(b) The continuous quality improvement program for surgery shall include at least:

1. Monitoring the volume of each service provided;

2. Infection and complication rates;

3. The incidence of mortality, morbidity, and other adverse occurrences in each service;

4. Patient factors that affect risk of complications in each service; and

5. Retrospective evaluation of emergency procedures in each service.

Recodified from N.J.A.C. 8:43G-7.35 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).
Substituted references to continuous quality improvement for reference to quality assurance throughout.

8:43G-7.42 (Reserved)

Recodified from N.J.A.C. 8:43G-7.36 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).

8:43G-7.43 Pediatric cardiac catheterization policies and procedures

(a) Pediatric invasive cardiac diagnostic procedures shall be performed only at pediatric cardiac surgery centers.

(b) The pediatric cardiac catheterization service may share the catheterization laboratory with the adult cardiac catheterization program. However, the staff who participates in the pediatric catheterization shall be trained and experienced in the care of the pediatric cardiac patient and the equipment used shall be appropriate to meet the needs of the pediatric patient.

(c) The pediatric cardiac catheterization laboratory shall perform a minimum of 150 pediatric cardiac catheterizations per year, excluding the first three years following initiation of services as referenced at N.J.A.C. 8:33E-1.11(d).

Amended by R.1992 d.72, effective February 18, 1992.
See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).
Old text at (b) deleted; new requirements added.
Recodified from N.J.A.C. 8:43G-7.37 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).

8:43G-7.44 Pediatric cardiac catheterization staff qualifications

(a) There shall be a director of the pediatric cardiac catheterization service who is board certified in pediatrics, in the subspecialty of pediatric cardiology, and who has completed at least one year of additional training in an accredited program for interventional pediatric cardiac procedures.

(b) Any physician performing pediatric cardiac catheterization in the pediatric cardiac catheterization laboratory shall be board certified in the subspecialty of pediatric cardiology, or shall meet current requirements to be examined and shall be examined within two years of eligibility.

(c) Each physician performing diagnostic cardiac catheterization without supervision shall have performed at least 50 pediatric cardiac catheterizations as the primary operator. The hospital shall determine policy requiring the minimum number of annual procedures that a physician must perform.

(d) Each physician shall perform a minimum of 50 pediatric procedures per year with a minimum of 100 procedures over a two year period.

Recodified from N.J.A.C. 8:43G-7.38 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).
Added (d).

8:43G-7.45 Pediatric catheterization continuous quality improvement methods

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

Recodified from N.J.A.C. 8:43G-7.39 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).

8:43G-7.46 Staff qualifications waiver

(a) Exceptions for physicians with hospital privileges to these minimum board certification and training requirements may be granted by the Commissioner or his or her designee upon application by an institution providing acceptable documentation which assures that the physician's qualifications are at a level assuring the level of patient safety intended by the requirements of these rules. As part of the waiver request, the hospital shall provide documentation of the practitioner's qualifications that at a minimum addresses the following:

1. A curriculum vitae which describes the practitioner's academic training and professional experience;

2. Documentation of the volume of procedures that the practitioner has completed on an annual basis;

3. Length of experience in performance of procedure;

4. Current status and future intention to meet the requirements for board-certification; and

5. Documentation of the practitioner's complication rates in performing the procedure for which a waiver is sought.

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(b) Additional information may be requested from the hospital by the Department in making a determination or it may obtain the recommendations from the Commissioner's Cardiac Services Advisory Committee.

(c) Waivers may be granted for periods not to exceed three years and are renewable at the discretion of the Commissioner.

New Rule, R.1992 d.72, effective February 18, 1992.
See: 23 N.J.R. 2590(a), 24 N.J.R. 590(a).
Recodified from N.J.A.C. 8:43G-7.40 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).

SUBCHAPTER 7A. STROKE CENTERS

8:43G-7A.1 Stroke center standards; scope

This subchapter sets forth the standards for designation as a primary or comprehensive stroke center with which all applicants for the respective designations shall comply.

8:43G-7A.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings:

"Acute care rehabilitation" means the provision of occupational therapy, physical therapy and speech-language pathology, as medically necessary, during the acute phase of a stroke patient's hospital stay.

"Acute stroke" means the rapid onset of a focal neurological deficit with signs or symptoms persisting longer than 24 hours and not otherwise attributable to another disease process. The term "acute stroke" includes the subtype acute hemorrhagic stroke and the subtype acute ischemic stroke.

"Complex stroke" means a stroke occurring in a person who also suffers from one or more of the following comorbid conditions:

1. Any previous ipsilateral surgery or intervention;

2. Any previous ipsilateral stroke or intervention;

3. Known history of vascular disease or major vascular surgery within two years;

4. Severe (symptomatic) chronic obstructive pulmonary lung disease;

5. Class III or IV cardiac symptoms, or previous cardiac bypass surgery; or

6. History of radiation or any prior (even non-vascular) surgery to the neck.

"Comprehensive stroke center" means a licensed general hospital designated to evaluate, stabilize and provide emergency care to patients with acute stroke symptoms, that has the capability to provide specialized care to patients with complex strokes, including patients with acute stroke symptoms transferred from other general hospitals.

"Primary stroke center" means a licensed general hospital designated to evaluate, stabilize and provide emergency care to patients with acute stroke symptoms, and to admit such patients for inpatient services as appropriate to the needs of the patient, but which has limited capacity to provide inpatient care to patients with a complex stroke.

8:43G-7A.3 Primary stroke center licensure designation

(a) To be designated as a primary stroke center, a hospital shall, at a minimum, provide:

1. An acute stroke team available to see a patient identified as a potential acute stroke patient within 15 minutes following the patient's arrival at the hospital's emergency department or within 15 minutes following a diagnosis of a patient's potential acute stroke;

2. Written policies and procedures for stroke services that are reviewed at least every three years, revised more frequently as needed, and implemented.

i. These policies and procedures shall include written protocols and standardized orders for emergency care of stroke patients;

3. Neuro-imaging services capability that is available 24 hours a day, seven days a week, such that imaging shall be performed within 25 minutes following order entry. Such studies shall be interpreted by a board-certified radiologist, board-certified neurologist or residents who interpret such studies as part of their training in an Accreditation Council of Graduate Medical Education-approved radiology training program within 20 minutes of study completion.

i. Neuro-imaging services shall, at a minimum, include computerized tomography scanning or magnetic resonance imaging, as well as interpretation of the imaging.

ii. In the event that tele-radiology is used in image interpretation, all staffing and staff qualification requirements contained in this subchapter shall remain in effect and shall be documented by the hospital.

iii. For the purpose of this subsection, a qualified radiologist shall be board-certified by the American Board of Radiology or the American Osteopathic Board of Radiology.

iv. For the purpose of this subsection, a qualified neurologist shall be board-certified by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry;

4. Laboratory services capability 24 hours a day, seven days a week, such that services may be performed within 45 minutes following order entry.

i. Laboratory services shall, at a minimum, include blood testing, electrocardiography and x-ray services;

5. Intermediate, telemetry or critical care beds staffed in accordance with N.J.A.C. 8:43G-9.20 and 9.7, respectively;

6. Neurosurgical services that are available, including operating room availability, either directly or under agreement with a comprehensive stroke center, within two hours following admission of acute stroke patients to the primary stroke center;

7. Acute care rehabilitation services;

8. Documentation that it has current contractual agreements with at least one carrier that provides health insurance coverage through the State Medicaid Children's Health Care Coverage Program, established pursuant to N.J.S.A. 30:4I-1 et seq., and the New Jersey FamilyCare Health Coverage Program, established pursuant to N.J.S.A. 30:4J-8 et seq.; and

9. Transfer arrangements with a comprehensive stroke center in New Jersey that facilitate transfer of patients with complex strokes to the comprehensive stroke center for care when clinically warranted.

8:43G-7A.4 Primary stroke center staff qualifications

(a) There shall be a physician director of a primary stroke center, who may also serve as a physician member of a stroke team, who is board-certified in neurology or neurosurgery and who shall meet two or more of the following qualifications:

1. Completion of a stroke fellowship;

2. Participation (as an attendee or faculty) in at least two regional, national or international stroke courses or conferences each year;

3. Authorship of five or more peer-reviewed publications on stroke; and/or

4. Eight or more continuing medical education (CME) credits each year in the area of cerebrovascular disease.

(b) At a minimum, an acute care stroke team shall consist of:

1. A neurologist or emergency physician who is board-certified or board-eligible in neurology or emergency medicine with special competence in caring for acute stroke patients; and

2. A registered nurse, physician assistant or nurse practitioner who has demonstrated competency, as determined by the physician director described in (a) above, in caring for acute stroke patients.

(c) Each physician member of a stroke team, except residents functioning under supervision as part of the hospital's graduate residency training program, shall meet one or more of the following qualifications:

1. Completion of a stroke fellowship;

2. Participation (as an attendee or faculty) in at least two regional, national or international stroke courses or conferences each year;

3. Authorship of five or more peer-reviewed publications on stroke; or

4. Eight or more CME credits each year in the area of cerebrovascular disease.

(d) Neurology and emergency department personnel shall be trained in the diagnosis and treatment of acute stroke in accordance with the training and education requirements set forth in N.J.A.C. 8:43G-7A.5(a)1.

(e) Nursing staff and unlicensed assistive personnel assigned to intermediate or telemetry or critical care beds utilized for acute stroke patients shall be trained and experienced in caring for acute stroke patients in accordance with the training and education requirements set forth in N.J.A.C. 8:43G-7A.5(a)1.

8:43G-7A.5 Primary stroke center education and training

(a) A hospital designated as a primary stroke center shall, under the direction of a stroke center physician director, provide education regarding acute stroke to both the hospital's personnel and the public.

1. The hospital shall provide to personnel engaged in direct patient care of acute stroke patients continuing education annually regarding diagnosis and treatment of acute stroke as follows:

i. For those personnel who are assigned to an acute stroke team, a minimum of eight CME credits or eight continuing education units (CEU) or eight hours of training for unlicensed assistive personnel, as applicable, each year in the area of cerebrovascular disease; and

ii. For those personnel who are not assigned to a stroke team but are regularly assigned to the care of acute stroke patients, a minimum of four CME credits or four CEU or four hours of training for unlicensed assistive personnel, as applicable, each year in the area of cerebrovascular disease.

2. The hospital shall provide to the public ongoing education regarding prevention, recognition, diagnosis and treatment of acute stroke, hosting at least two such programs annually.

8:43G-7A.6 Primary stroke center continuous quality improvement

(a) A hospital designated as a primary stroke center shall collect patient-level data to support evaluation of outcomes and quality improvement activities.

1. Data shall be collected on each patient evaluated for stroke and each patient receiving acute interventional therapy.

(b) The hospital shall track, at a minimum:

1. The number of patients evaluated for acute stroke and transient ischemic attacks;

2. The number of patients receiving acute interventional therapy;

3. The amount of time from patient presentation to delivery of acute interventional therapy;

4. Patient length of stay;

5. Patient functional outcome at time of discharge from the acute care facility;

6. Patient morbidity; and

7. Discharge disposition.

(c) Every primary stroke center shall maintain the data required in (a) and (b) above in a database or registry capable of tracking patient outcomes.

1. The hospital shall have written policies regarding ongoing evaluation of the data and implementation of quality improvement activities based on data evaluation.

8:43G-7A.7 Comprehensive stroke center staffing

(a) In addition to meeting the requirements of N.J.A.C. 8:43G-7A.3 and 7A.4, a hospital designated as a comprehensive stroke center shall:

1. Satisfy the following staff qualifications, consistent with the on-call criteria set forth at N.J.A.C. 8:43G-5.1(*l*)2:

i. A neurosurgical team capable of assessing and treating complex stroke and stroke-like syndromes;

ii. A neuroradiologist with current Certificate of Added Qualifications in neuroradiology on staff; and

iii. A physician with neuro-interventional angiographic training and skills on staff as deemed by the hospital's credentialing process;

2. Have available 24 hours a day, seven days a week, digital subtraction angiography and a special procedures suite equipped for neuro-interventional procedures, such that the procedures shall be performed within 20 minutes following order entry.

i. In the event that tele-radiology is used in image interpretation, all staffing and staff qualification requirements contained in this subchapter shall remain in effect and shall be documented by the hospital.

ii. A qualified radiologist shall be board-certified by the American Board of Radiology or the American Osteopathic Board of Radiology.

iii. A qualified neurologist shall be board-certified by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry;

3. Provide comprehensive rehabilitation services either on site or by written transfer agreement with another health care facility licensed to provide such services; and

4. Enter into and maintain written transfer agreements with primary stroke centers in New Jersey to accept transfer of patients with complex strokes when clinically warranted.

8:43G-7A.8 Comprehensive stroke center education and training

(a) In addition to satisfying the requirements of N.J.A.C. 8:43G-7A.5, a hospital designated as a comprehensive stroke center shall:

1. Provide guidance and continuing medical education to hospitals designated as primary stroke centers with which they have transfer agreements;

2. Provide graduate medical education in stroke; and

3. Conduct research on stroke-related topics, such as laboratory research or clinical drug studies or both.

8:43G-7A.9 Comprehensive stroke center continuous quality improvement

A hospital designated as a comprehensive stroke center shall, in addition to satisfying the requirements of N.J.A.C. 8:43G-7A.6, develop and maintain de-identified outcomes data from affiliated primary stroke centers and shall integrate this data and its own patient-level data with available regional, State and national data in order to develop benchmarks for performance to be used in assessing and improving quality in the hospital and its affiliated primary stroke centers.

8:43G-7A.10 Licensing and compliance

(a) General hospitals seeking designation as a primary stroke center or a comprehensive stroke center shall meet the applicable minimum criteria and standards contained in this subchapter and file a licensing amendment in accordance with N.J.A.C. 8:43G-2.2.