

# SENATE, No. 2427

## STATE OF NEW JERSEY 218th LEGISLATURE

INTRODUCED APRIL 5, 2018

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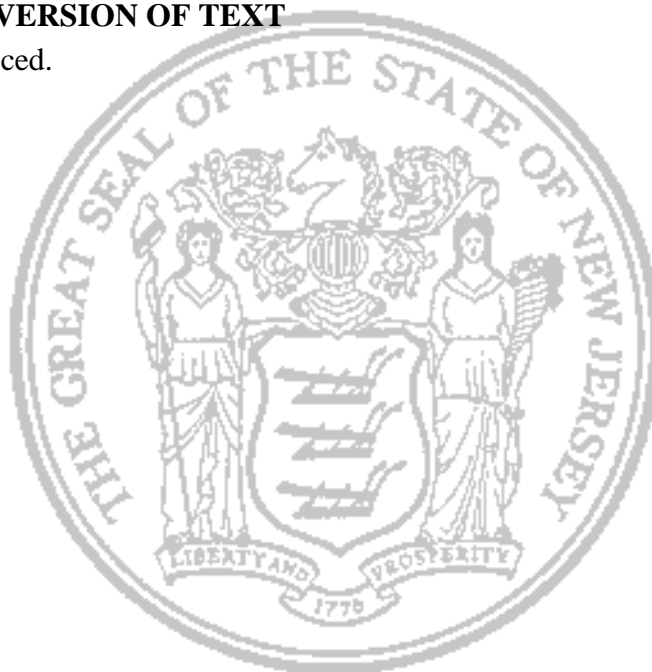
**Senators Doherty, Bateman and A.R.Bucco**

**SYNOPSIS**

Requires DOH to license certain qualifying hospitals to provide full service diagnostic cardiac catheterization, primary angioplasty, and elective angioplasty services.

**CURRENT VERSION OF TEXT**

As introduced.



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

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

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

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

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

28 “Commissioner” means the Commissioner of Health.

29 “Department” means the Department of Health.

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

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

34  
35 2. (New section) a. An applicant hospital may apply to the  
36 commissioner for a license to provide full service diagnostic cardiac  
37 catheterization services. The commissioner shall issue a license  
38 pursuant to such application to any hospital that:

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

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

42 (3) demonstrates the ability to provide full service diagnostic  
43 catheterization services consistent with national standards of care  
44 and current best practices;

45 (4) commencing in the second year of licensure pursuant to this  
46 subsection, and in each year thereafter, performs at least 250

**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 catheterizations per year, with each interventional cardiologist  
2 performing at least 50 catheterizations per year; and

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

5 b. An applicant hospital may apply to the commissioner for a  
6 license to provide primary angioplasty services. The commissioner  
7 shall issue a license pursuant to such application to any hospital  
8 that:

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

10 (2) has been licensed for at least six months pursuant to  
11 subsection a. of this section to provide full service diagnostic  
12 catheterization services;

13 (3) demonstrates the ability to provide primary angioplasty  
14 services consistent with national standards of care and current best  
15 practices; and

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

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

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

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

27 (3) demonstrates the ability to provide elective angioplasty  
28 services consistent with national standards of care and current best  
29 practices;

30 (4) commencing in the second year of licensure pursuant to this  
31 subsection, and in each year thereafter, performs a minimum of 200  
32 elective angioplasty procedures per year, with each interventional  
33 cardiologist performing at least 75 elective angioplasty procedures  
34 per year; and

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

37 d. The commissioner may waive any requirement for licensure  
38 established pursuant to this section based on the applicant hospital's  
39 special need or the applicant hospital's special experience with  
40 cardiac and endovascular catheterizations.

41

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

1 a. notice that the procedure is not being performed at a licensed  
2 cardiac surgery center, and in the event that the patient requires  
3 emergency cardiac surgery, the patient will be transferred to a  
4 licensed cardiac surgery center; and

5 b. details concerning the applicant hospital's plan and protocols  
6 for transferring patients who require emergency cardiac surgery,  
7 including the name and location of the cardiac surgery center with  
8 which the applicant hospital has entered into a collaboration  
9 agreement.

10 The applicant hospital shall, upon request, furnish the patient  
11 with a written copy of the hospital's transfer protocols and a  
12 summary of the collaboration agreement.

13

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

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

19 Community-based primary care centers;

20 Outpatient drug and alcohol services;

21 Hospital-based medical detoxification for drugs and alcohol;

22 Ambulance and invalid coach services;

23 Mental health services which are non-bed related outpatient  
24 services;

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

29 Residential health care facility services;

30 Dementia care homes;

31 Capital improvements and renovations to health care facilities;

32 Additions of medical/surgical, adult intensive care and adult  
33 critical care beds in hospitals;

34 Inpatient special psychiatric beds used solely for services for  
35 patients with co-occurring mental health and substance use  
36 disorders;

37 Replacement of existing major moveable equipment;

38 Inpatient operating rooms;

39 Alternate family care programs;

40 Hospital-based subacute care;

41 Ambulatory care facilities;

42 Comprehensive outpatient rehabilitation services;

43 Special child health clinics;

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

46 Transfer of ownership interest except in the case of an acute care  
47 hospital;

- 1 Change of site for approved certificate of need within the same
- 2 county;
- 3 Additions to vehicles or hours of operation of a mobile intensive
- 4 care unit;
- 5 Relocation or replacement of a health care facility within the
- 6 same county, except for an acute care hospital;
- 7 Continuing care retirement communities authorized pursuant to
- 8 P.L.1986, c.103 (C.52:27D-330 et seq.);
- 9 Magnetic resonance imaging;
- 10 Adult day health care facilities;
- 11 Pediatric day health care facilities;
- 12 Chronic or acute renal dialysis facilities; and
- 13 Transfer of ownership of a hospital to an authority in accordance
- 14 with P.L.2006, c.46 (C.30:9-23.15 et al.).
- 15 (cf: P.L.2017, c.94, s.1)

16

17 5. The Commissioner of Health may, pursuant to the

18 “Administrative Procedure Act,” P.L.1968, c.410 (C.52:14B-1 et

19 seq.), adopt such rules and regulations as shall be necessary to

20 implement the provisions of this act.

21

22 6. This act shall take effect immediately.

23

24 STATEMENT

25

26 This bill requires the Department of Health (DOH) to license

27 certain hospitals to provide full service diagnostic cardiac

28 catheterization, primary angioplasty, and elective angioplasty

29 services.

30 Specifically, the bill provides that a hospital that is not a licensed

31 cardiac surgery center may apply to the Commissioner of Health:

- 32 • For a license to provide full service diagnostic cardiac
- 33 catheterization services, provided the hospital is licensed by
- 34 DOH to provide low-risk catheterization services and,
- 35 commencing in the second year of licensure, and in each
- 36 year thereafter, performs at least 250 catheterizations per
- 37 year, with each interventional cardiologist performing at
- 38 least 50 catheterizations per year;
- 39 • For a license to provide primary angioplasty services, which
- 40 are angioplasty procedures performed on an acute or
- 41 emergency basis, provided the hospital has been licensed to
- 42 provide full service diagnostic catheterization services under
- 43 the bill for at least six months; and
- 44 • For a license to provide elective angioplasty services,
- 45 provided the hospital is licensed to provide primary
- 46 angioplasty services under the bill or was licensed to
- 47 participate in the Atlantic Cardiovascular Patient Outcomes
- 48 Research Team Elective Angioplasty Study (C-PORT-E)

1 clinical trial or the State Elective Angioplasty Demonstration  
2 Project, and, commencing in the second year of licensure,  
3 and in each year thereafter, performs a minimum of 200  
4 elective angioplasty procedures per year, with each  
5 interventional cardiologist performing at least 75 elective  
6 angioplasty procedures per year.

7 A hospital applying for licensure under the bill will be required  
8 to enter into a collaboration agreement with a licensed cardiac  
9 surgery center; the agreement is to include written protocols for  
10 transferring patients requiring emergency cardiac surgery to the  
11 licensed cardiac surgery center, regular consultation between the  
12 hospitals on individual cases, and evidence of adequate cardiac  
13 surgery on-call backup. Applicant hospitals will further be required  
14 to demonstrate the ability to provide services consistent with  
15 national standards of care and current best practices and to meet any  
16 other requirements established by the commissioner by regulation.  
17 The commissioner will be permitted to waive any requirement for  
18 licensure based on the applicant hospital's special need or the  
19 applicant hospital's special experience with cardiac and  
20 endovascular catheterizations.

21 Before providing services authorized pursuant to a license issued  
22 under the bill or requesting written consent for the procedures, a  
23 hospital will be required to ensure that patients receive, and have an  
24 opportunity to review, written notice providing that the procedure is  
25 not being performed at a licensed cardiac surgery center, the patient  
26 will be transferred to a licensed cardiac surgery center in the event  
27 of an emergency, and the name and location of the cardiac surgery  
28 center with which the applicant hospital has entered into a  
29 collaboration agreement. The hospital is to additionally provide  
30 patients, upon request, with a written copy of the hospital's transfer  
31 protocols and a summary of the collaboration agreement.

32 The bill provides an exception from the certificate of need  
33 requirement for diagnostic catheterization and angioplasty services  
34 authorized by a license issued under the bill.

35 Angioplasty, which is also known as percutaneous coronary  
36 intervention (PCI), is a procedure used to widen clogged arteries  
37 and help remove blockages, restoring blood flow and potentially  
38 reducing the risk of an adverse cardiac event. In 2012, the C-  
39 PORT-E study found that there is no increased risk of death or  
40 complications from an elective angioplasty procedure performed at  
41 a facility that does not have cardiac surgery capabilities, as  
42 compared with a licensed cardiac surgery center.

43 It is the sponsor's belief that expanding the number of facilities  
44 that are authorized to perform certain cardiac interventions,  
45 consistent with studies suggesting that these procedures can safely  
46 and routinely be performed outside of licensed cardiac surgery  
47 centers, will improve access to high quality cardiovascular care for  
48 patients throughout New Jersey.