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TO: Health Care Administration Board Members

THROUGH: William Conroy, Deputy Commissioner
Susan Dougherty, Assistant Commissioner

FROM: John Calabria, Director
Certificate of Need and Healthcare Facility Licensure

SUBJECT: Notice of Adoption for Rule Amendments Governing the Standards for
Certificate of Need Application and Review Process, Codified at N.J.A.C.
8:33

At an upcoming meeting of the Health Care Administration Board (HCAB), the Department of Health (Department) will present the readoption with amendments, repeal and new rules for the Standards for Certificate of Need Application and Review Process, Codified at N.J.A.C. 8:33. These rules provide the regulatory framework to fulfill the Department's obligation to assure access to health care services of the highest quality under the jurisdiction of the Health Care Facilities Planning Act, as set forth at N.J.S.A. 26:2H-1 et seq.

The Department has reviewed the rules of this chapter and has determined that they remain necessary, reasonable, and proper for the purpose for which they were originally promulgated. The rules to be adopted would continue to provide the regulatory framework to assure access to health care services of the highest quality while taking into consideration the significant changes in the economics of the health care system since the inception of the certificate of need program.

The Department's proposed amendments are as follows:

The proposed amendments would correct the name of the Department throughout the rule.

The Department is proposing amendments to remove the definitions for "Atlantic Cardiovascular Patient Outcomes Research Team trial" or "Atlantic C-PORT-E trial"; "Bloodless surgery"; "Elective angioplasty demonstration project"; "Inner city cardiac satellite demonstration project"; "Inner city hospital"; and "Satellite hospital."

The Department is proposing to define the following terms: "American Board of Internal Medicine"; "Applicant hospital"; "Atherectomy device"; "Atlantic C-PORT-E Manual of Operations"; "Atlantic C-PORT-E registry"; "Cardiovascular Subspecialty Board of the American Board of Internal Medicine"; "Elective"; "In-stent restenosis"; "Interventionalist"; "Participating hospital"; "Percutaneous Coronary Intervention"; "Primary"; "Safety Monitor"; and "State elective angioplasty demonstration project."

The Department is proposing amendments to the demonstration project subsections that would remove inner city cardiac satellite demonstration projects and bloodless surgery demonstration projects.

The Department is adopting new rules at N.J.A.C. 8:33-3.11(c) to establish a State elective angioplasty demonstration project (State demonstration project). Also set forth in the rules are specific requirements for hospital participation in the State demonstration project. The rules set forth the Commissioner's authority to accept expedited certificate of need applications from the eleven hospitals that are currently unconditionally licensed by the Department to participate in the Atlantic C-PORT-E registry for participation in the State demonstration project, in accordance with the expedited review process.

The Department is also proposing amendments to N.J.A.C. 8:33-4.3(a) and 5.2(e) to provide a link to the Department's website where the full and expedited review applications are available. The proposed amendments would also require the submission of the applications on an electronic media, as well as the paper copies which are already required.

The proposed amendment to Appendix E would delete the Attachments Checklist information from the form. The Department intends to develop a new checklist on its website that would serve as a reminder for applicants to include with their certificate of need application for expedited review. The checklist would be accessible on the Department's website at:
<http://web.doh.state.nj.us/apps2/forms/subforms.aspx?pro=healthfacilities>.

Following is a summary of the rules proposed for re-adoption:

N.J.A.C. 8:33-1 would continue to set forth the general provisions of the rule, including the scope and purpose; general statements regarding the public policy of the State and rules of general application with respect to the certificate of need process; and definitions.

N.J.A.C. 8:33-2 provides a description of the applicability of certificate of need requirements. The applicability of the two categories of certificate of need review, that is, full and expedited review, is discussed as well as the process of determining whether a particular health care entity or modality of health care constitutes a "health care facility" or "health care service" that would be subject to the provisions of the Health Care Facilities Planning Act (N.J.S.A. 26:2H-1 et seq.) and this chapter.

N.J.A.C. 8:33-3 describes the various types of certificate of need applications including: the initiation of a health care service; termination/discontinuance of a service or facility; reduction of licensed bed capacity; transfers of ownership of a facility or service; changes in licensed beds or services; buildings requirements; major and minor moveable equipment requirements; and changes in cost/scope.

N.J.A.C. 8:33-4 details the administrative process for the full certificate of need review process.

N.J.A.C. 8:33-5 sets forth the Department's expedited certificate of need review process.

N.J.A.C. 8:33-6 would continue to set forth the health care services that are exempt from the certificate of need process that are consistent with the provisions of the Health Care Facilities Planning Act (N.J.S.A. 26:2H-7.2), as amended.

N.J.A.C. 8:33-7 would continue to be reserved.

Appendix A includes exhibits that list the types of health care services that continue to require a certificate of need (Exhibit 1), that provide examples of major movable equipment (Exhibit 2) and that provide a summary listing of certificate of need activities and the type of certificate of need review that is required or if the activity is exempt from the review requirement (Exhibit 3).

Appendix B contains form CN-1, Full Review Certificate of Need Application for Long Term Care Facilities: General Long Term Care Beds; Specialized Long Term Care Beds.

Appendix C contains form CN-3, Certificate of Need Application for Hospital-Related Projects.

Appendix D contains form CN-4, Certificate of Need Application for Designation as a Perinatal Facility.

Appendix E contains form CN-19, Certificate of Need Application - Expedited Review for Facilities and Services Identified at N.J.A.C. 8:33-5.1(a).

A total of 17 commenters submitted comments during the 60-day public comment period which ended on April 3, 2015. Two commenters support the Department's proposal to remove inner city cardiac satellite demonstration projects and bloodless surgery demonstration projects. The remaining comments address specifics of the State demonstration project.

Many of these commenters, which are existing Atlantic C-PORT-E participants, support the Department's proposal but request that they be exempt from the full review

certificate of need (CN) process when new licensing rules governing elective angioplasty without on-site cardiac surgery are promulgated. The Department responded that the review criteria and the demonstration of need of a demonstration project subject to N.J.A.C. 8:33-3.11 is defined by regulation; whereas, statewide full review CNs are subject to the statutory criteria for CN review enumerated in the Health Care Facilities Planning Act (N.J.S.A. 26:2H-8) and the rules governing the CN process (N.J.A.C. 8:33-1.1 et seq.). Due to the noted differences between demonstration project CN approval and full CN review, the Department will make no change upon adoption in response to the comments.

The existing Atlantic C-PORT-E participants also expressed concern that the reporting requirements proposed in the State demonstration project were a more burdensome standard than that found in the Atlantic C-PORT-E Study and registry. The Department is proposing two technical changes upon adoption regarding reporting deadlines to be consistent with the current Atlantic C-PORT-E reporting requirements. Many of the existing Atlantic C-PORT-E participants also sought clarification regarding the informed consent process and requested changes to the proposed amendments. The Department, in its efforts to maintain the consistency of the State demonstration project with the Atlantic C-PORT-E registry, will not make changes upon final adoption.

In addition, the existing Atlantic C-PORT-E participants also expressed concern that the proposed new rules governing when the informed consent must be obtained was inconsistent with the Atlantic C-PORT-E Study and registry. Specifically, they noted that the new rules precluded from enrollment in the State demonstration project patients who had earlier diagnostic catheterizations at either participating facilities (on an emergent, that is "primary," basis) or non-participating facilities, as well as patients who obtain diagnostic catheterizations at non-participating facilities and may be referred to interventionalists practicing at participating facilities. The Department is proposing technical changes upon adoption to delete the preclusion from enrollment into the State demonstration project of patients who have already received diagnostic cardiac catheterization at non-participating hospitals or emergent PCI at participating hospitals, permit referrals of patients receiving diagnostic catheterizations at non-participating hospitals to interventionalists who practice at participating hospitals, and maintain consistency with the Atlantic C-PORT-E Study and registry protocols to facilitate result comparisons.

The American Heart Association comments on the State demonstration project's adherence to its guidelines. Deborah Heart and Lung Center supports the full review CN requirement for elective PCI and seeks clarification of the role of tertiary hospitals and the Data Monitor in the study. The Department made no changes based on these comments. Several of the commenters sought clarification of the duration of the project. The Department is proposing a technical change upon adoption to clarify that, although the Department does not anticipate that the State demonstration project will last more than eighteen months, the State demonstration project will continue until the promulgation of new rules at N.J.A.C. 8:33E that establish minimum standards for

hospitals performing elective angioplasty without cardiac surgery backup and the issuance of licenses under those rules.

Primary PCI providers that did not participate in the Atlantic C-PORT-E study are critical of the further delays that an additional demonstration project would have on their ability to provide elective PCI, and recommend that the State demonstration project be opened up to primary PCI providers that did not participate in the Atlantic C-PORT-E registry. Hackensack University Health Network proposes a Network approach whereby Hackensack UMC-Mountainside, which is not an Atlantic C-PORT-E participant, is eligible to provide elective PCI as part of its Network with Hackensack University Hospital. The Department will make no change upon adoption in response to the comment.

Based on public comment, the Department is proposing four technical modifications upon adoption to the February 2, 2015 published proposal. Changes one and two are proposed in an effort to replicate the Atlantic C-PORT-E registry and so as not to impose a more burdensome standard on the participating hospitals. Proposed change three removes the preclusion of certain patients who are currently able to enroll in the Atlantic C-PORT-E registry. Proposed change four clarifies when the State demonstration project ends. The proposed technical changes are as follows:

(1) The Department is proposing to modify N.J.A.C. 8:33-3.11(c)4xvi to read "Maintain the equivalent of one full-time employee (FTE) responsible for the timely and accurate collection and submission of data on each elective PCI case, who shall initiate submission of data to the Data Monitor within 24 hours of procedure completion and complete such submission as promptly as possible in accordance with N.J.A.C. 8:33E-1.9 and 2.10."

(2) The Department is proposing to modify N.J.A.C. 8:33-3.11(c)4xvii to read "Report to the Data Monitor, within 72 hours thereof, the occurrence of a death from any cause, a need for emergency cardiac surgery, and other events as the Data Monitor may identify, and, within seven days thereof, the occurrence of other adverse event such as recurrent myocardial infarction, stroke, bleeding, a need for vascular surgery or repair, unplanned cardiac catheterization, a subsequent PCI and/or CABG for any other reason, or renal failure."

(3) The Department is proposing to modify N.J.A.C. 8:33-3.11(c)5, and add new N.J.A.C. 8:33-3.11(c)6, to read, "5. Participating hospitals shall ensure that each enrolled patient provides written informed consent pursuant to 6 below to participate in the State demonstration project:

- i. Before the commencement of diagnostic cardiac catheterization;
- ii. After a patient has received primary PCI at a participating hospital and before the patient undergoes elective PCI at that hospital; or

iii. After a patient has received diagnostic cardiac catheterization at a non-participating hospital and before the patient undergoes elective PCI at a participating hospital;

6. Participating hospitals shall ensure that patients receive the following information and an opportunity to review and consider such information before being asked to consent in writing to participate in the State demonstration project:”

(4) The Department is proposing to modify N.J.A.C. 8:33-3.11(c)16 to read, “Notwithstanding (d)4 below, and the Department’s intention that the State demonstration project will last no more than 18 months, the State demonstration project shall be in effect until the Department promulgates new rules at N.J.A.C. 8:33E for elective angioplasty without cardiac surgery backup and issues licenses under those rules ”

I or a member of my staff will be available at the meeting to answer any questions you may have regarding this adoption. Thank you.