

P.L. 2021, CHAPTER 18, *approved February 22, 2021*  
Assembly Committee Substitute for  
Assembly, No. 1176

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 P.L.        , c.        (C.        ) (pending  
9        before the Legislature as this bill):

10        “Angioplasty” or “percutaneous coronary intervention” means  
11        the mechanical reopening of an occluded vessel in the heart or  
12        corona using a balloon-tipped catheter.

13        “Applicant hospital” means a general hospital that has entered  
14        into a collaboration agreement with a cardiac surgery center  
15        licensed in New Jersey.

16        “Application” means all information required by the  
17        commissioner of an applicant hospital to determine compliance with  
18        P.L.        , c.        (C.        ) (pending before the Legislature as this bill).

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

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

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

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

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

32        “Commissioner” means the Commissioner of Health.

33        “Department” means the Department of Health.

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

36        "Full service adult diagnostic cardiac catheterization facility"  
37        means an acute care general hospital that provides invasive cardiac  
38        diagnostic services to adult patients without cardiac surgery backup,

**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 is equipped with laboratories, and performs at least 250 cardiac  
2 catheterizations each year.

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

5

6 2. (New section) a. An applicant hospital may apply to the  
7 commissioner for a license to provide full service adult diagnostic  
8 cardiac catheterization services. The commissioner shall issue a  
9 license pursuant to such application to any hospital that:

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

11 (2) demonstrates the ability to provide full service adult  
12 diagnostic catheterization services consistent with national  
13 standards of care and current best practices;

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

18 (4) meets such other requirements as the commissioner may  
19 establish by regulation including, but not limited to, participation in  
20 the department’s data collection programs and in national registries  
21 such as the National Cardiovascular Data Registry to monitor  
22 quality, outcomes, and compliance with State regulations.

23 b. An applicant hospital may apply to the commissioner for a  
24 license to provide primary angioplasty services. The commissioner  
25 shall issue a license pursuant to such application to any hospital  
26 that:

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

28 (2) has been licensed for at least six months pursuant to  
29 subsection a. of this section to provide full service adult diagnostic  
30 catheterization services;

31 (3) demonstrates the ability to consistently provide primary  
32 angioplasty services 24 hour per day and seven days per week,  
33 consistent with national standards of care and current best practices;  
34 and

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

37 c. An applicant hospital may apply to the commissioner for a  
38 license to provide elective angioplasty services. The commissioner  
39 shall issue a license pursuant to such application to any hospital  
40 that:

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

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

46 (3) demonstrates the ability to provide elective angioplasty  
47 services consistent with the provisions of N.J.A.C.8:33-3.11 or any  
48 successor regulation, as well as national standards of care and

1 current best practices, including ensuring that all patients  
2 considered for elective angioplasty undergo careful selection,  
3 screening, and risk stratification pursuant to requirements  
4 promulgated by the department by regulation, and ensuring that  
5 patients who do not meet such screening criteria are transferred to  
6 an appropriate cardiac surgery facility for elective angioplasty;

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 angioplasty procedures per year, with each interventional  
10 cardiologist performing at least 50 angioplasty procedures per year;  
11 and

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

14 d. (1) A hospital issued a license pursuant to subsection a. or  
15 b. of this section that fails to meet the qualification requirements for  
16 that license shall be subject to corrective administrative action or  
17 other remedial action as the commissioner may establish by  
18 regulation, including, but not limited to, submitting a corrective  
19 action plan to the department for approval and meeting any  
20 benchmarks or deadlines for compliance as may be required by the  
21 department.

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

40 e. The department may impose fines, suspend or revoke a  
41 license, require corrective administrative action or other remedial  
42 action, including requiring submission of a corrective action plan,  
43 or impose other lawful remedies against any entity issued a license  
44 pursuant to this section that violates any of the requirements of this  
45 section. Subject to the provisions of subsection d. of this section,  
46 the department may revoke the license of a hospital authorized to  
47 provide any cardiac service, including elective angioplasty, which  
48 fails to comply with the licensing requirements set forth in this

1 section related to that license, including facility volume  
2 requirements, within two years after the date of licensure.

3 f. (1) Diagnostic cardiac catheterization and angioplasty  
4 programs in all cardiac surgery facilities shall meet such other  
5 requirements as the commissioner may establish by regulation  
6 including, but not limited to, participation in the department's data  
7 collection programs and in national registries such as the National  
8 Cardiovascular Data Registry to monitor quality, outcomes, and  
9 compliance with State regulations.

10 (2) A licensed cardiac surgery facility may request a waiver  
11 based on documented and continued accreditation by the  
12 Accreditation for Cardiovascular Excellence or by a national  
13 organization or association that meets similar standards specific to  
14 cardiac catheterization and percutaneous coronary intervention.  
15 Licensed facilities that seek accreditation shall provide the  
16 department with access to reports, site visits, site visit reviews, any  
17 notice related to compliance standards, and notices related to  
18 change of accreditation status.

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

23

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

30 a. notice included with the informed consent form that the  
31 procedure is not being performed at a licensed cardiac surgery  
32 center, and in the event that the patient requires emergency cardiac  
33 surgery, the patient will be transferred to a licensed cardiac surgery  
34 center; and

35 b. details concerning the applicant hospital's plan and protocols  
36 for transferring patients who require emergency cardiac surgery,  
37 including the name and location of the cardiac surgery center with  
38 which the applicant hospital has entered into a collaboration  
39 agreement.

40 The applicant hospital shall, upon request, furnish the patient  
41 with a written copy of the hospital's transfer protocols, including  
42 transportation and associated charges for transportation, and a  
43 summary of the collaboration agreement.

44

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

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

4 Community-based primary care centers;

5 Outpatient drug and alcohol services;

6 Hospital-based medical detoxification for drugs and alcohol;

7 Ambulance and invalid coach services;

8 Mental health services which are non-bed related outpatient  
9 services;

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

14 Residential health care facility services;

15 Dementia care homes;

16 Capital improvements and renovations to health care facilities;

17 Additions of medical/surgical, adult intensive care and adult  
18 critical care beds in hospitals;

19 Inpatient special psychiatric beds used solely for services for  
20 patients with co-occurring mental health and substance use  
21 disorders;

22 Replacement of existing major moveable equipment;

23 Inpatient operating rooms;

24 Alternate family care programs;

25 Hospital-based subacute care;

26 Ambulatory care facilities;

27 Comprehensive outpatient rehabilitation services;

28 Special child health clinics;

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

31 Transfer of ownership interest except in the case of an acute care  
32 hospital;

33 Change of site for approved certificate of need within the same  
34 county;

35 Additions to vehicles or hours of operation of a mobile intensive  
36 care unit;

37 Relocation or replacement of a health care facility within the  
38 same county, except for an acute care hospital;

39 Continuing care retirement communities authorized pursuant to  
40 P.L.1986, c.103 (C.52:27D-330 et seq.);

41 Magnetic resonance imaging;

42 Adult day health care facilities;

43 Pediatric day health care facilities;

44 Chronic or acute renal dialysis facilities; and

45 Transfer of ownership of a hospital to an authority in accordance  
46 with P.L.2006, c.46 (C.30:9-23.15 et al.).

47 (cf: P.L.2017, c.94, s.1)

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

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6       6. This act shall take effect on the 90th day after the date of  
7 enactment, except that the Commissioner of Health may take  
8 anticipatory administrative action in advance as shall be necessary  
9 for the implementation of the provisions of this act.

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