

HUMAN SERVICES

DIVISION OF MEDICAL ASSISTANCE AND HEALTH SERVICES

Medicaid Accountable Care Organization Demonstration Project

Implementation of Demonstration Project

Proposed New Rules: N.J.A.C. 10:79A

Authorized By: Jennifer Velez, Commissioner, Department of Human Services.

Authority: P.L. 2011, c. 114 and N.J.S.A. 30:4D-1 et seq.

Calendar Reference: See Summary below for explanation of the exception to the rulemaking calendar requirements.

Agency Control Number: 11-P-22.

Proposal Number: PRN 2013-054.

Submit comments by July 8, 2013 to:

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The agency proposal follows:

Summary

The Department is proposing new N.J.A.C. 10:79A in order to implement a three-year Medicaid Accountable Care Organization (ACO) Demonstration Project pursuant to P.L. 2011, c. 114 (the Act).

New N.J.A.C. 10:79A-1.1, Definitions, would provide definitions of "ACO," "ACO participant," "access to care," "Act," "behavioral healthcare provider," "consumer organization," "designated area," "Demonstration Project objectives," "Demonstration Project year," "Department," "disproportionate share hospital," "Division," "gainsharing," "general hospital," "health outcomes," "HIPAA," "Medicaid," "Medicaid ACO Demonstration Project," "Demonstration Project," "patient-level health data," "primary care provider," "qualified behavioral healthcare provider," "qualified primary care provider," "quality measures," and "Taxpayer Identification Number (TIN)."

New N.J.A.C. 10:79A-1.2, Statement of purpose and goals, would state that the chapter implements P.L. 2011, c. 114 by establishing rules that address issues such as project standards, antitrust laws (including the active supervision under the State Action Immunity Doctrine (*California Retail Liquor Dealer's Association v. Midcal Aluminum, Inc.*, 445 US 97 (1980))), and the Department's exercise of independent judgment and control in its oversight and regulation of the conduct of the Medicaid ACOs in the Demonstration Project. It would also list the policy goals of the Demonstration Project regarding patient care and provide that the

Department, in consultation with the Office of the Attorney General, will exercise ongoing oversight and regulation of the conduct of the Medicaid ACOs in the Demonstration Project.

New N.J.A.C. 10:79A-1.3, General requirements and provisions, would contain provisions regarding collusion among ACO participants, sufficient clinical integration, sharing of savings within the ACO, and the pro-competitive nature of the project. It would also provide that actions under this chapter do not extend beyond the Demonstration Project or its timeframes, and that an ACO shall not negotiate reimbursement rates for clinical services.

New N.J.A.C. 10:79A-1.4, Review and oversight, would describe the Department's role, in consultation with the Office of the Attorney General, to review ACO certification applications, gainsharing plans, Medicaid ACOs' annual reports, and the Demonstration Project and, in consultation with the Department of Banking and Insurance and the Office of the Attorney General, to evaluate the Demonstration Project annually to assess potential anticompetitive effect. It also provides that the Department, together with the Office of the Attorney General, will provide a mechanism for potentially affected parties to lodge complaints about anticompetitive activity. It would further state that the Department, in consultation with the Department of Health and the Office of the Attorney General, will design and implement an ACO application process, collect data, and approve a methodology for calculation of cost savings and for monitoring of health outcomes and quality of care under the Demonstration Project. It also would state that the Department, in consultation with the Department of Health, will evaluate the Demonstration Project annually to assess cost savings, improvement in health screening, health outcomes, and hospitalization and readmission rates.

New N.J.A.C. 10:79A-1.5, Application process for approval of Medicaid ACOs in the Demonstration Project, would outline the application process by which an entity could become

certified as an ACO in the Demonstration Project, including the contents, required documentation, form, and deadline for such an application. Minimum standards are also provided regarding incorporation, area covered, governance, bylaws, management, board membership, support from providers and the community, quality of care, antitrust compliance, gainsharing, accountability, use of electronic records, protection of privacy, data collection, and compliance with applicable laws and regulations. The section provides for public comment followed by a decision on the application, and establishes an appeal process.

New N.J.A.C. 10:79A-1.6, Gainsharing plan submission and review, would establish the process by which an ACO would obtain approval of a gainsharing plan under the Demonstration Project. The required elements of a gainsharing plan and the criteria that will be applied in the Department's review are also provided. An appeal process is also established.

New N.J.A.C. 10:79A-1.7, Annual ACO reporting requirements, would establish the various reporting requirements that would be required of a Medicaid ACO regarding savings, gainsharing, quality of care, and patient experiences, as well as certifications required annually. It also describes the Department's review of ACO annual reports. An appeal process is also established.

New N.J.A.C. 10:79A-1.8, Data analyses and annual project evaluation, would describe the review of the Demonstration Project required under the Act, which occurs in cooperation with the Rutgers Center for State Health Policy and the Department of Health. As part of that process, ACOs will be required to execute a HIPAA-required business associate agreement between the ACO and its providers, as needed, to permit sharing of patient-level health data. ACOs will also be required to perform data analyses of hospital utilization. Such agreements shall require that beneficiaries are to be notified by all such members or providers that the ACO

will obtain beneficiary identifiable data and beneficiaries shall be given the opportunity to decline such data sharing.

New N.J.A.C. 10:79A-1.9, Use of savings by a managed care organization, would provide that a managed care organization that participates in the Demonstration Project and expects to earn savings pursuant to a contract with an ACO shall report to the Department and make available to the public how savings earned by the managed care organization will be used and describe possible uses for shared savings.

The Department has determined that the comment period for this notice of proposal will be at least 60 days; therefore, pursuant to N.J.A.C. 1:30-3.3(a)5, this notice is excepted from the rulemaking calendar requirement.

Social Impact

As noted in the Summary above, the proposed new rules would implement a demonstration project creating and utilizing ACOs in the Medicaid program, the results of which cannot be predicted because of the lack of precedent for such a project. The proposed new rules are expected to have a positive social impact on beneficiaries and providers by allowing improved access and a more effective experience of interaction and patient care between the beneficiaries and providers who are participating in the project, resulting in improvements in health outcomes.

Economic Impact

As noted in the Summary and Social Impact above, the proposed new rules would implement a demonstration project creating and utilizing ACOs in the Medicaid program, the results of which cannot be predicted because of the lack of precedent for such a project. The proposed new rules

are expected to have a positive economic impact on health care providers and the State by facilitating the reduction or stabilization of the costs of medical care under the Medicaid program throughout the region of an ACO and the distribution of such cost savings. There is no application fee to apply under the ACO Program. As described in the proposed rule, an ACO that volunteers to participate in the program will incur costs associated with preparing the necessary application and gainsharing plan, obtaining the required support of other healthcare entities, and gathering and reporting information, all of which cannot be quantified; however, such an ACO would likely be operating with a plan of having such costs exceeded by amounts received through gainsharing.

Federal Standards Statement

The Department of Human Services, in accordance with 42 CFR 431.10 and Section 1902(a)(5) of the Social Security Act, is the single State agency designated for the administration of the New Jersey Medicaid and NJ FamilyCare program. The Patient Protection and Affordable Care Act (PPACA), 111 P.L. 148, at section 3022, contains provisions establishing a Medicare shared savings program including ACOs. Implementing regulations for that Medicare program have been adopted at 42 CFR Part 425. PPACA, at section 2706, also establishes an opportunity for states to establish a Pediatric ACO demonstration project. However, the Medicaid ACO Demonstration Project established in this chapter under the authority of P.L. 2011, c. 114, which applies to individuals of all ages and is not established under the Medicare system, does not arise from either of those two provisions. There are no Federal laws or rules establishing guidelines or standards for a Medicaid demonstration project such as the one established in the proposed new rules.

The Department has determined that the proposed new rules do not exceed any Federal standards for Medicaid ACO demonstration projects. Therefore, a Federal standards analysis is not required.

Jobs Impact

The Department anticipates that a small number of jobs may be created in the State of New Jersey as a result of ACO participants' additional activities in the course of the Demonstration Project.

Agriculture Industry Impact

No impact on the agriculture industry in the State of New Jersey is expected to occur as a result of the proposed new rules.

Regulatory Flexibility Analysis

The proposed new rules would apply requirements to various entities that voluntarily become a part of the ACO Demonstration Project, including the newly created ACOs themselves, managed care organizations, hospitals, and other businesses that provide health care services to Medicaid/NJ FamilyCare beneficiaries. The managed care organizations and hospitals would not be considered small businesses under the terms of the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq., because they employ more than 100 full-time employees. Many of the other providers, as well as the ACOs, would be considered small businesses in that they employ fewer than 100 full-time employees.

Application, reporting, recordkeeping, and compliance requirements are contained in N.J.A.C. 10:79A-1.3, 1.5, 1.6, 1.7, and 1.8(c), as follows:

ACO applicants must submit an application to the Department to become certified as a Medicaid ACO, and must submit a signed ACO Application Checklist. An ACO applicant must document that it is a nonprofit corporation under the laws of the State of New Jersey, attaching a copy of the Certificate of Incorporation.

An ACO must submit to the Department its bylaws and any other relevant materials to demonstrate the ACO's structure and ability to carry out its functions. An ACO's bylaws must include an antitrust compliance policy.

An ACO must have a governing board and a mechanism for shared governance among its members. An ACO must provide a list of governing board members and the organizing documents of consumer organizations represented on its board. An ACO's management structure must include a quality committee, medical director or governance structure that is responsible for overseeing quality performance and access to medically necessary care.

An ACO must provide letters of support from providers that contain the provider's commitment: to participate in the program, to provide timely information, to share patient medical information with participating ACO members pursuant to necessary data sharing agreements, to retain responsibility for treatment and documentation, to not reduce access to care or increase costs, and to abide by the ACO's antitrust compliance policy.

An ACO must have a process for engaging members of the community and for receiving and addressing public comments. An ACO must establish reporting policies and structures. An ACO must provide a project plan for achieving its quality measures, efficiency, patient safety, and satisfaction measurement obligations. An ACO must explain the policies, technical

capabilities, and organizational structures it expects to develop to meet these obligations with implementation timelines, goals/objectives, and project benchmarks. An ACO must certify that it will not negotiate rates for services provided by its participating providers with any public or private payer and that it and its participants will provide all data requested by the State.

An ACO must obtain approval by the Department of a gainsharing plan. An ACO must engage the public and receive comments regarding its gainsharing plan and must have processes for receiving and distributing gainsharing payments. The gainsharing plan must set forth the ACO's plans and processes for accomplishing the demonstration project objectives, must include its fee-for-service plan and managed care contracts, and must explain the ACO's clinical and programmatic goals, proposed savings calculations, plan for distributing savings, and the ACO's expected use of savings. A gainsharing plan must include a letter of support from all participating hospitals and set forth the quality measures that the ACO will meet. The ACO's gainsharing plan must identify savings and describe how savings earned by the ACO will be used to meet the demonstration project objectives. The ACO must explain in its gainsharing plan how it proposes to allocate the savings earned by the ACO to the State, the ACO, and any voluntarily participating Medicaid managed care organization.

The gainsharing plan must explain how patient experience findings will be collected, analyzed, and acted upon, including the types of tools to be used to collect this information. It must explain how often the information will be collected, who will collect the information and their qualifications for conducting this work, how the findings will be summarized for reporting purposes, and any sampling method used with an explanation of its validity. The gainsharing plan must explain how patients will be provided with improved healthcare quality and access and be protected from improper physician self-referrals, and inappropriate reductions or limitations

in patient care or services. The gainsharing plan must include a calculation of the expenditures per recipient by the Medicaid fee-for-service program during a benchmark period, all risk adjustments, and the assumptions used to determine the adjustments applied.

The ACO must submit a separate Medicaid managed care organization gainsharing plan to the Department for review and approval; the ACO must attach all of its managed care contracts as exhibits to the proposed gainsharing plan. The gainsharing plan must explain how the ACO will divide the savings among its membership.

An ACO must provide a way for patients or consumers to make complaints and provide a timely process for reviewing and addressing complaints. An ACO must report annually to the Department the number of complaints received at a provider/practice level, the types of complaints received, and the resolutions implemented. An ACO must determine how its activities will have an impact on the revenues of each participating hospital and share this assessment with the Department of Health.

An ACO must allow inspection and copying by members of the public of the ACO's application, Certificate of Incorporation, bylaws, and gainsharing plan, and must ensure availability of the ACO's gainsharing plan for inspection by the public at the offices of the consumer organizations that participate on the ACO's governing board, and on-line where feasible. A public meeting must be held by the ACO at which time members of the public are permitted to comment, with meeting minutes and a meeting sign-in sheet to verify this process. The gainsharing plan must summarize the community comments received and whether such comments were incorporated in the gainsharing plan and, if not, why such comments were not accepted. An ACO must distribute a summary of the ACO's gainsharing plan in terms that are understandable to the public.

An ACO must provide information to the Department to document its activities. The ACO must report annually to the Department: the total savings achieved, including a benchmark payment calculation and the expenditures made, which must be reported within 30 days of savings distribution; the amount of savings distributed to each member; how each participating ACO member spent its savings distribution; quality performance at the practice level and for the ACO as a whole; patient experience findings; and the cumulative and categorical number of complaints received at a practice level, the types of complaints received, and the resolutions implemented. If the ACO learns of a material concern regarding patient safety and/or satisfaction the ACO must report such concern to the Department within three business days; the ACO must renew its certification that it will not negotiate rates for participants' services with any public or private payer, and attest that it has not done so in the previous year. An ACO must certify that it and its participants have complied with any request to provide all data necessary for the State to monitor the ACO's impact on commercial rates in its designated area.

An ACO must execute a HIPAA required business associate agreement between the ACO and its participating hospitals, primary care offices, and other members, as needed, to permit sharing of patient-level health data. An ACO must perform data analyses of patient utilization of local hospitals to improve care coordination and monitor program performance.

The various application, reporting, recordkeeping, and compliance requirements that are contained throughout the entirety of N.J.A.C. 10:79A-1.3, 1.5, 1.6, 1.7, and 1.8(c), which would apply to the entities that voluntarily create ACOs, are considered the minimum requirements necessary in order to ensure that this new concept of Medicaid ACO implementation is accomplished in a manner that provides quality access to service, achieves cost savings, and does not violate any Federal or State antitrust law or patient privacy law. Additionally, many of the

requirements and standards that are applied, such as the necessity to apply for certification, obtain approval of a gainsharing plan, incorporate public notice and public involvement into the ACO development process, ensure that antitrust laws and privacy laws are not violated, utilize particular organizational and management features, and other requirements, are mandated under P.L. 2011, c. 114, which created the demonstration project. See, for example, N.J.S.A. 30:4D-8.3.b, 8.4.c, 8.5, and 8.7.a. Additionally, since participation in the demonstration project is voluntary, any entity that does not want to become a Medicaid ACO under the demonstration project can simply decline to apply to become a Medicaid ACO. The requirements and standards that are applied to the individual businesses volunteering to provide health care services under the ACO demonstration project are necessary to ensure that Federal and State antitrust laws, privacy laws and health care provider laws are not violated. The costs of such requirements will depend on the size and existing resources of any entity seeking to become an ACO or to provide services under this demonstration project and therefore cannot be estimated by the Department. ACOs may incur some legal and bookkeeping costs in connection with the requirement that they be incorporated. Those costs additionally cannot be estimated by the Department.

Housing Affordability Impact Analysis

Since the proposed new rules would regulate an accountable care organization Demonstration Project in the State's Medicaid program, the Department anticipates that they will have no impact on the development of affordable housing and would not evoke a change in the average costs associated with housing.

Smart Growth Development Impact Analysis

Since the proposed new rules would regulate an accountable care organization Demonstration Project in the State's Medicaid program, the Department anticipates that they will have no impact on construction within Planning Areas 1 and 2, or within designated centers, under the State Development and Redevelopment Plan and would have an insignificant impact on smart growth.

Full text of the proposed new rules follows:

CHAPTER 79A

ACCOUNTABLE CARE ORGANIZATION DEMONSTRATION PROJECT

SUBCHAPTER 1. GENERAL PROVISIONS

10:79A-1.1 Definitions

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise:

"ACO" means an accountable care organization, a legal entity that is recognized and authorized under applicable State law, as identified by a Taxpayer Identification number and comprised of an eligible group of ACO participants that work together to manage and coordinate care for Medicaid beneficiaries and have established a mechanism for shared governance that provides all ACO participants with an appropriate proportionate control over the ACO's decision-making processes.

"ACO participant" means a provider or a supplier as identified by a Taxpayer Identification number.

“Access to care” means the timely use of affordable personal health services to achieve the best possible health outcomes.

"Act" means P.L. 2011, c. 114, an act establishing a Medicaid accountable care demonstration project.

"Behavioral healthcare provider" means a provider licensed or designated by an authorized State agency or licensed or approved by the Department of Human Services to render behavioral healthcare (mental health and substance use disorder) services to New Jersey residents. Behavioral healthcare provider includes the following licensed individuals: physicians, clinical psychologists, professional counselors, clinical social workers, marriage and family therapists, or psychiatric clinical nurse specialists. Behavioral health provider also includes independent or hospital-based clinics and case management services.

"Consumer organization” means a formally organized entity that is capable of advocating on behalf of people who reside in the designated area who need medical care.

"Designated area" means a municipality or defined geographic area in which no fewer than 5,000 Medicaid beneficiaries reside.

"Demonstration Project objectives" means increasing access to primary care, behavioral health care, pharmaceuticals, and dental care and improving health outcomes and quality as measured by objective metrics and patient experience of care for vulnerable populations in a designated area while reducing unnecessary and inefficient spending of public Medicaid funds.

"Demonstration Project year" means an annual 12-month period specified in an approved gainsharing plan during which health care expenditures, quality improvements, and health outcomes are identified and compared with a benchmark period in order to determine whether savings were achieved and quality and health outcomes were improved.

"Department" means the New Jersey Department of Human Services.

"Disproportionate share hospital" means a hospital designated by the Commissioner of Human Services pursuant to Title XIX of the Social Security Act (42 U.S.C. §§ 1396a et seq.).

“‘Division’ or ‘DMAHS’” means the New Jersey Division of Medical Assistance and Health Services.

"Gainsharing" means the sharing of savings achieved by an ACO in the Medicaid ACO Demonstration Project established pursuant to P.L. 2011, c. 114, as calculated in accordance with a gainsharing plan approved by the Division. Gainsharing shall not mean the splitting of profits or the payment or sharing of revenue in a manner not identified in an approved gainsharing plan.

"General hospital" means a health care facility licensed as a general hospital pursuant to rules promulgated by the Department of Health.

“‘Health outcomes’” means outcomes measured by objective metrics and patient experience of care.

"HIPAA" means Health Insurance Portability and Accountability Act of 1996, P.L. 104-191, as amended and supplemented.

"Medicaid" means the Medicaid program established pursuant to N.J.S.A. 30:4D-1 et seq..

"Medicaid ACO Demonstration Project" or "Demonstration Project" means the three-year demonstration project established pursuant to P.L. 2011, c. 114.

“‘Patient-level health data’” means all necessary personal health information identifiers including, but not limited to: name, date of birth, provider, diagnosis codes, claims, and receipts.

"Primary care provider" includes the following licensed individuals: physicians, physician assistants, advanced practice nurses, and certified nurse midwives, whose professional

practice involves the provision of primary care, including internal medicine, family medicine, geriatric care, pediatric care, and/or obstetrical/gynecological care.

"Qualified behavioral healthcare provider" means a licensed behavioral health care provider who participates in the Medicaid program and renders clinic-based and home-based services to individuals residing in the designated area served by the Medicaid ACO. Qualified behavioral healthcare provider includes all services and providers referenced in the definition of behavioral healthcare provider.

"Qualified primary care provider" means a primary care provider who participates in the Medicaid program and who spends at least 25 percent of his or her professional time or 10 hours per seven-day week, whichever is less, rendering clinical or clinical supervision services at an office or clinic setting located within the designated area served by the Medicaid ACO.

"Quality measures" means measures to assess the quality of care furnished by an ACO, as measured by objective metrics and patient experience of care and utilization.

"Taxpayer Identification number (TIN)" means a Federal taxpayer identification number or employer identification number as described at 26 CFR 301.6109-1.

10:79A-1.2 Statement of purpose and goals

(a) This chapter implements P.L. 2011, c. 114, by establishing, and thereby allowing the Department to implement, rules for such a demonstration project in a manner that addresses issues including, but not limited to, project standards, antitrust laws (including the active supervision prong of the State Action Immunity Doctrine (*California Retail Liquor Dealer's Association v. Midcal Aluminum, Inc.*, 445 US 97 (1980))), and the Department's exercise of

independent judgment and control in its oversight and regulation of the conduct of the Medicaid ACOs in the Demonstration Project.

(b) The Demonstration Project encourages additional appropriate care, not reduced care, for the most vulnerable beneficiaries; and the Demonstration Project does not contain mechanisms to control access, such as pre-certification activities or processes for denying care.

(c) The Department, in consultation with the Office of the Attorney General, will exercise ongoing oversight and regulation of the conduct of the Medicaid ACOs in the Demonstration Project to safeguard against violations of Federal laws.

10:79A-1.3 General requirements and provisions

(a) Under the Demonstration Project, Medicaid ACOs shall refrain from, and implement appropriate safeguards against, conduct that may facilitate collusion among Medicaid ACO participants affecting the commercial health care marketplace, including, but not limited to, discussions among ACO participants about rates negotiated with commercial payers.

(b) Medicaid ACOs participating in the Demonstration Project shall include sufficient clinical integration. Any agreement reached by the Medicaid ACO, with the Division or a Medicaid managed care organization for sharing of savings within the ACO, must be necessary to improve care for Medicaid beneficiaries by incentivizing the integration of care between multiple distinct entities. Since the Demonstration Project does not impact the negotiated fee schedules between payers, hospitals, and providers, it is considered pro-competitive.

(c) All approvals, exceptions, or authorizations of any kind issued under this chapter or as part of the Demonstration Project established under the Act are for purposes of implementing the Act only and shall not extend beyond the Demonstration Project or beyond the timeframes for the

Demonstration Project that are established under the Act. This specifically includes, but is not limited to, any exception to a requirement to obtain a certificate of need.

(d) Under no circumstances shall a Medicaid ACO negotiate reimbursement rates for clinical services provided by its participating providers. A gainsharing plan may be negotiated and administered.

10:79A-1.4 Review and oversight

(a) In accordance with the Act, this chapter, and the Department's ongoing authority to oversee and regulate the Medicaid ACOs, the Department, in consultation with the Office of the Attorney General, shall:

1. Review each submitted ACO certification application and issue a written decision on the determination to approve or deny the application, specifying the reason(s) for approval or denial;

2. Review each gainsharing plan submitted by a certified Medicaid ACO or by a Medicaid ACO applicant and issue a written decision on the determination to approve or deny the gainsharing plan;

3. Review each Medicaid ACO's annual report and issue a written acceptance or rejection of the annual report;

4. Evaluate the Demonstration Project annually to assess whether cost savings are achieved and whether there is an improvement in outcomes including health screenings, emergency room visits, hospitalization, and inpatient recidivism rates;

5. In consultation with the Department of Banking and Insurance, evaluate the Demonstration Project annually to assess potential anticompetitive effects on commercial rates

for clinical services in the ACO's designated area. The evaluation should take the form of a written report and should recommend terminating the ACO if information available on commercial rates in the designated area supports a conclusion that the ACO is causing rates to rise more quickly than they do in comparable markets that do not have an ACO; and

6. Provide a mechanism whereby payors, non-ACO providers, or other potentially affected parties in the designated area can lodge complaints about any anticompetitive activity by ACOs and their participants.

(b) The Department, in consultation with the Department of Health and the Office of the Attorney General, shall:

1. Design and implement the application process for approval of participating ACOs in the Demonstration Project;

2. Collect data from participants in the Demonstration Project; and

3. Approve a methodology proposed by the Medicaid ACO applicant for calculation of cost savings and for monitoring of health outcomes and quality of care under the Demonstration Project.

(c) The Department, in consultation with the Department of Health, will evaluate the Demonstration Project annually to assess whether cost savings, including savings in administrative costs and savings due to improved health outcomes, is achieved through implementation of the Demonstration Project. The Department also will evaluate the Demonstration Project annually to assess whether there is improvement in the rates of health screening, the health outcomes, and hospitalization rates for persons with chronic illnesses, and

the hospitalization and readmission rates for patients residing in the designated areas served by the ACOs.

10:79A-1.5 Application process for approval of Medicaid ACOs in the Demonstration Project

(a) Certification is required in order to demonstrate that an entity seeking participation in the Demonstration Project meets the minimum governance and operational standards set forth in the Act and this chapter to carry out the Demonstration Project objectives.

(b) An entity seeking participation in the Demonstration Project must submit an application to the Department to become certified as a Medicaid ACO. In addition, a certified Medicaid ACO must obtain approval by the Department of a gainsharing plan in accordance with this chapter prior to the commencement of its second Demonstration Project year. ACO certification and gainsharing plan applications may be submitted to the Department simultaneously, or the applicant may apply for certification prior to submitting its gainsharing plan for approval. However, in no event shall a gainsharing plan be submitted more than one year following certification approval.

1. An ACO's certification application, including exhibits, is a government record subject to the Open Public Records Act, N.J.S.A. 47:1A-1 et seq., upon submission of such application to the Department for certification and approval.

2. The certification application shall be a maximum of 10 double-spaced, typed pages, 12-point font minimum.

3. The certification application must include the application checklist provided by the Department. The checklist must be signed by an individual with legal authority to bind the ACO to affirm that the applicant will function in accordance with all applicable State and Federal laws,

rules, and regulations, and that the information contained in the application is complete and accurate.

4. The certification application must be submitted to the Department by (60 days after the effective date of this chapter).

(c) An applicant must document that it meets the following minimum standards for certification in order to be certified by the Department as a Medicaid ACO eligible to participate in the Demonstration Project:

1. The applicant must be properly formed as a nonprofit corporation under the laws of the State of New Jersey. The application must include a copy of the Certificate of Incorporation as filed with the State.

2. The application must specify the applicant's designated area, which shall include a municipality or defined geographic area in which no fewer than 5,000 Medicaid fee-for-service and Medicaid managed care beneficiaries reside. An applicant may propose a designated area that includes zip codes or geographic regions that are not contiguous. The designated area shall be specified by a listing of zip codes or other geographic identifiers, such as county or municipal boundaries, that allow the Department to:

i. Verify the accuracy of the proposed number of Medicaid beneficiaries to be served by the applicant;

ii. Collect and report data related to the Medicaid ACO's activities; and

iii. Administer the project.

3. The ACO must have a governing board and an established mechanism for shared governance among its members.

i. The ACO must maintain a governing board with legal authority to execute the functions of an ACO, as described within the Act and this chapter, consistent with the board members' fiduciary duties of care, loyalty, and adherence to mission. The ACO shall submit the following to the Department to demonstrate its governance structure:

(1) The ACO's bylaws and other relevant materials that demonstrate the ACO's leadership and management structure and its ability to support the Demonstration Project objectives and carry out the ACO's functions.

(A) The ACO's bylaws must include a statement regarding the organization's intent to engage the public with respect to the ACO's work to have a positive impact on health access, outcomes, and costs, and to receive comments regarding the gainsharing plan.

(B) The ACO's management structure must include a quality committee, medical director, or governance structure responsible for overseeing the ACO's quality performance and its obligation to provide access to medically necessary care, as required in this chapter.

(C) The ACO's bylaws must include an antitrust compliance policy for the organization.

(2) A list of all governing board members, including a description of their organizational affiliations and whether each member serves the governing board in an individual or organizational capacity.

ii. An ACO board's membership should balance the interests of primary and specialty care providers, hospitals, and consumer beneficiaries. The ACO's governing board must include the following types of members:

(1) Individuals representing the interests of health care providers, such as: general hospitals, clinics, private practice offices, physicians, behavioral health care providers, and dentists;

(2) Individuals representing the interests of social service agencies or organizations, such as legal aid organizations, charitable and religious groups, and groups providing support for the needy and elderly;

(3) Voting representation from two or more consumer organizations capable of advocating on behalf of patients residing in the designated area;

(A) At least one of the organizations must have extensive leadership involvement by individuals residing within the designated area, such as: community organizing entities, faith-based organizations, and grassroots leadership development entities.

(B) At least one of the organizations must have an office or other physical presence in the designated area.

(C) At least one of the voting representatives must reside within the designated area.

(4) Organizations may fit the description of more than one of the categories in (c)3ii above. To ensure a balanced governing board, an organization can qualify in only one category for purposes of this requirement.

iii. The ACO shall provide with its certification application the bylaws, board membership list, and other organizing documents of the consumer organizations represented on its board to document compliance with this requirement.

4. The ACO must obtain support from providers in the designated area, as described in this paragraph.

i. The ACO must obtain the support of the following health care providers in the designated area:

(1) All of the general hospitals located in the designated area;

(2) At least 75 percent of the primary care providers located in the designated area; and

(3) At least four qualified behavioral health care providers located in the designated area. The qualified behavioral health care providers must include at least one Department-licensed mental health program and at least one Department-licensed substance abuse program.

ii. The ACO must document support by providers in the designated area by providing letters of support from the entities and providers listed in (c)5i above. Each letter of support, signed by an individual with legal authority to bind the provider, shall contain the following:

(1) The provider's commitment to participate in the program for the full length of the Demonstration Project (up to three years);

(2) The provider's commitment to support the Demonstration Project objectives;

(3) The provider's commitment to provide timely information to meet the ACO's reporting requirements, including quality measures and patient experience findings, as described in this chapter;

(4) The provider's commitment to share patient medical information with participating ACO members, pursuant to necessary data sharing agreements, for the purpose of

meeting the Demonstration Project objectives, including patient care, tracking, follow-up and coordination;

(5) The provider's acknowledgement that, notwithstanding any Demonstration Project objectives, the provider shall retain responsibility for medically appropriate treatment and referral decisions, document the basis for such decisions, and not limit treatment and referrals to providers participating in the ACO if treatment or referral to outside providers is medically indicated;

(6) The provider's acknowledgement that, consistent with the Demonstration Project objectives, the provider shall not organize his or her care delivery to reduce access to care or increase costs, but instead shall work to improve health outcomes and quality while reducing unnecessary and inefficient spending; and

(7) The provider's commitment to abide by the ACO's antitrust compliance policy.

5. The ACO must demonstrate that it has a process for engaging members of the community to develop health care goals and for receiving public comments with respect to its gainsharing plan.

i. The ACO must designate individuals in its leadership structure responsible for public engagement.

ii. Processes for engaging the public include, for example: annual public meeting(s) of the ACO board that provide a time for public comment; availability of the ACO's Certificate of Incorporation, bylaws, and gainsharing plan for public inspection and copying at a reasonable cost; availability of the ACO's reporting requirements related to gainsharing and quality measures for public inspection and copying at a reasonable cost; and other activities that

engage the community and encourage community input regarding the ACO's activities. The ACO should make documents available to the public on-line where feasible.

iii. Specific public comment requirements related to the ACO's gainsharing plan are set forth in N.J.A.C. 10:79A-1.6.

6. The ACO must have processes for receiving and distributing gainsharing payments.

i. The ACO may provide its processes for receiving and distributing gainsharing payments in its bylaws or other organizational documents in addition to including the processes within its ACO certification application.

ii. Procedures for calculation, distribution, and receipt of gainsharing amounts shall be set forth in the gainsharing plan approved in accordance with N.J.A.C. 10:79A-1.6.

7. The ACO must submit the ACO Application Checklist, signed by an individual who has the ability to legally bind the ACO to the Department, which expressly affirms that the:

i. Information contained in the ACO Demonstration Project certification application is accurate, complete, and truthful, that the signatory is familiar with the laws and regulations regarding the provision of healthcare services, and that the services are to be provided in compliance with such laws and regulations;

ii. ACO will be accountable for the health outcomes, quality, cost, and access to care of Medicaid beneficiaries;

iii. ACO will participate in the Demonstration Project for at least three years following certification;

iv. ACO will comply with the Demonstration Project requirements set forth by the Act and this chapter;

v. That the ACO shall function in accordance with all applicable State and Federal laws and regulations, including, but not limited to, laws and regulations designed to protect Medicaid beneficiaries' ability to access medically necessary care and HIPAA requirements protecting the privacy and security of protected health information;

vi. ACO is committed to ensuring the use of electronic prescribing and electronic medical records by health care providers located in the designated area and expressly affirms that the ACO has existing or planned infrastructure, such as information technology, that enables the ACO to collect and share data among its members;

vii. ACO acknowledges its affirmative obligation to notify the Department within 30 days of any material changes to its certification application any time during the certification process and following certification.

viii. ACO has included all necessary documents with its application, including its bylaws, Articles of Incorporation, list of members, letters of support, and relevant policies and agreements.

8. The ACO must demonstrate to the Department its capability to collect data from participants in the Demonstration Project and report quality measures, efficiency measurements, patient safety measurements, and patient satisfaction findings.

i. The ACO must provide a project plan for achieving its quality measures, efficiency, patient safety, and satisfaction measurement obligations. The ACO must also explain the policies, technical capabilities, and organizational structures it expects to develop to meet these obligations with implementation timelines, goals/objectives, and project benchmarks.

(1) Specific quality, safety, efficiency, and satisfaction measurement benchmarks and tools shall be set forth in the gainsharing plan approved pursuant to N.J.A.C. 10:79A-1.6.

(2) The ACO must explain how it expects to address any failures to meet its quality, efficiency, patient safety, and patient satisfaction measurements or to resolve other issues identified during its monitoring of patient access and care.

ii. The ACO's management structure must include a quality committee, medical director, or governance structure that is responsible for setting and evaluating standards of care, receiving and addressing patient complaints, and conducting ongoing monitoring to ensure access to quality care and to prevent inappropriate provider self-referrals, reductions in care, or limitations on services.

9. The ACO must certify that it will not negotiate rates for services provided by its participating providers with any public or private payer. Failure to comply with this requirement is grounds for decertification of the ACO.

10. The ACO must certify that it and its participants will provide the Department, the Department of Law and Public Safety, and the Department of Banking and Insurance with all data requested by any such State agency, including, but not limited to, any such data requested in order to monitor the ACO's impact on commercial rates in its designated area.

(d) The Department will independently review, evaluate, and accept or deny each certification application as follows:

1. The Department will post ACO certification applications on its website and provide a 30-day public comment period regarding each application.

2. The Department will accept and review any public comment regarding an application that is submitted within the deadline.

3. The Department will review the application materials including all attachments. The Department may request additional documentation or explanations necessary to conduct its review.

4. When the review process is completed, the Department will issue a decision in writing to accept or deny the application. The Department's decision will set forth the basis on which the decision was made. The ACO may request an administrative appeal of a denial of its application pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and 52:14F-1 et seq. However, any such action shall take effect immediately, or at such later date as the Department determines.

(e) If an ACO notifies the Department of a material change to its certification application materials during the certification process or following certification, the Department will advise the ACO of what action, if any, the ACO needs to take. The Department may suspend its certification review, request additional information from the ACO, decertify the ACO, require reconsideration or reapplication, or take other actions consistent with its authority under the Act or this chapter. The ACO may request an administrative appeal of a decertification action pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and 52:14F-1 et seq. However, any such action shall take effect immediately, or at such later date as the Department determines.

10:79A-1.6 Gainsharing plan submission and review

(a) The gainsharing plan shall set forth the ACO's comprehensive plans and processes for accomplishing the Medicaid ACO Demonstration Project objectives. The gainsharing plan shall outline the ACO's vision for improving health outcomes and the quality of care, as measured by objective benchmarks, as well as patient experience of care, for vulnerable populations by increasing access to primary and behavioral health care services and utilization of preventive care and reducing use of emergency rooms and in-patient care settings for routine care.

1. Criteria to be considered by the Department and the Department of Health in approving a gainsharing plan shall include, but are not limited to whether the gainsharing plan:

i. Promotes the following:

(1) Care coordination through multi-disciplinary teams, including care coordination of patients with chronic diseases and the elderly;

(2) Expansion of the medical home and chronic care models;

(3) Increased patient medication adherence and use of medication therapy management services;

(4) Use of health information technology and sharing of health information; and

(5) Use of open access scheduling in clinical and behavioral health care settings;

ii. Encourages services, such as patient or family health education and health promotion, home-based services, telephonic communication, group care, and culturally and linguistically appropriate care;

iii. Payment system is structured to reward quality and improved patient outcomes and experience of care;

iv. Funds interdisciplinary collaboration between behavioral health and primary care providers for patients with complex care needs likely to inappropriately access an emergency department and general hospital for preventable conditions;

v. Funds improved access to dental services for high-risk patients likely to inappropriately access an emergency department and general hospital for untreated dental conditions; and

vi. Has been developed with community input and will be made available for inspection by members of the community served by the ACO.

(b) An ACO's gainsharing plan must include its fee-for-service plan and managed care contracts, and must explain the ACO's clinical and programmatic goals, proposed savings calculations, plan for distributing savings, and the ACO's expected use of savings.

(c) Except as provided under the Open Public Records Act, N.J.S.A. 47:1A-1 et seq., an ACO's gainsharing plan, including exhibits and attachments, will be considered a government record subject to the Open Public Records Act upon submission of such plan to the State for approval. However, reimbursement or rate information, including individual unit costs, or provider fee schedules between an ACO provider and a managed care organization, does not need to be included in the gainsharing plan. If applicants include such information in a gainsharing plan, that information may be redacted in accordance with the Open Public Records Act.

(d) A gainsharing plan submitted to the Department shall include the following elements:

1. The ACO must explain how the Demonstration Project objectives will be achieved, including the implementation plan the ACO will follow and the independent benchmarks the ACO will use to measure the success of each objective. Important care approaches and/or techniques to be included in the gainsharing plan include:

- i. The use of multidisciplinary teams to coordinate patient care across members of the ACO, including care coordination of patients with chronic diseases and the elderly;
- ii. Expansion of the medical home and chronic care models by participating ACO members;
- iii. The improvement of access to services for primary care;
- iv. The encouragement of patient and/or family health education and promotion, home-based services, and telephonic and web-based communications, group care, and the use of culturally and linguistically appropriate care;
- v. Programs to increase patient medication adherence and the use of medication therapy management services;
- vi. Plans to use health information technology and share health information across the ACO to improve outcomes and the patient care experience;
- vii. Strategies to use open access scheduling in clinical and behavioral health care settings to increase patient access to services;
- viii. Programs to promote healthy lifestyles, prevention and wellness activities, smoking cessation, improved nutrition, developing skills in help-seeking behavior, self-management and illness management, and reducing substance use;
- ix. A plan to improve service coordination to ensure integrated care for primary care, behavioral health care, dental, and other health care needs, including prescription drugs.
- x. An assessment of the expected impact of revenues on hospitals that agree to participate, including estimates for changes in both direct patient care reimbursement and indirect revenue, such as disproportionate share payments, graduate medical education payments, and other similar payments. The assessment shall include a review of whether participation in the

Demonstration Project could significantly impact the financial stability of any hospital through rapid reductions in revenue and how this impact will be mitigated. The assessment shall be based only on publicly available data and ACO members shall not share confidential revenue and rate information among themselves while conducting the assessment.

2. The gainsharing plan shall include a letter of support from all participating hospitals in order to be accepted by the Department.

3. Regarding quality standards and reporting, the ACO gainsharing plan shall set forth:

i. The quality measures the ACO will meet.

(1) The ACO shall use the quality measures determined or approved by the Department to measure its health and quality outcomes.

(2) The ACO must select at least five quality performance measures that each participating practice shall use and report on. These measures must provide a valid mix of preventive measures, at-risk population measures, and appropriate use of providers and access to care measures by which the ACO will gauge quality performance and efficiency; and

ii. The quality performance standard levels the ACO intends to achieve at the practice level and at the ACO level for each year of the Demonstration Project, as follows:

(1) For the first year following certification, the quality performance standard shall be at the level of structured and routine reporting by the ACO at the practice level and at the ACO level.

(A) To meet the structured and routine reporting standard, the ACO must establish a method for collecting data from each participating provider. For this performance period collecting sampled data from fewer than all of the patients served is acceptable. If sampling is used, a description of the sampling method used and an explanation of

its validity must be provided. Quarterly, manual chart reviews are an appropriate way to meet this initial standard.

(2) For the second year following certification, the quality performance standard shall be at the level of complete and accurate reporting of the measures selected under (d)3i(2) above and achieving a relative performance improvement of at least two measures. Relative performance improvement means a percentage improvement at the practice level over the prior year baseline performance. For example, the practice will improve the number of eligible patients receiving mammograms by 15 percent over the baseline performance the previous year.

(A) An ACO will meet the level of complete and accurate reporting if it submits registry data at the patient level for each participating provider.

(B) An ACO will meet the level of relative performance improvement for at least two measures if it improves its own performance in the two areas at the practice level and at the ACO level by a percentage amount set by the ACO in the ACO's gainsharing plan over the practices' prior baseline year.

(3) For the third year following certification, the quality performance standard shall be at the level of relative performance for all five measures and absolute performance of at least two measures. Absolute performance improvement means achieving a preset performance metric regardless of baseline performance. For example, a practice must achieve a mammogram completion rate of 60 percent for all eligible patients.

(A) An ACO will meet the level of relative performance improvement at the practice level and at the ACO level if it improves its performance in the five measured areas by an amount set by the ACO in the ACO's gainsharing plan.

(B) An ACO will meet the level of absolute performance at the practice level and the ACO level if it improves its performance to meet a defined quality threshold set by the ACO in the ACO's gainsharing plan.

(4) The Department will review and analyze the ACO's quality measurement plan and annual performance to ensure the ACO is helping to facilitate improvements in health care access and quality while protecting the provision of medically necessary care. If an ACO does not achieve its performance standards, the Department will notify the ACO of the deficiency and provide the ACO with the opportunity to implement a corrective action plan. The Department has the authority to hold all or a portion of the ACO's shared savings payments in escrow or to have a managed care payer hold all or a portion of their shared savings payments until the ACO corrects its performance measure deficiency.

4. The gainsharing plan must explain how patient experience findings regarding the promotion of improved health outcomes and quality of care will be collected, analyzed, and acted upon, including:

i. The type of tools to be used to collect this information. Appropriate tools include the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey or similar survey instruments, valid patient care experience measurement tools, interviews, and other recognized and accepted methods;

ii. How often the information will be collected;

iii. Who will collect the information and their qualifications for conducting this work;

iv. How the findings will be summarized for reporting purposes; and

v. If the applicant proposes to sample fewer than all of the patients served, a description of the sampling method used and an explanation of its validity.

5. Collecting and analyzing patient and consumer feedback is the best mechanism to detect and remediate any potential improper limitations in care. The gainsharing plan must explain how patients will be provided with improved healthcare quality and access and be protected from improper provider self-referrals, as well as inappropriate reductions or limitations in patient care or services. The ACO must report annually to the Department and the public on the number of complaints received at a provider/practice level, the types of complaints received, and the resolutions implemented. To develop its report and to ensure appropriate care and service are being provided, an ACO must:

i. Provide a clear and easy way for patients or consumers to make complaints or speak up regarding a possible improper provider self-referral, or reduction or limitation of services by a participating ACO member. The mechanism for collecting complaints may include the use of on-line feedback forms, hard copy documents, and/or a telephone “hotline”;

ii. Provide a timely process for reviewing and addressing complaints. The ACO shall track and review complaints and have a process by which it direct complaints to the ACO and/or to an individual provider or practice for resolution.

(1) The ACO must ensure that its members put into practice a process for responding to complaints;

iii. Document, at the practice level, instances in which a self-referral, or a reduction or limitation of care is appropriate because the care provided is more effective, will result in better outcomes, and/or is medically appropriate; and

iv. Through its medical director, quality committee, or other governance structure, monitor each participating ACO member's provision of care and take appropriate disciplinary actions, which may include withholding gainshare savings in a given year or excluding a practice from the ACO, if a provider improperly reduces care, limits services, or engages in inappropriate self-referral.

6. An ACO must determine how its activities will have an impact on the revenues of each participating hospital over the life of the Demonstration Project and shall share this assessment with the Department of Health and the Health Care Financing Authority. The assessment shall include estimates for changes in direct care patient reimbursement and indirect revenue, such as disproportionate share hospital payments, graduate medical education payments, and other similar payments for each participating hospital. The assessment shall also indicate whether a hospital's participation will have a significant impact on the financial stability of that hospital through rapid reductions in revenue. The assessment only shall be based on publicly available data and ACO members shall not share confidential revenue and rate information among themselves while conducting the assessment.

7. The following provisions apply regarding shared savings:

i. A key component of the Medicaid ACO Demonstration Project is the availability of incentives to providers in a designated area who promote Demonstration Project objectives. Shared savings payments to the ACO are intended to lessen the State's Medicaid burden by reducing the amount of unnecessary and inefficient care that is provided to Medicaid beneficiaries. The economic benefit of the shared savings payment is expected at a minimum to be proportional to the benefits and contributions the ACO makes to improving health care quality and reducing costs within its designated area.

ii. An ACO may seek to pursue shared savings in phases. For example, an ACO may choose to focus on shared savings in a specific spending area, such as diabetes treatment for the first year of the project. By the final year of the project, the ACO's gainsharing plan must identify savings for all Medicaid costs within the designated area.

iii. A gainsharing plan must describe how savings earned by the ACO will be used to meet the Demonstration Project objectives. Acceptable uses for shared savings include:

(1) Expenditures that reward quality and improve patient outcomes and care experience, for example, funding activities not otherwise reimbursed, such as exercise classes, weight loss programs, and group and peer education classes;

(2) The funding of interdisciplinary collaboration activities between providers for complex patients, including activities like case conferencing;

(3) Spending funds to improve dental services and access for high risk patients in the ACO area;

(4) Expenditures that expand nursing, primary care, and behavioral health services in the ACO area, for example, funding staff and services to transition primary care practices to the medical home model;

(5) Spending funds to support the infrastructure of the ACO, so that it may achieve its mission and expand the scope of its activities; and

(6) Expanding the nursing, primary care, behavioral health care, and dental workforces and services in the area served by the ACO.

iv. The ACO must explain in its gainsharing plan how it proposes to allocate the savings earned by the ACO to: the State, the ACO, and any voluntarily participating Medicaid

managed care organization (if the plan includes any managed care contracts). The percentage of savings allocated to each entity is public information.

(1) To be approved, the gainsharing plan must allocate the savings as follows:

(A) To the State, a meaningful portion of the savings and support the ongoing operation of the Demonstration Project;

(B) To the ACO, a sufficient portion of the savings for the ACO to achieve its mission and expand its scope of activities; and

(C) To the managed care organization, if any, a share of the savings that is proportional to the benefits or contributions the managed care organization provides to the ACO.

(2) With respect to managed care contracts, the ACO shall submit a separate Medicaid managed care organization gainsharing plan to the Department for review and approval. It is expected that an ACO may negotiate different savings allocations with different managed care organizations. The Department will independently review the savings allocations within each ACO-managed care contract to ensure that the agreement is in furtherance of the Demonstration Project objectives. The savings allocation of each contract will not affect the review or analysis of savings allocations in other contracts or the ACO's Medicaid fee-for-service program.

(A) The ACO must attach all of its managed care contracts as exhibits to the proposed gainsharing plan.

(B) Managed care organizations may establish contracts with multiple ACOs. Each MCO-ACO contract may be unique, so long as it meets the requirements of this chapter.

(C) While methods for calculating shared savings and specific provisions may vary in each MCO-ACO contract it is anticipated that over time best practices will be identified and a standardized MCO-ACO contract template and methodology will be developed. This will allow more rapid adoption and spread of the Demonstration Project to new communities.

v. The following provisions apply regarding distribution of savings among participating ACO members. The ACO can choose to pool its shared savings rather than make a distribution to the participating ACO members. However, should the ACO decide to distribute its shared savings, the gainsharing plan must explain how the ACO will divide the savings among its membership. The distribution method must be approved by the ACO governance board in accordance with the ACO's bylaws.

(1) The distribution method must be metric-driven, objective, and supported by data.

(A) Appropriate criteria to consider in determining the distribution method should include the level of achievement of quality performance standards by a member as determined by the Department.

(2) Savings shall be distributed in accordance with an approved gainsharing plan.

(A) The Department expects that the act of distributing savings or pooling of savings may raise conflict-of-interest concerns for the ACO. An ACO shall have a

conflict-of-interest policy and shall address conflict-of-interest concerns including the distribution or pooling of savings pursuant to its policy.

(3) The distribution method must be calculated to produce results consistent with the Demonstration Project objectives.

(4) The distribution method must not provide direct or indirect financial incentives for the reduction or limitation of medically necessary and appropriate items or services provided to patients under a health care provider's clinical care.

(5) The distribution method must not provide direct or indirect financial incentives for provider self-referrals in violation of Federal law (42 U.S.C. § 1395nn) or State law (N.J.S.A. 45:9-22.5) or reward providers based on the volume of referrals.

8. The ACO's gainsharing plan must explain how cost savings will be calculated, using the following basic methodology:

i. The gainsharing plan shall define a benchmark period against which cost savings can be measured on an annual basis through the Demonstration Project. The benchmark period must be a defined period of time with specific start and end dates that are no more than three years before the beginning of the Demonstration Project. The benchmark period must be long enough to yield a statistically stable measurement.

ii. The gainsharing plan must include a calculation of the expenditures per recipient by the Medicaid fee-for-service program during the benchmark period.

(1) The basic benchmark period expenditures may be adjusted for characteristics of recipients and local conditions that predict future Medicaid spending but are not amenable to the care coordination or management activities of the ACO. The intent is to share savings based on work performed and outcomes achieved and eliminate

random or uncontrollable events in the benchmark calculations. For example, a change in the mix of case severity, changes in Medicaid eligibility, or other factors or events that affect the fair distribution of savings may be risk adjusted within the benchmark payment calculation methodology.

(A) All risk adjustments, and the assumptions used to determine the adjustments applied, must be clearly documented in the ACO's gainsharing plan.

(2) The benchmark savings calculation shall remain fixed for the life of the Demonstration Project.

iii. The method for calculating savings shall compare the expenditures during the benchmark period (that is, the benchmark payment calculation) with expenditures during each year of the Demonstration Project.

9. The Act expresses the intent to include public comment in the ACO's gainsharing plan development process. The public comment process shall include:

i. The availability for inspection by members of the public, in-person at reasonable business hours and where feasible on-line of the following: the ACO's application, Certificate of Incorporation, bylaws, and gainsharing plan. Individuals should be permitted to obtain a copy of these documents at minimal cost, which shall be no more than the cost to request a copy of a government record pursuant to the Open Public Records Act, N.J.S.A. 47:1A-1 et seq.

ii. The availability of the ACO's gainsharing plan for inspection by the public at the offices of the consumer organizations that participate on the ACO's governing board, and on-line where feasible.

iii. A public meeting held by the ACO at which time the proposed gainsharing plan is reviewed by members of the ACO governing board and members of the public are permitted to comment. The ACO shall maintain meeting minutes and the meeting sign-in sheet to verify this process.

iv. A statement in the gainsharing plan that summarizes the community comments received by the ACO, whether such comments were incorporated in the gainsharing plan submitted for approval, and, if not, why such comments were not accepted.

v. Distribution of a summary of the ACO's gainsharing plan in terms that are understandable to the public and in a language that is appropriate to the community that the ACO serves. Such summary should explain the manner in which health outcomes, quality, care coordination, and access are to be improved by the ACO, and the manner in which cost savings are to be achieved and distributed as gainsharing payments. The identities of the practices the ACO expects to be eligible to receive distributions shall be specified. The ACO must also identify the purposes for which it intends to use gainsharing payments. The percentage of cost savings to be distributed to the ACO, retained by any voluntary participating Medicaid managed care organization, and retained by the State, shall be included in the summary of the gainsharing plan.

10. Nothing in (d)9 above prohibits an ACO from establishing additional methods to engage the community in the affairs of the ACO and the development of its gainsharing plan.

(e) The following provisions apply regarding the Department's review of a gainsharing plan:

1. Pursuant to (a)1 above, the Department will independently review, evaluate, and accept or reject each ACO gainsharing plan.

i. Upon receipt of an ACO gainsharing, plan the Department shall post the plan on its website and provide for a 30-day public notice and comment period on the plan. The Department shall review any public comment regarding the plan that is submitted by the deadline.

2. The Department will review, analyze, and verify the gainsharing plan materials, including all attachments and public comments received. The Department may request additional documentation or explanations necessary to conduct its review.

3. The Department shall issue a decision in writing to accept or deny the plan. The Department's decision shall set forth the basis, including the factual record compiled by the Department, on which the decision was made, enumerating the manner in which the ACO proposes to meet criteria specified in this chapter, including, but not limited to, whether the gainsharing plan demonstrates that the ACO:

i. Has a sound plan for carrying out the objectives of the Demonstration Project for the length of the project; and

ii. Will monitor compliance with all project requirements and State and Federal laws, including laws designed to protect Medicaid beneficiaries' ability to access medically necessary care;

4. The ACO may request an administrative appeal of a denial of its proposed gainsharing plan pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and 52:14F-1 et seq. However, any such denial shall take effect immediately, or at such later date as the Department determines.

(f) The following provisions apply regarding amendments to a gainsharing plan.

1. An ACO has an ongoing obligation to notify the Department of any material changes to its gainsharing plan.

2. If an ACO notifies the Department of a material change to its gainsharing plan materials during the approval process or following approval, the Department shall, in writing, acknowledge receipt of the notice and advise the ACO of what action, if any, it needs to take. The Department may suspend its gainsharing plan review, request additional information from the ACO, require reconsideration or resubmission of the gainsharing plan, decertify the ACO, or take other actions consistent with its authority under the Act or this chapter. The ACO may request an administrative appeal of a decertification action pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and 52:14F-1 et seq. However, any such action shall take effect immediately, or at such later date as the Department determines.

10:79A-1.7 Annual ACO reporting requirements

(a) An ACO shall provide information to the Department to document its activities and the Department shall review and evaluate information provided by the ACO to ensure the Demonstration Project is being administered in a way that achieves the Demonstration Project objectives while protecting patient safety and safeguarding the use of public funds.

(b) With the exception of any commercial rate data provided pursuant to (c)8 below, the ACO's annual report will be considered a government record subject to the Open Public Records Act, N.J.S.A. 47:1A-1 et seq., upon submission to the Department.

(c) To enable the Department to carry out its monitoring, oversight, and evaluation responsibilities, the ACO shall report annually to the Department as follows:

1. The total savings achieved pursuant to the savings calculation methodology in this chapter. The annual savings achieved report must provide the benchmark payment calculation and the expenditures made during that year of the Demonstration Project and must be reported within 30 days of savings distribution;

2. The amount of savings distributed to each participating ACO member pursuant to the distribution of savings methodology contained in the ACO's gainsharing plan;

3. How each participating ACO member spent its savings distribution;

4. Quality performance at the practice level and for the ACO as a whole;

5. Patient experience findings at the practice level and for the ACO as a whole;

6. The cumulative and categorical number of complaints received at a practice level, the types of complaints received, and the resolutions implemented.

i. The ACO must collect and respond in a timely manner to patients' and consumers' comments and complaints and ensure compliance with all State and Federal laws affecting patient access to appropriate care and services. If the ACO learns of a material concern regarding patient safety and/or satisfaction, the ACO shall promptly report such concern to the Department within three business days independent of the annual reporting requirements so that such concern can be properly addressed;

7. The ACO must renew its certification that it will not negotiate rates for participants' services with any public or private payer and attest that it has not done so in the previous year. Failure to comply with this requirement is grounds for decertification of the ACO; and

8. The ACO shall certify that it and its participants have complied with any request to provide the Department and the Department of Banking and Insurance with all data necessary for the State to monitor the ACO's impact on commercial rates in its designated area.

(d) The Department will review and analyze the ACO annual reports to ensure the data provided is complete and accurate and that the ACO is achieving the Demonstration Project objectives per the ACO's gainsharing plan. The Department will independently review, evaluate, and accept or reject the ACO's annual report as follows:

1. Upon receipt of an ACO's annual report the Department shall post the report on its website and provide for public comment within 30 days.

i. The Department shall review any public comment regarding the report that is submitted by the deadline.

2. The Department shall review, analyze and, as needed, verify the annual report. The Department may request additional documentation or explanations necessary to conduct its review.

3. The Department shall issue a decision in writing to accept or deny the report. The Department's decision shall set forth the basis, including the factual record compiled by the Department, on which the decision was made, including, but not limited to, the following:

i. The annual report demonstrates that the ACO has been carrying out the Demonstration Project objectives.

ii. The annual report demonstrates that the ACO has been in compliance with all Demonstration Project requirements and State and Federal laws, in particular laws designed to protect Medicaid beneficiaries' ability to access medically necessary care.

4. If the annual report is rejected, the ACO must seek reconsideration by submitting corrections or amendments to the Department within 15 days of the rejection, and the Department shall thereafter issue a final decision.

i. The Department will review its decision to reject the annual report with the ACO, in person or by conference call, to explain the rationale for its decision and to provide guidance to assist the ACO's resubmission of its report.

5. If the ACO fails to provide the annual report in a timely manner, the Department may place it on a remediation plan, suspend its participation in the project, or take other appropriate action. The ACO may request an administrative appeal of a suspension action pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and 52:14F-1 et seq. However, any such action shall take effect immediately, or at such later date as the Department determines.

6. If the Department discovers material issues with an ACO's performance during its review and evaluation of the ACO's annual report or at any other time, the Department has the authority to request additional information from the ACO, require reconsideration or resubmission of the annual report, decertify the ACO, or take other actions consistent with its obligations under the Act and this chapter. The ACO may request an administrative appeal of a decertification action pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and 52:14F-1 et seq. However, any such action shall take effect immediately, or at such later date as the Department determines.

10:79A-1.8 Data analyses and annual project evaluation

(a) Pursuant to the Act, the Rutgers Center for State Health Policy (the Center) shall make HIPAA-compliant data requests to the Department and the Department of Health to support the Demonstration Project.

(b) The Department, in consultation with the Department of Health, shall review the Center's assessment of the gainsharing plans in accordance with the Act.

(c) Certified ACOs shall execute a HIPAA-required business associate agreement between the ACO and its participating hospitals, primary care offices, and other members, as needed, to permit sharing of patient-level health data. Certified ACOs shall perform data analyses of patient utilization of local hospitals to improve care coordination and monitor program performance. All such agreements shall require that beneficiaries are to be notified by all such members or providers that the ACO will obtain beneficiary-identifiable data, and that beneficiaries shall be given the opportunity to decline such data sharing, in which case no such data sharing shall occur.

10:79A-1.9 Use of savings by a managed care organization

(a) A managed care organization that participates in the Demonstration Project and expects to earn savings pursuant to a contract with an ACO shall report to the Department and make available to the public how savings earned by the managed care organization will be used.

1. Possible uses for shared savings include:

- i. Program administration costs;
- ii. Retained earnings;
- iii. Increased care coordination activities; and
- iv. Increased payments to providers for medical home activities.