A. Agenda

For Information | Program Area | Unit Representative
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Amendments to Section 709.14 – Cardiac Services | Office of Primary Care and Health Systems Management | Tracy Raleigh

B. Information Announcements

1. Anyone wishing to make oral comments at this meeting should contact the Bureau of Policy and Standards Development by 11:00 A.M. on Wednesday, December 11, at (212) 417-6218 to arrange for placement on the speakers’ list. Please give your name, affiliation, if any and the agenda item(s) you wish to address. To ensure that all commenters have an opportunity to address the Committee, speakers should limit their comments to 3-4 minutes maximum.

2. All meeting attendees including Committee members are requested to sign the Attendance Sheet, which will be circulated in the meeting room.
Pursuant to the authority vested in the Public Health and Health Planning Council and the
Commissioner of Health by section 2803 of the Public Health Law, section 709.14 of
Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New
York is hereby amended, to be effective after publication of Notice of Adoption in the
New York State Register, to read as follows:

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 \[500\] 300 cardiac surgery cases and a projected
annual volume of at least 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.
REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) § 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, including the establishment of minimum standards governing the operation of health care facilities.

Legislative Objectives:

The legislative objectives of PHL Article 28 include 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:

Section 709.14 of Title 10 of the New York Codes Rules and Regulations (10 NYCRR) 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 § 709.1 they represent 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.
The volume thresholds for determining Public Need for additional adult cardiac surgery centers were last updated in 1994. A Regulatory Modernization Initiative convened by the Department of Health (Department) in the Fall of 2017 with industry and stakeholder input considered advances in technology and medical practice, as well as data analysis conducted by the Department’s Cardiac Services Program located at the University at Albany School of Public Health. The recommendations resulting from the Regulatory Modernization Initiative form the basis for these amendments.

Although there is a clear volume-outcome relationship in the field of cardiac surgery, the existence of high-performing programs with relatively low case volumes is well established. The data analysis conducted by the Cardiac Services Program supported retaining but lowering the volume thresholds for Cardiac Surgery Center approval, effectively allowing the consideration of additional programs that would not be permissible under the 1994 thresholds. Using data from the Cardiac Surgery Reporting System, which is the Department’s clinical registry for cardiac surgery, this analysis found that risk-adjusted mortality was statistically significantly higher than the statewide average when program volume was less than 300 cases per year. The Department determined that this volume reflects the appropriate threshold for minimum volume requirements. The result of reducing the volume requirements for Cardiac Surgery Centers in accordance with this analysis will be increased access for consumers to safe, quality cardiac surgery services in local communities as part of regionally integrated delivery system models.
Costs for the Implementation of and Continuing Compliance with these Regulations to the Regulated Entity:

Becoming a Cardiac Surgery Center is a voluntary choice for hospitals, not a mandate. There are approximately 39 hospitals that are currently Cardiac Surgery Centers out of 223 hospitals in New York State. The cost of implementation and compliance with these proposed regulations is expected to be minimal for the affected entities already caring for these patients. Hospitals that choose to provide such services, and that have not done so previously, will need to adhere to programmatic standards set forth in 10 NYCRR §§ 405.29 and 711.4 and may incur costs to upgrade their services. 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 already.

Cost to State and Local Government:

Any hospital in New York State that is operated by State or local government and that voluntarily chooses to become a cardiac surgery center 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 will need to monitor and provide surveillance and oversight for the system of care provided to these patients. The Department is not expected to incur any additional costs, as existing staff and resources will be utilized to conduct such surveillance and oversight.
Local Government Mandates:

This proposed regulation does not impose any new programs, services, duties or responsibilities on local government.

Paperwork:

Hospitals seeking to become a Cardiac Surgery Center will continue to be required to submit a Certificate of Need application to the Department and, once approved, 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 a full range of cardiac surgery case volumes for approval of a new program. Although the Cardiac Surgery and PCI Services Health Care Regulatory Modernization Initiative workgroup recommended the elimination of the requirement for 500 cardiac surgery cases to become a Cardiac Surgery Center, the workgroup did not recommend an alternative number. The Department concluded that 300 cases was an appropriate number given medical advances in cardiac care since the requirement was last amended, as well as recent studies on the link between cardiac surgery volumes and quality outcomes.
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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Effect of Rule:

These proposed regulations would allow any facility defined as a general hospital pursuant to PHL § 2801(10), including those operated by a small business or local government, to initiate a Cardiac Surgery Center if they can demonstrate a patient base sufficient to support 300 cardiac surgery cases annually. Three hospitals that will be affected by this proposed regulation are small businesses (defined as 100 employees or less).

Compliance Requirements:

Becoming a Cardiac Surgery Center is a voluntary choice for hospitals, not a mandate. Hospitals, including hospitals that are small businesses, that choose to provide such services, and that have not done so previously, will need to adhere to programmatic standards set forth in in 10 NYCRR §§ 405.29 and 711.4. 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 already.

Professional Services:

This proposed regulation does not appreciably change the professional services required to provide Cardiac Surgery Center Services.
**Compliance Costs:**

The cost of implementation and compliance with these proposed regulations is expected to be minimal for the affected entities already caring for these patients. Hospitals that choose to provide Cardiac Surgery Center services, and that have not done so previously, may incur costs to upgrade their services.

**Economic and Technological Feasibility:**

This proposal is economically and technically feasible.

**Minimizing Adverse Impact:**

This amendment does not create any adverse effect on regulated parties.

**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.
RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

This rule applies uniformly throughout the state, including rural areas. Rural areas are defined as counties with a population less than 200,000 and counties with a population of 200,000 or greater that have towns with population densities of 150 persons or fewer per square mile. The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010 (http://quickfacts.census.gov).

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

The following counties have a population of 200,000 or greater and towns with population densities of 150 persons or fewer per square mile. Data is based upon the United States Census estimated county populations for 2010.

Albany County  Monroe County  Orange County
Broome County  Niagara County  Saratoga County
Dutchess County  Oneida County  Suffolk County
Erie County  Onondaga County
Reporting, Recordkeeping and Other Compliance Requirements; and Professional Services:

Becoming a Cardiac Surgery Center is a voluntary choice for hospitals, not a mandate. Hospitals, including hospitals that are small businesses, that choose to provide such services, and that have not done so previously, will need to adhere to programmatic standards set forth in 10 NYCRR §§ 405.29 and 711.4. 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 already.

Costs:

The cost of implementation and compliance with these proposed regulations is expected to be minimal for the affected entities already caring for these patients. Hospitals that choose to provide Cardiac Surgery Center services, and that have not done so previously, may incur costs to upgrade their services.

Minimizing Adverse Impact:

This amendment does not create any adverse effect on regulated parties.

Rural Area Participation:

Outreach to the affected parties was conducted through the Regulatory Modernization Initiative. 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 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
JOB IMPACT STATEMENT

No Job Impact Statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act (SAPA). It is apparent, from the nature of the proposed amendment, that it will have no impact on jobs and employment opportunities.