Certificate of Public Advantage

Effective date: 12/17/14

SUMMARY OF EXPRESS TERMS

The proposed rule would add a new Subpart 83-2 to 10 NYCRR titled Certificate of Public Advantage.

Section 83-2.1 Contains definitions for purposes of this Subpart, including definitions for "Attorney General," "Certificate of Public Advantage," "Cooperative Agreement," "Federal or State Antitrust Laws," "Health Care Provider," "Mental Hygiene Agency," "Person," "Planning Process" and "Primary Service Area."

Section 83-2.2 Certificate of Public Advantage. Describes the effect of obtaining a Certificate of Public Advantage ("COPA") and sets forth the basic contents of an application.

Section 83-2.3 Public notice. Provides for public notice of an application, by both the department and each party to the agreement or proposed agreement for which approval is sought.

Section 83-2.4 Fees for applications and monitoring. Sets forth fees and costs to be paid in relation to applications and renewals.

Section 83-2.5 Review process. Sets forth the factors to be considered by the Department in its review of applications for a COPA.

Section 83-2.6 Issuance of a Certificate of Public Advantage. Provides for consultation with the Attorney General, the mental hygiene agencies (as appropriate), and the Public Health and Health Planning Council ("PHHPC") in the issuance of a COPA, sets forth examples of conditions which may be imposed in the issuance of a COPA, and provides for the period for which such COPA may be valid.

Section 83-2.7 Record keeping. Requires the Department to maintain a record of all Cooperative Agreements for which COPAs are in effect and a copy of the certificate, including any conditions imposed in it.

Section 83-2.8 Modification and termination. Provides that any material modification of an approved Cooperative Agreement is subject to the prior review and approval of the Department in consultation with the Attorney General, mental hygiene agencies (as appropriate), and the PHHPC, and that any party to a Cooperative Agreement covered by a COPA must file notice of such termination with the Department at least thirty days prior to the termination. The notice of

termination will be provided by the Department to the Attorney General and the mental hygiene agencies (as appropriate).

Section 83-2.9 Periodic reports. Requires periodic filing of reports of activity pursuant to a COPA, and sets forth the frequency and contents of such reports.

Section 83-2.10 Review after issuance of Certificate of Public Advantage. Provides for Department review of reports, and includes provisions addressing corrective measures the Department may take under certain circumstances.

Section 83-2.11 Application for renewal. Provides for renewal of an approved COPA.

Section 83-2.12 Revocation. Provides for revocation of a COPA by the Department under certain circumstances, and a procedure for doing so.

Section 83-2.13 Hearing rights. Provides for a right of hearing prior to the Department's revocation of a COPA.

Section 83-2.14 Voluntary surrender. Allows for the voluntary surrender of a COPA.

Section 83-2.15 Effect of consultation or recommendations. Clarifies treatment of input received pursuant to consultations with, or recommendations from, the Attorney General, mental hygiene agencies (as appropriate), or the PHHPC.

Section 83-2.16 Certificate of need and other requirements. Provides that nothing in this Subpart shall relieve parties from any responsibility for compliance with laws or regulations governing certificate of need or other approval or notice submission requirements.

A copy of the full text of the regulatory proposal is available on the Department of Health website (www.health.ny.gov).

Pursuant to the authority vested in the Commissioner of Health pursuant to section 2999-bb of the Public Health Law, the Official Compilation of Title 10 of the Codes, Rules and Regulations of the State of New York ("NYCRR") is amended to add a new Subpart 83-2, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

A new Subpart 83-2 is added to the Subchapter L of Chapter II of 10 NYCRR, to read as follows:

SUBPART 83-2

CERTIFICATE OF PUBLIC ADVANTAGE

83.2.13 Hearing rights

83-2.14 Voluntary surrender

83-2.15 Effect of consultation or recommendations

83-2.16 Certificate of need and other requirements

83-2.1 Definitions. The following terms shall have the following meanings for purposes of this Article:

(a) “Attorney General” means the Attorney General of the State of New York.

(b) “Certificate of Public Advantage” or “Certificate” means a Certificate issued by the Department pursuant to this Subpart signifying the approval of a Cooperative Agreement or of a planning process.

(c) “Cooperative Agreement” means an executed agreement among a health care provider and one or more persons or entities, including other health care providers, governing any of the following:

(1) The sharing, allocation, or referral of patients, personnel, instructional programs, information technology resources, support services and facilities, or medical, diagnostic, or laboratory facilities or equipment, or procedures or other services traditionally offered by health care providers or health care-related entities, including but not limited to, the implementation of clinical integration programs and payment mechanisms that involve the sharing of data and resources to develop, implement, and monitor the effectiveness of, and adherence to, performance standards, clinical protocols and evidence-based practices; or

(2) A merger, consolidation, purchase of stock or assets, partnership, joint venture, or any other transaction or affiliation by which ownership or control over all or substantially all of the

stock, assets, or activities of one or more health care providers, or health care-related entities, is transferred to another entity who controls a health care provider or health care-related entity.

"Cooperative Agreement" shall not include any Agreement that would permit a health care provider to act in a manner which would be otherwise prohibited by law, except as authorized pursuant to Article 29-F of the Public Health Law.

(d) "Federal or state antitrust laws" means any and all federal or state laws prohibiting monopolies or agreements in restraint of trade, including the federal Sherman Act, Clayton Act, Federal Trade Commission Act and laws set forth in Article 22 of the New York General Business Law, including amendments thereto.

(e) "Health care provider" shall include, but not be limited to, a facility, agency or program licensed or certified pursuant to Article twenty-eight, thirty-six, or forty of the Public Health Law; a health care professional licensed pursuant to title eight of the Education Law or a lawful combination of such health care professionals; or an entity licensed, certified or funded pursuant to Article sixteen, thirty-one, thirty-two or forty-one of the Mental Hygiene Law.

(f) "Mental hygiene agency" means one of the autonomous offices of the state Department of Mental Hygiene established under section 5.01 of the Mental Hygiene Law.

(g) "Person" means any individual, firm, partnership, corporation, association, public or private institution, political subdivision, or government agency.

(h) "Planning process" means a process, including a process convened and overseen by a planning entity approved by the Department, intended to plan for and result in a Cooperative Agreement.

(i) "Primary service area" means the lowest number of postal zip codes from which the party draws at least 75 percent of its patients for each service or group of services provided.

83-2.2 Certificate of Public Advantage.

(a) Effect. Parties that have received a Certificate of Public Advantage issued by the Department shall be provided state action immunity under federal antitrust laws and immunity from private claims under state antitrust laws and may negotiate, enter into, and conduct business pursuant to, a Cooperative Agreement or a planning process covered by a duly issued Certificate of Public Advantage. The Attorney General may seek relief under state antitrust law after: (i) consulting with the Department, the mental hygiene agencies as appropriate, and the parties to the Certificate of Public Advantage; and (ii) providing the parties with a reasonable opportunity to modify their conduct or Agreement, if the challenged conduct is inconsistent with or beyond the scope of the Certificate of Public Advantage or if the Attorney General determines that the anticompetitive effects of the parties' conduct or business arrangement outweigh the benefits of the conduct or business arrangement.

(b) Application.

(1) Parties to a Cooperative Agreement or planning process may apply to the Department for a Certificate of Public Advantage governing that Cooperative Agreement or planning process. The application must be submitted in a format determined by the Department and shall be provided by the Department to the Attorney General and, as appropriate, the mental hygiene agencies.

(2) The application for a Certificate of Public Advantage governing a Cooperative Agreement must include a copy of the Cooperative Agreement, any related agreements or side letters (including a description of any related oral agreement), a description of the nature and scope of the activities and cooperation included in the Cooperative Agreement, a full description

of any consideration passing to any party under the Cooperative Agreement and any additional documentation or information required by the Department.

(3) The application for a Certificate of Public Advantage governing a planning process must include a detailed letter of intent with respect to the potential Cooperative Agreement, a description of the nature and scope of the activities and cooperation likely to be included in the potential Cooperative Agreement and any additional documentation or information required by the Department.

(4) The applicants must supply any additional documentation or information requested by the Department within 30 days, or any other stated time frame of such request, or must obtain from the Department an extension of the time in which to provide such documentation or information which is requested during the review of the application. Any request for an extension of time shall set forth reasons why such documentation or information could not be obtained within the prescribed time. The granting of a request for an extension shall be at the discretion of the Department.

(5) Failure to provide such documentation or information within the time prescribed or as extended by the Department shall constitute an abandonment or withdrawal of the application without any further action from the Department, the Attorney General, mental hygiene agencies as appropriate, or the Public Health and Health Planning Council.

(c) To the extent that the Cooperative Agreement contemplates activities that are subject to certificate of need or other approval or notice submission requirements pursuant to law or regulation, the parties shall also submit the required applications or notices.

83-2.3 Public notice.

(a) Upon submission of an application for a Certificate of Public Advantage or an application to renew a Certificate of Public Advantage, each party to be covered by the Certificate shall conspicuously post on its public website, in a form determined by the Department, a description of the application with an electronic link to the section of the Department's public website where applications for Certificates of Public Advantage are summarized. If the party has no public website, it shall provide notice to the public in a manner acceptable to the Department.

(b) The Department shall publish on the Department's public website a notice of the receipt of each application for a Certificate of Public Advantage, with a brief summary of the application and instructions for persons wishing to provide comments.

83-2.4 Fees for applications and monitoring.

(a) An application filing fee of $5,000 must be paid to the Department at the time an application for a Certificate of Public Advantage or for renewal of a Certificate of Public Advantage is submitted pursuant to this Subpart.

(b) The applicant shall also cover the cost of consultants needed by the Department to assist in the review of the application for a Certificate of Public Advantage and any subsequent applications for renewal and in periodic monitoring, as determined by the Department.

83-2.5 Review process. The Department shall review applications pursuant to this Subpart, in consultation with the Attorney General and, as appropriate, the mental hygiene agencies. The factors to be considered in evaluating applications shall include, but shall not be limited to:

(a) the financial condition of the parties to the Cooperative Agreement, including whether any health care provider party is experiencing financial distress and may be forced to cease operations or eliminate a service in the absence of the Cooperative Agreement;

(b) the dynamics of the relevant primary service area, including the availability of suitable and accessible health care services and the level of competition in the primary service area, the likelihood that other health care providers will enter or exit the primary service area, the health care workforce and the existence of unique challenges such as difficulties in recruiting and retaining health care professionals;

(c) the potential benefits of a Cooperative Agreement or planning process, including but not limited to the likelihood that one or more of the following may result from such Cooperative Agreement or planning process:

(1) Preservation of needed health care services in the relevant primary service area that would be at risk of elimination in the absence of a Cooperative Agreement;

(2) Improvement in the nature or distribution of health care services in the primary service area, including expansion of needed health care services or elimination of unnecessary health care services;

(3) Enhancement of the quality of health care provided by the parties to the Cooperative Agreement;

(4) Expansion of access to care by medically-underserved populations;

(5) Lower costs and improved efficiency of delivering health care services, including reductions in administrative and capital costs and improvements in the utilization of health care provider resources and equipment; or

(6) Implementation of payment methodologies that control excess utilization and costs, while improving outcomes;

(d) the potential disadvantages of a Cooperative Agreement or planning process, including but not limited to the likelihood that one or more of the following may result from such Cooperative Agreement or planning process:

(1) Increased costs or prices of health care in the primary service area resulting from the Cooperative Agreement, after taking into consideration improvements in quality and outcomes;

(2) Diminished quality, availability, and efficiency of health care services;

(3) Inability of health care payers or health care providers to negotiate reasonable payment and service arrangements; or

(4) Reduced competition among physicians, allied health professionals, other health care providers, or other persons furnishing goods or services to, or in competition with, health care providers and the potential for adverse health system quality, accessibility and cost consequences;

(e) the availability of arrangements that are less restrictive to competition and achieve the same benefits or a more favorable balance of benefits over disadvantages attributable to any reduction in competition;

(f) other benefits or disadvantages identified in the course of review; and

(g) the extent to which active supervision is likely to mitigate the disadvantages.

83-2.6 Issuance of a Certificate of Public Advantage.

(a) The Department shall not issue a Certificate of Public Advantage without first consulting with the Attorney General and, as appropriate, the mental hygiene agencies, and consulting with, and receiving a recommendation from, the Public Health and Health Planning Council.

(b) After consulting with the Attorney General, the mental hygiene agencies as appropriate, and the Public Health and Health Planning Council, and receiving a recommendation from the Public Health and Health Planning Council, the Department may issue a Certificate of Public Advantage for the Cooperative Agreement or planning process, if it determines that the benefits likely to result from the Agreement or planning process outweigh the disadvantages.

(c) The Certificate shall include any conditions that the Department, in consultation with the Attorney General, the mental hygiene agencies as appropriate, and the Public Health and Health Planning Council, and receiving a recommendation from the Public Health and Health Planning Council, determines to be appropriate in order to ensure that the Cooperative Agreement or the planning process and the activities conducted under it are consistent with Article 29-F of the Public Health Law and its purpose to improve health care quality, access, efficiency and clinical outcomes. Such conditions shall be related to the proposed activities and goals of the Cooperative Agreement or the planning process and may include, but need not be limited to:

(1) Implementation of a clinical integration plan;

(2) Achievement of quality benchmarks, implementing evidence-based practices and clinical protocols, reducing preventable admissions and readmissions and sub-optimal emergency department use, and achieving other outcomes as identified by the Department;

(3) Maintaining or expanding certain services or levels of access by under-served populations;

(4) Investment in primary care and population health activities;

(5) Improvement in population health benchmarks;

(6) Measures to prevent unwarranted price increases and achieve savings;

(7) Measures to promote efficiencies and achieve savings, including reductions in duplication of services, unnecessary or preventable utilization, capital expenditures, and administrative overhead;

(8) Improvement in recruitment and retention of needed health care professionals; and

(9) Conditions reasonably necessary to ameliorate likely disadvantages, including potential disadvantages identified in section 83-2.5(d) of this Subpart.

(e) A Certificate of Public Advantage may be issued for a period to be determined by the Department, which shall be no less than two years in duration, and shall be subject to active supervision as provided in this Subpart and renewal, as applicable, pursuant to the procedure set forth in sections 83-2.10 and 83-2.11 of this Subpart.

83-2.7 Record keeping.

The Department shall maintain on file each Cooperative Agreement for which a Certificate of Public Advantage is in effect and a copy of the Certificate, including any conditions imposed on it.

83-2.8 Modification and termination.

(a) Any material modification of a Cooperative Agreement or planning process which is the subject of a Certificate of Public Advantage issued pursuant to this Subpart shall be subject to the prior review and approval of the Department in consultation with the Attorney General, the

mental hygiene agencies as appropriate, and the Public Health and Health Planning Council, and the receipt of a recommendation from the Public Health and Health Planning Council.

(b) Any party to a Cooperative Agreement covered by a Certificate of Public Advantage that terminates such Agreement shall file a notice of termination with the Department at least 30 days prior to termination of the Agreement, in addition to any other notices or approvals required by applicable law or regulations. Such notice of termination shall be provided by the Department to the Attorney General and, as appropriate, the mental hygiene agencies, and shall be deemed a voluntary surrender of a Certificate of Public Advantage pursuant to section 83-2.14.

83-2.9 Periodic reports.

(a) A report of activities pursuant to the Cooperative Agreement or the planning process shall be filed with the Department in such form as the Department, in consultation with the Attorney General and the mental hygiene agencies as appropriate, may require. Such report of activities shall be provided by the Department to the Attorney General and, as appropriate, the mental hygiene agencies. Subject to the terms of the Certificate of Public Advantage and any extensions thereof, such reports shall be filed annually after the issuance of the Certificate of Public Advantage, on or before the anniversary date on which the Certificate was issued, for each year that the Certificate is in effect and at such other times as the Department, in consultation with the Attorney General and the mental hygiene agencies as appropriate, may require.

(b) Such report shall include the following, unless waived by the Department:

(1) A description of the activities conducted pursuant to the Cooperative Agreement or planning process.

(2) Price, cost, and savings information, including efficiencies achieved and additional information requested by the Department, the Attorney General or the mental hygiene agencies as appropriate, related to conditions required under section 83-2.6(c)(9) of this Subpart.

(3) The nature and scope of the activities expected to be undertaken pursuant to the Cooperative Agreement or planning process during the next two years or for the remainder of the Certificate of Public Advantage, if the balance of the Certificate's term is less than two years, and the likely effect of those activities.

(4) Data concerning the utilization of services in the communities served by the Cooperative Agreement and quality of care delivered by the health care provider parties to the Agreement, including any data on progress in achieving quality benchmarks or targets for reducing preventable hospital admissions or readmissions or sub-optimal emergency department use specified by the Department.

(5) Most recent available data concerning population health in the communities served by the Agreement and progress in meeting any population health benchmarks.

(6) Data concerning health care professional recruitment and retention under the Cooperative Agreement or planning process.

(7) An analysis of the benefits and/or expected benefits of the Cooperative Agreement or planning process under the Certificate of Public Advantage, taking into account any conditions imposed by the Department, and how they outweigh the disadvantages or likely disadvantages of any reduction in competition from the Agreement.

(8) A description of the measures taken to comply with conditions imposed by the Department in issuing the Certificate of Public Advantage, along with an assessment of compliance with, and the effectiveness of, such measures.

(9) Any additional information requested by the Department, the Attorney General or, as appropriate, the mental hygiene agencies.

83-2.10 Review after issuance of Certificate of Public Advantage.

(a) The Department shall review each periodic report, application for renewal, and any information submitted in response to a request under this Subpart, and consult with the Attorney General and, as appropriate, the mental hygiene agencies, to determine, based on the factors set forth in section 83-2.5 of this Subpart, whether:

(1) the benefits or likely benefits of the Cooperative Agreement or the planning process continue to outweigh the disadvantages or likely disadvantages that flow from the Cooperative Agreement or planning process; and

(2) the parties to the Cooperative Agreement or planning process are in compliance with the conditions imposed on the Certificate of Public Advantage.

(b) If upon review of a periodic report or application for renewal and any information submitted in response to a request, or at any time following the issuance of a Certificate of Public Advantage, it appears to the Department, in consultation with the Attorney General and, as appropriate, the mental hygiene agencies, that the parties to the Cooperative Agreement or planning process have failed to comply with any condition of the Certificate or that the benefits or likely benefits resulting from a Cooperative Agreement or planning process no longer outweigh the disadvantages or likely disadvantages resulting from the Agreement, the Department shall advise the parties to the Agreement and request any documentation or information necessary to complete a review of the matter.

(c) The parties must supply any additional documentation or information requested by the Department within 30 days, or any other stated time frame, of such request, or must obtain from the Department an extension of the time in which to provide such documentation or information which is requested. Any request for an extension of time shall set forth reasons why such documentation or information could not be obtained within the prescribed time. The granting of a request for an extension shall be at the discretion of the Department. Failure to provide such documentation or information within the time prescribed or as extended by the Department may result in revocation of the Certificate of Public Advantage pursuant to section 83-2.12 of this Subpart.

(d) Following a review of a periodic report, an application for renewal, or of information submitted in response to a request made pursuant to this Subpart, if the Department determines, in consultation with the Attorney General and, as appropriate, the mental hygiene agencies, that the standards set forth in subdivision (a) of this section are satisfied, the Certificate of Public Advantage shall be continued or, if appropriate, renewed.

(e) The Department may, in consultation with the Attorney General and the mental hygiene agencies, as appropriate, at any time following the issuance of a Certificate of Public Advantage, require modifications to the Cooperative Agreement or the planning process and impose changes in the conditions of the Certificate of Public Advantage to promote the goals of Article 29-F of the Public Health Law and assure that the benefits or likely benefits of the Cooperative Agreement or planning process continue to outweigh the disadvantages or likely disadvantages.

(f) The parties shall be notified in writing of the Department's decision and any required modifications to the Cooperative Agreement or planning process and/or changes in the

conditions of the Certificate of Public Advantage and shall be given an opportunity to implement any required modifications by a date set by the Department.

83-2.11 Application for renewal.

(a) The parties to a Certificate of Public Advantage issued for a definite term may renew such Certificate. An application to renew the Certificate of Public Advantage shall, no later than 120 days prior to the expiration of the Certificate, be submitted to the Department in a format determined by the Department and shall be provided by the Department to the Attorney General and, as appropriate, the mental hygiene agencies.

(b) The application for renewal shall include the information required pursuant to subdivision (b) of section 83-2.9 of this Subpart, unless waived by the Department, and any other information requested by the Department, and shall be accompanied by the fee set forth in section 83-2.4 of this Subpart.

(c) A Certificate of Public Advantage may be renewed pursuant to the procedure set forth in section 83-2.10 of this Subpart for a period determined by the Department, which shall be no less than two years in duration, and shall be subject to active state supervision pursuant to this Subpart.

83-2.12 Revocation.

(a) The Department may revoke, at any time, the Certificate of Public Advantage, if any of the following occur:

(1) the Department, after consultation with the Attorney General and, as appropriate, the mental hygiene agencies, determines that the parties to a Certificate of Public Advantage have not complied with a condition or terms of such Certificate of Public Advantage;

(2) the Department, after consultation with the Attorney General and, as appropriate, the mental hygiene agencies, determines that the benefits or likely benefits of the Cooperative Agreement and the unavoidable costs of terminating the Agreement do not continue to outweigh the disadvantages or likely disadvantages resulting from the Agreement;

(3) the Attorney General or, as appropriate, the mental hygiene agencies, objects to the continuation of a Certificate of Public Advantage and the Department determines, after consultation with the Attorney General and, as appropriate, the mental hygiene agencies, that such objections are not overcome by modifying the Cooperative Agreement or planning process or changing the conditions imposed on the Certificate of Public Advantage. Any modifications or changed conditions must be satisfied by a date set or agreed to by the Department;

(4) the holder of a Certificate of Public Advantage fails to file a report required by this Subpart or fails to provide information requested pursuant to a review under this Subpart, after notice of default; or

(5) a change in state or federal law or regulations warrants revocation of the Certificate of Public Advantage.

(b) Upon a decision to revoke the Certificate of Public Advantage, the Department shall notify the parties to the Certificate of Public Advantage in writing of its determination, and any objections or concerns of the Department that are part of the basis for the determination. The parties to the Certificate of Public Advantage shall have 90 days to respond to such determination, and any objections or concerns. If the objections or concerns are not resolved to

the satisfaction of the Department based on its review of such response, the Department may revoke the Certificate.

(c) If the Certificate is revoked, the parties shall be entitled to no benefits under Article 29-F of the Public Health Law and this Subpart, beginning on the date of revocation.

83-2.13 Hearing rights.

No Certificate of Public Advantage shall be revoked without affording the applicant an opportunity to request a hearing pursuant to part 51 of this title.

83-2.14 Voluntary Surrender.

(a) The parties to a Cooperative Agreement or a planning process may mutually agree to voluntarily surrender their Certificate of Public Advantage. At least 30 days prior to the surrender of the Certificate of Public Advantage, the parties shall file a notice of such decision with the Department. Such notice shall be provided by the Department to the Attorney General and, as appropriate, the mental hygiene agencies.

(b) The termination of the Cooperative Agreement which is the subject of the Certificate of Public Advantage by one or more parties to such Cooperative Agreement shall be considered to result in a voluntary surrender.

83-2.15 Effect of consultation or recommendations.

The response and recommendations of the Attorney General, the mental hygiene agencies as appropriate, and the Public Health and Health Planning Council, when sought or required pursuant to any provision of this Subpart, shall be considered by the Department; provided

however that such recommendations or the result of such consultation shall not be binding on the Department.

83-2.16 Certificate of need and other requirements.

Nothing in this Subpart shall relieve parties from any responsibility for compliance with laws or regulations governing certificate of need or other approval or notice submission requirements.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for the proposed addition of a new Subpart 83-2 to Title 10 NYCRR is Article 29-F of the Public Health Law ("PHL").

Legislative Objectives:

In March 2011, Governor Cuomo's Medicaid Redesign Team ("MRT") recommended providing support for integration and collaboration among health care providers by conferring immunity from state and federal antitrust liability through the active state supervision of such activities. Subsequently, the Legislature accepted the recommendation of the MRT and enacted PHL Article 29-F (Chapter 59 of the Laws of 2011, Part H, §§ 50-51).

In enacting PHL Article 29-F, the Legislature found that coordination of health care services is essential to the improvement of health care quality, efficiency, access and outcomes. In addition, the Legislature found that collaborative arrangements among, or consolidation, mergers or acquisition of, providers may be necessary to preserve access to essential services in some communities. Such collaborative agreements also may improve the quality of the services provided to patients, the efficiency of provider operations, and help contain costs. Furthermore, health system reform proposals at the federal and state levels, including mechanisms such as accountable care organizations, health homes, patient-centered medical homes and payment reforms such as penalties for potentially preventable readmissions all rely on integration and collaboration among providers.

The statute reflects the Legislature's finding that competition as currently mandated by federal and state antitrust laws should be supplanted by a regulatory program to permit and encourage mergers, acquisitions, and cooperative, collaborative and integrative agreements among health care providers and others in order to assure access to essential health care services, to improve health care quality and outcomes, to enhance efficiency, or to minimize the cost of health care. Further, active state supervision should be provided to ensure that the benefits of such agreements outweigh any disadvantages attributable to any reduction in competition that may result from the agreements, and to provide "state action immunity" to the parties engaged in such activities. The proposed regulations provide a mechanism for accomplishing this objective.

Current Requirements:

Providers seeking to merge or to create a common active parent are currently required to receive approval from the Department as part of the Certificate of Need process. However, an operating certificate issued as a result of the Certificate of Need process does not provide protection from antitrust liability at the state or federal levels. Many other collaborative arrangements among providers and other entities, or between non-provider entities, may proceed without Department approval, are subject to little or no state oversight, and have no protection from antitrust scrutiny.

Other statutory provisions already provide for state supervision for the purpose of promoting health care collaborations and immunity from antitrust liability in specific contexts. These include the multipayor patient-centered medical home program (PHL Article 29-AA),

accountable care organization program (PHL Article 29-E) and PHL Article 29-A, relating to rural health networks and rural health care access.

Needs and Benefits:

Increased integration and collaboration among health care providers, and among providers, payors and other healthcare-related entities, are essential to implementing many of the health system reform proposals under the Affordable Care Act and the state MRT initiatives. In addition, payment reforms, such as penalties for potentially preventable readmissions and value-based purchasing, will encourage integration and collaboration among providers. These collaborations promise to improve health care quality and outcomes, strengthen care coordination among providers, reduce inappropriate utilization, increase efficiency and contain health care costs. Further, a collaboration between an economically strong provider and an economically weak one may be able to protect the weaker provider from financial failure and preserve access to care in the community.

However, some collaborative arrangements might be construed as anti-competitive under the antitrust laws and might expose the participants to antitrust liability. Federal case law provides a defense against federal antitrust claims ("state action immunity") where the arrangement is: subject to active state supervision to ensure that the public benefits derived from the integrative and collaborative arrangements outweigh any anticompetitive effects; pursuant to a state-created oversight and approval process; and based upon the state's explicit intent to supplant competition with state oversight and to confer state action immunity upon those entities and activities approved under the process. PHL Article 29-F expresses that intent, and the proposed

regulations implement the program provided for by the statute, including the active supervision necessary to provide a state action immunity defense to a federal antitrust claim.

Health care providers that are entering into Cooperative Agreements or a planning process with other providers, or other health care-related entities, may gain a defense against federal antitrust claims and protection from private claims under state antitrust laws by obtaining a Certificate of Public Advantage and complying with these regulations.

This process is optional – providers and other entities may continue to enter into Cooperative Agreements or a planning process without seeking such protection. For example, an entity may determine that the risk of antitrust liability resulting from their arrangement is low and that a Certificate of Public Advantage is not necessary. However, these regulations will provide a path to pursue protection from antitrust liability for those providers that choose to seek a Certificate of Public Advantage, and engage in collaborations that would preserve or expand access to care, improve quality and outcomes, enhance efficiency, and/or curb costs, and which otherwise meet the criteria for approval under the program.

COSTS

Costs to Private Regulated Parties:

As a Certificate of Public Advantage is optional, this regulation creates no mandatory burdens or costs to regulated parties. However, applicants will be charged a $5,000 fee for applications, and for renewals, and will be required to pay for any consultants needed by the Department to analyze the application and the balance of benefits and disadvantages presented by the proposed

collaborative arrangement. Applicants will also have ongoing costs with regard to periodic reporting and response to issues arising in the course of oversight. Those costs will vary depending on the size and nature of the project, the complexity of the review, the extent of any issues arising subsequent to initial approval, and other factors. In most cases, however, such costs will be more than offset by the savings resulting from not having to go through federal antitrust reviews, which require similar analysis. Such costs could be several multiples of the cost of participating in the program, even with imposition of the application and consultant fees. Entities need not participate if they choose not to, whether for financial or any other reason. Accordingly, the program may often provide an opportunity for cost savings.

Costs to Local Government:

There are no costs to local government, except to the extent that a local government chooses to seek a certificate of public advantage for its covered activity.

Costs to the Department of Health:

The review of Certificate of Public Advantage applications will require the commitment of staff resources. However, the number of applications is expected to be small, and the reviews will be conducted largely by consultants paid for by the applicants.

Costs to Other State Agencies:

The regulations will require the dedication of some staff resources by the Antitrust Bureau of the Attorney General's Office and, as appropriate, the mental hygiene agencies, which will also review these applications. However, the number of applications is expected to be small, and the

Attorney General already engages in antitrust-related reviews. Accordingly, the associated costs to other state agencies should be nonexistent or minimal.

Local Government Mandates:

The proposed regulation does not impose any new programs, services, duties or responsibilities upon any county, city, town, village, school district, fire district or other special district.

Paperwork:

The proposed regulation requires the submission of an application if the parties to a cooperative agreement wish to seek protection from antitrust liability, together with subsequent ongoing reports and provision of additional information as requested by the Department where necessary during the course of its active supervision of the arrangement. Such paperwork will likely be less burdensome than would be associated with obtaining approval from state and federal antitrust authorities, in addition to possible ongoing enforcement risks in the absence of state action immunity.

Duplication:

There are no relevant State regulations which duplicate, overlap or conflict with the proposed amendment.

Alternatives:

The Certificate of Public Advantage (COPA) process has been adopted in several other states. The Department opted for this type of process because it is known to the federal antitrust

enforcement agencies and has withstood their scrutiny. The Department considered alternative fee requirements and determined that a $5,000 fee plus the costs of needed consultants would be appropriate for both applications and renewals. The Department also considered making all COPAs valid for the same number of years, but determined that the better course would be to tailor the COPA and its duration to the particular arrangement in question.

Federal Standards:

These regulations do not duplicate or conflict with any federal regulations.

Compliance Schedule:

The proposed amendment will be effective upon publication of a Notice of Adoption in the New York State Register.

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REGULATORY FLEXIBILITY ANALYSIS

No regulatory flexibility analysis is required pursuant to section 202-(b)(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments. The Department bases this determination on the voluntary nature of the program, the fact that any obligations associated with participation in the program are no different for small business or local governments than for any other participant, and the fact that participation will likely be chosen only if the costs and burdens associated with participation, including those associated with reporting or other obligations, will be less than the overall costs associated with not participating, and foregoing the opportunity for obtaining state action immunity for the relevant activity.

STATEMENT IN LIEU OF

RURAL AREA FLEXIBILITY ANALYSIS

No rural area flexibility analysis is required pursuant to section 202-bb(4)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse impact on facilities in rural areas, and it does not impose reporting, record keeping or other compliance requirements on facilities in rural areas. The Department bases this determination on the voluntary nature of the program, the fact that any obligations associated with participation in the program are no different for rural areas than for any other participant, and the fact that participation will likely be chosen only if the costs and burdens associated with participation, including those associated with reporting or other obligations, will be less than the overall costs associated with not participating, and foregoing the opportunity for obtaining state action immunity for the relevant activity.

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. It is apparent, from the nature of the proposed amendment, that it will not have an adverse impact on jobs and employment opportunities.

[NOTE: Although the regulations were initially proposed as a new Subpart 83-1 of Title 10 of the New York Codes, Rules and Regulations, they have been codified as a new Subpart 83-2. Thus, for example, earlier references to section 83-1.1 should be cited as 10 NYCRR § 83-2.1.**]**

SUMMARY OF ASSESSMENT OF PUBLIC COMMENT

A Notice of Proposed Rule Making was published in the *State Register* on September 18, 2013. The proposed regulations were revised in light of public comments received and a Notice of Revised Rule Making was published in the *State Register* on August 27, 2014. During the public comment period for the revised rulemaking, comments were received from hospitals, hospital associations, health plan associations, and a bar association. Clarifications and technical, non-substantive changes have been made to the regulations in light of the comments received. The regulations will take effect today pursuant to a Notice of Adoption filed in today's *State Register*. The full text of the regulations and Assessment of Public Comment is available on the Department of Health's website.

All comments received were reviewed and evaluated. In response to comments, section 83-1.1(c)(2) has been revised to clarify certain types of transactions for which a COPA may be available. In addition, technical clarifications were made to section 83-1.2(b)(2) and (3). As explained below, other suggestions were not incorporated because they were inconsistent with the statutory authority underlying the proposed rulemaking or concerned issues outside the scope of the proposed rulemaking.

A number of comments related to the intersection of the Certificate of Public Advantage (COPA) and the Delivery System Reform Incentive Payment (DSRIP). As noted in the comments and

responses, the Department has indicated that Performing Provider Systems (PPSs) may submit COPA applications along with their DSRIP Project Plan applications. In response to a number of comments, the Department advises that it soon will issue Frequently Asked Questions to assist PPSs in submitting COPA applications which will address the matters raised.

A number of comments expressed concern about the Attorney General's ability to seek retroactive enforcement of state antitrust laws, which they assert is inconsistent with the statutory purpose underlying the COPA regulations. In response, the Department notes that the proposed regulations achieve the statute's intent to provide state action immunity under the state and federal antitrust laws for collaborative arrangements that promote improved quality, efficiency of and access to health care services through the COPA process, while preserving the Attorney General's authority as authorized by law.

The Assessment of Public Comment is available on the Department of Health's website at www.health.ny.gov.

ASSESSMENT OF PUBLIC COMMENT

Comment: Section 83-1.1 defines a "Cooperative Agreement" should be revised to be consistent with corporate law principles

Response: The definition has been revised to clarify references to types of transactions.

Comment: The Department of Health (DOH) has advised that Performing Provider Systems (PPSs) will have the opportunity to submit applications for COPAs when submitting their Project Plan applications under the Delivery System Reform Incentive Payment (DSRIP) Program. The use of the Certificate of Public Advantage (COPA) regulations in the DSRIP context was not contemplated by the Legislature and the statute did not anticipate that the COPA process would be used for a large number of providers.

Response: PHL Article 29-F and the legislative findings supporting its enactment expressly state that it is "the policy of the state to encourage, where appropriate, cooperative, collaborative and integrative arrangements including but not limited to, mergers and acquisitions among health care providers or among others who might otherwise be competitors, under the active supervision of the commissioner." Collaborative activities engaged in by providers participating in PPSs may fall within this universe and therefore can appropriately be considered in COPA applications, which may be submitted in conjunction with the DSRIP application. DOH will be issuing Frequently Asked Questions ("FAQs") to assist PPSs in doing so.

Comment: Under DSRIP, multiple health care entities will join in PPSs and the arrangement between the PPS entities may not be set forth in a single document that could qualify as a Cooperative Agreement. The regulations should be revised so that a Cooperative Agreement could be comprised of multiple agreements or documents and a party to any one of these agreements would be deemed to be entitled to the COPA's protections.

Response: DOH will issue FAQs to assist PPSs in completing the COPA portion of the DSRIP application which will address this issue in further detail.

Comment: The regulations should be revised to clarify that addition or removal of participants to a PPS under DSRIP is permitted and termination of an agreement with a participant is not grounds for surrender of a COPA.

Response: In general, the addition of a party to a Cooperative Agreement is likely to constitute a material change and would be governed by § 83-1.8(a). The FAQs that will be issued to assist PPSs in completing the COPA portion of the DSRIP application will address this question as it pertains to DSRIP.

Comment: Section 83-1.2(b)(3) offers the opportunity for applicants to seek state action immunity for a "Planning Process," but the regulation requires submission of a "detailed letter of intent." Providers need protection for the discussions leading up to the execution of letter of intent.

Response: State action immunity can be provided only if DOH determines that the benefits of a Cooperative Agreement or planning process outweigh the anticompetitive effects, and DOH actively supervises the transaction governed by the Cooperative Agreement or the elements of the proposed transaction under development as part of a Planning Process. Without the detail provided in a Letter of Intent, DOH will not have enough information to make such determination or provide such active supervision.

Comment: The revised regulations do not define the "planning entity" that would oversee a planning process. The entity could be a health care provider that may be a party to an executed Cooperative Agreement and therefore may not exhibit the independence and objectivity needed for successful planning. Since a COPA is issued for no less than two years, it is possible that the planning process could last for at least two years, with state action immunity protections, but never result in an executed cooperative agreement.

Response: A planning entity approved by DOH would not include a health care provider that is a party to the process. It is possible that the planning process could last for two years without resulting in a Cooperative Agreement. If appropriate, DOH could impose conditions to minimize any potential issues arising in such a situation, or could revoke the COPA if it became clear that the process was not going to result in a Cooperative Agreement. No change to the regulations is necessary.

Comment: Pursuant to § 83-1.3, each party to a Cooperative Agreement must post on its public website a description of the application for the COPA. In the DSRIP context, this could be

interpreted to require that all PPS participants must post a description of the COPA application to their own websites. The regulations should be revised to allow DOH the flexibility to provide that it would be sufficient for such information to be posted on the PPS's website, without the necessity of it being posted on the website of every PPS participant.

Response: Guidance on this issue will be available in the FAQs that will be issued to assist PPSs in completing the COPA portion of the application. No change to the regulations is necessary.

Comment: Review and renewal of COPAs should provide for public input. At a minimum, COPA applications should undergo the same public process as Certificate of Need applications, including opportunity for public comment before and consideration by the Public Health and Health Planning Council (PHHPC).

Comment: Health plans should be included in the COPA application review process.

Response: Section 83-1.3(b) provides that a description of the COPA application, including a renewal application, will be available on DOH's website. There will be opportunity for public comment on a COPA application, either in writing prior to a meeting of a designated PHHPC committee or in person at such meeting. The recommendation of the committee will be presented to the full PHHPC for review and recommendation.

Comment: The regulations should be revised to ensure that all confidential and proprietary information included in reports required pursuant to § 83-1.9 does not become available to the public under a Freedom of Information Law (FOIL) request or otherwise.

Response: FOIL generally requires DOH to make records available in response to a request unless an exception applies. The COPA application will afford applicants the opportunity to identify any such records that may fall within an exception submitted as part of the application, and DOH will evaluate whether the exception applies. No change to the regulations is necessary.

Comment: DOH should establish a schedule of fees for the filing of initial application, a renewal application, and periodic reports, so that such fees are known to applicants in advance of submitting their application.

Response: The complexity of COPA applications is likely to vary greatly and will consist of a broad range of factual circumstances. The application fee will be the same for each application submitted to DOH, while the consulting fee will vary based on the complexity of the application. No change to the regulations is necessary. However, DOH intends to provide each applicant with an estimate of expected consulting fees after submission of an application.

Comment: Section 83-1.4(b) related to fees for applications and monitoring should limit an applicant's liability for costs so that applicants are only required to cover the reasonable cost of consultants needed.

Response: Consultants will be retained by DOH and estimated fees will be reviewed by DOH for reasonableness. No change to the regulations is necessary.

Comment: The State should not balance the benefits of a COPA against competition itself. Instead, the State should take into account the benefits and disadvantages of issuing a COPA against the benefits and disadvantages of not having one.

Response: Because the regulations appropriately require consideration of the benefits against the disadvantages of a transaction, including the potential impact on competition, no change to the regulations is necessary.

Comment: The regulatory language should be clarified to mean that when DOH weighs the benefits versus the disadvantages, it does so only on the basis of the collaboration's effect on health care.

Response: The factors taken into consideration in the evaluation of a COPA application, set forth in § 83-1.15, sufficiently establish the focus of the analysis upon health care. No change to the regulations is necessary.

Comment: DOH should issue guidance advising PPSs of the types of conditions, if any, that would be imposed on PPSs under their COPAs, along with a template list of conditions, so that each PPS could take such information in account in advance of applying for a COPA.

Response: DOH is in the process of issuing guidance that will assist COPA applicants in understanding, among other things, what types of conditions may be included as part of a COPA. In addition, DOH is in the process of issuing FAQs to assist PPSs in completing the COPA portion of their DSRIP applications, which will address these issues as they specifically pertain to PPSs seeking COPAs.

Comment: Parties to a Cooperative Agreement should be prohibited from exchanging price information and the COPA should not result in increased costs to the community affected by the COPA. Instead, a COPA should be required to produce greater price efficiencies, which should be enforced through annual reporting. The regulations should require achievement of quality benchmarks as a possible condition for an approved COPA.

Response: Section 83-1.6 provides that DOH may impose conditions when issuing a COPA, which may include, among other things, requiring measures to prevent unwarranted price increases and achieve savings. DOH is in the process of issuing guidance that will assist COPA applicants in understanding the types of conditions that may be included as part of a COPA.

Comment: The antitrust protections afforded a PPS through the issuance of a COPA should be limited to the collaboration necessary to achieve the quality improvement goals of the DSRIP projects in accordance with the terms and conditions of the DSRIP waiver.

Response: DOH is in the process of issuing FAQs to assist PPSs in submitting COPA applications as part of their DSRIP applications, which will address this issue.

Comment: The proposed regulations do not set forth a timeframe for the approval or disapproval of COPA applications or requests for a material modification and should be revised to establish such timeframes.

Response: COPA reviews will be conducted in accordance with the process and standards set forth in the regulations. The complexity of COPA applications is likely to vary greatly and will consist of a broad range of factual circumstances. Each application and modification request will be reviewed as quickly as possible but flexibility is necessary to ensure that a thorough analysis is conducted of each application. No change to the regulations is necessary.

Comment: Section 83-1.6(e) provides that a COPA may be issued for a period to be determined by DOH, which shall be not less than two years in duration This may not be sufficient, particularly for PPSs.

Response: The two year period referenced in the regulation is the minimum period, but a COPA can be issued for a longer period of time, depending on the circumstances. In addition, § 83-1.11 sets forth a process for parties to an expiring COPA to seek its renewal. With respect to COPAs sought by PPSs in the DSRIP context, DOH is in the process of issuing FAQs to assist PPSs in submitting COPA applications as part of their DSRIP applications, which will address this issue. No change to the regulations is necessary.

Comment: The regulations should be revised to define what constitutes a "material modification" so that modifications that are minor or that do not have any consequences of an anti-competitive nature can occur without the necessity of obtaining such prior review and approval.

Response: The complexity of COPA applications is likely to vary greatly and will consist of a broad range of factual circumstances. The determination as to whether a modification is material will depend on the circumstances at issue, but the use of the "material" modifier was meant to exclude minor modifications with no impact on competition. Parties to a COPA attempting to determine whether to seek approval of a potential modification in a particular case may contact DOH for assistance. No change to the regulations is necessary.

Comment: Applications for COPA renewals should undergo the same review as the initial applications.

Response: Section 83-1.10(a) provides that applications for renewal shall take into consideration the same considerations set forth in § 83-1.5.

Comment: The proposed regulations do not permit an appeal of a denial of an application.

Response: Requests for reconsideration may be made in writing to the Department. No change to the regulation is necessary.

Comment: The regulations should include specific criteria as the basis for any DOH intervention and ample due process protections should be built into any course of action that may result in significant damage to participants.

Response: Section 83-1.12 sets forth specific circumstances in which a COPA may be revoked, and provides that upon notification of a determination to revoke, the parties have 90 days to respond thereto. If the COPA is revoked, pursuant to § 83-1.13, the parties will have an opportunity to request a hearing. No change to the regulations is necessary.

Comment: The regulations do not establish a process for complaints.

Response: The regulations provide that a description of the COPA application, including a renewal application, will be available on DOH's website. There will be opportunity for public comment on a COPA application, either in writing or in person at a meeting of a designated PHHPC committee. Any subsequent complaints can be made directly to DOH or the Attorney General. No change to the regulations is necessary.

Comment: The regulations should be revised to afford DOH the same degree of oversight and enforcement authority that it has with any other DOH regulated/licensed/certified entity, including the ability to conduct surveys, issue statement of deficiencies, require the submission of acceptable plans of correction, and issue fines.

Response: Article 29-F authorizes DOH to engage in appropriate supervision necessary to promote state action immunity under the state and federal antitrust laws, and revocation or amendment of a COPA is the appropriate remedy for any lack of compliance. No change to the regulations is necessary.

Comment: Sections 83-1.2(a) does not specify that the Attorney General's ability to seek relief under state antitrust laws is limited to prospective relief. If a COPA can be revoked retroactively, it would undermine the purposes that DOH seeks to promote in the COPA regulations. The regulations should permit the Attorney General to seek relief only: (1) where the challenged conduct exceeds the approved COPA (either prospectively or retroactively), as interpreted reasonably and in good faith by the parties to the COPA; or (2) when the Attorney General determines that the anticompetitive effects outweigh the benefits of the conduct, but only with respect to behavior undertaken after the Attorney General has exhausted the process stated in the proposed regulations (i.e., consultation with DOH and providing the parties with the opportunity to modify their conduct).

Response: The regulations achieve the statute's intent to provide state action immunity under the state and federal antitrust laws for collaborative arrangements that promote improved quality, efficiency of and access to health care services through the COPA process, while preserving the Attorney General's authority as authorized by law.

Comment: The regulations should clearly state that a grant of a COPA does not impact the need for a Certificate of Need.

Response: Section 83-1.16 expressly provides that nothing in the regulations relieves parties from the responsibility to comply with laws or regulations governing Certificates of Need. No change to the regulations is necessary.