"Diagnostic cardiac catheterization facility" means an acute care general hospital providing invasive cardiac diagnostic (cardiac catheterization) services to adult patients without surgery backup. These facilities have laboratories which must meet the higher requirement of procedures performed on 500 patients annually.

"Hospital–based" means the provision of a health care service that is physically located on the campus of, and is a permanent structure within, a licensed acute care hospital offering inpatient support services.

"Left–heart catheterization" refers to the measurement of left heart hemodynamics and definition of left heart anatomy/function by catheter delivered radiopaque contrast media.

"Low–risk patients" shall be as defined by the November 1, 1994 participation guidelines of the American College of Cardiology's Database Committee, and "low-risk patients" are those patients excluded from the definition of "high risk" who are able to be managed by the pilot facilities for diagnostic cardiac catheterization.

"Medically underserved" means segments of the population whose utilization of health care services is less than those numbers approximately proportionate to their presence in the population as adjusted to account for their need for such services. Medically underserved includes, but is not limited to, racial and ethnic minority populations, migrant workers, the handicapped, Medicaid recipients, and the medically indigent, defined as those individuals lacking third party insurance coverage whose income is less than or equal to 200 percent of the United States Department of Health and Human Services Income Poverty Guidelines, 42 U.S.C. § 9902(2).

"Open heart surgery" refers to a procedure using a heart-lung by-pass machine to perform the functions of circulation during surgery.

"Pediatric cardiac surgery centers" are those cardiac surgery centers specifically designated to provide the full range of invasive cardiac diagnostic, therapeutic and surgical services to patients less than 16 years of age.

"Percutaneous transluminal coronary angioplasty" (PTCA) means the passage of a balloon-tipped catheter (thin tube) to the site of narrowing in an artery and the inflation of the balloon to reduce the obstruction. For purposes of these rules, PTCA also includes other invasive procedures to dilate coronary obstruction such as atherectomy of various kinds (for example, excisional, laser) and arterial stenting procedures.

"Pilot catheterization program" means an acute care general hospital providing invasive cardiac diagnostic (cardiac catheterization) services within its permanent structure as defined in "hospital-based" above that is limited in the provision of its service to low risk adult patients. Patients with the following conditions listed below are to be considered high risk and shall be excluded from catheterization at pilot facilities and transferred in accordance with N.J.A.C. 8:33E–1.8:

1. Left main coronary syndrome;
2. Unstable myocardial infarction;
3. Acute myocardiac infarction within three days;
4. Unstable angina with persistent angina;
5. Congestive heart failure, defined as NYHA Class III or IV;
6. Cardiogenic shock or severe hemodynamic instability;
7. Aortic stenosis, as measured by Doppler mean gradient over 40 mm of Hg;
8. Ejection fraction below 30 percent; or
9. Concomitant severe medical or vascular problems.

8:33E–1.3 General criteria for invasive cardiac diagnostic facilities

(a) For the purposes of certificate of need application and licensure, invasive cardiac diagnostic facilities shall be categorized as follows:

1. Cardiac surgery center;
2. Cardiac catheterization facility (without cardiac surgery);
3. Low–risk diagnostic cardiac catheterization facility hereinafter referred to as pilot catheterization program; and
4. Pediatric cardiac surgery center.

(b) All cardiac catheterization procedures, regardless of the category, shall be performed in a hospital-based facility where inpatient services are available on site.

(c) Only facilities with invasive cardiac diagnostic and pediatric cardiac surgery programs shall be licensed to perform invasive cardiac diagnostic procedures on pediatric patients.

(d) Electrophysiology studies (EPS and/or percutaneous transluminal coronary angioplasty (PTCA) shall only be performed in hospital-based facilities where licensed cardiac surgery services are immediately available on site. Facilities providing EPS and/or PTCA shall also be required to meet all applicable standards and criteria at N.J.A.C. 8:33E–2.3(d).

Case Notes

Denial of Certificate of Need for cardiac-catherization laboratory was not arbitrary or capricious. Pascack Valley Hospital v. New Jersey Department of Health. 93 N.J.A.R.2d (HLT) 21.

8:33E–1.4 Utilization criteria for invasive cardiac diagnostic facilities

(a) Utilization criteria for all invasive cardiac diagnostic facilities are based on the number of patients upon whom invasive cardiac diagnostic procedures (cardiac catheterization) are performed.

(b) Except as specifically set forth with respect to pilot catheterization program, at (c) below, all facilities licensed to provide invasive cardiac diagnostic services shall, as a condition of continued licensure, be required to maintain the following basic utilization criteria:

1. The minimum acceptable number of adult cardiac catheterization patients per cardiac laboratory is 500 per year. New services must attain this minimum utilization level within three years of operation. Existing services must achieve minimum utilization levels by February 20, 1997. Those laboratories unable to achieve the minimum level as set forth in this paragraph will not be issued a license renewal to continue to provide this service.

2. Each physician must perform procedures on a minimum of 50 patients a year with a minimum of 100 patients over a two year period. (This minimum caseload may be accomplished at more than one laboratory).

3. Diagnostic cardiac catheterization facilities (without cardiac surgery) shall meet the minimum criteria and standards outlined in this subchapter by February 20, 1997, and each year thereafter, or will not be issued a license renewal to continue to provide this service.

(c) All facilities licensed to provide low risk invasive cardiac diagnostic services pursuant to pilot catheterization program described in this subchapter shall be required, as a condition of continued licensure, to maintain the following basic utilization criteria:

1. The minimum acceptable number of adult cardiac catheterization patients per year is 350. Those laboratories unable to achieve this minimum level by the end of the second year of operation as set forth at N.J.A.C. 8:33E–1.14, will not be issued license renewal to continue to provide this service.

2. Physicians practicing in hospitals participating in the pilot catheterization program shall meet minimum volume criteria in order for the hospital to retain a license after the initial two years of operation. For the Director of the laboratory, the standard is left-heart catheterizations on 150 patients per year, at least 100 of which must be performed at the pilot laboratory of which the physician is Director. For other physicians with privileges in the pilot laboratory, the standard is left-heart catheterizations on 50 patients per year. (This minimum caseload may be accomplished at more than one laboratory.)

8:33E–1.5 Facility personnel

(a) All facilities applying to provide or providing any invasive cardiac diagnostic services pursuant to this subchapter shall provide for and maintain the following minimum staff members:

1. One physician;

2. One registered nurse; and

3. One technician who must be qualified in at least one of the technician categories listed at (b)6 through 8 below.

(b) While the following functions shall be performed within each facility, more than one function may be executed by a single individual if that individual has been appropriately cross-trained to perform the required functions:

1. The laboratory director (physician in charge) shall be the chief diagnostician within the unit, and shall be certified by the Cardiovascular Sub–Specialty Board of the American Board of Internal Medicine or by the Sub–Specialty Board of Pediatric Cardiology of the American Board of Pediatrics. In addition to Board certification, the director shall have broad experience and training in invasive cardiac diagnostic procedures, including, but not limited to, a minimum of 12 months in a cardiac catheterization training program and the performance of 200 cardiac catheterization procedures with 100 of these procedures performed as the primary operator.

2. Associate physicians may be assigned to the laboratory and shall meet the identical training and certification requirements for laboratory director contained in (b)1 above. In addition, all catheterizing physicians shall adhere to the minimum physician volume standards established by each laboratory in accordance with N.J.A.C. 8:33E–1.4(b)2.

i. Exceptions to these minimum training and certification requirements for incumbent Directors and associate physicians requirements may be granted by the Commissioner upon application by an institution providing documentation as to the physician's qualifications, in accordance with the requirements of this chapter, N.J.A.C. 8:43G–7.15(b), 7.40, 7.28, and N.J.A.C. 13:35.

3. Physicians practicing in hospitals participating in the pilot catheterization program shall meet minimum volume criteria in order for the hospital to retain a license after the initial two years of operation. For the director of the laboratory, the standard is left-heart catheterizations on 150 patients per year, at least 100 of which must be performed at the pilot laboratory of which the physician is director. For other physicians with privileges in the pilot laboratory, the standard is left-heart catheterizations on 50 patients per year. (This minimum caseload may be accomplished at more than one laboratory.)