

Cardiac Services Need Methodology

Effective Date: 11/4/09

Summary of Express Terms

This amendment to Title 10 of the Official Code of Rules and Regulations of the State of New York Section 709.14, which amends subdivisions (a) and (b), repeals Subdivisions (c) and (d) and replaces Subdivisions (c) and (d) with new subdivisions (c) and (d), updates the planning and need methodology for cardiac surgery and provides methodologies for determining need for PCI Capable Cardiac Catheterization Laboratory Centers, Cardiac Electrophysiology (EP) Laboratory Programs and Pediatric Cardiac Catheterization Laboratory Centers.

Section 709.14(a) is amended by updating terminology and adding a reference to percutaneous coronary interventions (PCI) in the statement of intent.

Section 709.14(b) - relating to Cardiac Surgery Centers is amended as follows:

- Section 709.14(b)(3) retains the existing need methodology and adds a requirement that annual volume projections include a projected annual volume of at least 300 PCI cases within two years of approval for facilities proposing to initiate an Adult Cardiac Surgery Center. (Cardiac Surgery Centers will be approved to provide Cardiac Surgery Center and PCI Capable Cardiac Catheterization Laboratory Center services as per 709.14(b)(9)).
- Section 709.14(b)(4) changes the Pediatric Cardiac Surgery Center services

projected annual volume requirement from 100 to 200 pediatric cardiac surgical procedures per year. A provision is also added allowing for a facility demonstrating the ability to perform 50 cases a year and operate as part of a coordinated program with another pediatric Cardiac Surgery Center to be considered for approval.

- Section 709.14(b)(5)(ii) updates standards for Hospital Based Prevention Programs to reflect more recent thinking in Public Health, focuses efforts on inpatients with a principal diagnosis of ischemic heart disease, reduces tracking and follow up requirements, and retains the philosophy that hospitals approved to provide cardiac services carry a responsibility for stewardship in the area of prevention. Requirements include: treatment plans that include risk factor assessment and education for cardiac patients, professional education, heart health promotion and an administrative team.
- Section 709.14(b)(9) specifies that all hospitals approved as adult Cardiac Surgery Centers shall be approved as PCI Capable Cardiac Laboratory Centers and must meet the standards at 405.29(c), 405.29(e)(1) and 405.29(e)(2) of this Title and specifies that all hospitals approved as Pediatric Cardiac Surgery Centers shall be approved as Pediatric Cardiac Catheterization Laboratory Centers and must meet the standards at 405.29(c), 405.29(e)(1) and 405.29(e)(4) of this Title.

Subdivision (c) of Section 709.14 is repealed and a new 709.14(c) is added to provide a

definition for Cardiac Catheterization Laboratory Centers and the categories of Cardiac Catheterization Laboratory Centers, including PCI Capable Cardiac Catheterization Laboratory Centers, Cardiac EP Laboratory Programs and Pediatric Cardiac Catheterization Laboratory Centers by referencing definitions in 405.29(a)

Subdivision (d) of Section 709.14 is repealed and a new 709.14(d) is added to provide a need methodology for Cardiac Catheterization Laboratory Centers.

- Section 709.14(d)(1)(i) specifies that applicants approved as Cardiac Surgery Centers are approved PCI Capable Cardiac Catheterization Laboratory Centers
- Section 709.14(d)(1)(ii) provides the methodology to be used in determining need for PCI Capable Cardiac Catheterization Laboratory Centers at hospitals with no cardiac surgery on-site. Factors for determining need include:
 - Evidence that existing centers cannot meet the needs of patients in need of emergency PCI due to conditions such as capacity, geography and or EMS limitations.
 - Defines the planning area as the area within 1 hour average surface travel time of the applicant institution.
 - Applicants must demonstrate the ability to provide high quality appropriate care with a minimum of 36 emergency PCI cases within the first year of operation and 200 cases within two years of start up and must demonstrate the ability to comply with standards at Section 405.29. Documentation in support of volume projections must include: discharge data indicating the number of patients with a diagnosis of acute MI and or

other diagnoses associated with PCI, the number of doses of thrombolytic therapy ordered for acute MI patient in the applicant hospital's emergency department, and documentation of transfers to existing PCI Capable Cardiac Catheterization Laboratory Centers for PCI. Additional factors that may be considered are enumerated and include a provision specifying volume considerations for a Cardiac Catheterization Laboratory Center that is co-operated with an approved Cardiac Surgery Center.

- Applicants must demonstrate that the addition of the proposed program will not jeopardize the ability of existing centers to continue to meet minimum volume and quality expectations and that one of the following conditions exists: the applicant is greater than one hour from existing PCI sites or all existing PCI centers within an hour of the applicant perform at least 300 cases a year and are expected to continue to perform at that level after the addition of the proposed program.
 - The applicant must submit a plan regarding initiatives in the area of access, outreach and continuity of care.
 - A written, signed affiliation agreement with a New York State Cardiac Surgery Center is required in accordance with Section 405.29.
- Section 709.14(d)(2) provides the methodology to be used in determining need for Cardiac EP Laboratory Programs. Factors include:
 - Applicant must be an approved PCI Capable Cardiac Catheterization Laboratory Center, an approved Diagnostic Cardiac Catheterization

Laboratory Center, or be applying for EP in conjunction with an application to become a PCI center

- Applicant must demonstrate ability to comply with standards at Section 405.29(e)(5) of this Title.
 - Documentation of exiting referrals for cardiac electrophysiology patients treated by cardiologists on staff at the hospital must be submitted.
 - Applicants from hospitals with no cardiac surgery on-site must submit a copy of the patient selection criteria.
 - Hospitals approved as Cardiac Surgery Centers shall be deemed to have demonstrated public need for a Cardiac EP Laboratory Program.
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- Section 709.14(d)(3) specifies that need for a Pediatric Cardiac Catheterization Laboratory Center shall be determined only in conjunction with an application for a Pediatric Cardiac Surgery Center.

Pursuant to the authority vested in the State Hospital Review and Planning Council and subject to the approval of the Commissioner of Health by Section 2803 of the Public Health Law, Section 709.14 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is hereby amended, Subdivisions (a) and (b) are amended, Subdivisions (c) and (d) are repealed and replaced with new Subdivisions (c) and (d) to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Subdivisions (a) and (b) of Section 709.14 are amended to read as follows:

709.14 [Cardiac care services.] Cardiac services.

(a) These standards will be used to evaluate certificate of need applications for [cardiac catheterization laboratory center] Cardiac Catheterization Laboratory Center services and [cardiac surgical] Cardiac Surgery Center services. All need determinations are hospital site specific. It is the intent of the State Hospital Review and Planning Council that these standards, when used in conjunction with the planning standards and criteria set forth in section 709.1 of this Part, become a statement of planning principles and decision making tools for directing the distribution of [cardiac catheterization] Cardiac Catheterization Laboratory Center services and [cardiac surgical] Cardiac Surgery Center services. These planning principles and decision making tools build on the existing regional resources that have been developed through the regulatory planning process. The goals and objectives of the standards expressed herein are expected to promote [insure

adequate] access to [cardiac catheterization] Cardiac Catheterization Laboratory Center services and [cardiac surgical] Cardiac Surgery Center services, maintain provider volumes associated with high quality care, and avoid the unnecessary duplication of resources while addressing the geographic distribution of services necessary to meet the needs of patients in need of emergency percutaneous coronary interventional (PCI) procedures. Additionally, it is intended that the methodology provide sufficient flexibility to consider additional circumstances that reflect on the need for cardiac services.

(b) Cardiac Surgery Centers. The factors for determining the public need for [cardiac surgical] Cardiac Surgery Center services shall include, but not be limited to the following:

(1) The planning area for determining the public need for [cardiac surgical] Cardiac Surgery Center services shall include the applicant's designated Health Systems Agency (HSA) region and the use area of the applicant facility. For purposes of determining [cardiac surgical] Cardiac Surgery Center services need, the use area of a facility is defined as the area within a 100 mile radius of the applicant facility.

(2) Planning for [cardiac surgical] Cardiac Surgery Center services shall ensure that, to the extent possible, 80 percent of the total population of each HSA region resides within 100 miles of a facility providing cardiac surgical services.

(3) [When public need is established herein, a] A facility proposing to initiate an [adult cardiac surgical] Adult Cardiac Surgery Center [program] must [currently operate an

approved cardiac catheterization program with existing volume and current cardiac surgical referrals] document a cardiac patient base and current cardiac interventional referrals sufficient to support [a cardiac surgical program with] a projected annual volume of at least 500 cardiac surgery cases and a projected annual volume of at least 300 PCI cases within [three] two years of approval. The criteria for evaluating the need for additional [adult cardiac surgical services] Adult Cardiac Surgery Centers within the planning area shall include consideration of appropriate access and utilization, and the ability of existing services within the planning area to provide such services. Approval of additional [cardiac surgical] Adult Cardiac Surgery Center services may be considered when each existing [adult cardiac surgical service] Adult Cardiac Surgery Center in the planning area is operating and expected to continue to operate at a level of at least 500 cardiac surgical procedures per year. Waiver of this planning area volume requirement may be considered if:

(i) the HSA region's age adjusted, population based use rate is less than the statewide average use rate; and

(ii) existing [adult cardiac surgical services] Adult Cardiac Surgery Centers in the applicant facility's planning area do not have the capacity or cannot adequately address the need for additional cardiac surgical procedures, such determinations to be based on factors including but not necessarily limited to analyses of recent volume trends, analyses of Cardiac [Surgical] Reporting System data, and review by the area health systems agency(s); and

(iii) existing cardiac surgical referral patterns within the planning area indicate that approval of an additional service at the applicant facility will not jeopardize the minimum volume required at other existing cardiac surgical programs [which are currently meeting quality of care expectations as determined through analysis of annual risk-adjusted Cardiac Surgical Reporting System data and other pertinent assessment information].

(4) No finding of need for the addition of [pediatric cardiac surgical] Pediatric Cardiac Surgery Center services will be made unless each existing [pediatric cardiac surgical] Pediatric Cardiac Surgery Center service in the [State] planning area is operating and expected to continue to operate at a level of at least [100] 200 pediatric cardiac surgical procedures per year, and unless such existing [pediatric cardiac surgical] Pediatric Cardiac Surgery Center services do not have the further capacity to meet projected need for additional pediatric cardiac surgical procedures. Where public need is established herein, a facility proposing to provide pediatric cardiac surgical services must demonstrate the ability to perform a minimum of [50] 200 pediatric cardiac surgical procedures per year by the end of the second full calendar year of operation or demonstrate the ability to perform a minimum of 50 cases a year on-site and operate as part of a coordinated program based on a fully executed written agreement, approved by the Commissioner, with another pediatric cardiac surgery program in accordance with standards at 405.29(d)(5)(ii). For hospitals seeking approval as part of a coordinated program, the agreement must be submitted with the certificate of need application and must be approved by the Department prior to initiation of the service.

(5) A facility proposing to provide [cardiac surgical] Adult and or Pediatric Cardiac

Surgery Center services shall:

(i) submit a written plan to the Department of Health which, when implemented, will ensure access to cardiac surgical services for all segments of the HSA region's population. Such plan shall provide a detailed plan to reach patients not currently served within the planning area, ensure continuity of care for patients transferred between facilities, and shall otherwise promote planning for cardiac services within the region; and

(ii) propose a hospital based heart disease prevention program [consistent with the recommendations of the Cardiac Advisory Committee of the New York State Department of Health which] that, when implemented, shall include:

(a) [Clinical intervention for cardiac patients (any inpatient or outpatient) Treatment plans for cardiac inpatients with a principal diagnosis of ischemic heart disease [)]. These patients are at high risk for development of adverse cardiovascular events and the program shall provide for the following in a comprehensive, systematic way:

(1) protocols shall be developed and implemented for the assessment of risk factors including lipid disorders, hypertension, diabetes, obesity, cigarette smoking, and sedentary lifestyle. Such protocols shall be in keeping with generally accepted standards;

[(2) assessment of risk factors and referral for appropriate care in first-degree

relatives;

(3) assure risk management including modification of lipid disorders by diet/drugs, modification of blood pressure level by diet/exercise/drugs, control of blood glucose level by diet/drugs, dietary counseling aimed at reduced caloric and fat intake and appropriate weight management, smoking cessation, and exercise prescription. Patients should be referred to their primary care provider with documentation of treatments provided and actions recommended; and

(4) establishment and maintenance of systems to assist in tracking and follow-up to determine attendance at referred services and status of risk management.

(b) Clinical intervention for non-cardiac patients (any inpatient or outpatient whose principal diagnosis is not ischemic heart disease). For these patients, the program shall encourage the following:

(1) assessment of risk factors including, hypertension, hypercholesterolemia, smoking, obesity, sedentary lifestyle, history of diabetes;

(2) provision of appropriate counseling and referral for diagnostic evaluation, treatment and risk factor modification; and

(3) establishment and maintenance of record systems to assist in documenting risk

factors identified, referrals made, and other follow-up action taken.

(c) Cardiac rehabilitation:

(1) The program shall assure access to organized cardiac rehabilitation programs, provided either by the hospital itself or through formal referral agreements.]

(2) The hospital shall provide patient education that shall include, but not be limited to, information on the importance of assessing risk factors for heart disease in first-degree relatives, and the importance of cardiopulmonary (CPR) training for family members and care givers;

(3) Discharge plans must include:

(i) a request for consent to allow patient medical information to be shared with the patient's primary care providers;

(ii) patient referral to their primary care provider with documentation of treatments provided by the hospital and follow-up care recommended by the hospital; and

(iii) patient referral to cardiac rehabilitation programs appropriate to their needs.

[(d)](b) Professional education:

(1) The [program] hospital shall [provide for participation in] sponsor or

co-sponsor at least three professional education programs per year [targeted to community based health professionals,] related to heart disease risk assessment and control [in clinical settings] and that are open to local community based health professionals.

[(e) (c) Hospital-based heart health promotion:

(1) The program shall implement policies and health programs in the hospital and establish environments that promote heart-healthy behaviors among hospital staff, employees and visitors, including:

- (i) prohibiting the sale and use of tobacco products on hospital premises;
- (ii) offering and [drawing attention to] promoting, on a regular basis, healthful choices in hospital cafeterias and patient menus; and
- (iii) offering employee wellness and fitness programs that [may consist of preventive health screenings, contests, campaigns, educational classes, etc.] provide opportunities for employees to make healthy choices.

[(f) (d) Community based heart health promotion:

(1) the [program] hospital shall [provide for organization or participation] organize or participate in a consortium of existing community-based organizations and key

community leaders to[complete an assessment of heart disease risk factors in the community as well as resources available to provide programs and services. The objective of this consortium is to mobilize and coordinate resources for target populations in the community;] engage in activities to improve cardiac health in the community; and

(2) [organization of or participation] organize or participate in at least one major community based campaign (not including health fairs) each year related to major heart disease risk factors.

[(g)] (e) Program administration:

(1) Hospitals shall identify a team within their organization to coordinate heart disease prevention activities. Members of the team shall include a broad range of expertise, including but not limited to: [staff for this program shall include people with experience in] community [organizing] organization, planning, and social marketing, [as well as those with] public health skills [(e.g.,) and health education, [nutrition, epidemiology)]; and.

(2) internal mechanisms shall be established to assure coordination of heart disease prevention activities within the hospital.]

(6) When considering an application to meet public need for [cardiac surgical] Adult and or Pediatric Cardiac Surgery Center services, priority consideration shall be given to the expansion of an existing service as opposed to the initiation of a new [cardiac surgical service] Cardiac Surgery Center.

(7) Where public need is established herein, priority consideration will be given to applicants that agree to serve the medically indigent and patients regardless of the source of payment.

(8) Applicants proposing to initiate [a cardiac surgical] an Adult and or Pediatric Cardiac Surgery Center service must:

- (i) demonstrate the [availability of a designated director, support staff, in-patient and outpatient services, facilities, and equipment as specified in sections 405.22(d)-(e),] ability to comply with standards set forth in 405.29 (c), 405.29(d), and 711.4(h), [712.5 and 712.7(f)] of this Title; and
- (ii) in addition, a facility providing [pediatric cardiac surgical] Pediatric Cardiac Surgery Center services also must comply with the requirements specified in section 711.4(f) of this Title.

(9) All hospitals approved as Adult Cardiac Surgery Centers shall be approved as PCI Capable Cardiac Catheterization Laboratory Centers and must meet standards in Sections 405.29(c), 405.29(e)(1), and 405.29(e)(2) of this Title. All hospitals approved as Pediatric Cardiac Surgery Centers shall be approved as Pediatric Cardiac Catheterization Laboratory centers and must meet the standards at 405.29(c), 405.29(e)(1) and 405.29(e)(4) of this Title.

Subdivision (c) of Section 709.14 of Part 709 is repealed.

A new subdivision (c) of Section 709.14 of Part 709 is added to read as follows:

(c) For the purposes of this section the terms Cardiac Catheterization Laboratory Center, Percutaneous Coronary Intervention (PCI) Capable Cardiac Catheterization Laboratory Center, Cardiac Electrophysiology (EP) Laboratory Program and Pediatric Cardiac Catheterization Laboratory Center shall have the same meanings as in section 405.29 (a)(4) of this Title.

Subdivision (d) of Section 709.14 of Part 709 is repealed.

A new subdivision (d) of Section 709.14 of Part 709 is added to read as follows:

(d) Public need for Cardiac Catheterization Laboratory Centers:

(1) PCI Capable Cardiac Catheterization Laboratory Centers. The factors and methodology for determining the public need for PCI Capable Cardiac Laboratory Centers shall include, but not be limited to the following:

- (i) PCI Capable Cardiac Catheterization Laboratory Centers at hospitals with a Cardiac Surgery Center on site. Applicants approved as Cardiac Surgery Centers are approved PCI Capable Cardiac Catheterization Laboratory Centers as provided under section 709.14 (b)(9) of this Part and must meet

standards at Sections 405.29(c), 405.29(e)(1) and 405.29(e)(2) of this Title.

(ii) PCI Capable Cardiac Catheterization Laboratory Centers at hospitals with no cardiac surgery on site. Factors for determining public need for PCI Capable Cardiac Catheterization Laboratory Centers at hospitals with no cardiac surgery on-site include, but are not limited to:

(a) The planning area for determining the public need for PCI Capable Cardiac Catheterization Laboratory Centers at hospitals with no cardiac surgery on-site shall be the area within a 1 hour average surface travel time, as determined by the department of transportation and adjusted for typical weather conditions, of the applicant facility, unless otherwise determined by the Commissioner in accordance with section 709.1(c) of this title;

(b) Evidence that existing PCI Capable Cardiac Catheterization Laboratory Centers within the planning area cannot adequately meet the needs of patients in need of emergency percutaneous coronary interventions due to conditions such as capacity, geography, and or EMS limitations;

(c) Documentation by the applicant must demonstrate the hospital's ability to provide high quality appropriate care that would yield a minimum of 36

emergency PCI procedures per year within the first year of operation and would yield a minimum of 200 total PCI cases per year within two years of start-up.

- (1) Documentation of the number of cardiologists on staff at the proposed site who currently perform percutaneous coronary interventions at other hospital sites and a summary of experience (including the most recent 3 years of volume and outcomes) for each.
- (2) Documentation in support of volume projections must include, at a minimum: discharge data indicating the number of patients with a diagnosis of acute myocardial infarction (AMI) and/or other diagnoses associated with PCI, the number of doses of thrombolytic therapy ordered for acute MI patients in the applicant hospital's emergency department (as documented through hospital pharmacy records), and documentation of transfers to existing PCI Capable Cardiac Catheterization Laboratory Centers for PCI.
- (3) Additional documentation that may be submitted in support of projected volume and need for a proposed PCI Capable Cardiac Catheterization Laboratory Center include:
 - (i) The number of acute care beds at the applicant hospital and the range of acute care services provided;

- (ii) Documentation by the applicant of barriers that impact care experienced by specific population groups within the planning area and demonstration of cultural competency at the applicant site specific to the proposed populations to be served by the applicant;
- (iii) Documentation by the applicant demonstrating outreach to underserved populations that identifies potential new PCI cases within the service area;
- (iv) Emergency department discharge data;
- (v) Documentation by the applicant of regional demographics and transport patterns within the applicant's Emergency Medical Service (EMS) Region that impact the provision of cardiac care;
- (vi) The geographic distribution of PCI Capable Cardiac Catheterization Laboratory Center services and the ability of such existing centers to serve the patients in the applicant's service area;
- (vii) Letters from local physicians quantifying the number of PCI referrals from their practice and the portion of those that would have been treated at the applicant facility if PCI had been available;
- (viii) Additional information that may be considered in projecting volume for an applicant from an established Article 28 network, or multi-site facility as defined at section 401.1 of this Title, with an approved Cardiac Surgery Center within its system that is seeking to add a PCI Capable Cardiac Catheterization Laboratory Center at a non-cardiac surgery hospital site within the system and for a

co- applicant proposing to operate a PCI Capable Cardiac Catheterization Laboratory Center without surgery onsite, under a co-operator agreement, approved by the department, with an existing Cardiac Surgery Center. Such additional volume projection criteria include documentation by the applicant of the number of patients residing in the service area of the proposed site who have received percutaneous coronary interventions at the Cardiac Surgery Center site and who would have been candidates to receive their procedures at the proposed non-surgery site.

(d) Existing referral patterns indicate that approval of an additional service at the applicant facility will not jeopardize the minimum volume required at other existing PCI Capable Cardiac Catheterization Laboratory Centers and one of the following conditions exists:

- (1) The proposed PCI Capable Cardiac Catheterization Laboratory Center is located more than one hour average surface travel time, as determined by the department of transportation and adjusted for typical weather and traffic conditions, from the nearest existing PCI Capable Cardiac Catheterization Laboratory Center; or
- (2) All existing PCI Capable Cardiac Catheterization Laboratory Centers

within one hour average surface travel time of the applicant facility, as determined by the department of transportation and adjusted for typical weather and traffic conditions, perform and are expected to continue to perform at a level of at least 300 PCI procedures per year after the addition of the proposed new program. Evidence for evaluating this expectation shall include, but not be limited to:

- (i) Data indicating the number of patients residing in the applicant's primary service area who are currently receiving percutaneous coronary intervention procedures at existing centers and the location of the centers where patients are receiving that care;
- (ii) Volume at existing PCI Capable Cardiac Catheterization Laboratory Centers within one hour of the applicant hospital;
- (iii) Analysis provided by the applicant evaluating the portion of its proposed patient case load that would result in a redistribution of cases from existing centers and the portion that would represent new cases from currently under served populations. Such analysis shall include documentation of any outreach programs by the applicant facility that would support projections of new cases.

- (e) A written plan submitted by the applicant that demonstrates the hospital's ability to comply with standards for PCI Capable Cardiac Catheterization

Laboratory Centers at sections 405.29(c), 405.29(e)(1) and 405.29(e)(2) of this Title;

- (f) A written plan submitted by the applicant that outlines staff training and demonstrates the hospital's readiness to accommodate the needs of the PCI patients;

- (g) A written plan has been submitted by the applicant which would promote access to Cardiac Catheterization Laboratory Center services for all segments of the hospital service area's population. The document shall include:
 - (1) a description of current and proposed initiatives for improving outcomes for patients with heart disease,
 - (2) a plan documenting the hospital's ability to maintain a comprehensive program in which high quality interventional procedures are provided as a component of a broad range of cardiovascular care within the hospital and within the community, to include an emphasis on processes of care and a description of how a patient will traverse through the system of care to be offered,
 - (3) a plan for ensuring continuity of care for patients transferred between facilities,
 - (4) documentation of outreach to regional EMS councils served by the applicant,

- (5) documentation that EMS system capabilities have been taken into consideration in the delivery of cardiac services;
 - (6) a description of activities that promote planning for cardiac services within the region; and
 - (7) a description of current and proposed initiatives and strategies for reaching patients not currently served within the area.
- (h) Comments and recommendations received from community organizations;
- (i) The hospital shall propose and implement a hospital heart disease prevention program as set forth at section 709.14(b)(5)(ii) of this Part;
- (j) Where public need is established herein, priority consideration shall be given to applicants that agree to serve the medically indigent and patients regardless of payment and can document a history of the provision of services to populations that experience health disparities.
- (k) Where public need is established herein, priority consideration shall be given to applicants that can demonstrate projected volume in excess of 300 PCI cases a year.
- (l) Where public need is established herein, priority consideration will be given to the expansion of an existing service as opposed to the initiation of

a new service.

(m) A written and signed affiliation agreement with a New York State Cardiac Surgery Center, acceptable to the department, has been submitted in accordance with standards at Section 405.29(c)(8)(i) of this title.

(n) In addition, hospital applicants proposing to jointly operate a PCI Capable Cardiac Catheterization Laboratory Center at a hospital without cardiac surgery on-site under a co-operator agreement with a Cardiac Surgery Center must:

(1) Submit a written and signed operational agreement between the applicant Cardiac Surgery Center and the applicant hospital without cardiac surgery on site that demonstrates there will be an integration of expertise and resources from the Cardiac Surgery Center that would support a high quality program at the proposed site and that is acceptable to the department. The agreement must specify that the department shall be provided 60 day prior written notification of any proposed change, termination or expiration of the agreement, and any changes must be found acceptable to the Department prior to implementation. The agreement shall further provide that the parties agree that termination or expiration of the agreement shall result in closure of the co-operated Cardiac Catheterization Laboratory Center.

- (2) Submit documentation that demonstrates high quality cardiac care is provided at the applicant Cardiac Surgery Center site and that expanding the service to the proposed site would serve as a benefit to patients and the community.
 - (3) Submit written documentation of governing body approval of the co-operator contract.
- (2) Cardiac EP Laboratory Programs. Factors for determining public need for Cardiac EP Laboratory Programs shall include but not be limited to the following:
- (i) Each applicant for a Cardiac EP Laboratory Program shall be an approved PCI Capable Cardiac Catheterization Laboratory Center or an approved Diagnostic Cardiac Catheterization Service operating in compliance with standards at sections 405.29(c) and 405.29(e). Applicants for EP laboratory programs will also be considered in conjunction with requests for approval of PCI Capable Cardiac Catheterization Laboratory Center services.
 - (ii) Each applicant shall submit documentation, describing how the hospital will comply with standards at 405.29(e)(5) of this Title.
 - (iii) Each applicant shall submit documentation of existing referrals for cardiac electrophysiology patients treated by cardiologists on staff at the hospital.
 - (iv) Applicants for cardiac EP Laboratory Programs at hospitals with no Cardiac

Surgery Center on-site must submit a copy of the patient selection criteria for the proposed program in accordance with the standards at section 405.29(e)(5)(iii) of this Title.

(vi) Hospitals approved as Cardiac Surgery Centers shall be deemed to have demonstrated public need to perform cardiac electrophysiology.

(3) Pediatric Cardiac Catheterization Laboratory Centers. Public need for a Pediatric Cardiac Catheterization Laboratory Center shall be determined only in conjunction with an application for a Pediatric Cardiac Surgery Center and when need has been demonstrated for Pediatric Cardiac Surgery Centers in accordance with standards at Section 709.14(b) of this Part.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for the promulgation of these regulations is contained in Sections 2800 and 2803 (2). PHL Article 28 (Hospitals), Section 2800 specifies that “Hospital and related services including health-related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health. In order to provide for the protection and promotion of the health of the inhabitants of the state, pursuant to section three of article seventeen of the constitution, the Department of Health shall have the central, comprehensive responsibility for the development and administration of the state’s policy with respect to hospital and related services, and all public and private institutions, whether state, county, municipal, incorporated or not incorporated, serving principally as facilities for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition or for the rendering of health-related service shall be subject to the provisions of this article.”

PHL Section 2803 (2) authorizes the State Hospital Review and Planning Council (SHRPC) to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of health care facilities.

Legislative Objectives:

The legislative objective of PHL Article 28 includes the protection and promotion of the health of the residents of the State by requiring the efficient provision and proper utilization of health services, of the highest quality at a reasonable cost.

Needs and Benefits:

Title 10 Health Codes Rules and Regulations (10 NYCRR) Section 709.14 provides standards to be used in evaluating certificate of need (CON) applications for cardiac catheterization laboratory and cardiac surgery services in NYS hospitals. When used in conjunction with 10 NYCRR Section 709.1 they are intended as a set of planning principles and decision making tools for directing the distribution of these services, with a goal of ensuring appropriate access to high quality services while avoiding the unnecessary duplication of resources.

Section 709.14 was last updated in January 1994. The many changes and advancements in the provision of cardiac care that have taken place since adoption and last amendment of these regulations have rendered them outdated and incomplete.

Currently, the most widely used procedural intervention for the treatment of coronary artery disease is Percutaneous Coronary Interventions (PCI); also commonly referred to as angioplasty or stenting. When the existing need regulations were

developed, PCI was still a relatively new procedure, provided ONLY in the setting of a Cardiac Surgery Center. As such, approval to perform the procedure was considered part-and-parcel of the cardiac surgery need methodology, and no PCI specific standards were set forth in regulation.

Changes in cardiac care over the years also include recognition of the life saving capability of rapid PCI for patients in the early phases of a heart attack, and recognition that under carefully controlled circumstances, the procedure can be performed in facilities with no cardiac surgery on site (SOS). In addition, performing PCI in conjunction with a diagnostic catheterization (thereby saving a second catheterization lab procedure for patients identified with significant pathologies) is now relatively routine in PCI capable hospitals.

Similarly, intra-cardiac electrophysiology (EP) is a growing subspecialty in cardiology. EP procedures are now used to effectively identify and treat life threatening conditions in the electrical system of the heart such as rapid heart beat. They require a highly specialized team of clinicians. In 2006, approximately 14,200 diagnostic EPs, 9,000 Implantable Cardiac Defibrillator (ICD) procedures and 6,800 ablations were reported in EP labs across the state. While we have developed some guidelines over the years regarding minimum criteria for the provision of EP, there are currently no regulations governing the EP procedures.

These regulations, when enacted, will allow non-SOS cardiac laboratory hospitals

that meet specific criteria to perform PCI. The number of hospitals initially involved in this change would be relatively small. As of June, 2007, there were 40 hospitals approved through the Certificate of Need (CON) process to perform diagnostic only cardiac catheterization. Twelve of those hospitals have waivers to perform PCI with no SOS.

The proposed regulatory changes will supersede existing guidelines and, once enacted, will provide a formal CON review mechanism.

Costs for the Implementation of and Continuing Compliance with these Regulations to the Regulated Entity:

It is a voluntary choice for hospitals to provide these cardiac services and not a mandate. There are approximately 55 hospitals that are currently PCI Capable Cardiac Catheterization Laboratory Centers out of 228 hospitals.

The cost of implementation and compliance of these regulations is expected to be minimal for the affected entities already caring for these patients. Other companion regulations are being updated to reflect medical standards of care. Hospitals that choose to provide such services will need to adhere to the standards in the companion regulations (the medical standard of care), and may incur costs to upgrade their services. Hospitals approved as PCI Capable Cardiac Catheterization Laboratory Centers will be required to

provide emergency PCI on a 24-hour, 7 day a week, 365 days a year basis. Hospitals approved as PCI Capable Cardiac Catheterization Laboratory Centers and hospitals approved as Cardiac Surgery Centers will be required to provide data to the Cardiac Reporting System as those who already provide this care do now.

Cost to State and Local Government:

Any hospital in New York State that is part of State or local government that chooses to provide cardiac services will need to comply with these provisions. Costs for these hospitals will be the same as for any hospital providing these services in New York State.

Cost to the Department of Health:

The Department of Health will need to monitor and provide surveillance and oversight for the system of care provided to these patients. It is not expected to incur any additional costs, as existing staff will be utilized to conduct such surveillance and oversight.

Local Government Mandates:

None

Paperwork:

Hospitals seeking to provide Cardiac Catheterization Laboratory Center Services with no Cardiac surgery onsite will be required to maintain an affiliation agreement with an existing Cardiac Surgery Center. Cardiac Surgery and Cardiac Catheterization Laboratory Centers will continue to be required to report data to the Department. Amendments to Section 709.14(b)(5)(ii) would reduce the work required for hospital based heart disease prevention programs by deleting portions of regulations that require follow-up and tracking of prevention services, particularly for outpatients.

Duplication:

This regulation does not duplicate any other state or federal law or regulation

Alternative Approaches:

The Department considered maintaining the current policy that limits PCI to approved Cardiac Surgery Centers. In order to facilitate access to timely PCI procedures, requirements will be implemented that allow PCI at non-surgery centers where the volume and standards associated with high quality care can be maintained.

Federal Requirements:

This regulatory amendment does not exceed any minimum standards of the federal government for the same or similar subject areas.

Compliance Schedule:

This proposal will go into effect upon a Notice of Adoption in the New York *State Register*.

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**REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESS AND LOCAL GOVERNMENTS**

Effect of Rule:

Any facility defined as a general hospital pursuant to PHL Section 2801 (10) will be required to comply. Small businesses (defined as 100 employees or less), independently owned and operated, affected by this rule will include 3 hospitals.

Compliance Requirements:

The hospitals that are considered a small business will be required to have written transfer agreements in place with hospitals that will be receiving cardiac patients and also with emergency medical services to transport these patients to the appropriate facility for definitive care in a timely and appropriate manner.

Professional Services:

None

Compliance Costs:

None

Economic and Technological Feasibility:

This proposal is economically and technically feasible.

Minimizing Adverse Impact:

There is no adverse impact.

Small Business and Local Government Participation:

Outreach to the affected parties is being conducted. Organizations who represent the affected parties and the public can obtain the agenda of the Codes and Regulations Committee of the State Hospital Review and Planning Council (SHRPC) and a copy of the proposed regulation on the Department's website. The public, including any affected party, is invited to comment during the Codes and Regulations Committee meeting.

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

Rural areas are defined as counties with a population of less than 200,000 and, for counties with a population greater than 200,000, includes towns with population densities of 150 persons or less per square mile. All rural areas will be affected by this rule.

The following 43 counties have a population less than 200,000.

Allegany	Hamilton	Schenectady
Cattaraugus	Herkimer	Schoharie
Cayuga	Jefferson	Schuyler
Chautauqua	Lewis	Seneca
Chemung	Livingston	Steuben
Chenango	Madison	Sullivan
Clinton	Montgomery	Tioga
Columbia	Ontario	Tompkins
Cortland	Orleans	Ulster
Delaware	Oswego	Warren
Essex	Otsego	Washington
Franklin	Putnam	Wayne
Fulton	Rensselaer	Wyoming

Genessee

St. Lawrence

Yates

Greene

The following 10 counties have certain townships with population densities of 150 persons or less per square mile:

Albany

Erie

Oneida

Saratoga

Broome

Monroe

Onondaga

Dutchess

Niagara

Orange

Reporting, Recordkeeping and Other Compliance Requirements; and Professional Services:

None

Costs:

None

Minimizing Adverse Impact:

This regulation is designed to minimize adverse impact on patients living in rural areas by improving timely access to appropriate care.

Rural Area Participation:

Outreach to the affected parties is being conducted. They include general hospitals, county health departments and emergency medical services. Organizations who represent the affected parties and the public can obtain the agenda of the Codes and Regulations Committee of the State Hospital Review and Planning Council (SHRPC) and a copy of the proposed regulation on the Department's website. The public, including any affected party, is invited to comment during the Codes and Regulations Committee meeting.

JOB IMPACT STATEMENT

Nature of Impact:

This rule is not expected to have a significant impact on jobs and employment opportunities. The intent is to promote effective and appropriate care for acute myocardial infarction patients. It is also intended to clarify standards for appropriately credentialed staff who provide services to cardiac patients. This proposal is necessary to update the current provisions to address medical standards of care. Most facilities already have appropriate staff to meet these requirements.

The 24-hour cardiac team availability requirements may require some hospitals to increase staff if they are seeking approval to perform PCI. It is not mandatory that all hospitals perform PCI.

Categories and Numbers of Jobs and Employment Opportunities Affected:

This proposal is not expected to have any significant impact on jobs and employment activities.

Regions of Adverse Impact:

This rule will not impose a disproportionate or adverse impact on jobs and employment opportunities in any region in the State.

Minimizing Adverse Impact:

There is no adverse impact.