

[First Reprint]

**ASSEMBLY, No. 3769**

**STATE OF NEW JERSEY**  
**218th LEGISLATURE**

INTRODUCED APRIL 5, 2018

**Sponsored by:**

**Assemblyman ANDREW ZWICKER**

**District 16 (Hunterdon, Mercer, Middlesex and Somerset)**

**Assemblyman ROY FREIMAN**

**District 16 (Hunterdon, Mercer, Middlesex and Somerset)**

**Assemblywoman JOANN DOWNEY**

**District 11 (Monmouth)**

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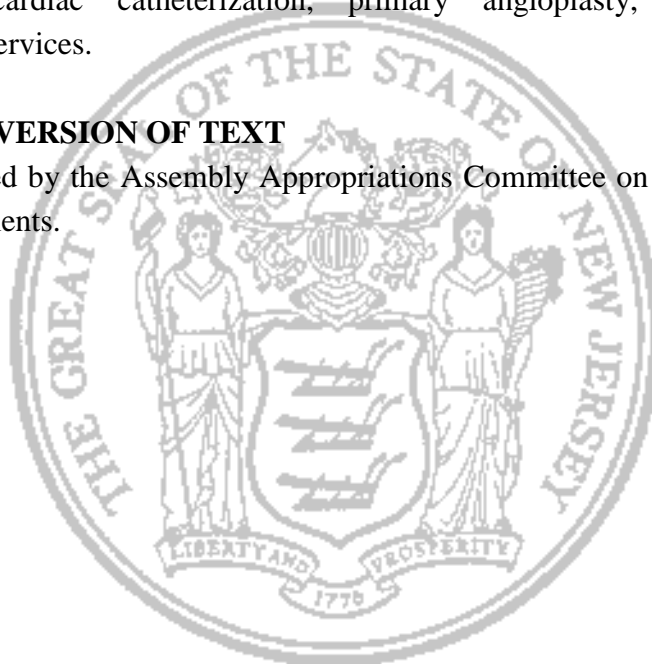
**Assemblywoman McKnight, Assemblymen Benson, DiMaio, Armato,  
Peterson and Houghtaling**

**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)**

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 <sup>1</sup>“Application” means all information required by the  
16 Commissioner of an applicant hospital to determine compliance  
17 with this act.<sup>1</sup>

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 <sup>1</sup>“Full service adult diagnostic cardiac catheterization facility”  
36 means an acute care general hospital providing invasive cardiac  
37 diagnostic services to adult patients, without cardiac surgery  
38 backup, equipped with laboratories, and performing at least 250  
39 cardiac catheterizations annually.<sup>1</sup>

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 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:

<sup>1</sup>Assembly AAP committee amendments adopted May 20, 2019.

1 catheterization services. The commissioner shall issue a license  
2 pursuant to such application to any hospital that <sup>1</sup>is compliant with  
3 the following provisions<sup>1</sup>:

- 4 (1) is not licensed as a cardiac surgery center;
- 5 (2) is licensed by the department to provide low-risk  
6 catheterization services;
- 7 (3) demonstrates the ability to provide full service diagnostic  
8 catheterization services consistent with national standards of care  
9 and current best practices;
- 10 (4) commencing in the second year of licensure pursuant to this  
11 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 (5) meets such other requirements as the commissioner may  
15 establish by regulation <sup>1</sup>including, but not limited to, participation  
16 in the Department of Health's data collection programs and national  
17 registries to monitor quality and outcomes<sup>1</sup>.

18 b. An applicant hospital may apply to the commissioner for a  
19 license to provide primary angioplasty services. The commissioner  
20 shall issue a license pursuant to such application to any hospital that  
21 <sup>1</sup>is compliant with the following provisions<sup>1</sup>:

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

31 c. An applicant hospital may apply to the commissioner for a  
32 license to provide elective angioplasty services. The commissioner  
33 shall issue a license pursuant to such application to any hospital that  
34 <sup>1</sup>is compliant with the following provisions<sup>1</sup>:

- 35 (1) is not licensed as a cardiac surgery center;
- 36 (2) holds licensure to participate in the C-PORT-E study or the  
37 Elective Angioplasty Demonstration Project, or is an applicant  
38 hospital licensed by the department to provide primary angioplasty  
39 services pursuant to subsection b. of this section;
- 40 (3) demonstrates the ability to provide elective angioplasty  
41 services consistent with national standards of care and current best  
42 practices <sup>1</sup>, including ensuring that all patients considered for  
43 elective angioplasty undergo careful selection, screening, and risk  
44 stratification as promulgated by the Department of Health, and  
45 ensuring that patients who do not meet such screening criteria are  
46 transferred to an appropriate cardiac surgery facility for elective  
47 angioplasty<sup>1</sup>;

1 (4) commencing in the second year of licensure pursuant to this  
2 subsection, and in each year thereafter, performs a minimum of 200  
3 elective angioplasty procedures per year, with each interventional  
4 cardiologist performing at least <sup>1</sup>~~75~~ 50<sup>1</sup> elective angioplasty  
5 procedures per year; and

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

8 d. The commissioner may waive any requirement for licensure  
9 established pursuant to this section based on <sup>1</sup>~~the applicant~~  
10 hospital's request to waive specific rule provisions based on<sup>1</sup> the  
11 applicant hospital's special need or the applicant hospital's special  
12 experience with cardiac and endovascular catheterizations.

13 <sup>1</sup>(1) An application shall state specific circumstances that  
14 support the need for a waiver including, but not limited to,  
15 circumstances that support the need for a waiver; information and  
16 data sufficient to support a waiver; the duration of the requested  
17 waiver; and, the ability to comply with the Department of Health's  
18 requirement to provide access to the highest quality health care  
19 services.

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

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

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

44 (2) A licensed cardiac surgery facility may request a waiver  
45 based on documented and continued accreditation such as the  
46 Accreditation for Cardiovascular Excellence or by a national  
47 organization or association that meet similar standards specific to  
48 cardiac catheterization and percutaneous coronary intervention.

1 Licensed facilities that seek accreditation shall provide the  
2 Department of Health with access to reports, site visits, site visit  
3 reviews, any notice related to compliance standards and notices  
4 related to change of accreditation status.

5 g. The commissioner shall impose a nonrefundable application  
6 fee in the amount of \$5,000. The commissioner shall from time to  
7 time fix application fees and license fees imposed under the  
8 provisions of this act.<sup>1</sup>

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

16 a. notice <sup>1</sup>included with the informed consent form<sup>1</sup> that the  
17 procedure is not being performed at a licensed cardiac surgery  
18 center, and in the event that the patient requires emergency cardiac  
19 surgery, the patient will be transferred to a licensed cardiac surgery  
20 center; and

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

26 The applicant hospital shall, upon request, furnish the patient  
27 with a written copy of the hospital's transfer protocols <sup>1</sup>, including  
28 transportation and associated charges for transportation,<sup>1</sup> and a  
29 summary of the collaboration agreement.

30  
31 4. Section 19 of P.L.1992, c.160 (C.26:2H-7a) is amended to  
32 read as follows:

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

36 Community-based primary care centers;

37 Outpatient drug and alcohol services;

38 Hospital-based medical detoxification for drugs and alcohol;

39 Ambulance and invalid coach services;

40 Mental health services which are non-bed related outpatient  
41 services;

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

46 Residential health care facility services;

47 Dementia care homes;

48 Capital improvements and renovations to health care facilities;

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

32

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

37

38 6. This act shall take effect <sup>1</sup>**【immediately】** on the 60th day  
39 after the date of enactment except that the Commissioner of Health  
40 may take anticipatory administrative action in advance as shall be  
41 necessary for the implementation of the provisions of this act<sup>1</sup>.