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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REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

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 located in rural areas, 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.

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.

Assessment of Public Comment

The New York State Department of Health ("Department") received correspondence from one public commenter containing several comments in response to the proposed rulemaking amending section 709.14 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: The commenter agrees that the threshold volume for hospitals seeking to be certified for cardiac surgery should be lowered from the current 500 surgical cases, but believes that the 300 cases in the proposed rule is too low. The commenter recommends a threshold of 350-400 cases to allow a margin for safety and account for applicant overestimation.

Response: Using data from the Cardiac Surgery Reporting System, which is the Department's clinical registry for cardiac surgery, the Department 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.

Comment: The commenter recommends abandoning the removal of the requirement that each existing adult cardiac surgery center in the planning area is operating and expected to continue to operate at the minimum volume (currently 500 procedures per year; proposed 300 procedures per year) to be able to consider approving a new program. The commenter cites limited cases being distributed amongst more programs, endangering volume at existing facilities and thus quality while increasing resources devoted to those same number of cases. The commenter asserts that

if this volume threshold for existing programs is removed, the Department could be creating an environment where large integrated health systems squeeze out smaller systems or individual hospitals that are currently performing cardiothoracic surgery and are of high quality, but have a vulnerable case volume.

Response: Significant advances in technology and medical practice have made 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, increasing the potential for expanded access to quality cardiac care in these communities. Such networks improve the coordination and delivery of health care services and help improve quality and ensure the financial sustainability of community hospitals within the network. The result will be greater, more convenient access to safe, quality cardiac services. The existing regulations have the effect of limiting new program entrants into geographic markets and are not aligned with these industry trends.

Comment: The commenter asserts that including transcutaneous aortic valve replacement (TAVR) procedures in cardiac thoracic surgery volume numbers used for the thresholds inflates those numbers while requiring a very different skill set.

Response: The analyses the Department performed that supports the recommendation of a 300 procedures threshold does not include TAVR procedures.

Based on the comments received, the Department has made no revisions to the proposed rulemaking.