



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*

SHEREEF M. ELNAHAL, MD, MBA  
*Commissioner*

February 8, 2019

**VIA ELECTRONIC AND FIRST-CLASS MAIL**

Joseph DiPaolo, FACHE  
President  
Atlantic Health System  
Newton Medical Center  
175 High Street  
Newton, New Jersey 07860

Re: CN# ER 180803-19-01  
Emergency PCI with Off-site Cardiac  
Surgery Back-Up  
Total Project Cost: \$0  
Expiration Date: February 8, 2024

Dear Mr. DiPaolo:

Please be advised that the Department of Health (Department) is approving Atlantic Health System- Newton Medical Center's (Newton) certificate of need (CN) application, submitted on August 1, 2018, pursuant to N.J.A.C. 8:33-5.1(a)3 and 8:33E-2.16, for the establishment of an emergency or primary percutaneous transluminal coronary intervention (PCI) program with off-site cardiac surgery back-up at Morristown Memorial Hospital in Morristown, Morris County. This application is being approved at the total project cost noted above.

The Department's goal in considering applications for the provision of PCI without the availability of on-site cardiac surgery in emergent situations, or primary PCI, is to promote wider access to appropriate emergency PCI services while assuring quality of care to patients with acute myocardial infarction (AMI). Any New Jersey general hospital licensed as a full service adult diagnostic cardiac catheterization program may apply, provided it has documented to the satisfaction of the Department, licensure and full compliance with all cardiac catheterization program and facility utilization requirements, as set forth at N.J.A.C. 8:33E-1.1 et seq. and N.J.A.C. 8:43G-7.1 et seq., for the most recent four quarters of operation fully documented by the Department.

N.J.S.A. 26:2H-8 provides for the issuance of a CN only where: a) the action proposed in the application for such certificate is necessary to provide required health care in the area to be served; b) can be economically accomplished and maintained; c) will not have an adverse economic or financial impact on the delivery of health care services in the region or statewide; and d) will contribute to the orderly development of adequate and effective health care services.

In making such determinations, the Department must consider the following criteria: a) the availability of facilities or services which may serve as alternatives or substitutes; b) the need for special equipment and services in the area; c) the possible economies and improvement in services to be anticipated from the operation of joint central services; d) the adequacy of financial resources and sources of present and future revenues; e) the availability of sufficient manpower in the several professional disciplines; and f) such other factors as may be established by regulation.

The Department is, therefore, required by statute to review the Newton CN application in accordance with the statutory criteria contained in the Health Care Facilities Planning Act (N.J.S.A. 26:2H-1.1 et seq.) as amended, the regulatory criteria for primary PCI as set forth at N.J.A.C. 8:33E, and the CN administrative process rules as set forth at N.J.A.C. 8:33.

With respect to the first criterion (i.e., whether the action proposed is necessary to provide health care in the area to be served), the Department considered that the establishment of primary PCI at Newton will provide greater access to cardiac services in Sussex County. Newton is the only acute care provider in Sussex County serving the inpatient and emergent needs of the county's 150,000 residents.

As to the second criterion (i.e., whether the proposed project can be economically accomplished and maintained), a financial analysis undertaken by staff of this Department indicates that Newton would have sufficient future revenue to sustain the project once it has been licensed.

Moving to the third criterion (i.e., whether the action proposed would have an adverse economic or financial impact on the delivery of health care services in the region or statewide), there is no evidence to suggest that the addition of a primary PCI program at Newton would jeopardize the delivery of health care in the region, but would alternately enhance delivery through increased access for Sussex County residents.

With respect to the fourth criterion (i.e., whether the proposed action will contribute to the orderly development of adequate and effective health care services), the project would contribute to the orderly development of adequate and effective health care services by providing increased access to primary PCI services for Sussex County residents.

Finally, the Department has taken into consideration the applicable regulations governing the expedited review process and performance of primary PCI (i.e., N.J.A.C. 8:33-5.3 and 8:33E-2.16). I find that Newton has provided an appropriate project description, which includes information as to the total project cost, operating costs and revenues, services affected, equipment involved, source of funds, utilization statistics and justification for the proposed project (N.J.A.C. 8:33-5.3(a)1); assurances that all residents of the area, particularly the medically underserved, will have access to the program (N.J.A.C. 8:33-5.3(a)2); documentation that it will meet appropriate licensing and construction standards (N.J.A.C. 8:33-5.3(a)3i); demonstration of an acceptable track record of past and current compliance with State licensure requirements (N.J.A.C. 8:33-5.3(a)3ii and 4.10(d)); and documentation as to the project's impact on its financial condition (N.J.A.C. 8:33-5.3(a)3iii.)

Newton has also provided documentation of compliance with applicable standards set forth at N.J.A.C. 8:33E-2.16, including collaboration with a New Jersey cardiac surgery center within the same or contiguous county (i.e., Morristown Memorial Hospital); case selection for primary PCI that will comply with criteria identified in N.J.A.C. 8:33E-2.16(c), and that the general public will be advised of availability of the service through the development of comprehensive informational material. Newton documents that 36 cases will be performed each year by the second year of operation, based on the 135 acute myocardial infarction cases deemed eligible for primary PCI in the past two years; the service will be available 24 hours a day/7 days a week; each operator will be an experienced interventionalist who performed at least 75 PCI procedures in the previous year; technical staff will have been trained at an interventional lab; door to balloon inflation time will be no later than 120 minutes after admission; the cardiac catheterization laboratory will be equipped with resuscitative equipment; the medical director will be board certified in interventional cardiology; and an ongoing outcomes analysis program and formalized periodic case review will be part of a broader quality assessment and error management system. Therefore, the Department is approving Newton's application for the establishment of a primary PCI program.

The Department will strictly enforce standards set forth at N.J.A.C. 8:33E-2.16 et seq. and those providers who fail to meet those standards will be subject to the licensure enforcement criteria established at N.J.A.C. 8:33E-2.16(e). Therefore, Newton is strongly advised to review N.J.A.C. 8:33E-2.16 et seq. and to familiarize itself with all the requirements set forth therein. Newton is cautioned to pay particular attention to the standards set forth at N.J.A.C. 8:33E-2.16 (b), which mandates that all facilities licensed to perform primary PCI will perform at least 36 cases each year by the end of the second year after licensure. Newton should also be especially cognizant of the reporting requirements set forth at N.J.A.C. 8:33E-2.16(d).

As provided for at N.J.A.C. 8:33-4.16, this certificate of need is granted to Newton Medical Center subject to the following conditions:

1. Within 30 days of the date of this letter, the applicant shall contact the Department's Health Care Quality Assessment Program at (609) 984-7334 to ensure accurate and timely reporting of primary PCI data.
2. Prior to the commencement of services, the applicant shall file a licensing amendment application and obtain licensure approval from the Certificate of Need and Healthcare Facility Licensure Program.
3. Prior to licensure, the applicant shall supply the Certificate of Need and Healthcare Facility Licensure Program with documentation that it has provided the local emergency transport provider(s) with an education program on the transport of primary PCI patients.
4. Prior to licensure, the applicant shall supply the Certificate of Need and Healthcare Facility Licensure Program with documentation that its technical catheterization laboratory staff has been trained at an interventional laboratory in a cardiac surgery center.
5. Prior to licensure, the applicant shall supply the Certificate of Need and Healthcare Facility Licensure Program with a finalized cardiac surgery transfer agreement with Morristown Memorial Hospital.
6. Prior to licensure, the applicant shall supply the Certificate of Need and Healthcare Facility Licensure Program with a signed and executed "Primary PCI Scope of Care Policy."
7. Prior to licensure, the applicant shall supply the Certificate of Need and Healthcare Facility Licensure Program with a signed and executed "Code STEMI Guidelines", including treatment of inpatient AMI patients.
8. Prior to licensure, the applicant shall supply the Certificate of Need and Healthcare Facility Licensure Program with a signed and executed "Emergency Transfer to Tertiary Facility Post PCI Policy."
9. Prior to licensure, the applicant shall supply the Certificate of Need and Healthcare Facility Licensure Program with a signed and executed "IABP Transfer to Tertiary Facility Post PCI Policy."
10. In accordance with N.J.A.C. 8:33E-2.16(b)6, each operator performing primary PCI is an experienced operator who performed 75 PCI cases in the previous year and continues to do so during his or her tenure at the primary PCI site.



Failure to satisfy the aforementioned conditions of approval may result in sanctions, including license suspension, monetary penalties and other sanctions in accordance with N.J.S.A. 26:2H-1 et seq. and all applicable requirements. Acceptance of these conditions will be presumed unless written objections are submitted to the Department within 30 days of receipt of this letter. Upon receipt of such objections, this approval will be deemed suspended and the project shall be reexamined in light of the objections.

Please be advised that this approval is limited to the proposal as presented and reviewed. An additional review by the Department may be necessary if there is any change in project scope, as defined at N.J.A.C. 8:33-3.9. However, a change in cost of an approved CN is exempt from CN review, subject to the following:

1. The applicant shall file a signed certification as to the final total project cost expended for the project at the time of the application for licensure for the beds/services with the Certificate of Need and Healthcare Facility Licensure Program.
2. Where the total project cost exceeds the CN approved total project cost and is greater than \$1,000,000, the applicant shall remit the additional CN application fee due to the Certificate of Need and Healthcare Facility Licensure Program. The required additional fee shall be 0.25 percent of the total project cost in excess of the CN approved total project cost.
3. The Department will not issue a license for the beds/services until the additional fee is remitted in full.

This approval is not intended to preempt in any way any municipality's authority to regulate land use within its borders and shall not be used by you to represent that the Department has made any findings or determination relative to the use of any specific property. In addition, any alteration, renovation, or new construction of the physical plant requires the submission of plans to the Department of Community Affairs, Division of Codes and Standards, Healthcare Facilities Plan Review, for review and approval prior to the initiation of work.

The Department looks forward to working with you and helping you to provide a high quality of care. If you have any questions concerning this certificate of need, please do not hesitate to telephone the Certificate of Need and Healthcare Facility Licensure Program at (609) 292-8773.

Sincerely,



Marcela Ospina Maziarz, MPA  
Deputy Commissioner  
Health Systems