



State of New Jersey  
DEPARTMENT OF HEALTH  
PO BOX 360  
TRENTON, N.J. 08625-0360  
[www.nj.gov/health](http://www.nj.gov/health)

PHILIP D. MURPHY  
Governor

SHEILA Y. OLIVER  
Lt. Governor

JUDITH M. PERSICILLI, RN, BSN, MA  
Commissioner

To: General Hospitals Licensed Pursuant to N.J.A.C. 8:43G

From: Marcela Maziarz, MPH  
Deputy Commissioner *MM*

Date: July 6, 2021<sup>1</sup>

Re: Statutory Amendments to the licensing of cardiac services pursuant to P.L. 2021, c. 18

This memorandum is to advise you of the changes to the Department of Health's ("Department") licensing process for full-service adult diagnostic cardiac catheterization, primary angioplasty and elective angioplasty due to P.L. 2021, c. 18 ("Cardiac Law"). The Cardiac Law was signed on February 22, 2021 and takes effect on May 23, 2021.

Specifically, the Cardiac Law removes the requirement for an expedited review certificate of need for the licensure of full-service adult diagnostic cardiac catheterization facilities in N.J.A.C. 8:33 and primary angioplasty without on-site cardiac surgery backup in N.J.A.C. 8:33E. Effective May 23, 2021 general hospitals (facilities) meeting requirements set in the Cardiac Law and by the Department in regulation may submit a licensure application to add these services, as well as adult diagnostic cardiac catheterization services. The Cardiac Law authorizes the Commissioner to "take anticipatory administrative action in advance as shall be necessary for the implementation of the provisions of this Act."

The application process for the licensure of full-service adult diagnostic cardiac catheterization will follow the normal course for licensure of a new or additional service in an existing general acute care hospital. The licensure process is set forth in N.J.A.C. 8:43G-2.2, with specific requirements for cardiac services found in N.J.A.C. 8:43G-7.1, et seq.

The Cardiac Law also removes the requirement that a facility seeking licensure for elective angioplasty, without on-site cardiac surgery backup, must have participated in the C-PORT-E study via being awarded a Certificate of Need pursuant to the standards in N.J.A.C. 8:33. Pursuant to the Cardiac Law, any facility licensed for

---

<sup>1</sup> This revised memorandum replaces and supersedes the memorandum of the same name dated May 24, 2021.

primary angioplasty may apply to provide elective angioplasty services by submitting a licensure application to the Department. The Cardiac Law also requires that facilities currently participating in the C-PORT-E study apply for licensure. The deadline for C-PORT-E study facilities intending to continue to provide elective angioplasty to apply for licensure is July 23, 2021.

The Cardiac Law allows the Department to set data reporting requirements. Facilities that receive a new license to perform cardiac services or are already licensed for cardiac services must register and begin entering data into the National Cardiovascular Data Registry (<https://cvquality.acc.org/NCDR-Home>) into the CathPCI registry module (<https://cvquality.acc.org/NCDR-Home>) and must complete the waiver for publication of the data. Facilities already licensed for cardiac services must comply with this requirement by July 23, 2021.

### The Licensing Process

The license application process established by the Department for all three licenses requires the submission of the following:

1. A completed CN-7, Application for New or Amended Acute Care Facility License, which is available at <https://www.nj.gov/health/forms/cn-7.pdf> along with the \$5,000 fee to add the desired service; and
2. A project narrative which must include timeframes and phases for implementation with detailed descriptions on how the proposed service will be implemented, including but not limited to: location and number of catheterizations labs, recovery areas, patient criteria for service, including those considered high risk and excluded for service in accordance of with the type of cardiac service to be provided, and shall include either:
  - i. Architectural drawings if renovation/construction is necessary which shall require the Department of Community Affairs approval prior to work being started; or
  - ii. If no renovation/construction is required, schematics showing existing location(s) where the newly added service will be provided for the Department's review.
3. Documentation that demonstrates the facility has the ability to consistently provide the requested cardiac service 24 hours a day and seven days per week (unless the license sought is for diagnostic catheterization services);
4. As applicable to the cardiac service to be added, submission of a copy of a signed/dated contract/agreement with a referring facility that is licensed to provide full service cardiac surgical services; and

5. An acknowledgement of the facility's understanding and acceptance of regulatory and statutory criteria, including compliance with the standards for the service being licensed in N.J.A.C. 8:33E and 8:43G that are not affected by the Cardiac Law; and

6. Registration for and data reporting into the National Cardiovascular Data Registry.

#### Other Changes

The Law also makes the following changes to the applicable licensing categories:

#### I. Full-service adult diagnostic cardiac catheterization

1. The requirement for the number of adult diagnostic cardiac catheterizations is lowered from at least 400 a year to 250 a year.

2. A newly licensed facility shall have until the completion of the facility's fourth year of licensure to reach the 250 catheterizations a year requirement, with each interventional cardiologist performing at least 50 catheterization procedures per year in order for the Department to continue licensure of the facility.

#### II. Primary Angioplasty without On-site Cardiac Surgery Back-up

A general hospital seeking to be licensed for primary angioplasty without on-site cardiac surgery back-up may apply for licensure:

1. After being licensed for at least six months to provide full-service adult diagnostic catheterization services;

2. If it demonstrates the ability to consistently provide primary angioplasty services 24 hours per day and seven days per week, consistent with national standards of care and current best practices; and

3. Meets such other requirements as the commissioner may establish by regulation.

#### III. Elective Angioplasty without On-site Cardiac Surgery Back-up

1. Each interventionalist is to perform at least 50 cases per year instead of the current requirement of 75 cases.

2. Informed consent will require the hospital to furnish the following information to the patient and afford the patient the opportunity to review and consider such information before being asked to consent in writing to the procedure:

i. Notice included with the informed consent form that the procedure is not being performed at a licensed cardiac surgery center, and in the event that the

patient requires emergency cardiac surgery, the patient will be transferred to a licensed cardiac surgery center; and

ii. Details concerning the applicant hospital's plan and protocols for transferring patients who require emergency cardiac surgery, including the name and location of the cardiac surgery center with which the applicant hospital has entered into a collaboration agreement.

In addition, the hospital shall, upon request, furnish the patient with a written copy of the hospital's transfer protocols, including transportation and associated charges for transportation, and a summary of the collaboration agreement.

3. The Cardiac Law requires a collaboration agreement between a cardiac surgery center and the facility licensed for elective angioplasty that must include the following:

i. Written protocols for enrolled patients who require transfer to, and receipt at, a cardiac surgery center's operating room within one hour of the determination of the need for such transfer, including the emergency transport of patients who require an intra-aortic balloon pump (IABP);

ii. Regular consultation between the two hospitals on individual cases, including use of technology to share case information in a rapid manner; and

iii. Evidence of adequate cardiac surgery on-call backup.

4. The Cardiac Law requires that commencing in the second year of licensure, and in each year thereafter, the general hospital performs a minimum of 200 angioplasty procedures per year, with each interventional cardiologist performing at least 50 angioplasty procedures per year.

Questions regarding this memo and the application process may be directed to Michael Kennedy, at [Michael.Kennedy@doh.nj.gov](mailto:Michael.Kennedy@doh.nj.gov) and 609-376-7760.