

ASSEMBLY COMMITTEE SUBSTITUTE FOR
ASSEMBLY, No. 1176

STATE OF NEW JERSEY
219th LEGISLATURE

ADOPTED JANUARY 27, 2020

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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

Substitute as adopted by the Assembly Health Committee.



(Sponsorship Updated As Of: 12/17/2020)

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 P.L. , c. (C.) (pending
9 before the Legislature as this bill):

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

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

16 “Application” means all information required by the
17 commissioner of an applicant hospital to determine compliance with
18 P.L. , c. (C.) (pending before the Legislature as this bill).

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

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

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

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

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

32 “Commissioner” means the Commissioner of Health.

33 “Department” means the Department of Health.

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

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

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

43
44 2. (New section) a. An applicant hospital may apply to the
45 commissioner for a license to provide full service adult 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.

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

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

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

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

- 34 (1) is not licensed as a cardiac surgery center;
- 35 (2) holds licensure to participate in the C-PORT-E study or the
36 Elective Angioplasty Demonstration Project, or is an applicant
37 hospital licensed by the department to provide primary angioplasty
38 services pursuant to subsection b. of this section;
- 39 (3) demonstrates the ability to provide elective angioplasty
40 services consistent with the provisions of N.J.A.C.8:33-3.11 or any
41 successor regulation, as well as national standards of care and
42 current best practices, including ensuring that all patients
43 considered for elective angioplasty undergo careful selection,
44 screening, and risk stratification pursuant to requirements
45 promulgated by the department by regulation, and ensuring that
46 patients who do not meet such screening criteria are transferred to
47 an appropriate cardiac surgery facility for elective angioplasty;
- 48 (4) commencing in the second year of licensure pursuant to this
49 subsection, and in each year thereafter, performs a minimum of 200

1 angioplasty procedures per year, with each interventional
2 cardiologist performing at least 50 angioplasty procedures per year;
3 and

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

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

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

32 e. The department may impose fines, suspend or revoke a
33 license, require corrective administrative action or other remedial
34 action, including requiring submission of a corrective action plan,
35 or impose other lawful remedies against any entity issued a license
36 pursuant to this section that violates any of the requirements of this
37 section. Subject to the provisions of subsection d. of this section,
38 the department may revoke the license of a hospital authorized to
39 provide any cardiac service, including elective angioplasty, which
40 fails to comply with the licensing requirements set forth in this
41 section related to that license, including facility volume
42 requirements, within two years after the date of licensure.

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

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

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

14

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

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

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

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

35

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

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

41 Community-based primary care centers;

42 Outpatient drug and alcohol services;

43 Hospital-based medical detoxification for drugs and alcohol;

44 Ambulance and invalid coach services;

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

47 Full service diagnostic catheterization services, primary
48 angioplasty services, and elective angioplasty services in

1 accordance with a license issued under section 2 of
2 P.L. , c. (C.) (pending before the Legislature as this bill);
3 Residential health care facility services;
4 Dementia care homes;
5 Capital improvements and renovations to health care facilities;
6 Additions of medical/surgical, adult intensive care and adult
7 critical care beds in hospitals;
8 Inpatient special psychiatric beds used solely for services for
9 patients with co-occurring mental health and substance use
10 disorders;
11 Replacement of existing major moveable equipment;
12 Inpatient operating rooms;
13 Alternate family care programs;
14 Hospital-based subacute care;
15 Ambulatory care facilities;
16 Comprehensive outpatient rehabilitation services;
17 Special child health clinics;
18 New technology in accordance with the provisions of section 18
19 of P.L.1998, c.43 (C.26:2H-7d);
20 Transfer of ownership interest except in the case of an acute care
21 hospital;
22 Change of site for approved certificate of need within the same
23 county;
24 Additions to vehicles or hours of operation of a mobile intensive
25 care unit;
26 Relocation or replacement of a health care facility within the
27 same county, except for an acute care hospital;
28 Continuing care retirement communities authorized pursuant to
29 P.L.1986, c.103 (C.52:27D-330 et seq.);
30 Magnetic resonance imaging;
31 Adult day health care facilities;
32 Pediatric day health care facilities;
33 Chronic or acute renal dialysis facilities; and
34 Transfer of ownership of a hospital to an authority in accordance
35 with P.L.2006, c.46 (C.30:9-23.15 et al.).
36 (cf: P.L.2017, c.94, s.1)
37
38 5. The Commissioner of Health may, pursuant to the
39 “Administrative Procedure Act,” P.L.1968, c.410 (C.52:14B-1 et
40 seq.), adopt such rules and regulations as shall be necessary to
41 implement the provisions of this act.
42
43 6. This act shall take effect on the 90th day after the date of
44 enactment, except that the Commissioner of Health may take
45 anticipatory administrative action in advance as shall be necessary
46 for the implementation of the provisions of this act.