CHAPTER 33S

CERTIFICATE OF NEED: SURGICAL FACILITIES

Authority

N.J.S.A. 26:2H–1 et seq., specifically 26:2H–5 and 2H–7.

Source and Effective Date

R.1993 d.498, effective October 4, 1993.
See: 25 N.J.R. 2790(a), 25 N.J.R. 4626(a).

Executive Order No. 66(1978) Expiration Date

Chapter 33S, Certificate of Need: Surgical Facilities, expires on October 4, 1998.

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SUBCHAPTER 1. REQUIREMENTS

8:33S–1.1 Scope and purpose

This chapter encompasses both hospital-based and free-standing surgical facilities and services and identifies standards and criteria for the planning and certificate of need review for surgical resources. These rules do not apply to the provision of cardiac surgical services or any other special surgical service which is the subject of separate Department of Health Planning rules. The chapter is intended to support a standard of quality in the performance of surgery in the State of New Jersey, through the provision of state-of-the-art surgical facilities which are accessible to all who are in need of these services. The purpose of the rules is to minimize the costly duplication of surgical services and to promote needed services that maintain and improve the health status of the population.

8:33S–1.2 Definitions

As used in this chapter, the following words and terms shall have the following meanings unless the context clearly indicates otherwise:

"Ambulatory surgery facilities" means a surgical facility that is licensed as an ambulatory care facility-surgery, separate and apart from any other facility license. It may be physically connected to another licensed facility, such as a hospital, but must be corporately and administratively distinct. The ambulatory surgical facilities shall comply with Chapter 9, Sections 9.1 and 9.2, and with Chapter 9, Section 9.5, Outpatient Surgical Facility, of the Guidelines for Construction and Equipment of Hospital and Medical Facilities, 1987 edition, as amended, incorporated herein by reference, which is available from the U.S. Government Printing Office, Washington, D.C., or from the Department.

"Ambulatory surgical cases" and "same day surgical cases" are synonymous terms for surgical procedures performed on patients who have these procedures performed in a licensed health care facility without the requirement of an overnight stay and generally requiring some form of anesthesia and a facility-based post surgery period of at least one hour.

"Operating room" means a room specifically dedicated to the performance of surgical cases. It must meet the requirements established by the U.S. Department of Health and Human Services as cited in the Minimum Requirements of Construction and Equipment for Hospital and Medical Facilities, U.S. Department of Health and Human Services 1987, Sections 7.7 Surgical Facilities and 9.5 Outpatient Surgical facilities, as amended, incorporated herein by reference and available from the U.S. Government Printing Office, Washington, D.C. and the Department.

"Outpatient surgery" means a very minor surgery appropriately performed in private settings, or in hospital outpatient departments, on patients who do not require a licensed free-standing ambulatory surgery facility or same-day surgery (SDS) status in a hospital. In a hospital setting, outpatient surgery is counted as an outpatient visit.

"Postanesthesia care unit" means a room, or area, used for post-anesthesia recovery of patients. It must meet the minimum requirements established by the U.S. Department of Health and Human Services as cited in the Minimum Requirements of Construction and Equipment for Hospital and Medical Facilities, U.S. Department of Health and Human Services 1987, Sections 7.0 and 9.5 as amended, incorporated herein by reference and available from the U.S. Government Printing Office, Washington, D.C., and the Department.

"Surgical facility" means a structure or suite of rooms which has the following characteristics:

1. At least one room dedicated for use as an operating room which is specifically equipped to perform surgery. These rooms are designed and constructed to accommodate invasive diagnostic and surgical procedures; and

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2. One or more postanesthesia care units as defined below and in hospital licensure standards (N.J.A.C. 8:35) or a dedicated recovery area where the patient may be closely monitored and observed until discharged; and

3. A surgical facility may be either a surgical suite within a hospital or a licensed ambulatory surgical facility as described below.

8:33S–1.3 Dates of submission of certificate of need applications

(a) A certificate of need shall be required for any new surgical facility as well as for additional operating rooms to be added to an existing surgical facility. A certificate of need shall also be required for the deletion of one or more operating rooms from an existing licensed facility or the replacement of existing operating rooms.

(b) Applications for additions, deletions, or alteration of surgical facilities will be accepted for processing in accordance with policies and procedures set forth in N.J.A.C. 8:33.

8:33S–1.4 Information to be submitted in the certificate of need application

(a) Information that must be provided by all applicants includes, but is not limited to, the following: (Note: The Department will determine prior to the initiation of each call for surgical applications the most recent Statewide and county-specific surgical data from licensed surgical facilities to be used in implementing the surgical need methodology outlined in this section, as well as identifying the population data and operating room inventory that are to be used to satisfy the surgical need methodology in this section. Non-licensed surgical facilities are not included in this surgical need methodology. Dedicated cardiac surgery and multiple trauma operating rooms shall be excluded from the Statewide inventory. Copies of this information can be obtained by contacting the Certificate of Need Program.)

1. The potential need or demand for the proposed surgical facility or proposed change in the number of operating rooms (OR), based on the surgical need methodology specified in this section.

i. The total capacity of the surgical OR's located within the county(ies) proposed to be served by the surgical facility. The capacity of each type of licensed OR shall be calculated as follows:

(1) Inpatient OR = 1,000 surgical cases annually;

(2) Mixed (inpatient/outpatient) OR = 1,090 surgical cases;

(3) Dedicated SDS OR = 1,500 surgical cases annually;

ii. The number of surgical cases performed within licensed OR's located in the county to be served by the proposed additional OR capacity for the most recent year of data available to the Department;

iii. The surgical use rate, both Statewide and countywide, shall be calculated for the most recent annual surgical data reported to the Department (derived from the Uniform Billing Patient Summary form) and using the most recent annual State and county population estimates available from the State Department of Labor. The surgical use rate is determined by dividing the number of surgical cases originating from each county by the estimated population of that county;

iv. The projected surgical caseload is calculated for five years in the future, using the latest available population projection for the county(ies) to be served by the proposed surgical applicant (and assuming the surgical use rate derived in (a)1iii above). The surgical rate is multiplied by the five year population projection to derive projected surgical caseload for the proposed service area;

v. Projected surgical demand for a service area is calculated by dividing the projected surgical caseload (see (a)1iv above) by the target surgical utilization level of 90 percent (.90). The projected utilization rate in the service area is calculated by dividing the projected surgical demand by the projected operating room capacity of the service area; and

vi. If the projected service area OR utilization rate is equal to or greater than 90 percent, then the proposed OR capacity can be expected to be sufficiently utilized to meet projected surgical demand in the proposed service area. If the projected utilization rate is less than 90 percent, then the number of proposed operating room(s) is/are in excess of service area need.

NEED METHODOLOGY FORMULA (as example):

Where: Total licensed service area surgical capacity = C

and:

Total Number of Existing Service Area Mixed ORs = M

Total Number of Existing Service Area Ambulatory/SDS ORs = A

Total Number of Existing Service Area Inpatient ORs = I

Total Number of Proposed Additional Service Area Mixed ORs = M′

Total Number of Proposed Additional Service Area Ambulatory/SDS ORs = A′

Total Number of Proposed Additional Service Area Inpatient ORs = I′

Existing Inpatient OR Surgical Capacity = I × 1,000

Existing Mixed OR Surgical Capacity = M × 1,090

Existing Ambulatory/SDS OR Capacity = A × 1,500

Proposed Inpatient OR Surgical Capacity = I′ × 1,000

Proposed Mixed OR Surgical Capacity = M′ × 1,090

Proposed Ambulatory/SDS OR Capacity = A′ × 1,500

(i) Existing Service Area Surgical Capacity (C) = (I × 1,000) + (M × 1,090) + (A × 1,500)

Proposed Additional Service Area Surgical Capacity (C′) = (I′ × 1,000) + (M′ × 1,090) + (A′ × 1,500)

Projected Service Area Surgical Capacity = (C + C′)

(ii) Number of Surgical Cases Performed on patients residing in the Proposed Service Area = S

(iii) Proposed Service Area Surgical Use Rate = S/P; where P = Latest Available Labor Department Population Estimate.

(iv) Projected Surgical Caseload = L = (S/P) × (P + 5); where, P + 5 = Service Area Population Five Years in Advance (Latest Department of Labor Estimate)

(v) Projected Surgical Demand = D = L/(.90); Projected Utilization Rate = U = D/(C + C′)

(vi) If U is > or = (.90); Then Need Exists; If U is < (.90); Then Excess OR Capacity Exists;

2. The proposed number and type (that is, inpatient, mixed, ambulatory/SDS) of operating rooms;

3. Pro forma showing all capital and operating costs and revenues to one year beyond break even; and

4. Information to indicate that licensure standards will be met.

(b) Additional information to be provided by applicants for surgical facilities shall include:

1. The expected number of recovery beds and/or recliners;

2. The total expected number of surgical cases, by each type of surgery, as determined by the surgical need methodology described in this section.

3. The expected payor percentages;

4. The procedures performed and the change per procedure, where applicable;

5. Documentation as to whether the physician(s) associated with the surgical facility accepts Medicare and Medicaid assignment; and

6. The proposed service area is to be described in detail and accompanied by a legible map which includes a distance scale and physical relationship to other existing surgical facilities within the proposed service area and immediately bordering the area. The methodology/rationale justifying the delineation of the service area chosen by the applicant will be included with supporting quantifiable evidence. The Department of Health shall determine the reasonableness of the defined service area, in accordance with N.J.A.C. 8:33 and this chapter.

8:33S–1.5 Exemption

A physician or professional association seeking to establish a single operating room surgical practice limited to his or her or their private practice is exempted from certificate of need requirements. However, in no case shall a surgical practice with more than a single operating room be permitted this physician practice exemption.

8:33S–1.6 Criteria for review

(a) No application for a new surgical facility, or increase in the number of operating rooms in an existing surgical facility, will be approved unless all of the following conditions are met:

1. The number of operating rooms proposed is needed when assessed according to the surgical need methodology described in N.J.A.C. 8:33S–1.4;

2. The utilization of the existing and proposed operating rooms (defined in the surgical need methodology as "projected OR utilization rate") available in the applicant's service area is expected to be in excess of 90 percent of service area OR capacity according to the surgical need methodology;

3. The applicant provides sufficient assurance that both licensure standards and Medicare certification standards will be met;

4. The applicant shall document in its application the proportion of Medicaid-eligible and medically indigent persons residing in the proposed service area. In addition, the applicant shall, in delivering the proposed service, provide care on a free or partial-pay basis to Medicaid-eligible and medically indigent persons at least in proportion to their representation in the approved service area;

5. The applicant indicates a willingness to seek contracts with health maintenance organizations and other managed care providers;

6. The proposal minimizes increases in systemic health care costs;

7. The applicant indicates and documents that contacts with community organizations which serve low income populations have been initiated; and

8. The applicant documents compliance with State and Federal requirements regarding self-referral.

(b) Waivers of (a)1 and 2, above, may be considered where the applicant has petitioned for a waiver identifying specific and quantifiable evidence that the methodology is inappropriate because of circumstances unique to a given application. The waiver, if approved, would apply only to the application for which the waiver is petitioned and the waiver request must give substantial evidence that in the absence of a waiver serious problems of access to a needed service would result.

(c) Exceptions to (a)1 and 2 above may be made as follows:

1. Where an applicant or a facility which is a subsidiary of an organization which has control over the applicant:

i. Has agreed, as part of the application, to close at least one existing inpatient or mixed operating room for each dedicated ambulatory surgical operating room proposed; and

ii. Has agreed, as part of the application, to reduce a sufficient number of its inpatient or mixed operating rooms to ensure a minimum utilization rate of 80 percent of its operating room capacity at the conclusion of the project; or

2. Where an applicant or a facility which is a subsidiary of an organization which has control over the applicant:

i. Has documented that its existing surgical caseload exceeds the capacity of its licensed operating rooms (in accordance with N.J.A.C. 8:33S–1.4(a)) for the past 12 months prior to the submission of this certificate of need application;

ii. Has agreed, as part of the application, to limit the proposed addition of operating room capacity to that number of operating rooms necessary to reduce its surgical case utilization level to 80 percent of its operating room capacity at the time that the application is submitted;

iii. Has documented that sufficient access to alternative surgical providers that share the service area is not readily available; and

iv. Has documented that the addition of operating room capacity in a service area where there is existing capacity will not add significant capital or operating costs to the system.

8:33S–1.7 Statistical data to be maintained and reported

(a) At a minimum, the following information shall be reported by the applicant on an annual basis to the Department of Health:

1. Characteristics of patients: age, sex, residence (county/municipality), insurance coverage, diagnosis and procedures (including primary procedure and all secondary procedures). The applicant shall also request information regarding race and ethnicity which shall also be reported to the Department of Health. This information, however, is voluntary on the part of the patient;

2. Whether anesthesia was used; if so, what type, that is, general or regional conduction blocks, conscious sedation, and minor conduction blocks;

3. The duration (in minutes) per case in which the operating room(s) was/were in use; and

4. The number of cases performed per operating room using the following categorization:

i. Dedicated inpatient operating room;

ii. Mixed same day surgery and inpatient operating room;

iii. Dedicated same day surgery operating room;

iv. Endoscopy rooms; and

v. Cystoscopy rooms.