

Accountable Care Organizations

Effective date: 12/31/14

## **SUMMARY OF EXPRESS TERMS**

These proposed regulations would: (1) add a new Part 1003 to 10 NYCRR, entitled “Accountable Care Organizations,” to establish standards for the issuance of certificates of authority by the Commissioner of Health (Commissioner) to Accountable Care Organizations (ACOs); and (2) amend Part 98 of 10 NYCRR, entitled “Managed Care Organizations,” to make conforming changes to provisions related to Independent Practice Associations.

### **Part 1003 (Accountable Care Organizations)**

Section 1003.1 (Applicability) provides that Part 1003 applies to persons or entities seeking certification as an ACO. The section further specifies that no application is required for a Medicare-only ACO whose contract with CMS does not permit shared losses to exceed 10 percent. This applies to the ACOs approved by CMS to participate in the Medicare Shared Savings Program. Such a Medicare-only ACO may receive certification through an expedited process and will be subject only to §§ 1003.6 (Legal Structure and Responsibilities), 1003.11 (Payment and Third Party Payers), 1003.12 (Termination), 1003.13 (Reporting) and 1003.14 (Legal Protections) of Part 1003. Similarly, a Medicare-only ACO whose contract with CMS allows shared losses to exceed 10 percent may receive certification through an expedited process and will be subject to the aforementioned provisions as well as § 1003.5 (Medicare-Only ACOs Sharing Losses).

Section 1003.2 (Definitions) sets forth definitions for certain terms. In particular, an “ACO” is defined as “an organization comprised of clinically integrated independent health care providers that work together to provide, manage, and coordinate health care (including primary care) for a defined population; with a mechanism for shared governance; the ability to negotiate, receive, and distribute payments; and to be accountable for the quality, cost, and delivery of health care to the ACO's patients and has been issued a “certificate of authority” by the Commissioner.

Section 1003.3 (Certificate of Authority) establishes the criteria that must be satisfied for the Commissioner to approve a certificate of authority. Among other things, the ACO must demonstrate the capability to provide, manage and coordinate health care for a defined population, and its operation must include the participation of clinically integrated health care providers and administrative support organizations that are accountable for the quality, cost and delivery of health care to the individuals it serves.

Section 1003.4 (Application Requirements) provides that a person or entity seeking to obtain a certificate of authority must submit an application on forms prescribed by the Commissioner.

Section 1003.5 (Medicare-Only ACOs Sharing Losses) applies only to a Medicare-only ACO which may have shared losses that exceed ten percent of the benchmark established under its contract with CMS (meaning ACOs that participate in the Pioneer Program). The section allows such Medicare-only ACOs the ability to share losses without having to obtain an insurance license, subject to meeting several stringent financial conditions.

Section 1003.6 (Legal Structure and Responsibilities) sets forth requirements pertaining to the legal structure of an ACO, and provides that an approved ACO must provide, manage and coordinate health care for a defined population; be accountable for quality, cost, and delivery of health care to ACO patients; negotiate, receive and distribute any shared savings or losses; and establish, report and ensure provider compliance with health care criteria including quality performance standards. The section also requires that providers that participate in an ACO provide notification of such to their patients.

Section 1003.7 (Governing Body) requires that the governing body of an ACO have a transparent governing process and be responsible for the oversight and strategic direction of the ACO, holding those responsible for management of the ACO accountable for the ACO's activities.

Section 1003.8 (Leadership and Management) provides that an ACO must have a leadership and management structure that supports the delivery of an array of health care services for the purpose of improving quality of care, health outcomes and coordination and accountability of services provided to patients.

Section 1003.9 (Quality Management and Improvement Program) requires ACOs to develop and implement a quality management and improvement program that identifies, evaluates and resolves quality related issues.

Section 1003.10 (Quality Performance Standards and Reporting) provides that the Department of Health (“Department”) shall collect from ACOs data related to quality assurance reporting requirements, which will be developed by the Department in conjunction with the National Committee on Quality Assurance. The ACO will be afforded the opportunity to review the information and correct any errors, and then the information will be posted on the Department’s public website. The section also provides that the ACO must demonstrate quality performance equal to or above statewide and/or national benchmarks.

Section 1003.11 (Payment and Third Party Health Care Payers) sets forth requirements for ACOs that enter into payment arrangements with a third party health care payer. In particular, the section clarifies that unless an ACO is licensed as an insurer under the Insurance Law or certified under Article 44 of the Public Health Law, the ACO is prohibited from engaging in any activity that would constitute the business of insurance under Insurance Law § 1101, except as provided in § 1003.11(b)(1) and (2).

Section 1003.12 (Termination) specifies that the Commissioner may limit, suspend or terminate the certificate of authority of an ACO after written notice and an opportunity for review and/or hearing. The section provides, among other things, that the failure to adhere to established quality measures or comply with corrective action plans related to poor performance on established quality of care standards constitute grounds for termination.

Section 1003.13 (Reporting) requires ACOs to submit data to the Commissioner annually and as otherwise requested. The data requested would include information about ACO participants and

enrollees, utilization of services, complaints and grievances, quality metrics and shared savings or losses.

Section 1003.14 (Legal Protections; State Action Immunity) reflects the statutory intent to promote ACOs by excluding them from the application of certain provisions that might otherwise inhibit such arrangements:

- ACOs certified pursuant to Part 1003 shall not be considered to be in violation of Article 22 of the General Business Law relating to contracts or agreements in restraint of trade, if the ACO's actions qualify for the safety zone, subject to the antitrust analysis set forth in the *Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program* issued by the Federal Trade Commission and U.S. Department of Justice and published in the Federal Register on October 28, 2011. (§ 1003.14(a));
- As part of its application for a certificate of authority under this part, an ACO may request that the State provide state action immunity from federal and state antitrust laws;
- ACOs certified pursuant to Part 1003 shall not be considered to be in violation of Education Law Article 131-A relating to fee splitting when certain criteria are satisfied (§ 1003.14(b));
- Health care providers shall not be considered to be in violation of Title 2-D of Article 2 of the Public Health Law when making referrals to other health care practitioners that are part of their ACO activities (§ 1003.14(c));
- Medicaid providers that enter into arrangements with an ACO, one or more of its ACO participants or its ACO providers/suppliers, or a combination thereof shall not be in violation of Social Services Law ("SSL") § 366-d (§ 1003.14(d)); and

- The provision of health care services by an ACO shall not be considered the practice of a profession under Education Law Title 8 (§ 1003.14(f)).

### **Part 98 of NYCRR (Managed Care Organizations)**

Section 98-1.2(w) is amended to expand the definition of an IPA to allow certification as an ACO pursuant to PHL Article 29-E and Part 1003 and provide that if so certified, the IPA may contract with third party health care payers.

Section 98-1.5(b)(vii)(f) is amended to provide that an IPA may seek certification as an ACO pursuant to PHL Article 29-E and Part 1003 and, if so certified, must comply with all the requirements of Part 1003, including but not limited to the requirements of § 1003.6(e) and (g). Upon receiving such certification, an IPA acting as an ACO may contract with third party health care payers. § 98-1.5(b)(vii)(f).

Section 98-1.5(b)(vii)(g) is added to provide that an IPA may include any and all necessary powers and purposes as authorized, allowed or required under an approved Delivery System Reform Incentive Payment (“DSRIP”) Program.

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

Pursuant to the authority vested in the Commissioner of Health pursuant to Article 29-E of the Public Health Law, as added by section 66 of Part H of Chapter 59 of the Laws of 2011 and amended by Chapter 461 of the Laws of 2012, 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 Chapter XI and a new Part 1003, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

A new Chapter XI and a new Part 1003 is added 10 NYCRR, to read as follows:

## CHAPTER XI Innovative Delivery Models

### PART 1003 Accountable Care Organizations

#### 1003.1 Applicability

#### 1003.2 Definitions

#### 1003.3 Certificate of Authority

#### 1003.4 Application Requirements

#### 1003.5 Medicare-Only ACOs Sharing Losses

#### 1003.6 Legal Structure and Responsibilities

#### 1003.7 Governing Body

#### 1003.8 Leadership and Management

#### 1003.9 Quality Management and Improvement Program

#### 1003.10 Quality Performance Standards and Reporting

1003.11 Payment and Third Party Health Care Payer

1003.12 Termination

1003.13 Reporting

1003.14 Legal Protections; State Action Immunity

1003.1 Applicability

(a) This Part shall be applicable to every person or entity seeking state certification to establish and operate an accountable care organization (ACO) pursuant to Article 29-E of the Public Health Law. Only a person or entity issued a certificate of authority shall be afforded the protections under section 1003.14 or may avail itself of the exemptions from the Insurance Law under section 1003.11 of this Part.

(b) No application is required pursuant to this Part for a Medicare-only ACO whose shared losses may not exceed ten percent of the benchmark established under the contract with Centers for Medicare and Medicaid Services (CMS). Such Medicare-only ACO shall receive certification through an expedited process under subdivision (4) of section 2999-p of the Public Health Law and shall only be subject to sections 1003.6, 1003.11, 1003.12, 1003.13 and 1003.14 of this Part. A certificate of authority received through this expedited process shall only apply to the Medicare-only ACO's actions related to Medicare beneficiaries under its authorization from CMS.

(c) No application is required pursuant to this Part for a Medicare-only ACO whose shared losses may exceed ten percent of the benchmark established under the contract with CMS. Such Medicare-only ACO shall receive certification through an expedited process under subdivision 4 of section 2999-p of the Public Health Law and shall only be subject to sections 1003.5, 1003.6,



1003.11, 1003.12, 1003.13 and 1003.14 of this Part. A certificate of authority received through this expedited process shall only apply to the Medicare-only ACO's actions related to Medicare beneficiaries under its authorization from CMS.

## 1003.2 Definitions

The following words or terms when used in this Part shall have the following meanings:

(a) "Accountable care organization" or "ACO" means an organization comprised of clinically integrated independent health care providers that work together to provide, manage, and coordinate health care (including primary care) for a defined population; with a mechanism for shared governance; the ability to negotiate, receive, and distribute payments; and to be accountable for the quality, cost, and delivery of health care to the ACO's patients; and has been issued a certificate of authority.

(b) "ACO participant" means a health care provider as defined in subdivision (j) of this section, a health home, an administrative services organization or a provider/supplier that is one of the health care providers or other entities that comprise the ACO.

(c) "Administrative services organization" means an entity that provides ancillary services to an ACO, such as, but not limited to, technical assistance, information systems and services, and care coordination services. This includes, but is not limited to, an independent practice association that conforms to the requirements of this Part.

(d) "Capitation" or "capitation arrangement" means contractually based payments or prepayments (any payments made prior to the last day of the month shall be deemed a prepayment of the entire month's capitation) made to an ACO or a health care provider, or an arrangement for such payments or prepayments, on a per member per month or a percentage of

premium basis, in exchange for one or more covered health care services to be rendered, referred or otherwise arranged by such provider and by its participating providers.

(e) “Certificate of Authority” or “certificate” means a certificate of authority issued by the Commissioner under Article 29-E of the Public Health Law and this Part.

(f) “Clinical integration” means the systematic coordination of evidence-based physical and behavioral health care for patients across a broad spectrum of settings in which care is provided, including inpatient, outpatient, institutional and community based settings in order to promote health and better outcomes, particularly for populations at risk, while also managing total cost of care.

(g) “Commissioner” means Commissioner of the New York State Department of Health.

(h) “Defined population” means the individuals that will be served by an ACO.

(i) “Federal and 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.

(j) “Health care provider” includes but is not limited to an entity licensed or certified under article twenty-eight or thirty-six of the public health law; an entity licensed or certified under article sixteen, thirty-one or thirty-two of the mental hygiene law; or a health care practitioner licensed or certified under title eight of the education law or a lawful combination of such health care practitioners.

(k) “Health home” means an entity designated by the Commissioner pursuant to section 365-1 of the Social Services Law.

(l) "Medicaid dual eligible" or "dual eligible" means an individual who is in receipt of medical coverage paid for by both the Medicare and Medicaid programs.

(m) "Medical director" means a New York State licensed physician under Title 8 of the Education Law whose responsibilities for an ACO include but are not limited to, the supervision of quality assurance and improvement, monitoring utilization patterns and advising the governing authority on the adoption and implementation of policies concerning medical services.

(n) "Medicare-only ACO" means an ACO certified pursuant to subdivision (4) of section 2999-p of the Public Health Law that has been accepted by the Centers for Medicare and Medicaid Services (CMS), has entered into an approved participation agreement with CMS, and exclusively serves Medicare beneficiaries as its defined population that are not otherwise enrolled in Medicare Advantage or other Medicare managed care plans.

(o) "One-sided model" means a model under which an ACO may have shared savings with a third party health care payer with which it has contracted, if the ACO meets the requirements for doing so, but is not liable for shared losses incurred.

(p) "Patient centered medical home" means a health care setting recognized by a national accrediting organization that focuses on the patient and where the patient's primary care provider coordinates a team of health care professionals in arranging for and ensuring the patient receives necessary and appropriate care from other qualified individuals.

(q) "Primary care provider" means a physician, nurse practitioner, or midwife acting within his or her lawful scope of practice under Title 8 of the Education Law and who is practicing in a primary care specialty.

(r) "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.

(s) “Provider/supplier” means an individual or entity that is a provider or supplier of health care services to an ACO and may be an ACO participant.

(t) “Qualified health information technology entity” or “QE” means a not-for-profit entity that has been certified as a QE through a QE certification process recognized by the Commissioner. QEs provide the governance and policy framework for health information exchange activities at a local or regional level by fulfilling the purposes for which they were incorporated, following their bylaws, and meeting their contractual obligations to the state designated entity and their participation agreements with their participants.

(u) “Shared losses” means that portion of the losses incurred by an ACO when its expenditures for health care services to its defined population are above projected benchmark expenditures.

(v) “Shared savings” means that portion of savings generated by an ACO when its expenditures for health care services to its population are below projected benchmark expenditures, with no downside risk to the ACO for losses.

(w) “Superintendent” means the Superintendent of Financial Services.

(x) “Third party health care payer” has its ordinary meanings and includes the following:

(1) Centers for Medicare and Medicaid Services;

(2) the New York State Department of Health;

(3) insurers licensed under the laws of this state or any other state;

(4) managed care organizations certified under Article 44 of the Public Health Law;

(5) other entities doing an insurance business that are otherwise subject to the Insurance Law;

(6) entities exempted from being licensed under the Insurance Law pursuant to the federal Employee Retirement and Income Security Act (ERISA), 29 U.S.C. sections 1001-1461; or

(7) administrators acting on behalf of entities exempted from being licensed under the Insurance Law pursuant to ERISA.

(y) “Two-sided model” means a model under which the ACO may have both shared savings or losses with a third party health care payer with which it has contracted, if the ACO meets the requirements for doing so, and may have shared losses incurred.

### 1003.3 Certificate of Authority

(a) The Commissioner may issue a certificate of authority if the applicant has met the requirements of Article 29-E of the Public Health Law and this Part, except that a Medicare-only ACO need not meet such requirements except as provided in section 2999-r of the Public Health Law and specifically in this Part. The Commissioner shall evaluate an ACO application based on the information contained in and submitted with the application and any other relevant information known to the Commissioner. The Commissioner will notify an applicant if the application is incomplete and provide the applicant an opportunity to submit the required information to complete the application. An application that remains incomplete 90 days after receiving a request from the Commissioner for additional information may be denied.

(b) The following conditions must be satisfied in order for the Commissioner to approve an application:

(1) The ACO must demonstrate the capability to provide, manage and coordinate health care (including primary care) for a defined population including, where practicable, elevating the services of primary care health care providers to meet patient centered medical home standards, coordinating services for complex high need patients and providing access to health care providers that are not part of the ACO;

(2) There is participation of clinically integrated health care providers and other ACO participants that are accountable for the quality, cost and delivery of health care to the ACO's defined population;

(3) There is a governance, leadership and management structure which is reasonably and equitably representative of the ACO participants and its patients; and

(4) There is documentation of satisfactory character and competence required to conduct the affairs of the ACO in its best interests and in the public interest and so as to provide proper services for the patients to be served.

#### 1003.4 Application Requirements

(a) A person or entity seeking to obtain a certificate of authority shall submit such application on forms prescribed by the Commissioner. The application must be signed by the chief executive officer, president, chairman of the board, or other authorized representative of the applicant. The application shall include information about its ACO participants and its providers/suppliers participating in the program as is necessary to implement the program, including:

(1) The name and address of all ACO participants with a description of the services to be provided by each;

(2) Certification that the ACO and its ACO participants have agreed to become accountable for the quality, cost, and overall care of the individuals attributed to the ACO;

(3) Criteria for accepting health care providers and other ACO participants to participate in the ACO; and

(4) A plan detailing how the ACO will use best efforts to include among its participants federally qualified health center(s) (FQHCs) that are willing to be a participant and that serve the area and population served by the ACO.

(b) The application shall require applicants to submit copies of organizational documents or proposed organizational documents, including but not limited to, certificate of incorporation, bylaws, articles of organization, operating agreement, partnership agreement, a list of members of the governing body, and any additional applicable documents and agreements and all amendments thereto evidencing the ACO's legal structure, which conforms to this Part.

(c) Copies of financial statements of the ACO shall be made available to the Commissioner upon request.

(d) The application shall require applicants to submit documentation pertaining to the character and competence of the proposed ACO's participants and principals which shall include proposed incorporators, directors, officers, stockholders, sponsors, and individual operators or partners. This information shall include but not be limited to:

(1) Certification that the applicant has used best efforts to ascertain that none of its participants, principals or contractors and no individuals who are employees, principals or contractors of such entities are on any federal or state excluded list; and

(2) Any participation by the proposed ACO, its ACO participants, or its providers/suppliers in the federal Medicare Shared Savings Program under the same or different name:

(i) Existence of an affiliation with another ACO participating in the federal Medicare Shared Savings Program and whether the agreement is currently active or has been limited, suspended or terminated; and

(ii) If the agreement has been limited, suspended or terminated, an explanation of the circumstances including whether the action was voluntary or involuntary.

(e) Documents such as participation agreements, employment contracts, and operating policies sufficient to describe the ACO participants' and providers'/suppliers' rights and obligations in and representation by the ACO, including how the opportunity to receive shared savings or other financial arrangements will encourage ACO participants and providers/suppliers to adhere to the quality assurance and improvement program and evidence-based clinical guidelines, shall be made available to the Commissioner upon request.

(f) A copy of the ACO's compliance plan, or documentation describing the plan that will be put in place at the time of issuance of the certificate of authority, shall be made available to the Commissioner upon request.

(g) The application shall require the applicant to provide a description of the population to be served by the proposed ACO, which may include reference to the geographic area and, if applicable, shall include patient characteristics to be served. This shall include but not be limited to discussion of the impact of the establishment and operation of the ACO on access to health care for the population to be served in the defined area.

(h) The application shall require the applicant to provide a plan for care coordination to assure that all medically necessary health care services are available to and effectively used by the patient. Care coordination shall include but not be limited to, referral, service acquisition follow-up and monitoring. The ACO shall include a description of how it will act in a timely manner consistent with patient autonomy, including not requiring patients to obtain prior authorization or a referral to receive a health care service. Notwithstanding the foregoing, this



section does not prohibit a managed care organization from requiring use of network providers, use of referrals and prior authorization for its members.

(i) The application shall require the applicant to provide a description of how the proposed ACO will use evidence-based health care, patient engagement, coordination of care, electronic health records including participation in Qualified Health Information Technology Entities and other enabling technologies and services that promote integrated, efficient and effective health care services.

(j) The application shall require the applicant to provide a description of the proposed quality assurance and improvement procedures, including how performance standards and measures will be utilized to assess and improve quality and utilization of care.

(k) The application shall require the applicant to provide a description of the proposed ACO's policies and procedures for reviewing and responding to complaints from patients and providers.

(l) The application shall require the applicant to provide assurance that the proposed ACO will not by incentives or otherwise, discourage a health care provider from providing, or an enrollee or patient from seeking, appropriate health care services.

(m) The application shall require the applicant to provide assurance that the proposed ACO will not discriminate against or disadvantage a patient or patient's representative for the exercise of patient autonomy.

(n) The application shall require the applicant to provide assurance that the proposed ACO will not limit or restrict beneficiaries to providers contracted or affiliated with the ACO, including not requiring patients to obtain prior approval from a primary care gatekeeper or otherwise before utilizing the services of other providers. Notwithstanding the foregoing, this

section does not prohibit a managed care organization from requiring use of network providers, use of referrals and prior authorization for its members.

(o) Entities seeking state action immunity from federal or state antitrust laws shall submit such information as is required pursuant to subdivision (a) of section 1003.14.

(p) In addition to the above application requirements, entities seeking to enter into any “two-sided model” contract arrangements also are required to provide the following information;

(1) Type of arrangement, e.g., fee-for-service with a shared savings and loss payment tabulated and transferred at year end or a full or partial capitated arrangement into which the ACO proposes to enter;

(2) Baseline benchmark from which any savings or losses will be calculated;

(3) Percentage of the potential savings or losses to be split between the ACO and third party health care payer;

(4) Any reserve requirements imposed on the ACO by the third party health care payer; and

(5) Any other documents deemed relevant by the Commissioner.

(q) The application shall require the applicant to attest to the accuracy of the information contained in the application submitted to the Commissioner.

#### 1003.5 Medicare-Only ACOs Sharing Losses

(a) A Medicare-only ACO may not enter into a contract under which its shared losses may exceed ten percent of the benchmark established under its contract with CMS unless:

(1) Medical claims of the ACO participants are paid by CMS on a fee-for-service basis directly to the ACO participants and the ACO does not directly or indirectly receive, pay or transfer any claims payments;

(2) Any shared savings or shared losses under the two-sided model will be tabulated and transferred in a lump sum between CMS and the ACO only at year end;

(3) In lieu of a lump sum payment from the ACO to CMS, the ACO has an option to instead reduce future fee for service CMS payments below the standard Medicare fee schedule until the balance due has been extinguished;

(4) The ACO has placed funds in an escrow account (under terms and computations specified in the contract with CMS) equal to at least 25 percent of the potential maximum deficit payment due from the ACO to CMS in a particular year.

(b) The application for a certificate of authority of a Medicare-only ACO, whose shared losses may exceed ten percent of the benchmark established under the contract with CMS, must include the following information:

(1)(i) A financial statement in a form prescribed by the Commissioner in consultation with the Superintendent, sworn to under penalty of perjury by the ACO's chief financial officer, showing the ACO's financial condition at the close of its fiscal year, together with an opinion of an independent certified public accountant (CPA) on the financial statement of such health care provider.

(ii) When reviewing the financial condition of the ACO, the CPA's certification shall represent whether the liabilities of the ACO make adequate provision for any additional liability that may inure to the ACO by virtue of its assumption of risk under a financial risk transfer agreement or any similar transaction, including but not limited to information relating to section 1003.4(o) of this Part. The amount and adequacy of any such liability (and a description of the procedures used by the CPA to determine such liability) shall be disclosed and commented upon by the CPA in its certification.

(iii) In rendering the required opinion, the CPA may take into consideration the financial position of a guaranteeing parent corporation, provided that the terms and conditions of the guarantee have been reviewed by the CPA and the guaranteeing parent corporation includes the financial condition of the controlled health care provider in its consolidated financial statement as required by this Part. In such cases, the opinion of the CPA on the ACO's financial statement shall state to what extent, if any, the CPA relied upon the guarantee when rendering its opinion and to what extent the CPA reviewed the financial position of the guaranteeing parent corporation. A copy of the consolidated financial statement of the guaranteeing parent corporation for the same fiscal year together with an opinion of an independent CPA on the financial statement shall be attached to the CPA's opinion on the ACO's financial statement. For purposes of this paragraph, a "guaranteeing parent corporation" means an entity that controls, within the meaning of paragraph (16) of subdivision (a) of section 107 of the Insurance Law, an ACO and guarantees the performance of the ACO's obligations under the financial risk transfer agreement including the payment of any amounts owed by the ACO to participating providers for services rendered pursuant to a risk transfer agreement; provided that nothing in this paragraph shall be construed as permitting such entity to exercise control over the ACO's governing board with respect to ACO operations.

(iv) Such financial statement and opinion shall be available for public inspection at the offices of the Commissioner and the principal office of the ACO.

(2)(i) An actuarial certification that, after examining the ACO's ability to meet its responsibilities with respect to its use of in-network capitation funds received (from an insurer, the CMS or other government agency in regard to Medicare or Medicaid) and the ACO's compliance with the terms and conditions of any financial risk transfer agreement and the

provisions of this Part that such contracts are not expected to threaten the financial solvency of the ACO.

(ii) In rendering the required certification, the actuary may take into consideration the financial position of a guaranteeing parent corporation, provided that the terms and conditions of the guarantee have been reviewed by the actuary and the guaranteeing parent corporation includes the financial condition of the controlled health care provider in its consolidated financial statement as required by this Part. In such cases, the actuary's certification shall state to what extent, if any, the actuary relied upon the guarantee when rendering its certification and to what extent the actuary reviewed the financial position of the parent corporation.

(iii) The actuarial certification shall be available for public inspection at the offices of the Commissioner and the principal office of the ACO.

(c) A Medicare-only ACO whose shared losses may exceed ten percent of the benchmark established under the contract with CMS, shall submit to the Commissioner on an annual basis, within 120 days of the close of its fiscal year:

(1) A financial statement meeting the same requirements specified in subdivision (b)(1) of this section; and

(2) An actuarial certification meeting the same requirements specified in subdivision (b)(2) of this section.

(d) A Medicare-only ACO, whose shared losses may exceed ten percent of the benchmark established under the contract with CMS, and its participating providers may not collect or attempt to collect from a patient any amounts owed to such participating provider for covered services, but excluding any amounts owed by the patient to the provider pursuant to the patient's

subscriber contract. Such a “hold harmless” requirement is in addition to the protections afforded to subscribers under any applicable state or federal statute.

(e) The Commissioner may make an examination of the affairs of the ACO as often as the Commissioner deems prudent. The focus of the examination will be to ensure that the ACO is not subject to adverse conditions which in the Commissioner’s determination have the potential to impact the ACO’s ability to meet its responsibilities with respect to its use of in-network capitation funds received from an insurer, CMS or other government agency in regard to Medicare or Medicaid and the ACO’s compliance with the terms and conditions of any financial risk transfer agreement and the provisions of this Part.

#### 1003.6 Legal Structure and Responsibilities

(a)(1) The proposed ACO shall be a business corporation, not-for-profit corporation, limited liability company or partnership formed under the laws of New York State.

(2) A foreign corporation, limited liability company or partnership shall not be a proper applicant for a certificate of authority.

(3) If an ACO is formed among multiple independent ACO participants, it must be formed as a legal entity separate and apart from any of the ACO participants.

(4) No person shall file a certificate of incorporation or articles of organization, or amendment thereto, containing powers related to the operation of an ACO, or an independent practice association acting as an ACO, with the Secretary of State, without first having submitted the proposed certificate, articles or amendment to the Commissioner for his or her review and approval.

(b) Upon obtaining a certificate of authority, the ACO shall be authorized and required to establish, own, operate and manage an ACO of clinically integrated independent health care providers that work together through a shared governance structure to:

(1) Provide, manage and coordinate health care including primary care, for a defined population focusing on patient centeredness, patient engagement and promoting evidence-based medicine;

(2) Be accountable for quality, cost, and delivery of health care to ACO patients;

(3) Negotiate, receive and distribute any shared savings or losses; and

(4) Establish, report and ensure provider compliance with health care criteria including quality performance standards.

(c) The ACO shall, and shall require its participants, to:

(1) Provide notification to their patients at the point of care that the ACO participants are participating in an ACO pursuant to a certificate of authority issued by the Department;

(2) Post signs in their facilities to notify patients that they are participating in an ACO pursuant to a certificate of authority issued by the Department;

(3) Make available to patients upon request standardized written notices approved by the Department regarding participation in an ACO;

(4) Prohibit the provision of gifts or other remuneration to patients as inducements for receiving items or services from or remaining in an ACO or with ACO participants.

(5) Marketing materials promoting the ACO must:

(i) Use template language developed by the Department, if available;

(ii) Not be used in a discriminatory manner or for discriminatory purposes; and

(iii) Comply with paragraph (4) of this subdivision regarding inducements.

(d) The powers and purposes of the ACO shall include the following:

(1) Notwithstanding any other provision to the contrary, nothing contained herein shall, except to the extent the corporation or company has already received certification or licensure, authorize the corporation or company to:

(i) Establish, operate, construct, lease or maintain a hospital or to provide hospital services or health-related services or to operate a certified home health agency, a hospice, or a managed care organization, or to provide a comprehensive health services plan as defined and covered by Articles 28, 36, 40, and 44 of the Public Health Law, respectively, including to solicit, collect, or otherwise raise or obtain any funds, contributions or grants from any source for the establishment or operation of any hospital;

(ii) Establish, operate, construct, lease or maintain an adult care facility as provided by Article 7 of the Social Services Law, including to solicit, collect or otherwise raise or obtain funds, contributions or grants from any source for the establishment or operation of any such facility; and

(iii) Engage in the business of insurance unless authorized by a valid license in force and effect issued pursuant to or exempt under this Part or the Insurance Law.

(e) Expand the purposes and powers beyond the corporation's or company's current certification or licensure without seeking the appropriate regulatory approvals.

(f) If the ACO is formed as a partnership, the partnership agreement must contain the purposes and powers required in subdivision (d) of this section.

(g) Notwithstanding the provisions of sections 98-1.2(w) and 98-1.5(b)(6)(vii) of Part 98 of this Title, an independent practice association may be an ACO participant or may be certified as an ACO pursuant to Article 29-E of the Public Health Law and this Part.



(1) An independent practice association certified as an ACO under this Part may, subject to any limitations contained in its certificate of authority, also contract with third party health care payers.

(2) The functions, activities and services undertaken by the independent practice association acting as an ACO shall be clearly distinguished from its functions, activities and services as an independent practice association through the maintenance of separate records, reports and accounts for the ACO.

(h) A health home certified as an ACO under this Part, subject to any limitation contained in its certificate of authority, may contract with third party health care payers.

(i) A Medicare-only ACO that applied for a certificate of authority pursuant to Article 29-E of the Public Health Law prior to adoption of this Part, within ninety days of adoption, shall amend its certificate of incorporation, articles of organization or partnership agreement to comply with the requirements of this section.

#### 1003.7 Governing Body

(a) The governing body shall be responsible for the oversight and strategic direction of the ACO, holding those responsible for management of the ACO accountable for the ACO's activities as described in this Part.

(b) The governing body must have a transparent governing process which shall include, but not be limited to:

(1) Holding periodic meetings at least twice each calendar year, of the governing body to conduct the business of the ACO;

(2) Making available the schedule of governing body meetings and issuing prior notice of meetings to members of the governing body; and

(3) Consideration of input from ACO participants or their designated representatives in the composition and control of the ACO's governing body.

(c) The ACO governing body shall include at least one representative or designee from each of the following groups:

(1) Recipients of Medicaid or child health plus;

(2) Persons with other health coverage; and

(3) Persons who do not have health coverage. Such persons shall have no conflict of interest with the ACO and no immediate family member shall have a conflict of interest with the ACO.

(d) At least 75 percent control of the ACO's governing body shall be held by ACO participants and in addition to otherwise required representatives set forth above, an ACO shall use its best efforts to include a representative from each FQHC that serves the population to be served by the ACO.

(e) Members of the ACO governing body shall have a fiduciary relationship with the ACO and shall be subject to conflict of interest rules adopted by the ACO and in regulations of the Commissioner. The conflict of interest policy must:

(1) Require each member of the governing body to disclose relevant financial interests;

(2) Provide a procedure to determine whether a conflict of interest exists and set forth a process to address any conflicts that arise; and

(3) The conflict of interest policy must include remedial action for members of the governing body that fail to comply with the policy.

(f) The governing body members may serve on the governing board of an ACO participant provided there is no conflict of interest.

(g) If the ACO is composed of an existing entity, the ACO governing body may be the same as the governing body of that existing entity, provided it satisfies the other requirements of this section.

#### 1003.8 Leadership and Management

(a) An ACO must have a leadership and management structure that supports the delivery of an array of health care services for the purpose of improving quality of care, health outcomes and coordination and accountability of services provided to patients.

(b) The ACO's operations must be managed by an executive officer, manager, general partner, or similar party whose appointment and removal are under the control of the ACO's governing body and whose leadership team has demonstrated the ability to influence or direct clinical practice to improve efficiency processes and health outcomes.

(c) The ACO's organization and management structure must include an organizational chart, a list of committees (including names of committee members) and their structures, and job descriptions for senior administrative and clinical leaders.

(d) The ACO's finances, including dividends and other return on capital, debt structure, executive compensation, and ACO participant compensation, shall be arranged and conducted to maximize the goals of the ACO, as outlined in subdivision (a) of this section.

(e) The clinical management and oversight must be managed by a medical director who is a licensed physician pursuant to Title 8 of the Education Law and one of its ACO participants, and

who is physically present on a regular basis at any of the clinics, offices, or other locations participating in the ACO.

#### 1003.9 Quality Management and Improvement Program

(a) An ACO must develop and implement a quality management and improvement program that is supervised by a medical director and shall include organizational arrangements and ongoing procedures for the identification, evaluation, resolution and follow-up of potential and actual problems in health care administration and delivery.

(b) A health care information system shall be maintained that collects, analyzes, integrates and reports data necessary to develop and implement the quality management program.

(c) The quality management procedures shall include defined methods for the identification and selection of standardized quality measures applicable to the populations served by the ACO. Quality performance metrics are to be derived from multiple sources, including but not limited to administrative (claims and encounter) data, medical record reviews, participant complaints, consumer surveys, disease registries and other data sources as deemed necessary. The ACO shall address deficiencies identified through these processes using a standard quality improvement methodology.

(d) The ACO shall have a process for peer review to monitor provider performance.

(e) The ACO shall have a process for ensuring licensed, certified and/or registered health care professionals meet and maintain standards for the practice of their profession.

(f) The Commissioner shall have the right to review documents such as meeting minutes, and/or other materials related to the quality management and improvement program to ensure that an appropriate quality management and improvement program is in place.

### 1003.10 Quality Performance Standards and Reporting

(a) The Department shall collect for dissemination via a statewide health information system, health care data from ACO entities pursuant to the quality assurance reporting requirements developed by the Department in consultation with the National Committee on Quality Assurance (NCQA).

(b) The Department shall thereafter prepare the collected data from the ACO for publication. The Department will provide each ACO with a copy of the data prior to publication. The ACO will be provided an opportunity, in a manner and time determined by the Department, to correct factual inaccuracies, and to file a statement in a form prescribed by the Department concerning the data.

(c) The Department shall thereafter make the collected data from the ACOs, along with any corrections made pursuant to subdivision (b) of this section, organized and segregated by type of product and type of organization offering the product, available on its public website. Such data will be shared with the Superintendent of Financial Services. Information published on the website shall not include patient-identifying information and shall be subject to all applicable provisions of law and regulation regarding confidentiality of patient information.

(d) All ACO data published on the Department's website shall include the following statement: "THE DATA COLLECTED BY THE DEPARTMENT IS ACCURATE TO THE BEST OF THE KNOWLEDGE OF DEPARTMENT STAFF, BASED ON THE INFORMATION SUPPLIED BY THE ACO WHICH IS THE SUBJECT OF THE DATA."

(e) Notwithstanding the above, an ACO that has a contractual arrangement with a third party health care payer to cover health care services for a defined population must submit required measures for the eligible population attributed to the ACO.

(f) The ACO's quality performance shall be equal to or exceed statewide and/or national benchmarks and/or demonstrate improvement over time on multiple performance measures of care to maintain participation in the program.

#### 1003.11 Payment and Third Party Health Care Payers

(a) An ACO may enter into arrangements with one or more third party health care payers to establish payment methodologies for health care services provided to the third party health care payer's enrollees provided by the ACO or for which the ACO is responsible.

(b) Unless it has in force and effect a valid license issued pursuant to Article 11 of the Insurance Law or a certificate of authority issued pursuant to Article 44 of the Public Health Law, an ACO or a participant may not enter into any arrangement that constitutes doing an insurance business under section 1101 of the Insurance Law, including an arrangement that provides for full or partial capitation, shared losses or any other arrangement in which the ACO or the provider contractually assumes the liability for the delivery of specified health care services except:

(1) an ACO or an ACO participant may enter into such an arrangement when the ACO contracts with a managed care organization certified pursuant to Article 44 of the Public Health Law, an insurer authorized pursuant to the Insurance Law to write accident and health insurance in New York, or a corporation licensed pursuant to Article 43 of the Insurance Law; or

(2) a Medicare-only ACO that contracts with CMS may enter into an arrangement that provides for shared losses provided that, if the shared losses may exceed ten percent of the benchmark, the ACO meets all of the requirements of sections 1003.5, 1003.6, 1003.11, 1003.12, 1003.13 and 1003.14 of this Part.

(c) The contract between an ACO and a managed care organization shall be subject to all the requirements and reviews applicable under Article 44 of the Public Health Law and the Insurance Law and regulations promulgated thereunder.

(d) The contract between an ACO and an insurer authorized pursuant to the Insurance Law to write accident and health insurance in New York or a corporation licensed pursuant to Article 43 of the Insurance Law shall be subject to all the requirements and reviews applicable under the Insurance Law and regulations promulgated thereunder.

#### 1003.12 Termination

The Commissioner may limit, suspend or terminate the certificate of authority of an ACO after written notice and an opportunity for review and/or hearing based on, but not limited to, the following:

(a) Unsatisfactory performance by the ACO, ACO participants, providers/suppliers or other individuals or entities performing functions or services related to ACO activities;

(b) Unsatisfactory performance may include but is not limited to:

(1) Imminent harm to patients;

(2) Financial fraud and abuse;

(3) Fiscal insolvency of the ACO;

(4) The imposition of sanctions or other actions taken against the ACO by the accrediting organization, state, federal or local government agency leading to inability of the ACO to comply with the requirements under this Part;

(5) Violations of the physician self-referral prohibition, civil monetary penalties (CMP) law, federal or state anti-kickback statute, antitrust laws, or any other applicable federal or state laws, rules, or regulations that are relevant to ACO operations; and

(6) Failure to adhere to established quality measures or comply with corrective action plans related to poor performance on established quality of care standards.

#### 1003.13 Reporting

(a) An ACO shall submit data to the Commissioner annually or at such other times as requested and in such manner and form as prescribed by the Commissioner regarding ACO participants, patient characteristics, utilization of services, quality metrics, shared savings or losses information, complaints and grievances and other information deemed necessary to monitor the ACO's operations, eligibility and compliance. Entities with certificates of authority reflecting the provision of state action immunity pursuant to subdivision (a) of section 1003.14 shall submit such materials or information as is requested by the Department for purposes of active state supervision.

#### 1003.14 Legal Protections; State Action Immunity

(a)(1) An ACO certified pursuant to this Part shall not be considered to be in violation of Article 22 of the General Business Law relating to contracts or agreement in restraint of trade if



the ACO's actions qualify for the safety zone, subject to the antitrust analysis set forth in the *Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program* issued by the Federal Trade Commission and U.S. Department of Justice and published in the Federal Register on October 28, 2011. For ACOs that do not participate in one of the CMS Accountable Care Organization shared savings programs, certification under this Part will be considered equivalent to participation with CMS.

(2) As part of its application for a certificate of authority under this Part, an ACO may request that the state provide state action immunity from federal and state antitrust laws. An ACO requesting review shall submit, in addition to the application materials required by this Part, any additional materials or information requested by the Department to make a state action immunity determination. The factors to be considered in evaluating requests for state action immunity pursuant to this Part shall include, but shall not be limited to:

(i) the potential benefits of the ACO's collaborative activities, including but not limited to the likelihood that one or more of the following may result from such activities:

(a) Preservation of needed health care services in the relevant primary service area that would be at risk of elimination in the absence of the ACO's collaborative activities

(b) 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;

(c) Enhancement of the quality of health care provided by the ACO and its participants;

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

(e) 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

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

(ii) the health care provider landscape 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;

(iii) the potential disadvantages of the ACO's collaborative activities;

(iv) 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;

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

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

In determining whether to provide state action immunity, the Department may impose such conditions as necessary to ensure that the activities of the ACO are consistent with the purposes of Article 29-E and/or are necessary to ameliorate any potential disadvantages.

If the Department determines that state action immunity is appropriate, such determination shall be reflected on the certificate of authority or in an amendment thereto. In such case, the State shall actively supervise and the ACO shall provide such materials or information as is requested by the Department for such purpose. The ACO's failure to comply with any

requirements imposed by the Department in connection with its active supervision of the ACO may result in forfeiture of a claim of state action immunity from the antitrust laws.

(b) An ACO certified pursuant to this Part shall not be considered to be in violation of Article 131-A of the Education Law relating to fee splitting in the following circumstances:

(1) When as a function or activity of the ACO, the ACO enters into contracts or arrangements reasonably related to and necessary for operations of the ACO; or

(2) The shared savings are:

(i) Distributed to and among individuals or entities who were ACO participants during the year in which the shared savings were earned; or

(ii) Used for activities that are reasonably related to the purposes of the ACO.

(c) Health care providers, as defined in Title 2-D of Article 2 of the Public Health Law, who participate in or contract with an ACO certified pursuant to this Part, and who make referrals to other health care providers within the scope of the ACO's functions, activities and services, shall not be considered to be in violation of Title 2-D of Article 2 of the Public Health Law relating to health care practitioner referrals.

(d) A medical assistance provider, as defined in section 366-d of the Social Services Law, that enters into arrangements with an ACO certified pursuant to this Part, one or more of its ACO participants, or a combination thereof, shall not be in violation of section 366-d of the Social Services Law.

(e) In order to obtain the protections under subdivisions (b), (c), (d) and (e) of this section, contracts or arrangements shall be authorized as reasonably related to the purposes of the ACO and contemporaneously documented by the governing body of the ACO and a description of the contract or arrangement shall be publicly disclosed;

(1) The documentation must be made available to the appropriate governmental agencies upon request and include the following:

(i) A description of the contract or arrangement including all parties to the arrangement;

(ii) The date and purpose of the contract or arrangement;

(iii) The items, services, facilities, and/or goods covered by the contract or arrangement (including non-medical items, services, facilities or goods);

(iv) The financial or economic terms of the arrangement; and

(v) The date and manner of the governing body's authorization of the contract or arrangement including the basis that the contract or arrangement is reasonably related to the purposes of the ACO.

(2) The public disclosure shall be posted on the ACO's website within 60 days of the governing body's authorization and shall not contain the financial or economic terms of the contract or arrangement. Other proprietary or confidential business terms may also be omitted. The website posting must be such that generally used internet search engines will produce results listing the ACO's required disclosure.

(f) The provision of health care services directly or indirectly by an ACO certified pursuant to this Part shall not be considered the practice of a profession under Title 8 of the Education Law.

Subdivision (w) of section 98-1.2 of Part 98 is amended to read as follows:

(w) *Independent Practice Association* or *IPA* means a corporation, limited liability company, or professional services limited liability company, other than a corporation or limited liability

company established pursuant to articles 28, 36, 40, 44 or 47 of the Public Health Law, which contracts directly with providers of medical or medically related services or another IPA in order that it may then contract with one or more MCOs and/or workers' compensation preferred provider organizations to make the services of such providers available to the enrollees of an MCO and/or to injured workers participating in a workers' compensation preferred provider arrangement. An IPA may also be considered a provider within the meaning of section 4403(1)(c) of the Public Health law, but only for the purpose of and to the extent it shares risk with an MCO and/or the IPA's contracting providers, and shall be considered a provider for the purposes of paragraphs (1) and (2) of subdivision (a) of Section 98-1.21 of this Subpart. An IPA may be certified as an Accountable Care Organization pursuant to Article 29-E of the Public Health Law and Part 1003 of this title, and upon obtaining a certificate of authority may contract with third party health care payers defined in section 1003.2(x) of this title. To the extent allowed under New York's Partnership Plan section 1115(a) Medicaid Demonstration extension, as amended April 14, 2014, an IPA may participate in a Performing Provider System ("PPS") established as part of a Delivery System Reform Incentive Payment ("DSRIP") Program project.

New subclauses (f) and (g) are added to clause (vii) of paragraph (6) of subdivision (b) of section 98-1.5 of Part 98 to read as follows:

(f) An IPA, in addition to the powers and purposes allowed under this Part, may seek certification as an Accountable Care Organization ("ACO") pursuant to Article 29-E of the Public Health Law and Part 1003 of this Title. An IPA certified as an ACO shall comply with all the requirements of Part 1003, including but not limited to the requirements of section 1003.6(e)

and (g). Upon receiving such certification, an IPA acting as an ACO may contract with the entities listed in section 1003.2(x) of this title.

(g) An IPA, in addition to the powers and purposes allowed under this Part, may include any and all necessary powers and purposes as authorized, allowed, or required under an approved Delivery System Reform Incentive Payment (“DSRIP”) Program project pursuant to New York’s Partnership Plan section 1115(a) Medicaid Demonstration extension, as amended April 14, 2014.

## **REGULATORY IMPACT STATEMENT**

### **Statutory Authority:**

Article 29-E of the Public Health Law (“PHL”) requires the Commissioner to issue regulations pertaining to the certification of Accountable Care Organizations.

### **Legislative Objectives:**

An Accountable Care Organization (“ACO”) is a voluntary organization comprised of clinically integrated independent health care providers that work together to provide, manage, and coordinate health care for a defined population, has a mechanism for shared governance and the ability to negotiate, receive, and distribute payments, and is accountable for the quality, cost, and delivery of health care to the ACO’s patients.

In New York, based upon a recommendation of the Medicaid Redesign Team (“MRT”), the 2011-12 budget (Chapter 59 of the Laws of 2011, Part H, § 66) added new PHL Article 29-E to require the Commissioner of Health (“Commissioner”) to establish a program governing the approval of ACOs. Initially, the law was designed as a demonstration program to test the ability of ACOs to deliver an array of health care services for the purpose of improving the quality, coordination and accountability of services provided to patients. The Commissioner was authorized to issue certificates of authority to up to seven ACOs prior to December 31, 2015.

PHL Article 29-E was subsequently amended (Chapter 461 of the Laws of 2012) to make the program permanent and authorize an unlimited number of certificates prior to December 31,

2016. As amended, PHL Article 29-E reflects the legislative finding that the development of ACOs will “reduce health care costs, promote effective allocation of health care resources, and enhance the quality and accessibility of health care.” PHL § 2999-n.

**Current Requirements:**

Currently, there are no state regulations specific to ACOs in New York.

**Needs and Benefits:**

The proposed regulations advance the objectives of PHL Article 29-E by establishing requirements for certificates of authority in conjunction with the statutory requirements, including those pertaining to governance, quality standards and reporting requirements. Among other things, the statute authorizes the Commissioner to issue a certificate of authority to a “Medicare-only ACO” that documents its approval by the federal Centers for Medicare and Medicaid Services (CMS) to operate as an ACO under Medicare, without the need to meet all of the criteria applicable to ACOs receiving other sources of payment. The regulations are consistent with this objective. Specifically, no application is required for a Medicare-only ACO whose contract with CMS does not permit shared losses to exceed 10 percent (for ACOs participating in the federal Medicare Shared Savings Program) (§ 1003.1(b)) or a Medicare-only ACO whose contract with CMS allows shared losses to exceed 10 percent (for ACOs participating in the federal Pioneer Program) (§ 1003.1(c)). These ACOs may request a certificate of authority from the Department through an expedited process which requires submission of documentation establishing CMS approval.



Additionally, as required by PHL Article 29-E, the regulations establish the criteria that must be satisfied for ACOs to obtain and maintain certificates of authority and address matters such as: (1) the governance, leadership and management structure of the ACO; (2) the definition of the population proposed to be served by the ACO; (3) the character, competence and fiscal responsibility and soundness of an ACO and its principals, if deemed appropriate by the Department; (4) the adequacy of the ACO's network of participating health care providers; (5) mechanisms by which the ACO will provide, manage, and coordinate quality health care for its patients; (6) mechanisms by which the ACO will receive and distribute payments to its participating providers; (7) mechanisms for quality assurance and grievance procedures; (8) mechanisms that promote evidence-based health care, patient engagement, coordination of care and electronic health records; (9) performance standards and measures to assess the quality and utilization of care provided by the ACO; and (10) the protection of patient rights. As required by the statute, to the extent practical, the regulations are consistent with CMS regulations for ACOs under the Medicare program, which were issued in 2011. See 76 FR 67802 (<http://www.gpo.gov/fdsys/pkg/FR-2011-11-02/pdf/2011-27461.pdf>).

Further, the regulations include provisions consistent with the legislative objective of promoting the development of ACOs. Article 29-E states that the provision of health care services by an ACO shall not be considered the practice of a profession under Title 8 of the Education Law, and identifies several "safe harbors" that exempt ACOs from the application of existing statutes pertaining to the restraint of trade, fee splitting and referrals. In particular, PHL Article 29-E expressly sets forth the State's intent to supplant competition with active state supervision in order to provide state action immunity under state and federal antitrust laws, where necessary to

accomplish the statutory purposes. The regulations establish a process for such active state supervision, and further permit an ACO to proceed under the analysis set forth in the *Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program*, issued by the Federal Trade Commission (FTC) and the Department of Justice (DOJ). See 76 FR 67-26 (October 28, 2011) (<http://www.gpo.gov/fdsys/pkg/FR-2011-10-28/pdf/2011-27944.pdf>).

As contemplated by Article 29-E, the proposed regulations also include provisions pertaining to payment methodologies with third party payers. In general, if an entity bears insurance risk, it is “doing the business of insurance” and must either become licensed under the Insurance Law or, in the event of a managed care organization (“MCO”), certified under PHL Article 44, or it must meet the criteria for an exemption from licensure. Requiring licensure or certification ensures that the entity meets financial requirements such as maintaining adequate reserves to pay claims and complies with various consumer protections. DFS Regulation 164, found within Part 101 of Title 11 of the NYCRR, permits insurers and MCOs to transfer risk to a provider organization that is not licensed or certified so long as the provider organization meets certain financial requirements and consumer protections and the ultimate risk is borne by the insurer or MCO.

In keeping with these general principles, the proposed regulations provide that an ACO may not enter into any arrangement that involves risk sharing or otherwise constitutes the business of insurance, except in specific circumstances. The ACO may be or become certified as a MCO pursuant to PHL Article 44, authorized to write accident and health insurance as an insurer pursuant to the Insurance Law, or licensed as a corporation pursuant to Insurance Law Article

43. Alternatively, the ACO may contract with an entity that is certified, authorized or licensed under such statutory provisions.

The proposed regulations also permit an Independent Practice Association (“IPA”) to apply for and receive a certificate of authority as an ACO. IPAs, which are permitted to enter into arrangements with payers under Regulation 164, contract with providers of medical or medically related services or other IPAs and then contract with one or more MCOs and/or workers’ compensation preferred provider organizations to make the services of such providers available to the MCOs’ enrollees and/or to injured workers participating in a workers’ compensation preferred provider arrangement. In addition, the regulations are amended to permit IPAs to participate as Performing Provider Systems under New York’s Delivery System Reform Incentive Payment (DSRIP) Program.

Finally, the proposed regulations also provide that a Medicare-only ACO permitted to share losses greater than 10 percent pursuant to its contract with CMS can do so without having to become a licensed insurer under the Insurance Law, provided that several stringent financial conditions are satisfied. DFS will amend Regulation 164 to include ACOs within the types of providers that may enter into such arrangements.

As required by Article 29-E, in developing these regulations, the Commissioner consulted with the Superintendent of Financial Services, the Attorney General and State Education Department, health care providers, third-party health care payers, patient advocates, and other appropriate parties.

## **COSTS**

### **Costs to Private Regulated Parties:**

ACOs are not required to obtain certificates of authority. Therefore, the proposed regulations do not create any mandatory burdens or costs to regulated parties. Applicants may incur administrative costs associated with applying for or maintaining a certificate of authority, such as preparing the application or complying with periodic reporting requirements. However, both the ACA and Article 29-E anticipated that the utilization of ACOs will produce a substantial reduction in health care costs. For example, CMS reports that in 2012 the Medicare program realized \$87 million in gross spending savings with direct Medicare savings of \$33 million. CMS also reports that 70,000 potential hospital inpatient admissions were avoided and all ACOs reported they successfully met quality benchmarks.

### **Costs to Local Government:**

The proposed regulations do not impose any costs on local government, except to the extent that a local government operates a provider that participates in an ACO that chooses to seek a certificate of authority. In such cases, the analysis set forth above regarding costs to private regulated parties applies.

### **Costs to the Department of Health:**

Certifying and monitoring ACOs may result in minimal additional costs to the Department, which will be managed within existing resources.

**Costs to Other State Agencies:**

The proposed regulations will not result in any costs to other state agencies.

**Local Government Mandates:**

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

**Paperwork:**

Under the proposed regulations, paperwork is required for the submission of ACO applications and for annual data submissions by the ACOs. The regulations attempt to minimize administrative burdens by providing that various items need be submitted only upon request. In addition, the electronic submission of applications and reports will minimize or eliminate costs for printing and mailing.

**Duplication:**

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

**Alternatives:**

There are no alternatives to the proposed regulations. Article 29-E requires the Department to issue regulations to implement the statute for the purpose of establishing a program for the certification of ACOs.

**Federal Standards:**

The proposed regulations do not duplicate or conflict with any federal regulations. They comply with the Article 29-E requirement that the regulations be consistent, to the extent practical, with the federal Medicare regulations governing ACOs.

**Compliance Schedule:**

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

**Contact Person:** Katherine Ceroalo  
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**REGULATORY FLEXIBILITY ANALYSIS  
FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS**

**Effect of Rule:**

The proposed regulations are not expected to have an adverse impact on local governments or small businesses. Under the rule, health care providers and other entities that may participate in an ACO include entities licensed or certified under PHL Articles 28 or 36 or Articles 16, 31 or 32 of the Mental Hygiene Law, a health care practitioner licensed or certified under Title 8 of the Education Law or a combination of such practitioners, and other entities that provide technical assistance, information systems and services to health care providers and patients participating in the ACO. This may include providers operated by local governments or entities that qualify as small businesses.

However, pursuit of a certificate of authority is optional. Moreover, both the federal ACA and PHL Article 29-E anticipate that ACOs have the potential to reduce unnecessary utilization of health care services among patients served by ACOs, leading to overall savings in the health care system. For example, CMS reported that in 2012 the Medicare program realized \$87 million in gross spending savings with direct Medicare savings of \$33 million. CMS also has reported that 70,000 potential hospital inpatient admissions were avoided and all ACOs reported they successfully met quality benchmarks.

## **Compliance Requirements**

To obtain a certificate of authority under the proposed regulations, a prospective ACO must submit an application that demonstrates its ability to satisfy certain standards pertaining to legal structure, governance, leadership, management, quality management and improvement, quality performance standards, payment and shared savings, third party payer contracts and reporting.

## **Cure Period:**

Chapter 524 of the Laws of 2011 requires agencies to include a “cure period” or other opportunity for ameliorative action to prevent the imposition of penalties on a party subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one is not included. As these proposed regulations do not create a new penalty or sanction, no cure period is necessary.

## **Professional Services:**

Pursuit of a certificate of authority is optional. Some ACOs that elect to pursue a certificate of authority may decide to retain professional services, such as accounting services, to help carry out the functions required under the proposed regulations, while others may find it sufficient to utilize existing staff for such purposes.

## **Compliance Costs:**

Pursuit of a certificate of authority is optional but, as anticipated by Article 29-E, ACOs are expected to result in savings which should ultimately exceed any costs required to comply with the standards outlined in the proposed regulations.



**Economic and Technological Feasibility:**

This proposal is economically and technically feasible. In particular, pursuit of a certificate of authority is optional. Some ACOs that elect to pursue a certificate of authority may find it necessary to retain additional personnel or professional services to help carry out the functions required under the rule, while others may find it sufficient to utilize existing staff for such purposes.

**Minimizing Adverse Impact:**

The proposed regulations are consistent with PHL Article 29-E and its directive to closely follow the federal CMS ACO regulations. Where possible, efforts were made to streamline the administrative processes created by the rule. For example, the regulations require that reports, organizational charts, and other documentation must be made available to the Department “upon request,” rather than requiring that they be routinely submitted with all ACO applications. In addition, all documents are to be submitted and processed electronically.

**Small Business and Local Government Participation:**

The enactment of PHL Article 29-E, which requires the Department to adopt regulations establishing a process for issuing certificates of authority to ACOs, placed entities including local governments and small businesses on notice that such regulations would be forthcoming. Development of the proposed regulations included input from a variety of organizations representing health care providers and other stakeholders.

## RURAL AREA FLEXIBILITY ANALYSIS

### Types and Numbers of Rural Areas:

Rural areas are defined as counties with a population less than 200,000 and, for counties with a population greater than 200,000, includes towns with population densities of 150 persons or less per square mile. The following 44 counties have a population less than 200,000:

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

The following 9 counties have certain townships with population densities of 150 persons or less per square mile:

Albany	Erie	Oneida
Broome	Monroe	Onondaga
Dutchess	Niagara	Orange

There are 47 general hospitals, approximately 90 diagnostic and treatment centers, 159 nursing homes, and 92 certified home health agencies in rural areas. There are also other providers such as physician practices, behavioral health providers and organizations in rural areas that provide technical assistance that may opt to organize or otherwise participate in an ACO. These entities and organizations will not be affected differently than those in non-rural areas.

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

Pursuit of a certificate of authority is optional. The proposed regulations require an ACO or a prospective ACO to submit information to the Department as part of an initial application for a certificate of authority and requires an ACO that has been issued a certificate of authority to report information to the Department and maintain certain documentation in order to maintain its certificate of authority. Some ACOs that elect to pursue a certificate of authority may decide to retain professional services, such as accounting services, to help carry out the functions required under the proposed regulations, while others may find it sufficient to utilize existing staff for such purposes. The proposed regulations do not impose any obligations that are different for ACOs in rural areas than those in other areas.

**Costs:**

While an ACO may incur some administrative costs associated with the formation of the ACO, the federal ACA and PHL Article 29-E anticipate that ACOs have the potential to reduce unnecessary utilization of health care services among patients served by ACOs, leading to overall savings in the health care system. As an example, CMS reported that in 2012 the Medicare program realized \$87 million in gross spending savings with direct Medicare savings of \$33 million. CMS also has report that 70,000 potential hospital inpatient admissions were avoided and all ACOs reported they successfully met quality benchmarks.

**Minimizing Adverse Impact:**

The proposed regulations are consistent with PHL Article 29-E and its directive to closely follow the federal CMS ACO regulations. Where possible, efforts were made to streamline the administrative processes created by the rule. For example, the regulations require that reports, organizational charts, and other documentation must be made available to the Department “upon request,” rather than requiring that they be routinely submitted with all ACO applications. In addition, all documents are to be submitted and processed electronically.

**Rural Area Participation:**

The enactment of PHL Article 29-E, which requires the Department to adopt regulations establishing a process for issuing certificates of authority to ACOs, placed entities including prospective ACOs on notice that such regulations would be forthcoming. Development of these regulations included input from a variety of organizations representing health care providers and other stakeholders, including those located in rural areas.

## STATEMENT IN LIEU OF JOB IMPACT STATEMENT

### **Nature of Impact:**

No job impact statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. No adverse impact on jobs and employment opportunities is expected as a result of these proposed regulations.

## SUMMARY OF ASSESSMENT OF PUBLIC COMMENT

A Notice of Proposed Rule Making was initially published in the *State Register* on October 15, 2014. During the public comment period, comments were received from several health care providers, an association of behavioral health care providers, a hospital association, a health plan association, an accrediting organization, several organizations advocating on behalf of health care consumers, and legislators. 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*. Copies of the full text of the regulations and the full assessment of public comments are available on the Department of Health's website.

All comments received were reviewed and evaluated. In response to comments, 10 NYCRR § 1003.2 has been revised to: (1) include a definition of "health care provider" which utilizes the definition in PHL § 2999-o(6) instead of referring to PHL Article 29-E; (2) refer to "care coordination" rather than "care management" in the definition of "administrative services organization;" (3) add a reference to "an arrangement for such payments or prepayments" in the definition of a "capitation arrangement;" (4) change a reference from "systemic" to "systematic" in the definition of "clinical integration;" (5) move the definition of "guaranteeing parent corporation" to § 1003.5, which is the only place the term is referenced, and clarify that the definition should not be construed as permitting such entity to exercise control over the ACO's governing board with respect to ACO operations; (6) clarify that the reference to the "population" in the definition of "shared losses" means the "defined population;" (7) clarify that

the referenced certification of a “qualified health information technology entity” would mean a QE certification process recognized by the Commissioner of Health; and (8) clarify that a “third party payer” has its ordinary meanings, as set forth in PHL § 2999-o.

10 NYCRR § 1003.3 has been revised so that in addition to the information included in the application, the Commissioner shall consider any other relevant information known to him or her. 10 NYCRR § 1003.4 has been revised to require “proposed organizational documents” in lieu of organizational documents in case such documents are not yet final. 10 NYCRR § 1003.10 has been revised to clarify that the required statement about the accuracy of data applies to the ACO data that will be published on the Department’s website, as set forth in the preceding paragraph. 10 NYCRR § 1003.14 is revised to explicitly advise ACOs that the failure to comply with any requirements imposed by the Department in connection with its active supervision could impact their immunity.

Several proposed revisions were not incorporated because they were not consistent with the statutory authority underlying the proposed rulemaking. Other suggestions appeared to warrant further consideration for possible inclusion of future revisions to the regulations.

The full Assessment of Comments is available on the Department of Health’s website at [www.health.ny.gov](http://www.health.ny.gov).

## ASSESSMENT OF PUBLIC COMMENT

**Comment:** 10 NYCRR § 1003.1(c) should be eliminated and 10 NYCRR § 1003.1(b) should be revised so that it applies to all Medicare-only ACOs.

**Response:** Maintaining separate provisions for both types of Medicare-only ACOs is important for the sake of clarity, since 10 NYCRR § 1003.5 applies to one type of Medicare-only ACO but not the other.

**Comment:** There are numerous references throughout the regulations to “health care,” which should be expanded to include behavioral health providers.

**Response:** The definition of “clinical integration” in 10 NYCRR § 1003.2(f), which in turn is incorporated into the definition of “ACO” in 10 NYCRR § 1003.2(a), specifically refers to the coordination of both physical and behavioral health care. Further, 10 NYCRR § 1003.2(b), in defining “ACO participant,” references a health care provider, which as defined in PHL Article 29-E and in revised 10 NYCRR § 1003.2(k), includes entities licensed or certified under Mental Hygiene Law Article 16, 31 or 32 as well as any health care practitioner licensed or certified under Title 8 of the Education Law. Therefore, no additional change to the regulations is necessary.



**Comment:** 10 NYCRR § 1003.2(a) defines an ACO, in relevant part, as “an organization comprised of clinically integrated independent health care providers. . .” The reference to “independent” providers should be eliminated because some participants may be affiliated, and § 1003.6(a)(3) implies that an ACO’s participants may not all be independent entities. 10 NYCRR § 1003.6(b) contains a similar reference which should be eliminated.

**Response:** The inclusion of the term “independent” is consistent with the federal regulations.

**Comment:** The definition of “ACO participant” should be revised so that the reference to a “health care provider” mirrors the definition under Article 29-E.

**Response:** The regulations have been revised accordingly.

**Comment:** 10 NYCRR § 1003.2(c) defines an “administrative services organization” as an entity providing ancillary services to an ACO, including “care management services.” It would be more appropriate to refer to “care coordination services,” and to include in the regulations a definition thereof. “Care coordination” should be defined to mean and include, but should not be limited to, referral, service acquisition follow-up and monitoring, and does not include requiring patients to obtain prior authorization or a referral to receive a health care service.

**Response:** 10 NYCRR § 1003.2(c) has been revised to refer to “care coordination,” which as noted is consistent with statute. The Department will consider defining “care coordination” in future revisions to the regulations.

**Comment:** 10 NYCRR § 1003.2(d) defines “capitation” or “capitation arrangement” to mean contractually based payments or prepayments to an ACO or a health care provider. It should also include an arrangement for such payments or prepayments.

**Response:** The regulations have been revised accordingly.

**Comment:** 10 NYCRR § 1003.2(f) defines “clinical integration” as meaning the systemic coordination of evidence-based physical and behavioral health care. The reference should be to “systematic coordination” rather than “systemic coordination.”

**Response:** The regulations have been revised accordingly.

**Comment:** The reference to “evidenced-based” care should be removed from 10 NYCRR §§ 1003.2(f) and 1003.4(e) and (i) because some care, such as experimental treatments that insurers are required to cover by law or clinical trials, are not considered “evidence-based.”

**Response:** The phrase “evidence-based health care” appears in PHL § 2999-q(2)(i), which states that the regulations may provide for mechanisms that, among other things, promote

evidence-based health care. . .” Accordingly, the phrase is retained in the regulations. However, the Department will consider revising this phrase in future revisions to the regulations.

**Comments:** 10 NYCRR § 1003.2(h) defines the “defined population” to mean the individuals that will be served by an ACO, which suggests that the ACO must provide a list a names.

Instead, the definition should refer to the populations and groups that will be served by an ACO, as provided under 10 NYCRR § 1003.4(g).

**Response:** The Department will consider clarifying this issue in future revisions to the regulations.

**Comment:** 10 NYCRR § 1003.2(j) defines a “guaranteeing parent corporation,” which makes reference to a definition of “control” in the Insurance Law. The suggestion is that some other entity will “control” the ACO, whereas only its governing authority should have the ability to direct the decisions and activities of the ACO.

**Response:** The phrase “guaranteeing parent corporation,” defined in 10 NYCRR § 1003.2(j), is used only in 10 NYCRR § 1003.5, which applies to Medicare-only ACOs using two-sided models and is used solely for the purpose of allowing such an entity to help demonstrate its fiscal soundness. To clarify, the regulations have been revised so that the definition is moved from § 1003.2 to § 1003.5 and language is added to note that the guaranteeing parent corporation may not interfere with the governance of the ACO.

**Comment:** 10 NYCRR § 1003.2(o) defines a “one-sided model” as a model which an ACO may have shared savings with the “third party health care payer.” Because ACOs may have different kinds of contracts with different payers, the reference to “the third party health care payer” should be changed to “a third party health care payer.”

**Response:** The regulations have been revised accordingly.

**Comment:** 10 NYCRR § 1003.2(q) defines a “primary care provider” as a physician, nurse practitioner, or midwife acting within his or her lawful scope of practice under Title 8 of the Education Law and who is practicing in a primary care specialty. The definition should be changed to include a physician, physician assistant, or nurse practitioner acting within his or her lawful scope of practice under Title 8 of the Education Law and who is practicing primary care. “Primary care” should be defined to mean the clinical fields of family medicine, general pediatrics, primary care, internal medicine, primary care obstetrics, or primary care gynecology, without regard to board certification or licensed profession.

**Response:** The Department will consider clarifying this issue in a future revision to the regulations.

**Comment:** 10 NYCRR § 1003.2(s) defines “providers/suppliers” but should be referred to in the singular since the definition refers to “an individual or entity.”

**Response:** The regulations have been revised accordingly.

**Comment:** 10 NYCRR § 1003.2(t) defines a “Qualified Health Information Technology entity” or “QE” to mean a not-for-profit entity that has been certified as a QE through a “QE certification process.” There should be some additional explanation as to what is a QE certification process, such as one recognized by the Commissioner, to prevent anyone from setting up their own QE certification process.

**Response:** The regulations have been revised accordingly.

**Comment:** 10 NYCRR § 1003.2(u) defines “shared losses” to mean that portion of the losses incurred by an ACO when its expenditures for health care services to its population are above projected benchmark expenditures. It is not clear what the reference to “population” means.

**Response:** The subdivision has been revised to refer to the ACO’s “defined population.”

**Comment:** 10 NYCRR § 1003.2(x) provides that “third party health care payer” means the entities listed in the succeeding paragraphs. It would be better to state that the term has its ordinary meanings and includes the listed entities, which would be consistent with PHL Article 29-E.

**Response:** The regulations have been revised accordingly.

**Comment:** 10 NYCRR § 1003.2(y) defines a “two-sided model” to mean a model under which the ACO may have both shared savings or losses with “the third party health care payer” with which it has contracted. The reference to the “the third party health care payer” should be changed to “a third party health care payer.”

**Response:** The regulations have been revised accordingly.

**Comment:** 10 NYCRR § 1003.3(a) should be revised to permit the Commissioner to consider any other information known to him or her as well. If the Commissioner knows something relevant that is not in the application, the Commissioner should not ignore it.

**Response:** The regulations have been revised accordingly.

**Comment:** 10 NYCRR § 1003.3(b)(1) should be revised to clarify whether an ACO, including an Independent Practice Association (IPA), would be engaging in the business of “providing” health care or merely “arranging for the provision” of health care. The Part 98 regulations refer to an IPA as an organization that “arranges for the provision of health care.” Both those regulations, and § 1003.6(d)(1)(i), prohibit an organization from establishing or operating health-related services, yet there are multiple references in the regulations that allow an ACO to provide health care services.

**Response:** The legislative intent of PHL Article 29-E was to enable ACOs to provide, manage, and coordinate health care for a defined population, under the criteria set forth in the statute and regulations.

**Comment:** 10 NYCRR § 1003.4(a)(4) requires applicants to set forth a plan “. . .detailing how the ACO will use best efforts to include among its participants Federally Qualified Health Center(s) (FQHCs) that are willing to be a participant and that serve the area and population served by the ACO.” It is unclear what kind of plan the ACO would provide, or whether it would be sufficient for the ACO to state that it is willing to contract with a FQHC as a participant.

**Response:** The regulation is consistent with PHL § 2999-q(4)(a), which requires an ACO to “use its best efforts to include among its participants, on reasonable terms and conditions, any federally-qualified health center that is willing to be a participant and that serves the area and population served by the ACO.” Accordingly, the regulation anticipates that the ACO will provide at a minimum a narrative setting forth its intent to contact FQHCs that serve the area and population served by the ACO and, if those efforts have already been undertaken, explaining which FQHCs were contacted, whether those efforts were successful, and if not, why. If those efforts have not yet been undertaken at the time the application is submitted, the Department will request follow-up information. No change to the regulation itself is necessary.

**Comment:** 10 NYCRR § 1003.4(b) should refer to proposed organizational documents since a prospective ACO may not get a certificate of incorporation as an ACO until after obtaining the Certificate of Approval.

**Response:** The regulations have been revised accordingly.

**Comment:** 10 NYCRR § 1003.4(g) provides that the application shall require the applicant to “provide a description of the population to be served by the proposed ACO, which may include reference to the geographic area and, if applicable, shall include patient characteristics to be served. This shall include but not be limited to discussion of the impact of the establishment and operation of the ACO on access to health care for the population to be served in the defined area.” The regulations should require the applicant to describe the “populations or groups” to be served by the proposed ACO. If the population to be served is defined in part by geography, the reference to “the defined area” is unnecessary. If any part of the population is not geography-based (e.g., some highly specialized group), these words are inappropriate.

**Response:** The regulation is consistent with PHL § 2999-q(2)(b).

**Comment:** The ACO’s ability to use referrals to coordinate care should be clarified in § 1003.4(h), which indicates that a plan for care coordination shall include but not be limited to “referral, service acquisition follow-up and monitoring,” while noting that ACOs may not require



patients to obtain a referral to obtain a health care service and that the section is not intended to prohibit an MCO from requiring referrals.

**Response:** The intent of the regulations was not to require referrals within the ACO, unless required by an MCO, but also to make sure that the ACO provides referrals outside the ACO where appropriate. The Department will consider clarifying this issue in future revisions to the regulations.

**Comment:** The last sentence of § 1003.4(h) and (n) should be revised to apply to any licensed health plans (including insurers or MCOs).

**Response:** The regulation appropriately refers only to MCOs.

**Comment:** Clarification should be provided so it is clear that § 1003.4(p) is not intended to create a redundant level of review for ACOs seeking to enter a shared savings, partial capitation, or capitation financial arrangement with a third-party payer and instead the Department and other state agencies will use existing authority to review “two-sided” agreements, as necessary.

**Response:** The regulations are not intended to establish a duplicate level of review but the application must contain sufficient information for the Department to evaluate whether the standards of the statute are satisfied.

**Comment:** The Proposed Regulation should define “financial incentives” and include standards that clarify which incentives will be classified as acceptable and those considered to discourage appropriate care.

**Response:** The Department will consider clarifying this issue in future revisions to the regulations.

**Comment:** 10 NYCRR § 1003.5(b)(1)(i) requires an applicant to submit a sworn financial statement “showing the ACO’s financial condition at the close of its fiscal year.” However, an entity applying to be an ACO will not likely have existed for a fiscal year, and may not even have a certificate of incorporation, and will not have acted as an ACO for a fiscal year. This should be clarified.

**Response:** The Department will consider clarifying this issue in future revisions to the regulations.

**Comment:** 10 NYCRR § 1003.5(a) provides that a Medicare-only ACO may not enter into a contract under which its shared losses may exceed ten percent of the benchmark established under its contract with CMS unless several conditions are satisfied. What if an ACO that did not enter into such a contract has a bad year with heavy losses? Does this, and the definition of shared losses, mean that without such a contract, the payer must bear the burden and protect the ACO from excessive losses? This needs to be made clearer.

**Response:** ACOs are prohibited from engaging in the business of insurance under the regulations, unless they become licensed under the Public Health Law or the Insurance Law or meet another applicable exception such as Regulation 164.

**Comment:** 10 NYCRR § 1003.6(c)(1) requires the ACO to provide notification, and to require its participants to provide notification, to patients at the point of care that the ACO participants are participating in an ACO pursuant to an ACO's Certificate of Authority. There does not appear to be any provision requiring notice to patients that the patient has, in some form, been associated with the ACO, what the patient's rights and responsibilities are as a result of such association with the ACO, and any other matter pertinent to the patient.

**Response:** The Department will consider clarifying this issue in future revisions to the regulations.

**Comment:** §1003.6(c)(1) and (2) as proposed would require ACOs and ACO participants to post signs in their facilities and provide notification to patients at the point of care that they are

participating in an ACO pursuant to a certificate of authority issued by DOH. Medicare-only ACOs that participate in the Medicare Shared Savings Program and Pioneer ACO Model should be permitted to satisfy this requirement by meeting the Medicare standards for participation by notifying patients as required by federal regulation.

**Response:** In keeping with the PHL Article 29-E requirement that the regulations be consistent, to the extent practical, with the federal Medicare regulations governing ACOs, signage requirements under the regulations are intended to be consistent with CMS requirements.

**Comment:** While the regulations include a requirement that beneficiaries be notified of their providers' participation in an ACO at point of care, through signage at the participating facility, and through standard written notices, they do not require the ACO to notify the beneficiary that s/he is receiving care from an ACO and the rights, benefits and consequences of being a patient of an ACO in order to make informed decisions. In addition, the notification requirements should be expanded to offer additional consumer protections by requiring that:

- Standard written notices should be provided at settings in which beneficiaries receive primary care services;
- Notifications should meet all requirements specified for marketing materials, as described in 10 NYCRR § 1003.6(c)(5), which will help to ensure that beneficiary notifications are standardized and free from misleading information;
- Notices be written at no higher than a sixth grade reading level and tested to ensure that they are understandable to a low-literacy audience;

- Notices be translated into the eight most prevalent languages in the geographic area served;  
and
- Notices be made available in accessible formats, including Braille, large print and electronic.

**Response:** The regulations are consistent with federal regulations. However, the Department will undertake further consideration of this issue for potential clarification in future revisions to the regulations.

**Comment:** 10 NYCRR § 1003.6(c)(3) requires the ACO and its participants to make available upon a patient’s request standardized written notices approved by the Department regarding participation in an ACO. Since health care providers are referred to as “participants,” “participation in an ACO” presumably means what a health care provider does, not what a patient does. If this is intended to refer to a patient’s rights or responsibilities, it needs to be re-written.

**Response:** The Department will consider clarifying this issue in future revisions to the regulations.

**Comment:** 10 NYCRR § 1003.6(c)(4) prohibits the provision of gifts or other remuneration to patients as inducements for receiving items or services from or remaining in an ACO or with ACO participants. The regulation should be clarified to provide that the prohibition does not

extend to where the gift or remuneration is of not more than nominal value or serves a bona fide clinical purpose.

**Response:** The regulations are consistent with federal regulations. However, the Department will undertake further consideration of this issue for potential clarification in future revisions to the regulations.

**Comment:** 10 NYCRR § 1003.6(c)(5) requires that ACO marketing materials use template language developed by the Department. Medicare ACOs are required to use CMS-approved language in their marketing materials. There should either be an exemption from the regulatory requirement for Medicare ACOs using CMS-approved materials or the Department should commit to aligning its guidance to CMS's standards.

**Response:** In keeping with the PHL Article 29-E requirement that the regulations be consistent, to the extent practical, with the federal Medicare regulations governing ACOs and to avoid confusion among ACO providers, any template language developed by the Department will be consistent with CMS requirements.

**Comment:** It is not clear why 10 NYCRR § 1003.7(d) provides that each FQHC which participates in an ACO should be represented on the ACO governing body.

**Response:** 10 NYCRR § 1003.7(d) is reflective of PHL § 2999-q(4)(a), which requires an ACO to “use its best efforts to include among its participants, on reasonable terms and conditions, any federally-qualified health center that is willing to be a participant and that serves the area and population served by the ACO.”

**Comment:** In 10 NYCRR § 1003.7(g), the phrase “if the ACO is an existing entity” should be replaced with “if the ACO is composed of an existing entity.”

**Response:** The regulations have been revised accordingly.

**Comment:** As proposed, §1003.7 (c) would require the ACO’s governing body to include at least one representative or designee from each of the following groups: (1) recipients of Medicaid or Child Health Plus; (2) people with other health coverage; and (3) individuals who do not have health coverage. The State should attempt to provide flexibility to organizations that make a best effort to meet the proposed requirement and understand that due to the nature of certain patient populations and increased numbers of insured consumers, filling such board seats as prescribed will be challenging for ACO organizations.

**Response:** The regulations are consistent with PHL §2999-q (3)(b) and with federal requirements.

**Comment:** 10 NYCRR § 1003.9(d) should provide more detailed guidance on the nature of the peer review process that would be required to monitor provider performance.

**Response:** It is not clear what additional detail is needed.

**Comment:** Section 1003.10(d) requires ACOs to submit data that includes a statement that attests to the knowledge of the “Department Staff.” Section 1003.10 appears to use the word “Department” to refer to the Department of Health, rather than the ACO or one of its sub-units. Since an ACO cannot include a statement addressing the knowledge of Department of Health staff, the provisions appears to require revision or clarification.

**Response:** The regulations have been clarified to make it clear that this language will accompany ACO data published on the Department’s website.

**Comment:** 10 NYCRR § 1003.13(a) provides that ACOs must submit demographic and performance data to the Commissioner, but such requirements should not include patient identified data that would violate an ACO’s data use agreement with CMS.



**Response:** If an ACO believes that the submission of any data under 10 NYCRR § 1003.13 would conflict with its data use agreement with CMS, it should contact the Department to discuss further. If a potential conflict indeed exists, alternatives will be explored.

**Comment:** The regulations should address how the ACO and the Department, or an ACO and a third party health care payer, would share data with each other in compliance with state law and the Health Insurance Portability and Accountability Act (HIPAA). The federal ACO Medicare Shared Savings Program specifically sets forth a good framework for when data will be shared, what data will be shared and for what purposes. (See 42 CFR Part 425, Subpart H.)

**Response:** The Department will provide guidance on the sharing of data as required under 10 NYCRR § 1003.13, which will have to be consistent with applicable federal and state laws governing data-sharing.

**Comment:** The Department should ensure that the immunity protection should be robust and clear.

**Response:** The Department intends to actively oversee entities that receive ACO Certificates of Authority and, in particular, will actively supervise those that are provided state action immunity.

**Comment:** 10 NYCRR § 1003.14(f) states that the provision of health care services directly or indirectly by a certified ACO shall not be considered the practice of a profession under Title 8 of

the Education Law. This suggests that ACOs that do not receive a Certificate of Authority would be considered to be engaged in the unlawful practice of medicine. The regulations should state that this is not the case.

**Response:** The regulations satisfy the statutory provisions by establishing a process for issuance of a Certificate of Authority.

**Comment:** Some ACOs have already been accredited and the Department should rely on this status in determining whether such ACOs should be issued a Certificate of Authority.

**Response:** Accredited status may support an ACO's application for a Certificate of Authority, but the applicant will still have to sufficiently demonstrate that it satisfies the substantive requirements set forth in the regulations. No change to the regulations is necessary.

**Comment:** Safeguards against anticompetitive conduct should be strengthened. The important changes to New York's health care system will accelerate with the introduction of ACOs and DSRIP PPSs. Certain protections should apply to all requests for state action immunity. These include giving all interested parties an opportunity to comment about requests for state action immunity and prohibiting ACOs from acting as the exclusive bargaining entity for non-related entities that are part of the ACO, or to block or otherwise obstruct negotiations between payers and providers within the ACO. In addition, the Department should provide ongoing and specific active supervision (beyond periodic reporting requirements) to ensure that the ACO has

implemented promised efficiencies, is realizing the asserted benefit and has mitigated any anticipated or unanticipated disadvantages.

**Response:** The Department intends to actively supervise ACOs that are provided state action immunity under the regulations and will consider further clarifying this issue in future revisions to the regulations.