

1. The current status of the project;
2. The reasons for the delays; and
3. A proposed detailed time frame identifying the remaining time needed for the project to be licensed by the Department's Certificate of Need and Acute Care Licensure Program.

Amended by R.1998 d.280, effective June 1, 1998.

See: 30 N.J.R. 1008(a), 30 N.J.R. 1996(a).

In (a), deleted "reimbursement or" preceding "licensing sanctions"; and rewrote (b).

Recodified from N.J.A.C. 8:33E-2.14 and amended by R.2001 d.210, effective June 18, 2001.

See: 33 N.J.R. 616(b), 33 N.J.R. 2105(a).

Rewrote section. Former N.J.A.C. 8:33E-2.13, New facilities; diagnostic pilot cardiac catheterization programs at cardiac surgery centers, repealed.

8:33E-2.14 Petition for and submission of certificate of need applications

(a) All certificate of need applicants seeking to initiate cardiac surgical services shall be subject to the requirements of this subchapter, as applicable, and the following:

1. The Department shall only process certificate of need applications for the initiation of cardiac surgical services in accordance with procedures set forth in this section and in N.J.A.C. 8:33. Certificate of need applications shall only be accepted for processing from general hospitals after a hospital has petitioned the Department and established the potential need for new cardiac surgery services by demonstrating that it meets the following minimum standards, which indicate a potential unmet need and that the petitioner is qualified to meet the unmet need:

- i. The petitioner is an existing provider of full service invasive cardiac diagnostic services that has complied with all applicable requirements at N.J.A.C. 8:43G-7 and in this chapter and has for the previous three years met or exceeded the minimum acceptable number of adult cardiac catheterization cases required for a full service cardiac laboratory in accordance with N.J.A.C. 8:33E-1.4(b)1 as demonstrated by the most current data maintained by the Department;

- ii. The petitioner is not located in the same county as a facility which, in the previous 12 months, successfully petitioned the Department for a call;

- iii. The petitioner can demonstrate a potential volume of at least 350 cardiac surgery cases per year, based on one or more of the following. In demonstrating this potential volume, petitioners must provide a detailed explanation of the methodology used to identify potential cases based on minority, medically underserved and/or out-of-State residents and the Department shall indicate whether it accepts the number of cases identified through this methodology. The Department shall, on an annual basis, indicate what proportion

of the 350 cases shall be derived from each of the specific criteria listed below:

- (1) Patients receiving diagnostic cardiac catheterizations at the petitioner's facility who had cardiac surgery within the following 90 days;

- (2) People residing in the county where the petitioner is located who had cardiac surgery in the previous year at a facility outside the petitioner's service area, which shall include the petitioner's county and contiguous counties, including at out-of-State facilities;

- (3) Potential cases from minority and/or medically underserved patients in the petitioner's county or in a contiguous county; and/or

- (4) Potential cases from out-of-State residents;

- iv. The petitioner can demonstrate that retaining cardiac surgery cases that currently are referred to an existing New Jersey cardiac surgery center(s) is not likely to cause cardiac surgery volume at that facility(ies) to fall below the minimum annual volume required for maintenance of quality and is consistent with the findings of the Legislature as set forth at N.J.S.A. 26:2H-6.1(h); and

- v. The petitioner can demonstrate the current availability, and quantify the utilization of, its cardiology and/or cardiovascular disease community prevention services and clinics for all populations, specifically targeting minority and medically underserved population groups. Examples of community prevention programs are those primary and secondary prevention initiatives which include:

- (1) Diet and drug therapy for hypercholesterolemia in patients at high risk or with established coronary artery disease;

- (2) Smoking cessation programs with objective outcome measures;

- (3) Exercise rehabilitation programs for patients with established coronary artery disease; and

- (4) Public education programs.

2. The petition review process shall include four review cycles each year. The beginning of each cycle shall be the first business day of January, April, July and October. Petitions shall be accepted on the first business day of each cycle. A decision shall be rendered by the Commissioner no later than 90 days after the beginning of the cycle in which a petition is received as to whether the petitioner has met the minimum standards necessary for the Department to initiate a regional call for submission of certificate of need applications for a new cardiac surgery program. The petitioner shall submit a nonrefundable fee of \$5,000 to the Department along with the petition. If the Department makes a finding of potential

need and issues a regional call for cardiac surgery certificate of need applications, the petitioner may apply this fee toward the certificate of need application fee.

3. In the event the petitioner is unsuccessful in establishing the potential need for new cardiac surgery services, the Department shall not accept a petition for cardiac surgery services from that petitioner for two years subsequent to the date the unsuccessful petition was submitted to the Department for consideration. An unsuccessful petition, however, does not preclude the petitioner from submitting an application in response to any call resulting from the action of another petitioner and applying to the county in which the applicant whose own petition was denied is located.

4. Within 60 days of the Commissioner's determination that a petitioner has met the minimum standards necessary to issue a regional call for submission of certificate of need applications for a new cardiac surgery program, the Commissioner shall publish a call. The call shall invite cardiac surgery applications from any general hospital, including petitioner, located in the petitioner's county or a contiguous county that meets the criteria set forth in (a)1i above. It will also invite existing New Jersey cardiac surgery centers located in the petitioner's county or a contiguous county ("affected facilities") to file a written submission with the Department in response to any submitted certificate of need applications that have been deemed complete. The published call shall set forth time frames for the submission of applications, the determination of completeness of the applications, the opportunity for affected facilities to obtain copies of the applications, and the written submissions by affected facilities responding to the applications.

i. A written submission filed by an affected facility may address the anticipated impact on quality of care of the proposed new program on the affected facility, in accordance with the provisions of N.J.S.A. 26:2H-8, and may also document the impact of technological and/or medical advances on the future need for cardiac surgery services in the petitioner's county and contiguous counties.

ii. The State Health Planning Board shall consider the issues addressed in the submissions of existing New Jersey cardiac surgery centers in making its recommendation to the Commissioner. The State Health Planning Board shall also afford affected facilities and applicants the opportunity to address the impact of the application(s) on quality of care as well as the impact of technological and/or medical advances on the future need for cardiac surgery services in its open public meeting.

Amended by R.1998 d.280, effective June 1, 1998.

See: 30 N.J.R. 1008(a), 30 N.J.R. 1996(a).

Rewrote the section.

Recodified from N.J.A.C. 8:33E-2.15 and amended by R.2001 d.210, effective June 18, 2001.

See: 33 N.J.R. 616(b), 33 N.J.R. 2105(a).

Rewrote (a). Former N.J.A.C. 8:33E-2.14, Compliance, recodified to N.J.A.C. 8:33E-2.13.

Repeal and new rule, R.2001 d.482, effective December 17, 2001.

See: 33 N.J.R. 3256(a), 33 N.J.R. 4342(a).

Section was "Submission of Certificate of Need applications".

Public Notice: Cardiac surgery petition criteria.

See: 34 N.J.R. 1554(a).

Petition for Rulemaking.

See: 34 N.J.R. 3030(a).

Public Notice: Cardiac surgery center certificate of need applications.

See: 34 N.J.R. 3135(b), 3136(a).

8:33E-2.15 Competitive review criteria

(a) The Department's goal in considering applications for additional cardiac surgery programs is to improve access to all cardiac services, especially for medically underserved and minority populations, while at the same time ensuring the quality of services at cardiac surgery centers. The Department also seeks to foster collaboration among existing healthcare providers offering preventive, primary, diagnostic and therapeutic cardiac services when considering applications for additional invasive therapeutic cardiac services programs.

(b) During certificate of need review, consideration for approval shall be limited to the applicant(s) that meets the following requirements and does so to a greater extent than the competing applicants, has documented compliance with the following competitive review criteria and has documented compliance with all other applicable criteria in this subchapter and N.J.S.A. 26:2H-8. Unless otherwise specified in the certificate of need call issued by the Commissioner, a maximum of one new cardiac surgery program shall be considered for approval in any certificate of need call under these competitive review criteria.

1. The applicant is able to provide quantifiable documentation of its historic commitment to access to cardiac services, including preventive and primary cardiac services as well as invasive cardiac diagnostic services, for minority and medically underserved populations;

i. The applicant shall provide documentation which shows the proportion of minority and medically underserved residents residing in the proposed service area, which shall be no larger than the county in which the applicant is located as well as contiguous counties;

ii. The applicant is able to provide a plan that is designed to ensure that appropriate access to the preventive, primary, diagnostic, and therapeutic cardiac interventions by minority and medically underserved populations, and other population groups that have historically been underrepresented in the provision of cardiac surgical services (for example, Medicaid recipients, indigent/self-pay patients), shall be achieved. The plan is subject to review and approval by the Department. The Department's approval shall be based on the hospital's demonstration that, to the maximum extent possible, it will provide cardiac therapeutic interventions to minority and medically underserved populations in comparable proportion to the general population in the hospital's proposed service area. This plan may serve as a basis for conditions placed on certificate of need approval;