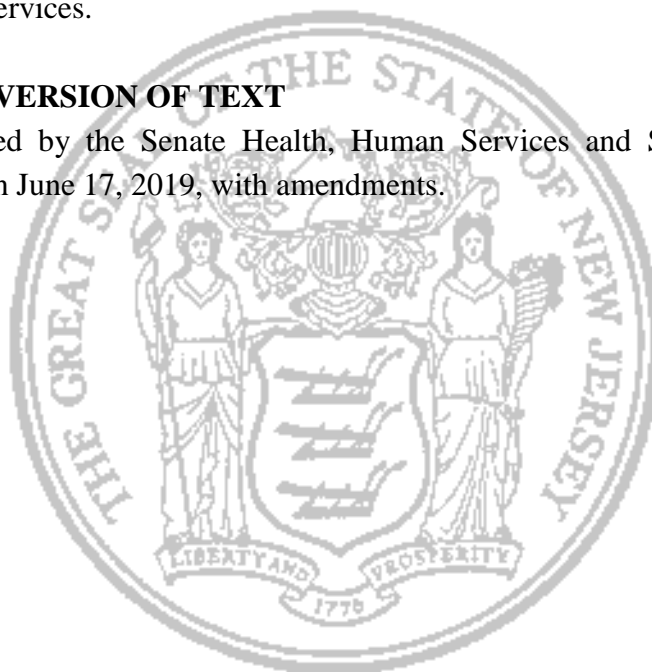
Senators Doherty, Bateman and A.R.Bucco

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 June 17, 2019, with amendments.



(Sponsorship Updated As Of: 6/14/2019)

1 AN ACT concerning hospital licensure to perform certain cardiac
2 procedures, amending P.L.1992, c.160, and supplementing Title
3 26 of the Revised Statutes.

4
5 **BE IT ENACTED** *by the Senate and General Assembly of the State*
6 *of New Jersey:*

7
8 1. (New section) As used in this act:

9 “Angioplasty” or “percutaneous coronary intervention” means
10 the mechanical reopening of an occluded vessel in the heart or
11 corona using a balloon-tipped catheter.

12 “Applicant hospital” means a general hospital that has entered
13 into a collaboration agreement with a cardiac surgery center
14 licensed in New Jersey.

15 ¹“Application” means all information required by the
16 commissioner of an applicant hospital to determine compliance with
17 this act.¹

18 “C-PORT-E study” means the Atlantic Cardiovascular Patient
19 Outcomes Research Team Elective Angioplasty Study clinical trial.

20 “Collaboration agreement” means an agreement between a
21 licensed cardiac surgery center and a general hospital that includes:

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

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

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

31 “Commissioner” means the Commissioner of Health.

32 “Department” means the Department of Health.

33 “Elective angioplasty” means an angioplasty or percutaneous
34 coronary intervention performed on a non-emergent basis.

35 ¹“Full service adult diagnostic cardiac catheterization facility”
36 means an acute care general hospital that provides invasive cardiac
37 diagnostic services to adult patients without cardiac surgery backup,
38 is equipped with laboratories, and performs at least 250 cardiac
39 catheterizations each year.¹

40 “Primary angioplasty” means an angioplasty or percutaneous
41 coronary intervention performed on an acute or emergent basis.

42
43 2. (New section) a. An applicant hospital may apply to the
44 commissioner for a license to provide full service ¹adult¹ diagnostic

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:

¹Senate SHH committee amendments adopted June 17, 2019.

1 cardiac catheterization services. The commissioner shall issue a
2 license pursuant to such application to any hospital that:

- 3 (1) is not licensed as a cardiac surgery center;
- 4 (2) ¹is licensed by the department to provide low-risk
5 catheterization services;
- 6 (3) ¹demonstrates the ability to provide full service ¹adult¹
7 diagnostic catheterization services consistent with national
8 standards of care and current best practices;
- 9 ¹[(4)] (3)¹ commencing in the second year of licensure pursuant
10 to this subsection, and in each year thereafter, performs at least 250
11 catheterizations per year, with each interventional cardiologist
12 performing at least 50 catheterizations per year; and
- 13 ¹[(5)] (4)¹ meets such other requirements as the commissioner
14 may establish by regulation ¹including, but not limited to,
15 participating in the department's data collection programs and in
16 national registries such as the National Cardiovascular Data
17 Registry to monitor quality, outcomes, and compliance with State
18 regulations¹.

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

- 23 (1) is not licensed as a cardiac surgery center;
- 24 (2) has been licensed for at least six months pursuant to
25 subsection a. of this section to provide full service ¹adult¹
26 diagnostic catheterization services;
- 27 (3) demonstrates the ability to ¹consistently¹ provide primary
28 angioplasty services ¹24 hour per day and seven days per week,¹
29 consistent with national standards of care and current best practices;
30 and
- 31 (4) meets such other requirements as the commissioner may
32 establish by regulation.

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

- 37 (1) is not licensed as a cardiac surgery center;
- 38 (2) holds licensure to participate in the C-PORT-E study or the
39 Elective Angioplasty Demonstration Project, or is an applicant
40 hospital licensed by the department to provide primary angioplasty
41 services pursuant to subsection b. of this section;
- 42 (3) demonstrates the ability to provide elective angioplasty
43 services consistent with ¹the provisions of N.J.A.C.8:33-3.11 or any
44 successor regulation, as well as¹ national standards of care and
45 current best practices ¹, including ensuring that all patients
46 considered for elective angioplasty undergo careful selection,
47 screening, and risk stratification pursuant to requirements

1 promulgated by the department by regulation, and ensuring that
2 patients who do not meet such screening criteria are transferred to
3 an appropriate surgery facility for elective angioplasty¹ ;

4 (4) commencing in the second year of licensure pursuant to this
5 subsection, and in each year thereafter, performs a minimum of 200
6 ¹~~elective~~ angioplasty procedures per year, with each
7 interventional cardiologist performing at least ¹~~75 elective~~ 50¹
8 angioplasty procedures per year; and

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

11 d. ¹~~The commissioner may waive any requirement for~~
12 ~~licensure established pursuant to this section based on the applicant~~
13 ~~hospital's special need or the applicant hospital's special experience~~
14 ~~with cardiac and endovascular catheterizations.] (1) A hospital~~
15 ~~issued a license pursuant to subsection a. or b. of this section that~~
16 ~~fails to meet the qualification requirements for that license shall be~~
17 ~~subject to corrective administrative action or other remedial action~~
18 ~~as the commissioner may establish by regulation, including, but not~~
19 ~~limited to, submitted a corrective action plan to the department for~~
20 ~~approval and meeting any benchmarks or deadlines for compliance~~
21 ~~as may be required by the department.~~

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

40 e. The department may impose fines, suspend or revoke a
41 license, or impose other lawful remedies against any entity issued a
42 license pursuant to this section that violates any of the requirements
43 of this section. Subject to the provisions of subsection d. of this
44 section, the department may revoke the license of a hospital
45 authorized to provide any cardiac service, including elective
46 angioplasty, which fails to comply with the licensing requirements

1 set forth in this section related to that license, including facility
2 volume requirements, within two years after the date of licensure.

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

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

19 g. The commissioner shall establish by regulation the
20 application and renewal fees for licenses issued pursuant to this
21 section, including a nonrefundable fee for initial licensure in the
22 amount of at least \$5,000.¹

23
24 3. (New section) Prior to performing any procedure authorized
25 under a license issued pursuant to section 2 of P.L. , c. (C.)
26 (pending before the Legislature as this bill), the applicant hospital
27 shall furnish the following information to the patient and afford the
28 patient the opportunity to review and consider such information
29 before being asked to consent in writing to the procedure:

30 a. notice ¹included with the informed consent form¹ that the
31 procedure is not being performed at a licensed cardiac surgery
32 center, and in the event that the patient requires emergency cardiac
33 surgery, the patient will be transferred to a licensed cardiac surgery
34 center; and

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

40 The applicant hospital shall, upon request, furnish the patient
41 with a written copy of the hospital's transfer protocols ¹, including
42 transportation and associated charges for transportation,¹ and a
43 summary of the collaboration agreement.

44
45 4. Section 19 of P.L.1992, c.160 (C.26:2H-7a) is amended to
46 read as follows:

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

4 Community-based primary care centers;

5 Outpatient drug and alcohol services;

6 Hospital-based medical detoxification for drugs and alcohol;

7 Ambulance and invalid coach services;

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

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

14 Residential health care facility services;

15 Dementia care homes;

16 Capital improvements and renovations to health care facilities;

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

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

22 Replacement of existing major moveable equipment;

23 Inpatient operating rooms;

24 Alternate family care programs;

25 Hospital-based subacute care;

26 Ambulatory care facilities;

27 Comprehensive outpatient rehabilitation services;

28 Special child health clinics;

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

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

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

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

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

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

41 Magnetic resonance imaging;

42 Adult day health care facilities;

43 Pediatric day health care facilities;

44 Chronic or acute renal dialysis facilities; and

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

47 (cf: P.L.2017, c.94, s.1)

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

5

6 6. This act shall take effect ¹**immediately** on the 90th day
7 after the date of enactment, except that the Commissioner of Health
8 may take anticipatory administrative action in advance as shall be
9 necessary for the implementation of the provisions of this act¹ .