

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)

Co-Sponsored by:

Assemblywoman McKnight, Assemblymen Benson, DiMaio, Armato and Peterson

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: 5/17/2019)

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;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

43

44 3. (New section) Prior to performing any procedure authorized
45 under a license issued pursuant to section 2 of P.L. , c. (C.)
46 (pending before the Legislature as this bill), the applicant hospital
47 shall furnish the following information to the patient and afford the

1 patient the opportunity to review and consider such information
2 before being asked to consent in writing to the procedure:

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

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

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

15

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

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

21 Community-based primary care centers;

22 Outpatient drug and alcohol services;

23 Hospital-based medical detoxification for drugs and alcohol;

24 Ambulance and invalid coach services;

25 Mental health services which are non-bed related outpatient
26 services;

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

31 Residential health care facility services;

32 Dementia care homes;

33 Capital improvements and renovations to health care facilities;

34 Additions of medical/surgical, adult intensive care and adult
35 critical care beds in hospitals;

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

39 Replacement of existing major moveable equipment;

40 Inpatient operating rooms;

41 Alternate family care programs;

42 Hospital-based subacute care;

43 Ambulatory care facilities;

44 Comprehensive outpatient rehabilitation services;

45 Special child health clinics;

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

1 angioplasty services under the bill or was licensed to
2 participate in the Atlantic Cardiovascular Patient Outcomes
3 Research Team Elective Angioplasty Study (C-PORT-E)
4 clinical trial or the State Elective Angioplasty Demonstration
5 Project, and, commencing in the second year of licensure,
6 and in each year thereafter, performs a minimum of 200
7 elective angioplasty procedures per year, with each
8 interventional cardiologist performing at least 75 elective
9 angioplasty procedures per year.

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

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

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

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

46 It is the sponsor's belief that expanding the number of facilities
47 that are authorized to perform certain cardiac interventions,
48 consistent with studies suggesting that these procedures can safely

- 1 and routinely be performed outside of licensed cardiac surgery
- 2 centers, will improve access to high quality cardiovascular care for
- 3 patients throughout New Jersey.