TO: Health Care Administration Board Members

THROUGH: William Conroy, Deputy Commissioner
          Alison Gibson, Assistant Commissioner

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

SUBJECT: Notice of the Readoption Without Change of Rules Governing Certificate of Need: Cardiac Diagnostic Facilities and Cardiac Surgery Centers, Codified at N.J.A.C. 8:33E

At the next available meeting of the Health Care Administration Board (HCAB), the Department of Health and Senior Services (Department) will request the HCAB’s approval to file the notice of the readoption without change of rules governing the Certificate of Need and Licensure of Cardiac Services, N.J.A.C. 8:33E. This chapter is scheduled to expire on June 19, 2013 in accordance with Executive Order No. 66 (1978). This notice of readoption without change is taken to maintain existing regulatory policies regarding invasive cardiac diagnostic services and therapeutic cardiac intervention services as set forth at N.J.A.C. 8:33E and, pursuant to N.J.S.A. 52:14B-1.5 and N.J.A.C. 1:30-6.4(h), would become effective on filing with the Office of Administrative Law. Pursuant to N.J.S.A. 52:14B-5.1, upon the approval of the HCAB the Department will file the notice and the chapter will continue in effect for another seven years.

The Department has reviewed N.J.A.C. 8:33E and has determined the notice of the readoption without change of rules to be necessary, proper, reasonable, efficient, understandable, and responsive to the purposes for which they were originally promulgated.

The Department has also determined that the notice of the readoption without change of rules at N.J.A.C. 8:33E are needed to implement the underlying statute; do not impede responsible economic growth; provide sufficient and non-contradictory guidance to applicants for licenses that do not, for the most part, lead to licensure delays or denials; and, do not exceed legislative intent or Federal standards without well-documented cause, thereby placing the state at a competitive advantage in attracting investment and jobs. The Department is proposing notice of the readoption
without change of rules governing invasive cardiac diagnostic and therapeutic hospital services in order to maintain these certificate of need and licensing standards for all licensed general and special hospitals providing these cardiac services or seeking to provide these cardiac services.

N.J.A.C. 8:33E, was developed as a result of: consultation with the Commissioner’s Cardiovascular Health Advisory Panel (CHAP), a review of pertinent research literature, clinical guidelines of the American College of Cardiology and the American Heart Association (ACC/AHA), an analysis of invasive cardiac diagnostic and therapeutic cardiac intervention performance data in New Jersey, a preliminary statewide evaluation of physician and facility invasive diagnostic cardiac catheterization and therapeutic cardiac intervention performance levels, and recent clinical advances in cardiac care.

The standards contained in this chapter establish minimum utilization, staffing, and professional credentialing requirements. They are designed to promote high quality invasive cardiac diagnostic services, therapeutic cardiac intervention services, and open heart surgery services. Setting appropriate staffing and volume levels assures that providers maintain their clinical skills and deliver efficient and effective medically necessary health care treatment.

As the Department indicated in its October 12, 2012 memo to all New Jersey hospitals, “to properly develop statewide policy regarding elective angioplasty, additional time is necessary to allow the Department to carefully evaluate the findings of the Atlantic C-PORT-E research study, to gather additional evidence-based scientific information, assess the impact of the elective angioplasty demonstration projects on existing cardiac surgery centers, and to solicit feedback from stakeholders including the medical, quality care and EMS communities and the public at large. The Department’s thorough review process will include a symposium on cardiac services in general, including elective angioplasty with and without on-site cardiac surgery and quality and patient safety perspectives, conducted under the auspices of the Commissioner’s Cardiovascular Health Advisory Panel (CHAP) and the New Jersey Chapter of the American College of Cardiology (NJACC) to be held in the fourth quarter of this year. Subsequently, the State Health Planning Board (SHPB) will conduct regional hearings on elective angioplasty to allow for a public and transparent discussion. The Department then will develop statewide cardiac services and elective angioplasty policy and will propose new rules through the administrative rule-making process.”

The notice of the readoption without change of rules therefore represents an interim step in the Department’s statewide policy review which is expected to conclude with future rule-making proposals.

I will be at the meeting to respond to any questions that you may have.

Attachments