



State of New Jersey  
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Commissioner

July 23, 2021

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

FROM: Marcela Maziarz, MPA  
Deputy Commissioner *MM*  
Health Systems

RE: Cardiac Services

Please be advised of the following protocols established for processing amended license applications for the addition of cardiac services pursuant to P.L. 2021, c. 18 (the "Statute"). The Statute removes the Certificate of Need requirement for full-service adult diagnostic cardiac catheterization, primary angioplasty and elective angioplasty and permits general hospitals to add these three services through a licensing process.

1. The Department of Health (Department) assigned a designated group of staff (the "cardiac group") to review the initial applications for the licensure of cardiac services from non-C-PORT hospitals, as well as applications from the C-PORT hospitals seeking licensure for the continued provision of elective angioplasty services.

A functional review of all schematic drawings submitted in connection with the application will be performed. An architect will conduct the functional review of all schematic drawings submissions prior to releasing the construction plans to the Department of Community Affairs ("DCA") for the DCA's review/approval.

2. The following licensing process established by the Department for all three licenses referred to in the first paragraph require the submission of the following:
  - a. 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;
  - b. A project narrative, which includes timeframes and phases for implementation of the proposed service. The narrative shall include the location and number of catheterization labs, recovery areas, patient criteria for service, including those considered high risk and excluded from the cardiac service to be provided. The project narrative shall include either:

- i. Architectural drawings if renovation/construction is necessary which shall require DCA approval prior to work being done; or
    - ii. If no renovation/construction is required, submit schematics showing existing location(s) where the newly added service will be provided for the Department's review.
  - c. Documentation that demonstrates the facility has the ability to consistently provide the requested cardiac service 24 hours per day and seven days per week.
    - i. 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
    - ii. An acknowledgement of the facility's understanding and acceptance of regulatory and statutory criteria, including data reporting requirements, that must be met.
3. Applications shall be reviewed/processed/completed in the order received, within 90 days of receipt. As with any amended license application, the 90-day timeframe for completion shall be dependent on the following:
  - a. Timely responses by the applicant to all completeness questions related to both the functional review and applications;
  - b. Timely Final Plan release/approval by DCA and completion of any construction/renovation; and
  - c. Completion of a satisfactory onsite survey inspection with recommendation of licensure approval.
4. C-PORT applicants may cease reporting data to the registry operated by Johns Hopkins University as of July 22, 2021 and shall begin reporting data to the National Cardiovascular Data Registry when advised to do so by the Department.
5. The protocols in place for the C-PORT Study at N.J.A.C. 8:33-3.11(c) continue to apply to all applicants and providers of elective angioplasty without on-site cardiac surgery back-up until rules governing the service are adopted. The elective angioplasty informed consent form shall be in compliance with the requirements at N.J.S.A. 26:2H-7.24.

Licensing questions regarding the cardiac services covered in this memo may be addressed to Theresa D'Errico at [Theresa.DErrico@doh.nj.gov](mailto:Theresa.DErrico@doh.nj.gov).