

SUMMARY OF EXPRESS TERMS

Pursuant to the authority vested in the Public Health and Health Planning Council, subject to the approval of the Commissioner of Health, by section 2803(2)(a) of the Public Health Law, sections 709.14 and 405.29 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York are hereby amended, to be effective after publication of Notice of Adoption in the New York State Register, to read as follows:

Section 709.14 (a) is amended to change the focus of need reviews for PCI services from being site specific to health system related and to reflect the transition from State Hospital Review and Planning Council to Public Health and Health Planning Council.

Section 709.14 (b) (2) is amended to reflect the increased prevalence of cardiac surgical services since the regulation was last amended.

Section 709.14 (b) (3) is amended to remove the requirement of a documented projected volume of 300 PCI cases within two years of approval to initiate an adult cardiac surgery center and replace it with a requirement for a documented projected volume of 36 emergency PCI cases within two years of approval.

Section 709.14 (d) is amended to differentiate between PCI capable cardiac catheterization laboratory centers at hospitals with no cardiac surgery on-site between (A)

those hospitals that are co-operated with a hospital that is a cardiac surgery center and (B) those hospitals that have a clinical sponsorship with a cardiac surgery center. The regulation sets forth factors in determining public need for both. The amendment removes site specific total volume requirements and focuses remaining volume requirements on only emergency cases at the applicant facility. The amendment of this subdivision goes on to set forth requirements specific to co-operated and clinically affiliated applicants.

Section 405.29 (a)(4)(i) is amended to make a non-material edit for readability.

Section 405.29 (c)(8)(i) is amended to include language delineating clinical sponsorship agreements and the required provisions thereof.

Section 405.29 (d)(2)(i)(b) is amended to make a non-material edit for readability.

Section 405.29 (e)(1)(iv)(j) is amended to revise cardiac catheterization laboratory center structure and service requirements to allow for clinical sponsorship agreements.

Section 405.29 (e)(2)(ii)(c) is amended to allow a co-operated parent cardiac surgery center to report to the cardiac reporting system on behalf of a PCI capable cardiac catheterization laboratory center.

Section 405.29 (e)(2)(iii) differentiates requirements for co-operated and sponsored PCI capable cardiac catheterization laboratory centers.

Section 405.29(e)(2)(iv) eliminates previous total volume threshold requirements and establishes minimum volume requirements focusing exclusively on emergency cases. PCI centers with an annual volume below 150 percutaneous coronary intervention cases a year for two consecutive calendar years, or a volume below 36 emergency percutaneous coronary intervention cases a year for two consecutive calendar years will no longer be required to immediately surrender their approval or have it revoked. Instead, centers falling below those volume thresholds will be required to retain an independent physician consultant to conduct an annual appropriateness and quality review from which the Department will determine the disposition of the program.

Section 405.29 (e)(3) is clarified to reflect that no additional diagnostic cardiac catheterization services have been eligible for approval since the regulations were last amended on November 4, 2009.

Pursuant to the authority vested in the Public Health and Health Planning Council, subject to the approval of the Commissioner of Health, by section 2803(2)(a) of the Public Health Law, sections 709.14 and 405.29 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York are hereby amended, to be effective after publication of Notice of Adoption in the New York State Register, to read as follows:

Subdivision (a) of section 709.14 is amended to read as follows:

(a) These standards will be used to evaluate certificate of need applications for cardiac catheterization laboratory center services and cardiac surgery center services. [All need determinations are hospital site specific.] It is the intent of the Public Health [State Hospital Review] and Health 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 laboratory center services and 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 access to cardiac catheterization laboratory center services and cardiac surgery center services, and maintain provider and operator 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[.], including providing flexibility for regional health systems to provide cardiac services at sites that are convenient to patients in the communities they serve.

Paragraph (2) of subdivision (b) of section 709.14 is amended to read as follows:

(2) Planning for cardiac surgery center services shall ensure that, to the extent possible, eighty percent of the total population of each HSA region resides within 100 miles of [a] one or more facilit[y]ies providing cardiac surgical services.

Paragraph (3) of subdivision (b) of section 709.14 is amended to read as follows:

(3) A facility proposing to initiate an adult cardiac surgery center must document a cardiac patient base and current cardiac interventional referrals sufficient to support a projected annual volume of at least 500 cardiac surgery cases and a projected annual volume of at least [300] 36 emergency PCI cases within two years of approval. The criteria for evaluating the need for additional 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 adult cardiac surgery center services may be considered when each existing 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 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 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.

Subdivision (d) of section 709.14 is amended 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 paragraph (b)(9) of this section and must meet standards at section 405.29(c), (e)(1) and (2) of this Title.

(ii) PCI capable cardiac catheterization laboratory centers at hospitals with no cardiac surgery on site. [Factors for determining] Determinations of public need for PCI capable cardiac catheterization laboratory centers at hospitals with no cardiac surgery on-site will be differentiated between: (A) hospitals that are established by the Public Health and Health Planning Council as co-operators with a hospital that is a cardiac surgery center as defined in section 405.29(a)(3) of this Title; and (B) hospitals that have a clinical sponsorship with a cardiac surgery center as defined in section 405.3(f)(3) of this Title and that are applying to be a PCI capable cardiac catheterization laboratory center. For the purposes of this section, clinical sponsorship shall mean that the hospital applying to be a PCI capable cardiac catheterization laboratory center has entered into a clinical sponsorship agreement with a cardiac surgery center acceptable to the department and in accordance with the standards established in section 405.29(c)(8)(i) of this Title.

(iii) For both co-operated hospitals and hospitals that are proposing to enter into a clinical sponsorship agreement, factors for determining public need shall 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 one 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, credentialed by the co-operated hospital, and/or employed by the clinical sponsorship hospital 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 for emergency PCI procedures 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] the 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]c) 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), (e)(1) and (2) of this Title;

([f]d) 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]e) 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]f) comments and recommendations received from community organizations;

([i]g) the hospital shall propose and implement a hospital heart disease prevention program as set forth at subparagraph (b)(5)(ii) of this section;

([j]h) [where public need is established herein, priority consideration shall be given to applicants that agree] a description of existing and planned activities 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:

(l) 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.]

Subparagraph (vi) of paragraph (2) of subdivision (d) of section 709.14 is amended to read as follows:

(~~vi~~) Hospitals approved as cardiac surgery centers shall be deemed to have demonstrated public need to perform cardiac electrophysiology.

Subdivision (d) of section 709.14 is amended by adding new paragraphs (4) and (5) as follows:

(4) For co-operated hospitals under subdivision (d)(1)(ii) of this section:

(i) The application for PCI services must be submitted jointly by the applicant facility and the co-operated parent.

(ii) Documentation acceptable to the department must be submitted demonstrating that all cardiac catheterization laboratory centers within the co-operated parent's system have staff sharing agreements that include, at a minimum, provisions for rotation and training of staff with the parent hospital and integration into the parent hospital's quality and patient safety programs, quality assurance and peer review.

(iii) Documentation acceptable to the department must be submitted demonstrating that the co-operated parent hospital will be responsible for maintaining the competency of the cardiac interventionalist physicians, nursing, and technical staff performing services at the applicant facility.

(iv) Documentation acceptable to the department must be submitted demonstrating that the co-operated parent hospital will be responsible for ensuring that the applicant facility can provide PCI services on a 24 hour a day, 365 days a year basis and is capable of

assembling a dedicated team within 30 minutes of the activation call to provide coronary interventions 24 hours a day and 365 days each year.

(v) If the co-operated parent is not in the planning area of the applicant facility, then the applicant facility must document that it has an emergency transfer agreement with a New York State Cardiac Surgery Center in the planning area that has an on-site cardiac surgery program.

(5) For applicant hospitals in a clinical sponsorship relationship with a New York State Cardiac Surgery Center:

(i) the application for PCI services must be submitted by the applicant hospital.

(ii) the sponsoring New York State Cardiac Surgery Center must be located in the same planning area as the applicant hospital.

(iii) the sponsoring New York State Cardiac Surgery Center must perform at a level of at least 600 PCI procedures per year.

(iv) a written and signed PCI clinical sponsorship agreement with the sponsoring New York State Cardiac Surgery Center, acceptable to the department and in accordance with standards at section 405.29(c)(8)(i) of this Title, must be submitted. The PCI clinical sponsorship agreement must specify that the department shall be provided 60 days 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 applicant hospital's cardiac catheterization laboratory center.

(v) both the applicant hospital and the sponsoring hospital must submit written documentation demonstrating that the respective governing bodies have approved the clinical sponsorship agreement.

Subparagraph (i) of paragraph (4) of subdivision (a) of section 405.29 is amended to read as follows:

(i) a PCI capable cardiac catheterization laboratory center [cardiac catheterization laboratory center] performs percutaneous coronary and other percutaneous procedures to diagnose and treat abnormalities of the heart or great vessels in adult patients. Such PCI capable cardiac catheterization laboratory centers may be approved with or without cardiac surgery at the same hospital site, however, those with no cardiac surgery on site must meet additional criteria at subparagraph (c)(8)(i) of this section;

Subparagraph (i) of paragraph (8) of subdivision (c) of section 405.29 is amended to read as follows:

(i) In addition, cardiac catheterization laboratory centers located in hospitals with no cardiac surgery on-site must enter into and comply with a fully executed written clinical sponsorship agreement with a New York State cardiac surgery center. The agreement will include provisions that address, at a minimum:

(a) cardiac surgery center representatives shall participate in the affiliated cardiac catheterization laboratory center hospital's quality assurance committee and other reviews of the quality of cardiac care provided by the affiliated cardiac catheterization laboratory center and in the provision of recommendations for quality improvement of cardiac services. Each cardiac surgery center and each affiliated cardiac catheterization laboratory center hospital shall take actions necessary, including but not limited to entering into a written agreement to authorize such participation by the cardiac surgery center representatives in the affiliated cardiac catheterization laboratory center hospital's quality assurance committee and for purposes of such participation, the cardiac surgery center representative or representatives shall be deemed members of the affiliated cardiac catheterization laboratory center hospital's quality assurance committee. Cardiac surgery center representatives may only access confidential patient information for quality assurance committees as set forth in the affiliation agreements and these regulations. Members of hospitals' quality assurance committees must maintain the confidentiality of patient information and are subject to the confidentiality restrictions of Public Health Law section 2805-m and other applicable confidentiality restrictions as provided by law. The cardiac surgery center representative(s) shall participate in the review of information and data for quality improvement purposes as described in the agreement which may include:

(1) statistical data and reports used in quality improvement activities;

(2) the affiliated cardiac catheterization laboratory center hospital's quality improvement program, policies, and procedures;

(3) care provided by medical, nursing, and other health care practitioners associated with the cardiac services;

(4) appropriateness and timeliness of patient referrals and of patients retained at the affiliated cardiac catheterization laboratory center hospital who met criteria for transfer to the cardiac surgery center hospital; and

(5) adverse events or occurrences including death and major complications for patients receiving cardiac care at the affiliated cardiac catheterization laboratory center hospital.

(b) Joint cardiology/cardiac surgery conferences to be held at least quarterly, with a focus on continuous quality improvement to include review of: all cardiac laboratory related morbidity and mortality, review of a random selection of uncomplicated routine cases, patient selection, rates of normal outcomes for diagnostic studies performed, rates of studies needed to be repeated prior to intervention, quality of the studies conducted, rates of patients referred for and receiving interventional procedures subsequent to the

diagnostic cardiac catheterization procedure, and the number and duration of cardiac catheterization laboratory system failures;

(c) A mechanism for a telemedicine link between the cardiac catheterization laboratory center and the cardiac surgery center that provides the capability for off-site review of digital studies, and a commitment on the part of each hospital to provide timely treatment consultation by appropriate physicians on an as needed basis;

(d) the cardiac surgery center's involvement in developing privileging criteria for physicians performing cardiac catheterization procedures at the hospital with no cardiac surgery on-site;

(e) development and ongoing review of patient selection criteria and review of implementation of those criteria. The process shall include a comprehensive review of the appropriateness of treatment for a random selection of cases;

(f) consultation on equipment, staffing, ancillary services, and policies and procedures for the provision of cardiac catheterization laboratory procedures;

(g) a pre-procedure risk stratification tool which ensures that high risk and or complex cases are treated at a cardiac surgery center;

(h) procedures to provide for appropriate patient transfers between facilities;

(i) an agreement to notify the department of any proposed changes to the initial agreement and to obtain department approval prior to the change; [and]

(j) an agreement to jointly sponsor and conduct annual studies of the impact that the cardiac catheterization laboratory center service has on costs and access to cardiac services in the hospital's service area[.];

(k) a plan for how the proficiency of physicians, nurses and other staff at the affiliated cardiac catheterization laboratory center will be maintained through rotational or other training opportunities; and

(l) a plan for how the cardiac catheterization laboratory center will maintain the capacity to provide PCI services on a 24 hour a day, 365 days a year basis and be capable of assembling a dedicated team within 30 minutes of the activation call to provide coronary interventions 24 hours a day and 365 days each year.

Clause (b) of subparagraph (i) of paragraph (2) of subdivision (d) of section 405.29 is amended to read as follows:

(b) coronary care organized, staffed and available [-] on a 24-hour basis by clinical personnel trained in the care of critical care patients and equipped to provide the specialized care required of complex cardiac conditions; and

Clause (j) of subparagraph (iv) of paragraph (1) of subdivision (e) of section 405.29 is amended to read as follows:

(j) in addition to standards at subparagraph (c)(8)(i) of this section, for cardiac catheterization laboratory centers approved under a [co-operator] clinical sponsorship agreement as set forth in section 709.14(d)[(1)(ii)(n)](5) of this Title, the written and signed [co-operator] clinical sponsorship agreement between a cardiac surgery center and the cardiac catheterization laboratory center without cardiac surgery on site must be maintained and must specify that the department shall be provided 60 day prior written notification of any proposed change, termination or expiration of the agreement, any changes must be found acceptable to the department prior to implementation and any proposed termination or expiration shall require prior submission of a plan of closure to the department. The agreement shall provide for an integration of expertise and resources from the cardiac surgery center that would support a high quality program at the hospital without cardiac surgery on site, and shall delineate responsibilities of each institution. 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.

Clause (c) of subparagraph (ii) of paragraph (2) of subdivision (e) of section 405.29 is amended to read as follows:

(c) the PCI capable cardiac catheterization laboratory center shall have a data manager who has special training in the clinical criteria used in the PCI module of the cardiac reporting system as provided by the department or its designee, is designated and authorized by the hospital and shall work in collaboration with the physician director to ensure accurate and timely reporting of cardiac reporting system data to the department. In addition to the data manager, relevant medical and administrative staff must be trained in the use of the cardiac reporting system and the specific data element definitions involved. For PCI capable cardiac catheterization laboratory centers that have a co-operated parent cardiac surgery center, responsibilities related to the cardiac reporting system may be performed by the cardiac surgery center on behalf of the data manager of the PCI capable cardiac catheterization laboratory center as long as all data is delineated at the facility level.

Subparagraph (iii) of paragraph (2) of subdivision (e) of section 405.29 is amended to read as follows:

(iii) patient selection criteria. PCI capable cardiac catheterization laboratory centers shall adopt criteria for appropriate coronary artery diagnostic and interventional procedures in accordance with generally accepted standards for cardiac patients. For centers with no

cardiac surgery on site and not co-operated with a New York State cardiac surgery center, patient selection criteria shall be reviewed and approved annually by the affiliated sponsored cardiac surgery center in accordance with subparagraph (c)(8)(i) of this section.

Subparagraph (iv) of paragraph (2) of subdivision (e) of section 405.29 is amended to read as follows:

(iv) minimum workload standards. [There shall be sufficient utilization of a center to ensure both quality and economy of services, as determined by the Commissioner.] Each PCI capable cardiac catheterization laboratory center must maintain a minimum volume of at least 36 emergency percutaneous coronary intervention cases per year. For hospitals that are part of [an] a co-operated article 28 network and multi-site facilities with more than one approved PCI capable cardiac catheterization laboratory center, and for PCI capable cardiac catheterization laboratory centers operating under a [co-operator]clinical sponsorship agreement pursuant to section 709.14(d)[(1)(ii)(c)(3)(viii)](5) of this Title, minimum volume standards for emergency PCI procedures are site specific and may not be combined for purposes of achieving minimum workload standards. [Any hospital seeking to maintain approval shall present evidence that the annual minimum workload standards have been achieved by the second full year following initiation of the service and maintained thereafter. Each PCI capable cardiac catheterization laboratory center must maintain a minimum volume of 150 percutaneous coronary intervention cases per

year including at least 36 emergency percutaneous coronary intervention cases per year. Hospitals with volumes below 400 percutaneous coronary intervention cases per year must comply with the following:

(a) PCI capable cardiac catheterization laboratory centers with an annual volume between 300 and 400 percutaneous coronary intervention cases shall undergo a review of cases and outcomes trends conducted by the department to evaluate the appropriateness and quality of care provided by the center;

(b) PCI capable cardiac catheterization laboratory centers with a volume between 150 and 300 percutaneous coronary intervention cases a year must procure the services of an independent physician consultant, acceptable to the department, who shall conduct an annual review of the appropriateness and quality of percutaneous coronary intervention cases performed at the facility and shall provide a copy of the findings directly to the department. Findings will be used by the department to determine whether continued approval or withdrawal of approval best meets the needs of the patients in the region; and]

([c]a) PCI capable cardiac catheterization laboratory centers with an annual volume below 150 percutaneous coronary intervention cases a year for two consecutive calendar years, or a volume below 36 emergency percutaneous coronary intervention cases a year for two consecutive calendar years, [shall surrender approval to perform percutaneous

coronary interventions or have approval to perform the procedure revoked] must procure the services of an independent physician consultant, acceptable to the department, who shall conduct an annual review of the appropriateness and quality of the percutaneous coronary intervention cases performed at the facility and shall provide a copy of the findings directly to the department. Findings will be used by the department to determine whether continued approval or withdrawal of approval best meets the needs of the patients in the planning area.

Paragraph (3) of subdivision (e) of section 405.29 is amended to read as follows:

(3) Diagnostic cardiac catheterization services. [As of the effective date of these regulations, no] No additional diagnostic cardiac catheterization services shall be approved. Diagnostic cardiac catheterization services hospitals are not approved to perform percutaneous coronary intervention or cardiac surgery, are subject to annual reviews of volume, appropriateness of cases and other quality indicators for diagnostic cardiac catheterization, and must meet the following standards:

REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for the promulgation of these regulations is contained in Sections 2800 and 2803(2) of the Public Health Law (PHL). In particular, PHL Section 2803 (2) authorizes the Public Health and Health Planning Council (PHHPC) 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 and 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 hospitals located in New York State. Alongside 10 NYCRR Section 709.1, these regulations 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. 10 NYCRR Section 405.29 provides standards for the provision of cardiac services.

Section 709.14 was last amended in November 2009 to allow the provision of Percutaneous Coronary Intervention (PCI) services (commonly referred to as angioplasty or stenting) outside of a Cardiac Surgery Center by defining and establishing a need methodology Cardiac Catheterization Laboratory Centers. The need methodology focused on the premise that a minimum volume of procedures at a facility ensures quality. Additional programs were deemed imprudent if they could not reasonably project certain volumes and unnecessary if their approval would cause an existing program at a facility in the same service area to fall below the minimum volume thresholds.

Since those last amendments, significant advances in technology and medical practice have made PCI and cardiac surgery procedures safer. In addition, standalone community hospitals are increasingly becoming part of integrated regional health care networks that are anchored by large academic medical centers. This transformation is increasing the potential for expanded access to quality cardiac care in these communities. Also, recent research by the University at Albany School of Public Health has shown that the correlation between volume and outcomes for PCI services has decreased in importance but that some minimal threshold is still needed.

The existing regulations have the effect of limiting new program entrants into geographic

markets, and they are not aligned with the increasing prevalence of integrated regional health care systems that are operated and governed by large academic medical centers. Such systems improve the coordination and delivery of health care services and help improve quality and ensure the financial sustainability of community hospitals within the network. In such systems, the co-established parent hospital governs the member hospitals through its reserve powers. Several of these systems have achieved broad clinical integration, including joint clinical department heads, quality assurance and training programs, information systems with data exchange and the sharing of clinical and support staff such as specialty teams.

A Regulatory Modernization Initiative convened by the Department of Health in the Fall of 2017 solicited industry and stakeholder input, considered all the above factors, and made recommendations that form the basis for these amendments herein. The regulations, once promulgated, will form a new basis for cardiac catheterization program approval and operation. The result will be greater, more convenient access to safe, quality PCI services and perhaps lifesaving and more timely access to emergency PCI.

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. Such hospitals will also be required to provide data to the Cardiac Reporting System as those who already provide this care do now.

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 PCI services and not a mandate.

There are approximately 66 hospitals that are currently PCI Capable Cardiac Catheterization Laboratory Centers out of 223 hospitals. The cost of implementation and compliance of these regulations is expected to be minimal for the affected entities already caring for these patients. Hospitals that voluntarily choose to provide such services, and that do not currently do so, will need to adhere to these standards and may incur costs to upgrade their services.

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. As discussed above, the cost of implementation and compliance of these regulations is expected to be minimal for entities already caring for these patients.

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:

There are no local mandates within this regulatory amendment.

Paperwork:

Hospitals seeking to provide Cardiac Catheterization Laboratory Center Services with no Cardiac surgery onsite under the sponsorship model will be required to maintain a clinical sponsorship agreement with an existing Cardiac Surgery Center. Hospitals seeking to provide Cardiac Catheterization Laboratory Center Services with no Cardiac surgery onsite under the co-operator model will be required to maintain a staff sharing agreement with the parent Cardiac Surgery Center. Cardiac Surgery and Cardiac Catheterization Laboratory Centers will continue to be required to report data to the Department.

Duplication:

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

Alternative Approaches:

The Department considered maintaining some lower total volume thresholds of PCI procedures for approval of a new program as an incremental approach. However, given the weakening correlation between volume and outcomes for PCI services generally, any threshold, albeit lower, would still be somewhat arbitrary and problematic. Instead, to facilitate access to timely emergency PCI procedures, volume requirements for non-emergency procedures will be eliminated where the emergency PCI 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.

Contact Person:

Katherine Ceroalo
New York State Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
Corning Tower Building, Rm 2438
Empire State Plaza
Albany, NY 12237
(518) 473-7488
(518) 473-2019 (FAX)
REGSQNA@health.ny.gov

REGULATORY FLEXIBILITY ANALYSIS

Effect of Rule:

Three hospitals are considered small businesses (defined as 100 employees or less) and will be affected by this rule. Similarly, any hospital that is operated by a local government will be affected by this rule.

Compliance Requirements:

Those 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 with emergency medical services to transport these patients to the appropriate facility for definitive care in a timely and appropriate manner.

Professional Services:

This regulatory amendment does not appreciably change the professional services required to provide Cardiac Catheterization Laboratory Center Services.

Compliance Costs:

This regulatory amendment does not appreciably change the compliance costs associated with the provision of Cardiac Catheterization Laboratory Center Services.

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 was conducted through the recent Regulatory Modernization Initiate Process. Organizations who represent the affected parties and the public can obtain the agenda of the Codes and Regulations Committee of the Public Health and Health Planning Council (PHHPC) 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.

**STATEMENT IN LIEU OF
RURAL AREA FLEXIBILITY ANALYSIS**

A Rural Area Flexibility Analysis for these amendments is not being submitted because amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

**STATEMENT IN LIEU OF
JOB IMPACT STATEMENT**

A Job Impact Statement for these amendments is not being submitted because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities.

ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health (“Department”) received two public comments in response to the proposed rulemaking amending sections 709.14 and 405.29 of Title 10 of the Codes, Rules and Regulations of the State of New York. The comments and the Department’s responses are summarized below.

Comment: A commenter stated concerns regarding the requirement for “staff sharing agreements that include provisions for rotation and training of staff with the parent hospital.” The commenter asserts that certain staff, including nurses and technicians, can only rotate to other hospitals for training purposes, because union contracts prohibit their rotation for patient care. The commenter requested that the regulation be amended to provide that staff sharing agreements do not require rotation in the parent hospital for patient care.

Response: This concern should be addressed through changes to the collective bargaining agreements. No changes were made to the proposed regulation as a result of this comment.

Comment: A commenter suggested that the regulation should define “emergency PCI” such that it would include ST-elevation myocardial infarction (“STEMI”) treatment and unscheduled, non-elective catherization procedures.

Response: The Department interprets “emergency PCI” as including unscheduled, non-elective catherization procedures. The Department will issue guidance to further clarify the difference between elective and non-elective catheterization procedures, which will

address STEMI. No changes were made to the proposed regulation as a result of this comment.

Comment: A commenter requested that the Department not require telemedicine capabilities beyond e-consults for the immediate future.

Response: This comment is outside the scope of the proposed rulemaking, as the regulatory amendments do not address telemedicine. No changes were made to the proposed regulations as a result of this comment.

Comment: A commenter requested that the Department review an existing regulatory requirement that Cardiac Catheterization Laboratory Centers located in hospitals with no cardiac surgery on-site enter into agreements to “jointly sponsor and conduct annual studies of the impact that the Cardiac Catheterization Laboratory Center has on costs and access to cardiac services in the hospital's service area.” The commenter requested guidance on the intent and expectations of the requirement.

Response: This request is outside the scope of the proposed rulemaking, which does not amend this provision. No changes were made to the proposed regulations as a result of this comment.

Comment: A commenter requested that the Department provide further guidance on the documentation required for a clinical services agreement and the requirements of a CON application under the two proposed models.

Response: The Department will be issuing guidance concerning these requirements. No changes were made to the proposed regulations as a result of this comment.

Comment: Two commenters expressed concern and the potential for confusion surrounding the term “parent hospital.”

Response: The Department recognizes that there are many forms of corporate governance that may be utilized within a health care system. The Department will issue guidance on the term “parent hospital.” No changes were made to the proposed regulations as a result of this comment.

Comment: A commenter suggested that clinical sponsorship agreements should comply with all of 10 NYCRR 405.3, as opposed to only 405.3(f)(3).

Response: Nothing in the amendment waives the mandatory regulatory and statutory duties of a proposed operator. The amended regulation requires clinical sponsorship agreements to comply with sections 405.3(f)(3) as well as 405.29(c)(8)(i). The purpose of the requirement to comply with section 405.3(f)(3) is to ensure that clinical sponsorship agreements meet the same rigorous regulatory standards for approval found in a hospital management contract; however, not all the provisions of section 405.3 are relevant to clinical sponsorship agreements. No changes were made to the proposed regulations as a result of this comment.

Comment: A commenter requested clarification of the provision that requires that an application for PCI services be “submitted jointly by the applicant facility and the co-operated parent.” The commenter indicated that joint submission could be burdensome to the parent operator.

Response: The Department will issue guidance to clarify what is required for joint submission and will seek to minimize the burden on operators. No changes were made to the proposed regulations a result of this comment.