

**8:43G-7.20 Cardiac catheterization staff education and training**

Requirements for the cardiac catheterization staff education program shall be as provided at N.J.A.C. 8:43G-5.9.

**8:43G-7.21 Cardiac catheterization quality assurance methods**

(a) The quality assurance program for cardiac catheterization shall include at least:

1. Monitoring the volume of procedures;
2. Infection and complication rates;
3. The incidence of mortality, morbidity, and other adverse occurrences;
4. Patient factors that affect risk of complications in each service; and
5. Retrospective evaluation of emergency procedures.

(b) There shall be a peer review committee for the cardiac catheterization service that includes at least the chief of the cardiac catheterization laboratory, the chief of cardiology, a catheterizing cardiologist, and a non-catheterizing cardiologist. The committee shall review all mortalities, serious complications, and selected procedures done in the cardiac catheterization suite to identify trends and problems in the service. Minutes of these meetings shall be maintained.

**8:43G-7.22 Scope of pilot catheterization program**

In addition to meeting all applicable standards in N.J.A.C. 8:43G-7.1 through 7.21, a pilot catheterization program established in accordance with N.J.A.C. 8:33E shall comply with all standards in N.J.A.C. 8:43G-7.23 through 7.27.

New Rule, R.1999 d.436, effective December 20, 1999.  
See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

Former N.J.A.C. 8:43G-7.22, Percutaneous transluminal coronary angioplasty policies and procedures, recodified to N.J.A.C. 8:43G-7.28.

**8:43G-7.23 Requirements for licensure**

(a) Initial licenses granted to pilot catheterization program facilities shall be valid for a period not to exceed 30 months from the month in which the facility initiates low risk invasive cardiac diagnostic services under the program and shall expire automatically without the need for further notification or other action by the Department of Health and Senior Services.

(b) Licenses that have expired at accordance with (a) above shall be renewed only upon demonstration of full compliance with all applicable standards and criteria for low risk invasive cardiac diagnostic pilot catheterization programs.

New Rule, R.1999 d.436, effective December 20, 1999.  
See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

Former N.J.A.C. 8:43G-7.23, PTCA staff qualifications, recodified to N.J.A.C. 8:43G-7.29.

**8:43G-7.24 Pilot catheterization program policies and procedures**

The pilot catheterization program shall perform a minimum of 350 left-heart catheterizations annually by the end of the second year of operation. In accordance with N.J.A.C. 8:33E-1.14, the program shall demonstrate and verify its ability to provide at least this level of service in order to obtain renewal of its license.

New Rule, R.1999 d.436, effective December 20, 1999.  
See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

Former N.J.A.C. 8:43G-7.24, PTCA staff time and availability, recodified to N.J.A.C. 8:43G-7.30.

**8:43G-7.25 Pilot catheterization program staff qualifications**

(a) There shall be a physician director of the program who is board certified in internal medicine in the subspecialty of cardiovascular disease. The director shall have completed at least one year of additional training and performed at least 200 cardiac procedures as the primary operator.

(b) The director shall perform at least 150 left-heart catheterization procedures per year, at least 100 of which shall be performed at the pilot program laboratory.

(c) Any physician performing invasive cardiac procedures in the pilot catheterization program shall meet the qualifications at N.J.A.C. 8:43G-7.15(b) and (c).

(d) Each physician with privileges in the pilot program laboratory shall perform at least 50 left-heart catheterization per year.

New Rule, R.1999 d.436, effective December 20, 1999.  
See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

Former N.J.A.C. 8:43G-7.25, PTCA space and environment, recodified to N.J.A.C. 8:43G-7.31.

**8:43G-7.26 Pilot catheterization program staff time and availability**

(a) There shall be at least one physician trained and experienced in cardiac catheterization present in the room during all catheterization and angiographic procedures.

(b) There shall be at least one registered professional nurse with appropriate training and experience, in accordance with N.J.A.C. 8:33E-1.5(b)4, present in the room during each procedure.

(c) There shall be at least one trained and experienced technician qualified in accordance with N.J.A.C. 8:33E-1.5(b)5 through 8 present in the room during each procedure.

New Rule, R.1999 d.436, effective December 20, 1999.  
See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

Former N.J.A.C. 8:43G-7.26, Electrophysiology studies staff qualifications, recodified to N.J.A.C. 8:43G-7.32.

#### **8:43G-7.27 Pilot catheterization program quality improvement**

(a) The pilot catheterization program shall include at least the following quality improvement indicators:

1. Low-risk patient mortality and morbidity rate;
2. Physician-specific and overall pilot laboratory percentage of normal studies (not to exceed 25 percent of total annual cases);
3. Increase in the number of normal studies during any reporting period (not to exceed 50 percent, with a plan for corrective action to be submitted to the Department within 60 days should the increase reach 50 percent or more);
4. Percentage of all patients undergoing diagnostic cardiac catheterization in the pilot program who subsequently undergo a therapeutic interventional cardiac procedure as a direct result of the findings of the initial diagnostic procedure; and
5. Clinical appropriateness of the performance of catheterization procedures other than left-heart procedures (that is, right-heart procedures).

New Rule, R.1999 d.436, effective December 20, 1999.

See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

Former N.J.A.C. 8:43G-7.27, EPS staff time and availability, recodified to N.J.A.C. 8:43G-7.33.

#### **8:43G-7.28 Percutaneous transluminal coronary angioplasty policies and procedures**

(a) Percutaneous transluminal coronary angioplasty (PTCA) shall be performed only in cardiac surgical centers approved by the New Jersey State Department of Health.

(b) There shall be at least 200 PTCA procedures performed in the hospital per year excluding the first three years following initiation of services as referenced at N.J.A.C. 8:33E-2.3(d)1.

Amended by R.1992 d.72, effective February 18, 1992.

See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Reference to elective surgery deleted at (a).

Recodified from N.J.A.C. 8:43G-7.22 by R.1999 d.436, effective December 20, 1999.

See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

Former N.J.A.C. 8:43G-7.28, Board eligibility status, recodified to N.J.A.C. 8:43G-7.34.

#### **8:43G-7.29 PTCA staff qualifications**

(a) Any physician performing PTCA as primary operator shall meet one of the following qualifications:

1. Is board certified in both internal medicine and the subspecialty of cardiovascular disease, or is board eligible in the subspecialty of cardiovascular disease and shall be examined within two years of initial cardiac eligibility. Physicians meeting either of these qualifications must additionally complete the training and experience requirement in cardiac catheterization including 24 months in the cardiac catheterization laboratory during which time the individual actively participated in at least 200 PTCA's under the supervision of primary operators provided by no more than two separate institutions; or

2. Is board certified in internal medicine and the subspecialty of cardiovascular disease as of July 1, 1990 and has performed at least 50 PTCA's per year as the primary operator for each of the past two years.

(b) Each physician performing PTCA shall perform a minimum of 75 cases per year or 150 over a two-year period, excluding the first year of practice after training. The physician shall perform at least 50 cases annually as the primary operator.

Amended by R.1992 d.72, effective February 18, 1992.

See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Qualifications for PCTA primary operator specified at (a).

Recodified from N.J.A.C. 8:43G-7.23 and amended by R.1999 d.436, effective December 20, 1999.

See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

Rewrote (b). Former N.J.A.C. 8:43G-7.29, Pediatric cardiac services standards; scope, recodified to N.J.A.C. 8:43G-7.35.

#### **8:43G-7.30 PTCA staff time and availability**

(a) The following staff shall be present for all PTCA procedures:

1. A physician who meets the requirements in N.J.A.C. 8:43G-7.23(a);

2. A registered professional nurse certified in basic cardiac life support, and trained and experienced in cardiac catheterization and PTCA who acts as the circulating nurse; and

3. One of the following individuals:

i. A scrub nurse who is either a registered professional nurse or a licensed practical nurse; or

ii. A technician who has been trained in assisting with cardiac catheterization and PTCA.

Amended by R.1992 d.72, effective February 18, 1992.

See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).

Physician and scrub nurse added.

Recodified from N.J.A.C. 8:43G-7.24 by R.1999 d.436, effective December 20, 1999.

See: 31 N.J.R. 367(a), 31 N.J.R. 614(a), 31 N.J.R. 4293(c).

Former N.J.A.C. 8:43G-7.30, Pediatric cardiac surgery policies and procedures, recodified to N.J.A.C. 8:43G-7.36.