

SENATE, No. 515

STATE OF NEW JERSEY 219th LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2020 SESSION

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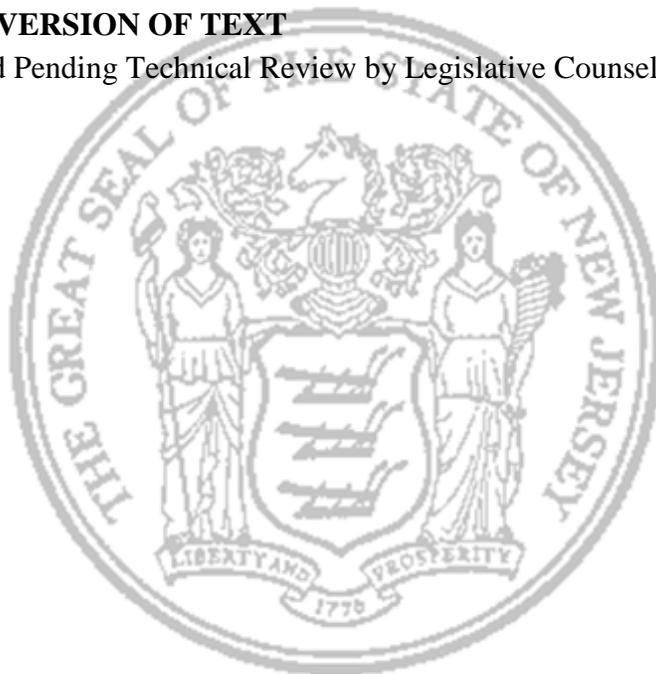
Senators Doherty and Bateman

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

Introduced Pending Technical Review by Legislative Counsel.



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

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 “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.

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 adult diagnostic
45 cardiac catheterization services. The commissioner shall issue a
46 license pursuant to such application to any hospital that:

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

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 (2) demonstrates the ability to provide full service adult
2 diagnostic catheterization services consistent with national
3 standards of care and current best practices;
- 4 (3) commencing in the second year of licensure pursuant to this
5 subsection, and in each year thereafter, performs at least 250
6 catheterizations per year, with each interventional cardiologist
7 performing at least 50 catheterizations per year; and
- 8 (4) meets such other requirements as the commissioner may
9 establish by regulation including, but not limited to, participating in
10 the department's data collection programs and in national registries
11 such as the National Cardiovascular Data Registry to monitor
12 quality, outcomes, and compliance with State regulations.
- 13 b. An applicant hospital may apply to the commissioner for a
14 license to provide primary angioplasty services. The commissioner
15 shall issue a license pursuant to such application to any hospital
16 that:
- 17 (1) is not licensed as a cardiac surgery center;
- 18 (2) has been licensed for at least six months pursuant to
19 subsection a. of this section to provide full service adult diagnostic
20 catheterization services;
- 21 (3) demonstrates the ability to consistently provide primary
22 angioplasty services 24 hour per day and seven days per week,
23 consistent with national standards of care and current best practices;
24 and
- 25 (4) meets such other requirements as the commissioner may
26 establish by regulation.
- 27 c. An applicant hospital may apply to the commissioner for a
28 license to provide elective angioplasty services. The commissioner
29 shall issue a license pursuant to such application to any hospital
30 that:
- 31 (1) is not licensed as a cardiac surgery center;
- 32 (2) holds licensure to participate in the C-PORT-E study or the
33 Elective Angioplasty Demonstration Project, or is an applicant
34 hospital licensed by the department to provide primary angioplasty
35 services pursuant to subsection b. of this section;
- 36 (3) demonstrates the ability to provide elective angioplasty
37 services consistent with the provisions of N.J.A.C.8:33-3.11 or any
38 successor regulation, as well as national standards of care and
39 current best practices, including ensuring that all patients
40 considered for elective angioplasty undergo careful selection,
41 screening, and risk stratification pursuant to requirements
42 promulgated by the department by regulation, and ensuring that
43 patients who do not meet such screening criteria are transferred to
44 an appropriate surgery facility for elective angioplasty;
- 45 (4) commencing in the second year of licensure pursuant to this
46 subsection, and in each year thereafter, performs a minimum of 200
47 angioplasty procedures per year, with each interventional

1 cardiologist performing at least 50 angioplasty procedures per year;
2 and

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

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

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

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

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

47 (2) A licensed cardiac surgery facility may request a waiver
48 based on documented and continued accreditation by the

1 Accreditation for Cardiovascular Excellence or by a national
2 organization or association that meets similar standards specific to
3 cardiac catheterization and percutaneous coronary intervention.
4 Licensed facilities that seek accreditation shall provide the
5 department with access to reports, site visits, site visit reviews, any
6 notice related to compliance standards and notices related to change
7 of accreditation status.

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

12

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

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

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

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

33

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

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

39 Community-based primary care centers;

40 Outpatient drug and alcohol services;

41 Hospital-based medical detoxification for drugs and alcohol;

42 Ambulance and invalid coach services;

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

45 Full service diagnostic catheterization services, primary
46 angioplasty services, and elective angioplasty services in

1 accordance with a license issued under section 2 of P.L. , c. (C.)
2 (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.

STATEMENT

1
2
3 This bill requires the Department of Health (DOH) to license
4 certain hospitals to provide full service adult diagnostic cardiac
5 catheterization, primary angioplasty, and elective angioplasty services.

6 Specifically, the bill provides that a hospital that is not a licensed
7 cardiac surgery center may apply to the Commissioner of Health:

8 • For a license to provide full service diagnostic cardiac
9 catheterization services, provided that, commencing in the second year
10 of licensure, and in each year thereafter, the hospital performs at least
11 250 catheterizations per year, with each interventional cardiologist
12 performing at least 50 catheterizations per year. In addition, the
13 hospital will be required to participate in the DOH's data collection
14 programs and in national registries to monitor quality, outcomes, and
15 compliance with State regulations;

16 • For a license to provide primary angioplasty services, which are
17 angioplasty procedures performed on an acute or emergency basis,
18 provided the hospital has been licensed to provide full service adult
19 diagnostic catheterization services under the bill for at least six
20 months; and

21 • For a license to provide elective angioplasty services, provided the
22 hospital is licensed to provide primary angioplasty services under the
23 bill or was licensed to participate in the Atlantic Cardiovascular
24 Patient Outcomes Research Team Elective Angioplasty Study (C-
25 PORT-E) clinical trial or the State Elective Angioplasty
26 Demonstration Project, and, commencing in the second year of
27 licensure, and in each year thereafter, performs a minimum of 200
28 elective angioplasty procedures per year, with each interventional
29 cardiologist performing at least 50 elective angioplasty procedures per
30 year. The hospital will additionally be required to ensure all
31 prospective elective angioplasty patients undergo careful selection,
32 screening, and risk stratification.

33 A hospital applying for licensure under the bill will be required to
34 enter into a collaboration agreement with a licensed cardiac surgery
35 center; the agreement is to include written protocols for transferring
36 patients requiring emergency cardiac surgery to the licensed cardiac
37 surgery center, regular consultation between the hospitals on
38 individual cases, and evidence of adequate cardiac surgery on-call
39 backup. Applicant hospitals will further be required to demonstrate
40 the ability to provide services consistent with national standards of
41 care and current best practices and to meet any other requirements
42 established by the commissioner by regulation. The commissioner
43 will be permitted to waive any requirement for licensure based on the
44 applicant hospital's special experience with cardiac and endovascular
45 catheterizations.

46 A hospital issued a license to provide elective angioplasty
47 procedures will have two years to meet the volume requirements for
48 that license as specified in the bill.

1 Any facility issued a license under the bill that fails to comply with
2 the qualification requirements for that license will be required to
3 submit a corrective action plan to the DOH and comply with any
4 benchmarks or deadline for compliance as the DOH may require. In
5 the case of a hospital issued a license to provide elective angioplasty
6 services that is subject to a corrective action plan, the hospital will
7 have two years to meet the requirements for licensure, including the
8 volume requirements set forth in the bill, or the hospital's license to
9 provide elective angioplasty services will be revoked. The DOH will
10 also be authorized to impose fines, suspend or revoke a license, or
11 impose other lawful remedies against a hospital issued any license
12 under the bill for a violation of the requirements of the bill.

13 Before providing services authorized pursuant to a license issued
14 under the bill or requesting written consent for the procedures, a
15 hospital will be required to ensure that patients receive, and have an
16 opportunity to review, written notice providing that the procedure is
17 not being performed at a licensed cardiac surgery center, the patient
18 will be transferred to a licensed cardiac surgery center in the event of
19 an emergency, and the name and location of the cardiac surgery center
20 with which the applicant hospital has entered into a collaboration
21 agreement. The hospital is to additionally provide patients, upon
22 request, with a written copy of the hospital's transfer protocols,
23 including transportation and associated charges for transportation, and
24 a summary of the collaboration agreement. The bill provides an
25 exception from the certificate of need requirement for diagnostic
26 catheterization and angioplasty services authorized by a license issued
27 under the bill.

28 Angioplasty, which is also known as percutaneous coronary
29 intervention, is a procedure used to widen clogged arteries and help
30 remove blockages, restoring blood flow and potentially reducing the
31 risk of an adverse cardiac event.