

[Second Reprint]

ASSEMBLY, No. 3769

STATE OF NEW JERSEY
218th LEGISLATURE

INTRODUCED APRIL 5, 2018

Sponsored by:

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District 16 (Hunterdon, Mercer, Middlesex and Somerset)

Assemblyman ROY FREIMAN

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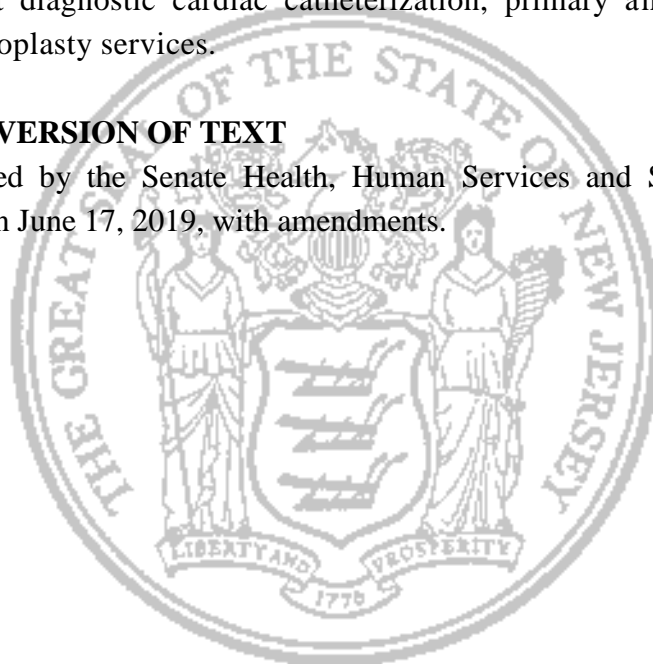
**Assemblywoman McKnight, Assemblymen Benson, DiMaio, Armato,
Peterson, Houghtaling, Space and Wirths**

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: 6/28/2019)

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 ²[Commissioner] commissioner² of an applicant hospital to
 17 determine compliance with 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 ²[providing] that provides²
 37 invasive cardiac diagnostic services to adult patients ²[.]² without
 38 cardiac surgery backup, ²is² equipped with laboratories, and
 39 ²[performing] performs² at least 250 cardiac catheterizations
 40 ²[annually] each year² .¹

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 ²adult² 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:

¹Assembly AAP committee amendments adopted May 20, 2019.

²Senate 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 ²is
3 compliant with the following provisions¹² :

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

5 (2) ²is licensed by the department to provide low-risk
6 catheterization services;

7 (3)² demonstrates the ability to provide full service ²adult²
8 diagnostic catheterization services consistent with national
9 standards of care and current best practices;

10 ²(4) (3)² commencing in the second year of licensure pursuant
11 to this subsection, and in each year thereafter, performs at least 250
12 catheterizations per year, with each interventional cardiologist
13 performing at least 50 catheterizations per year; and

14 ²(5) (4)² meets such other requirements as the commissioner
15 may establish by regulation ¹including, but not limited to,
16 participation in the ²[Department of Health's] department's² data
17 collection programs and ²in² national registries ²such as the
18 National Cardiovascular Data Registry² to monitor quality ²[and] ²
19 outcomes^{1 2}, and compliance with State regulations² .

20 b. An applicant hospital may apply to the commissioner for a
21 license to provide primary angioplasty services. The commissioner
22 shall issue a license pursuant to such application to any hospital that
23 ²is compliant with the following provisions¹² :

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

25 (2) has been licensed for at least six months pursuant to
26 subsection a. of this section to provide full service ²adult²
27 diagnostic catheterization services;

28 (3) demonstrates the ability to ²consistently² provide primary
29 angioplasty services ²24 hour per day and seven days per week,²
30 consistent with national standards of care and current best practices;
31 and

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

34 c. An applicant hospital may apply to the commissioner for a
35 license to provide elective angioplasty services. The commissioner
36 shall issue a license pursuant to such application to any hospital that
37 ²is compliant with the following provisions¹² :

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

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

43 (3) demonstrates the ability to provide elective angioplasty
44 services consistent with ²the provisions of N.J.A.C.8:33-3.11 or any
45 successor regulation, as well as² national standards of care and
46 current best practices ¹, including ensuring that all patients

1 considered for elective angioplasty undergo careful selection,
2 screening, and risk stratification ²[as promulgated by the
3 Department of Health] pursuant to requirements promulgated by
4 the department by regulation², and ensuring that patients who do
5 not meet such screening criteria are transferred to an appropriate
6 cardiac surgery facility for elective angioplasty¹ ;

7 (4) commencing in the second year of licensure pursuant to this
8 subsection, and in each year thereafter, performs a minimum of 200
9 ²[elective]² angioplasty procedures per year, with each
10 interventional cardiologist performing at least ¹[75] 50¹
11 ²[elective]² angioplasty procedures per year; and

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

14 d. ²[The commissioner may waive any requirement for
15 licensure established pursuant to this section based on ¹the
16 applicant hospital's request to waive specific rule provisions based
17 on¹ the applicant hospital's special need or the applicant hospital's
18 special experience with cardiac and endovascular catheterizations.

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

26 (2) An applicant hospital may request a waiver based on
27 documented and continued accreditation such as the Accreditation
28 for Cardiovascular Excellence Standards Platinum level or by a
29 national organization or association that meet similar standards
30 specific to cardiac catheterization and percutaneous coronary
31 intervention. Licensed facilities that seek accreditation shall
32 provide the Department of Health with access to reports, site visits,
33 site visit reviews, any notice related to compliance standards and
34 notices related to change of accreditation status] (1) A hospital
35 issued a license pursuant to subsection a. or b. of this section that
36 fails to meet the qualification requirements for that license shall be
37 subject to corrective administrative action or other remedial action
38 as the commissioner may establish by regulation, including, but not
39 limited to, submitted a corrective action plan to the department for
40 approval and meeting any benchmarks or deadlines for compliance
41 as may be required by the department.

42 (2) A hospital issued a license pursuant to subsection c. of this
43 section shall have two years to meet the volume requirements set
44 forth in paragraph (4) of subsection c. of this section. A hospital
45 that fails to meet or maintain the qualification requirements for that
46 license, including the volume requirements set forth in paragraph
47 (4) of subsection c. of this section, shall be subject to corrective

1 administrative action or other remedial action as the commissioner
2 may establish by regulation, including, but not limited to,
3 submitting a corrective action plan to the department for approval
4 and meeting any benchmarks or deadlines for compliance as may be
5 required by the department. If a hospital that has entered into a
6 corrective action plan pursuant to this subsection fails to meet and
7 maintain the qualification requirements for a license issued pursuant
8 to subsection c. of this section, including attaining the volume
9 requirements set forth in paragraph (4) of subsection c. of this
10 subsection, within two years after the hospital enters into a
11 corrective action plan, the hospital's license issued pursuant to
12 subsection c. of this section shall be revoked².

13 e. ²Unlawful acts committed by a recipient of a license issued
14 in accordance with the provisions of this act may result in fines
15 imposed by the Department of Health, the revocation or suspension
16 of the license, or other lawful remedies. The Department of
17 Health ²The department may impose fines, suspend or revoke a
18 license, require corrective administrative action or other remedial
19 action, including requiring submission of a corrective action plan,
20 or impose other lawful remedies against any entity issued a license
21 pursuant to this section that violates any of the requirements of this
22 section. Subject to the provisions of subsection d. of this section,
23 the department² may revoke the license of a hospital authorized to
24 provide any cardiac service, including elective angioplasty, which
25 fails to comply with ²the² licensing requirements ²[and] licensing
26 requirements set forth in this section related to that license,
27 including² facility volume requirements, within two years ²[of
28 licensing] after the date of licensure².

29 f. (1) Diagnostic cardiac catheterization and angioplasty
30 programs in all cardiac surgery facilities shall meet such other
31 requirements as the commissioner may establish by regulation
32 including, but not limited to, participation in ²[Department of
33 Health's] department's² data collection programs and ²in² national
34 registries such as the National Cardiovascular Data Registry to
35 monitor quality, outcomes, and compliance with State regulations.

36 (2) A licensed cardiac surgery facility may request a waiver
37 based on documented and continued accreditation ²[such as] by²
38 the Accreditation for Cardiovascular Excellence or by a national
39 organization or association that ²[meet] meets² similar standards
40 specific to cardiac catheterization and percutaneous coronary
41 intervention. Licensed facilities that seek accreditation shall
42 provide the ²[Department of Health] department² with access to
43 reports, site visits, site visit reviews, any notice related to
44 compliance standards and notices related to change of accreditation
45 status.

46 g. The commissioner shall ²[impose a nonrefundable
47 application fee in the amount of \$5,000. The commissioner shall

1 from time to time fix application fees and license fees imposed
 2 under the provisions of this act] establish by regulation the
 3 application and renewal fees for licenses issued pursuant to this
 4 section, including a nonrefundable fee for initial licensure in the
 5 amount of at least \$5,000² .¹
 6

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

13 a. notice ²[¹inlcuded] included² with the informed consent
 14 form¹ that the procedure is not being performed at a licensed
 15 cardiac surgery center, and in the event that the patient requires
 16 emergency cardiac surgery, the patient will be transferred to a
 17 licensed cardiac surgery center; and

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

23 The applicant hospital shall, upon request, furnish the patient
 24 with a written copy of the hospital's transfer protocols ¹, including
 25 transportation and associated charges for transportation,¹ and a
 26 summary of the collaboration agreement.
 27

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

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

- 33 Community-based primary care centers;
- 34 Outpatient drug and alcohol services;
- 35 Hospital-based medical detoxification for drugs and alcohol;
- 36 Ambulance and invalid coach services;
- 37 Mental health services which are non-bed related outpatient
- 38 services;
- 39 Full service diagnostic catheterization services, primary
 40 angioplasty services, and elective angioplasty services in
 41 accordance with a license issued under section 2 of
 42 P.L. , c. (C.) (pending before the Legislature as this bill);
- 43 Residential health care facility services;
- 44 Dementia care homes;
- 45 Capital improvements and renovations to health care facilities;
- 46 Additions of medical/surgical, adult intensive care and adult
- 47 critical care beds in hospitals;

1 Inpatient special psychiatric beds used solely for services for
2 patients with co-occurring mental health and substance use
3 disorders;
4 Replacement of existing major moveable equipment;
5 Inpatient operating rooms;
6 Alternate family care programs;
7 Hospital-based subacute care;
8 Ambulatory care facilities;
9 Comprehensive outpatient rehabilitation services;
10 Special child health clinics;
11 New technology in accordance with the provisions of section 18
12 of P.L.1998, c.43 (C.26:2H-7d);
13 Transfer of ownership interest except in the case of an acute care
14 hospital;
15 Change of site for approved certificate of need within the same
16 county;
17 Additions to vehicles or hours of operation of a mobile intensive
18 care unit;
19 Relocation or replacement of a health care facility within the
20 same county, except for an acute care hospital;
21 Continuing care retirement communities authorized pursuant to
22 P.L.1986, c.103 (C.52:27D-330 et seq.);
23 Magnetic resonance imaging;
24 Adult day health care facilities;
25 Pediatric day health care facilities;
26 Chronic or acute renal dialysis facilities; and
27 Transfer of ownership of a hospital to an authority in accordance
28 with P.L.2006, c.46 (C.30:9-23.15 et al.).
29 (cf: P.L.2017, c.94, s.1)

30
31 5. The Commissioner of Health may, pursuant to the
32 “Administrative Procedure Act,” P.L.1968, c.410 (C.52:14B-1 et
33 seq.), adopt such rules and regulations as shall be necessary to
34 implement the provisions of this act.
35

36 6. This act shall take effect ¹[immediately] on the ²[60th]
37 90th² day after the date of enactment ^{2, 2} except that the
38 Commissioner of Health may take anticipatory administrative
39 action in advance as shall be necessary for the implementation of
40 the provisions of this act¹.