

HUMAN SERVICES

DIVISION OF MEDICAL ASSISTANCE AND HEALTH SERVICES

Medicaid Accountable Care Organization Demonstration Project

Implementation of Demonstration Project

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

Proposed: May 6, 2013, at 45 N.J.R. 1080(a).

Adopted: December 20, 2013, by Jennifer Velez, Commissioner, Department of Human Services.

Filed: April 7, 2014, as R.2014 d.075, **with substantial and technical changes** not requiring additional public notice or comment (see N.J.A.C. 1:30-6.3).

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

Agency Control Number: 11-A-22.

Effective Date: May 5, 2014.

Expiration Date: May 5, 2018.

Summary of Public Comments and Agency Responses:

Comments were received from:

1. The New Jersey Society of Pathologists (NJSP) and College of American Pathologists (CAP), Parsippany, NJ;
2. The Rutgers University, Center for State Health Policy (the Center or CSHP), New Brunswick, NJ;
3. The New Jersey Psychological Association, West Orange, NJ;
4. The Independent Pharmacy Alliance (IPA), Cranbury, NJ;

5. The New Jersey Hospital Association, Princeton, NJ;
6. The Family Planning Association of New Jersey (FPANJ), Elizabeth, NJ;
7. The Affiliated Accountable Care Organizations (AACO), an initiative of the New Jersey Health Care Quality Institute (“Quality Institute”), Pennington, NJ;
8. Family Voices-NJ /Statewide Parent Advocacy Network (SPAN), Newark, NJ;
9. The New Jersey Appleseed Public Interest Law Center, on behalf of the NJ for Health Care Coalition, Newark, NJ;
10. The New Jersey Primary Care Association (NJPCA), Hamilton, NJ;
11. New Jersey Senator Joseph F. Vitale, District 19; Committee Chairman: Health, Human Services and Senior Citizens; Committee Vice Chairman: Economic Growth;
12. The Greater Newark Healthcare Coalition (GNHCC), Newark, NJ;
13. The New Jersey Association of Mental Health and Addiction Agencies, Inc. (NJAMHAA), Mercerville, NJ;
14. The National Association of Chain Drug Stores (NACDS), Alexandria, Virginia;
15. The Medical Society of New Jersey (MSNJ), Lawrenceville, NJ;
16. The Camden Coalition of Healthcare Providers, Camden, NJ.

1. COMMENT: The Department received numerous comments of general support for various aspects of the proposed chapter, including:

- Support for the proposed rule’s emphasis on consumer protection, including its creation of institutionalized processes to ensure meaningful consumer involvement in the ACO governance structure and development of the gainsharing plan.

- At N.J.A.C. 10:79-1.1, in the definitions of “health outcomes” and “quality measures,” support for the patient accountability measures in the form of both clinical quality/outcome metrics and patient experience survey data. In particular, support for the focus on improving data collection related to patient experience in the rule, in addition to patient safety and outcomes. Also, support for the rules providing ACOs with sufficient flexibility, protecting consumers, and satisfying concerns raised by several Federal anti-fraud and abuse laws.

- Belief that the requirement that each ACO maintain data on, and show improvement in, five measures of clinical quality is an appropriate method of tracking changes in outcomes that are attributable to the changed organizational structure of the ACO, because it is necessary to increase transparency, create an opportunity to improve data collection and analysis, and ensure provider accountability to patients and consumers.

- At N.J.A.C. 10:79A-1.5(b), regarding the application and application process, support for the information being made available to the public for examination.

- At N.J.A.C. 10:79A-1.5(c)4, regarding the requirement that the ACO must obtain support of providers, agreement that the ACO needs support from providers and hospitals, and agreement on the inclusion of behavioral, not just physical, health. Also, support for the emphasis on not reducing healthcare access as a means to save costs in the rule.

- At N.J.A.C. 10:79A-1.5(c)5, regarding the ACO allowing public comments regarding the gainsharing plan, agreement that there must be public input in this process and rectification of any findings.

- At N.J.A.C. 10:79A-1.5(c)8, support for the requirements on quality, safety, patient satisfaction, and addressing any failures in these areas, especially access to care.

- At N.J.A.C. 10:79A-1.5(d), support for the transparency in allowing the public to view and comment on applications and the Department's consideration of public input.
- At N.J.A.C. 10:79A-1.5(e), support to prevent major changes in the ACO operations after application acceptance, without review.
- At N.J.A.C. 10:79A-1.6(a)1i(1) and (2), which state that criteria to be considered in approving a gainsharing plan shall include whether the plan promotes care coordination and expansion of the medical home, support for care coordination and the use of the medical home as the most important aspects of ACO implementation.
- At N.J.A.C. 10:79A-1.6(a)1iv, which states that criteria to be used in approving a gainsharing plan shall include whether it funds interdisciplinary collaboration between behavioral health and primary care providers for patients with complex care needs likely to inappropriately access an emergency department and hospital for preventable conditions, support for the recognition of mental health in addition to physical health. Also, support for integration between primary care and mental health due to the shortage of specialists and because most patients would first be seen in primary care.
- At N.J.A.C. 10:79A-1.6(a)1v, which states that criteria to be considered in approving a gainsharing plan shall include whether the plan has been developed with community input and will be made available for inspection by members of the community served by the ACO, support for involving the patients that the ACO will serve.

RESPONSE: The Department appreciates the support for these various aspects of the new chapter.

2. COMMENT: The Department should require that each ACO implement a clinical laboratory testing advisory board (CLTAB). ACOs will need to utilize clinical laboratory tests to control health care costs and improve patient outcomes, and an advisory board would assist in meeting those objectives. The CLTAB should make recommendations of “protocols and guidelines” for laboratory testing to the ACO governance structure, which would improve patient care, health outcome and quality, and reduce unnecessary and inefficient care. The Department should insert the following language into the final rule: “An ACO participating in the Medicaid ACO Demonstration Project is required to establish a Clinical Laboratory Testing Advisory Board. The purpose of the Board is to make recommendations to the ACO on ‘guidelines or protocols’ for clinical laboratory testing. The composition of the Board is required to include at least one physician, legally affiliated with the ACO, who is a medical director of a laboratory regulated under the Federal Clinical Laboratory Improvement Amendments of 1988, that is providing service to the ACO.”

RESPONSE: The Department believes that it would be best to provide flexibility to the ACOs to determine the appropriate way to address the use of laboratory tests to control health care costs and improve patient outcomes, as well as how to determine which protocols and guidelines would be appropriate. For this reason, no change will be made.

3. COMMENT: At N.J.A.C. 10:79A-1.1, in order to ensure that ACOs include all of these essential team members, we request the following additions to the definition of “behavioral healthcare providers”:

1. Add licensed clinical alcohol and drug counselors (LCADC) to the list of licensed individuals, as LCADCs are essential members of treatment teams for individuals who have substance use disorders;

2. Add non-licensed providers of mental healthcare and substance use treatment services, as they are equally essential for delivering the full continuum of services that enable individuals to manage both behavioral and physical health conditions; and

3. Add a definition of “behavioral health services” to this paragraph.

4. COMMENT: At N.J.A.C. 10:79A-1.1, in the definition of a “behavioral healthcare provider,” the term “clinical psychologists” should be replaced with “licensed practicing psychologists,” since the Practicing Psychology Licensing Act (N.J.S.A. 45:14B-1 et seq.) uses the term licensed practicing psychologist to mean an individual to whom a license has been issued pursuant to the provisions of that act.

RESPONSE TO COMMENTS 3 AND 4: In response to the comments, the Department is revising the rule by deleting the specific references to types of health care providers that are contained in the second and third sentences of the definition and revising the first sentence to be more broad and clarify that the treatment is for residents with mental illnesses, substance use, or co-occurring disorders. These revisions will not significantly expand the scope of the rule, which applies to the voluntary participants in the ACO Demonstration Project. Likewise, the inclusion of the word “or” within the mention of mental health and substance use disorders, as well as the inclusion of co-occurring disorders, merely recognize that mental health and substance use disorders may occur singly, together, or in combination with other disorders and that medically necessary

treatment will be provided as appropriate. As always, all services provided to beneficiaries under the Medicaid program must be medically necessary.

5. COMMENT: At N.J.A.C. 10:79A-1.1, Definitions, the rules should include “reproductive health care” within the definition of "Demonstration Project objectives" in recognition of the value of these services as preventative health care.

RESPONSE: The ACO Demonstration Project rules are not intended to specifically mention or recognize every type of health service available under the Medicaid program. Therefore, the rule will not be revised upon adoption to add the requested additional reference to the definition of “Demonstration Project objectives”.

6. COMMENT: At N.J.A.C. 10:79A-1.1, Definitions, in the definition of “Demonstration Project year,” the phrase “an annual 12-month period specified ...” could lead to an interpretation that a gainsharing plan must be tied to a January to December schedule. It should be changed to “a 12-month period as described in the gainsharing plan” to make it clear that the 12-month period will be defined in each applicant’s gainsharing plan and allows for flexibility in designing a plan.

7. COMMENT: At N.J.A.C. 10:79A-1.1, the definition of “Demonstration Project year” would be less confusing if it used the annual fiscal year that each non-profit ACO will use under their official incorporation. The phrase “an annual 12-month period” could lead to an interpretation that a plan must be tied to a January to December schedule. Changing the definition makes it clear that flexibility is allowed. All non-profits have different fiscal years.

RESPONSE TO COMMENTS 6 AND 7: The first of the three Demonstration Project years would begin when the Demonstration Project is begun by the Department, and last for 12 months. The second and third project years would follow consecutively, with no interruptions. The Department believes that the Demonstration Project needs a definite start date and end date, so that it will last for a total of three years. For this reason, no change will be made.

8. COMMENT: At N.J.A.C. 10:79A-1.1, definition of “patient-level-health data,” that term should be replaced with “protected health information” as defined pursuant to 45 CFR 160.103. Use of a Health Insurance Portability and Accountability Act (HIPAA)-term will make privacy and security obligations and business associate agreements consistent with the Federal law and, thereby, less complicated for ACOs.

RESPONSE: The Department will delete the definition of “patient-level health data” and add a definition of “protected health information” that has the same meaning as that contained in the definition of that term at 45 CFR 160.103. Also, the Department is substituting the use of the existing term “patient-level health data” at N.J.A.C. 10:79A-1.8(c) with the new term “protected health information.” The Department believes that uniformity with the Federal terminology will, as the commenter suggests, allow ACOs to proceed in a manner that is clearer to them because they would already be familiar with the Federal definition. Since (other than the definition itself) the term is only used at N.J.A.C. 10:79A-1.8(c) and (d), regarding the ACO participants signing business associate and data use agreements that will comply with mandatory HIPAA requirements

for sharing of such information, the change will not significantly change what is required of those voluntary ACO participants in the Demonstration Project. In real terms, the actual information that is shared and the agreements that are signed will not vary as a result of the changes, despite the difference in the definition, because both definitions broadly describe the same information that will be shared.

9. COMMENT: At N.J.A.C. 10:79A-1.1, definition of "primary care provider," the commenter supports the broad definition of primary care provider, but the Department should include a requirement that ACOs use advance practice nurses and physician assistants in order to satisfy community primary care needs.

RESPONSE: The Department believes that additional language requiring such specific provider composition would infringe upon the ACOs' ability to design and implement individual business models. For this reason, no change will be made.

10. COMMENT: N.J.A.C. 10:79A-1.2 should be modified to make it clear that the purpose is not to necessarily provide additional care, but rather to provide more appropriate care and other social services and community supports.

RESPONSE: The Department believes that the use of the word "appropriate" in the proposed text makes it clear that the Demonstration Project encourages providing the most appropriate care, not providing additional non-appropriate care. For this reason, no change will be made.

11. COMMENT: At N.J.A.C. 10:79A-1.3(b), the commenter agrees that there must be “incentivizing the integration of care between multiple distinct entities ...” This will avoid duplicative tests, be cost-effective, and result in better outcomes. One such area would be interoperability of health information technology (HIT). Although there has been an increase in the use of HIT, interoperability remains an issue.

RESPONSE: The Department agrees with the commenter and appreciates the commenter’s support. However, the Department believes that resolution of such issues would be better addressed in implementation by the ACOs than through rulemaking under the Demonstration Project. For this reason, no change will be made.

12. COMMENT: N.J.A.C. 10:79A-1.3(c) states that “[a]ll 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. This specifically includes, but is not limited to, any exception to a requirement to obtain a certificate of need.” The commenter would like clarification under which conditions an exception may be granted and safeguards.

RESPONSE: The only exceptions to which the regulation refers are those contained within statute, at N.J.S.A. 26:2H-7.a, 26:2H-7.c, and 26:2H-7.d.. Any safeguards contained within those laws would also apply.

13. COMMENT: At N.J.A.C. 10:79A-1.4(a)4, the reference to screening does not imply an obligation to provide services on the basis of that screening. For example, the U.S. Preventive Services Task Force has found there is no benefit to screening for depression

if there are no staff-assisted depression care supports in place. The commenter believes the section should read “including health screenings and appropriate follow-up.”

RESPONSE: The Department disagrees with the assumption that services would not subsequently be provided based on the screening. If necessary services cannot be provided by the provider supplying the screening, that provider would be obligated to make the appropriate referral. For this reason, no change will be made.

14. COMMENT: At N.J.A.C. 10:79A-1.4(b)3, the commenter understands that the Department will approve a methodology proposed by the ACO for calculation of cost savings and for monitoring health outcomes and quality of care. The commenter thinks the most important concept is monitoring outcomes and health disparities and immediately addressing these as appropriate.

RESPONSE: The Department appreciates and agrees with the commenter. It is important to address the health care needs of the beneficiaries, monitoring outcomes and health disparities and immediately address these as appropriate, which in turn should reduce costs. The Department will be monitoring these issues through quality metrics and data analysis provided by the Rutgers Center for State Health Policy.

15. COMMENT: At N.J.A.C. 10:79A-1.4(c), the commenter understands that the Department will assess cost savings annually, improvement in the rates of health screening, health outcomes, and hospitalization rates. Monitoring outcomes, not merely costs, will determine if the project is obtaining its objectives. This is particularly true of hospital readmission rates, hospital acquired infections, and preventable medical errors.

RESPONSE: The Department agrees with the commenter and appreciates the support.

16. COMMENT: Regarding N.J.A.C. 10:79A-1.5 and the notice of proposal generally: The Act and proposed regulations identify prescription services as covered services in the Demonstration Project. The Act also recognizes the need for medication therapy management (MTM) services, which have been shown to be most effective when provided at the pharmacy level. Pharmacists offer a variety of patient care services to improve quality and outcomes. Community pharmacists are trusted and accessible to patients. Pharmacists have the training and skills needed to provide patients with their medications and other medication-related services. Pharmacists are medication experts with the ability to identify patient specific medication-related issues, communicate those issues both to the patient and their healthcare provider, and to improve patient compliance, outcomes and overall quality of care.

ACOs can improve patient care by promoting safe and effective medication use and facilitating partnerships between pharmacists and healthcare providers. Poor medication adherence results in avoidable and costly health complications, worsening of disease progression, increased emergency room visits and hospital stays, and nursing home admissions.

The proposed regulations do not include pharmacies or pharmacists as health care providers of prescription services eligible to participate in the Demonstration Project. The regulations should provide expressly for the participation of pharmacies and pharmacists in providing both prescription and MTM services in Medicaid ACOs. The

Department should add language to N.J.A.C. 10:79A-1.5 that requests ACOs to obtain the participation of at least two pharmacies and pharmacists in the designated area for providing prescription and MTM services. Alternatively, the Department could add language to N.J.A.C. 10:79A-1.5 to require, as a condition of the application process, that the ACOs' participating primary care providers produce documents of collaborative practice agreements between these providers and at least two pharmacists in two different pharmacy practice retail settings in the designated ACO area for the provision of MTM and other health care services.

RESPONSE: It is an ACO's responsibility to determine how an MTM and prescription network will provide access for beneficiaries to the extent needed to meet the goals of the Demonstration Project. The rule provides ACOs the flexibility to provide MTM through pharmacies and pharmacists, or in other ways such as in clinic settings. For these reasons, no revisions will be made.

17. COMMENT: At N.J.A.C. 10:79A-1.5, the Department should require applicants to specify how they will ensure the privacy and security of sensitive health information and the health information of minors within an electronic exchange environment. Consistent, transparent, and understandable policies are needed to ensure the appropriate use and confidentiality of sensitive data in an electronic exchange environment. Applicants must address the protection of minors' health information, specifically:

1. The extent to which the personal representatives of minors, such as a parent, will be able to request and obtain access to a minor's protected health information, given

that the HIPAA privacy rule leaves the decision of whether to release protected health information (PHI) in the hands of the treating health care professional; and

2. The extent to which minors have the same rights as adults and are able to consent to participate in the ACO or opt out of it without the involvement of a parent.

Applicants should be required to specify how they plan to ensure that providers retain the same level of discretion related to disclosure that they have in a paper-based environment and that only appropriate access to minors' health information is granted in an electronic environment. Furthermore, applicants should ensure that information pertinent to such discretionary judgments be available to other professionals who access a minor's health information. A primary provider's denial should be available to the next provider who may receive a request from the minor's parent for the same information.

Applicants should be required to develop sufficiently detailed policies to protect minors' health information in an electronic exchange environment, and to specifically outline how their ACO will approach a parent's request to access the health information of a minor and how the ACO will confirm that the provider who referred the minor to another health care provider has exercised her or his discretion not to disclose the minor's health information to her or his parent.

RESPONSE: Regardless of whether an individual or entity is dealing with paper or electronic medical records, or dealing with adults or minors, Federal and State privacy laws, rules, and regulations would still be effective and applicable within an ACO context. For this reason, no changes will be made.

18. COMMENT: The commenter supports the requirement at N.J.A.C. 10:79A-1.5(b)3, that ACOs need to affirm in their applications that they will function in accordance with all applicable State and Federal laws, rules, and regulations. To ensure that the language explicitly protects beneficiaries' access to services, the Department should amend the language to read as follows: ACOs will function in accordance with all applicable State and Federal laws, rules, and regulations, including providing access to covered services.

RESPONSE: The Department believes that access to services required under existing laws, rules, and regulations is already provided for under those laws, rules, and regulations and the existing proposed rule. For this reason, no changes will be made.

19. COMMENT: The Department received several comments regarding N.J.A.C. 10:79A-1.5(b)4, which states that an ACO's certification application must be submitted to the Department by (60 days after the effective date of the chapter). Those various comments stated:

- The Department is imposing a 60-day application period. The law, however, does not provide that the Demonstration Project would have a limited application period. See N.J.S.A. 30:4D-8.4.a (stating that "the department shall accept applications for certification from demonstration applicants beginning 60 days following the effective date of this act ..."). This restrictive application period runs counter to the letter and intent of the Act. The only temporal restrictions in the law are that the application period would begin 60 days after the effective date of the Act and that certified Medicaid ACOs must submit their three-year or longer gainsharing plans within one year of their certification. See N.J.S.A. 30:4D-8.4.c(6) and 30:4D-8.5.a. In addition to the language of the Act, the intent

of the Act is to encourage health care providers and communities across the State to create as many qualified ACOs as possible to improve health outcomes, quality, and access and reduce costs. This legislative goal can best be reached by having an unlimited rolling application period.

- The commenter does not believe the intent of the legislation was to limit the submission of potential applicants. The commenter believes that some geographic areas of the State may need more time to organize and submit a complete application. The Department should consider expanding the application submission to allow additional areas across New Jersey to benefit from the opportunity to participate.

- The commenter is concerned about the 60-day application period restriction. The commenter does not believe that the law states there will be a limited application window. The commenter believes that the law says certification from Demonstration Project applicants will begin 60 days following the effective date of the Act. This should mean that there will be rolling applications and flexibility as to when ACOs submit their applications. A one-time 60-day deadline for participation in the Demonstration Project will limit how many applications are submitted.

- A one-time, 60-day deadline will exclude potential participants from the Demonstration Project and limit the models that can be tested. The potential for the ACO model to improve health outcomes, quality, and access and reduce costs can best be recognized through the participation of as many qualified ACOs as possible. The Department should allow for applications to be submitted at any time. It is unlikely that the Department will receive more applications than it can reasonably review on a rolling basis. This section should be revised as follows: "The certification application may be

submitted to the Department at any time during the first two years of the Demonstration Project."

- The Act does not provide that the Demonstration Project would have a limited 60-day application window. The commenter read the law to allow for a rolling application and for maximum flexibility. A one-time 60-day deadline for participation in the Demonstration Project will exclude potential participants and limit the models that can be tested. The potential for the ACO model can best be recognized through the participation of as many qualified ACOs as possible. The certification application process should allow for applications to be submitted at any time.

RESPONSE: The Department believes that appropriate implementation of the Act would not allow for an unlimited application period. The Act directs that the Department shall establish "a three-year Medicaid ACO Demonstration Project," not a series of approvals of three-year ACO entities, and the Act itself expires May 5, 2017, three years after the effective date of this chapter. After the Demonstration Project is completed, the Commissioner will report to the Governor and to the Legislature on the results of the Demonstration Project and make recommendations as to whether Medicaid ACOs should be established on a permanent basis and in additional communities.

The Act does not address the issue of how far into the three-year Demonstration Project applications may still be submitted, but authorizes the Commissioner of Human Services to adopt rules containing such requirements as are deemed necessary to carry out the provisions of the Act. See N.J.S.A. 30:4D-8.15. The Department believes that in order for the Demonstration Project or an ACO's participation in the Demonstration Project to be meaningful, ACOs should participate for the full three-year period. Having

ACO applicants enter the program at any point they choose during the three-year Demonstration Project is contradictory to the fixed-length requirement that the Act establishes via its own three-year expiration date. Additionally, the Department believes that having all ACOs participate for the full three-year period with identical beginning and end dates will provide the Department with an optimum means to compare the data that is received from all participating ACOs.

The Department believes that a 60-day application period will allow the Demonstration Project to proceed in a manner that will provide a sufficient number of qualified participants to meet the goals of the Act and allow the State to meet its administrative, oversight, and analytical responsibilities, which are not limited to mere review of applications to participate. For all of these reasons, no change will be made.

20. COMMENT: At N.J.A.C. 10:79A-1.5(c), regarding composition of the ACO board, the rules should require that the board include at least one primary care physician and representation from other physician specialties. The Department should also require that the ACO's medical director and primary care physicians, in particular physicians who specialize in chronic diseases, be included on the quality committee.

RESPONSE: The Department is adding a requirement at N.J.A.C. 10:79A-1.5(c)3i(1)(B) that a quality committee must include the ACO's medical director, primary care physicians, and at least one physician who specializes in chronic diseases. Additionally, the Department is adding a requirement at N.J.A.C. 10:79A-1.5(c)3ii(1) that the governing board must include at least one primary care physician and also include representation from other physician specialties.

21. COMMENT: At N.J.A.C. 10:79A-1.5(c)3, the commenter supports the requirements regarding governing board structure. N.J.A.C. 10:79A-1.5(c)3i(A) protects consumers by requiring incorporation into bylaws of a statement regarding the ACO's intent "to engage with 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." However, this provision should be strengthened to require an ACO to do more than state its "intent" to engage the community, and instead to delineate some of the activities it intends to undertake to engage the community.

RESPONSE: The applicant will be required to define its process for engaging the community, as well as provide for a public comment period. The Department will not prescribe specifically what activities to use, in order to promote flexibility within each community. For this reason, no change will be made.

22. COMMENT: At N.J.A.C. 10:79A-1.5(c)3, regarding the minimum standards for certification and members of the governing board, the commenter strongly supports the inclusion of community-based organizations, which are aware of the resources available to families. The commenter thinks that the Family-to-Family Health Information Centers are in the unique situation to voice the concerns of families of children with special needs.

RESPONSE: The Department believes that it would be best to provide flexibility to the ACOs to determine which community-based organizations best represent their region and address its specific issues. For this reason, no change will be made.

23. COMMENT: At N.J.A.C. 10:79A-1.5(c)3i(1)(C), regarding the language: "[t]he ACO's bylaws must include an antitrust compliance policy for the organization." Could the Department please provide guidance regarding what provisions will be required in the ACOs antitrust compliance policy to meet this requirement.

RESPONSE: An antitrust compliance policy should include, at a minimum, an express statement that only the Medicaid ACO part of any participating entity is exempt from antitrust liability and a requirement that the ACO educate its employees, managers, contractors and agents about any and all laws pertaining to civil and criminal penalties for violations of the New Jersey Antitrust Act, N.J.S.A. 56:9-1 et seq.

24. COMMENT: At N.J.A.C. 10:79A-1.5(c)3ii, the commenter supports the requirement that governing boards have voting representation from at least two consumer organizations and support the qualification criteria for community representatives. The benefits of community leader involvement in board deliberation processes are often lost without the protection of institutionalized processes. Community leaders may feel outside of many board conversations because they do not have fluency in medical or financial terminology or they lack the familiarity assumed by colleagues in a similar profession/industry. Therefore, the commenter supports the proposed regulations defining the nature of the two community representatives, and the board's need to promulgate a plan to ensure meaningful participation. However, this provision should be strengthened to require boards to provide training to all its members to ensure that health providers listen to community representatives, and that such representatives are provided with the skills needed to effectively advocate and talk with those providers. Additionally, to prevent

potential dilution of the role of the community leader members, the rule should be revised to include, in addition to the minimum of two consumer representatives, a requirement that the community leaders constitute a minimum of one-quarter of the sitting board members. Two consumer representatives is appropriate for a board of eight; however, larger boards must be urged to include additional consumer leaders. Finally, the commenter would like to suggest the addition of a requirement that the board, or the quality committee, under N.J.A.C. 10:79A-1.5(c)8ii, include a current or former Medicaid recipient. Such an individual would have a unique and important perspective to contribute to the board's understanding of the implications of broad decisions on care coordination and access. The commenter believes that this perspective cannot be fully represented by community leaders, especially on the quality committee.

RESPONSE: The Department believes that the people and entities that choose to participate as, and in, ACOs will be sensitive to the issue of communication and will take appropriate action. The ACO members will have an inherent interest in addressing this issue. Regarding the suggestions relating to the composition of the board and quality committee, the Department would like to avoid being overly prescriptive and would like to allow the ACOs to have flexibility in selecting appropriate members. For this reason, no change will be made.

25. COMMENT: N.J.A.C. 10:79A-1.5(c)3ii(1) contains criteria concerning membership in the governing board. Since N.J.A.C. 10:79A-1.1 included physicians in the definition of behavioral health care providers, it would be possible to convene a governing board in which behavioral health care is represented exclusively by physicians. The discrimination

between physicians and behavioral health care providers in this section implies a preference for including both physicians and other professions meeting the definition for behavioral health care providers in the governance structure. The commenter would recommend either removing physicians from the definition of a “behavioral healthcare provider” in N.J.A.C. 10:79A-1.1, or referring instead to “other behavioral health care providers in addition to physicians” in this section.

RESPONSE: The Department believes that the current wording accurately reflects the intended policy, which would leave the ACOs flexibility in addressing the issue raised by the commenter. For this reason, no change will be made.

26. COMMENT: At N.J.A.C. 10:79A-1.5(c)4, which addresses the required contents of letters of support, the proposed regulations require that the letter of “support” bind the supporters to actually participate in the ACO. Specifically, it requires: “(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 ...; and (4) The provider’s commitment to share patient medical information with participating ACO members ...”

The proposed rule goes beyond the Act. The Act states that “the applicant has support of its application by: all of the general hospitals located in the designated area served by the ACO; no fewer than 75 percent of the qualified primary care providers located in the designated area; and at least four qualified behavioral health care providers located in the designated area.” N.J.S.A. 30:4D-8.4.c(3). The Act also states that “(t)he

gainsharing plan shall include a letter of support from all participating hospitals in order to be accepted by the department.” N.J.S.A. 30:4D-8.5.h.

The Act uses the words, “support” and “participate,” in two distinct ways. There is a vast difference between giving one’s “support” to an application and agreeing to “participate” in the ACO and gainsharing plan. The Act requires the ACO to have the support of its application by 100 percent of the hospitals in the designated area. The Act requires the ACO’s gainsharing plan to include a letter of support from all participating hospitals in the ACO. The Act does not include the requirement set forth in this section, that every hospital that supports the ACO application must also participate in the ACO.

The Department should not add this new requirement, which ignores the distinct terms used in the Act. This requirement will limit the ability of communities to form ACOs because not every hospital in the communities that are interested in becoming Medicaid ACOs is willing to participate in such an ACO. The proposed regulation at N.J.A.C. 10:79A-1.5(c)4 should distinguish between an indication of “support” and the more detailed requirements of what all participating providers must agree to as set forth in this regulatory section. The commenter suggests that the relevant section be revised as follows:

“The ACO must document the required support for the application by including letters of support from all entities listed in (c)5i above. In addition, for all providers participating in the ACO, the ACO must include a document signed by an individual with legal authority to bind the provider, which shall contain the following ...”

RESPONSE: The Department disagrees with the conclusion reached by the commenter regarding the intent of the Act. N.J.S.A. 30:4D–8.3 specifically refers to

ACOs being organized "... with the voluntary support and participation of local general hospitals, clinics, pharmacies, health centers, qualified primary care and behavioral health care providers, and public health and social services agencies ...” For this reason, the Department believes that the rules as proposed accurately embody the intent of the Act with regard to this issue and no changes will be made.

27. COMMENT: At N.J.A.C. 10:79A-1.5(c)4i(2), the commenter requests that the word “qualified” be added in front of “provider.” If the regulations were adopted as proposed, the ACO must obtain the support of “... at least 75 percent of the primary care providers located in the designated area ...” The requirement should be “at least 75 percent of the qualified primary care providers ...” See N.J.S.A. 30:4D-8.4.c(3).

RESPONSE: The Department agrees with the commenter and, in order to clarify the existing language, will make the suggested revision upon adoption.

28. COMMENT: At N.J.A.C. 10:79A-1.5(c)4i(3), the inclusion of physicians in the definition of behavioral health care providers in N.J.A.C. 10:79A-1.1 renders this section unclear as to whether other professions besides medicine are required in the mix of qualified behavioral health care providers. The commenter believes this is the intention, to ensure a mix of treatment options, but if so, the section needs revision.

RESPONSE: The Department believes that the current wording accurately reflects the intended policy, which would leave the ACOs with flexibility in addressing the appropriate types of qualified behavioral health care providers that will be utilized by the ACOs. For this reason, no change will be made.

29. COMMENT: At N.J.A.C. 10:79A-1.5(c)4ii, which addresses requirements for letters of support from entities and providers, a new N.J.A.C. 10:79A-1.5(c)4ii(8) should be added, which would require such letters to contain "the provider's commitment to cooperate with and participate in the annual evaluation."

RESPONSE: The Department agrees with the comment and believes that inclusion of the additional statement in the letter of support, and the follow through that would be involved, would not significantly add to the responsibilities inherent in participation in the Medicaid ACO Demonstration Project. Therefore, the Department will add the suggested language upon adoption.

30. COMMENT: At N.J.A.C. 10:79A-1.5(c)5i, ii, and iii, the commenter supports the requirement that each ACO establish a process for engaging members of the community, as well as receiving public comments on its gainsharing plan and on the development of its healthcare goals. In particular, the commenter supports the requirement of N.J.A.C. 10:79A-1.5(c)5i, that each applicant designate "individuals" in leadership to be accountable for community engagement and consumer input. The commenter is hopeful that participating organizations will meet the goals of the Demonstration Project by engaging in community outreach, creating a stronger role for community input and being responsive to the views of its community representatives. The commenter, therefore, supports the language of N.J.A.C. 10:79A-1.5(c)ii and understands this provision to permit board flexibility on how they intend to engage the community. On the other hand, the list included in the regulation is not to be exclusive of other ways in which a board

may achieve an adequate level of transparency and community engagement. At minimum, the regulation should make clear that the Department will require applicants to institutionalize processes for community engagement and participation in goal setting, and merely picking one activity off the list will not be deemed sufficient.

RESPONSE: The Department appreciates the support. However, the Department believes that the ACOs should be given the opportunity to decide which types of engagement will work best in the communities in which they will operate. The Department will not specifically prescribe these standards in the rules. For this reason, no change will be made.

31. COMMENT: At N.J.A.C. 10:79A-1.5(c)6, regarding the ACO having “processes for receiving and distributing gainsharing payments,” we are concerned with the implementation and monitoring of gainsharing plans as savings should not be to the detriment of consumers.

RESPONSE: The Department appreciates the comment. The Department will implement and monitor gainsharing plans and expects that consumers will receive more medically appropriate and intensive primary and preventative care in the hope of reducing the need for emergency room or hospital care.

32. COMMENT: At N.J.A.C. 10:79A-1.5(c)7 and (c)7ii, regarding the application checklist, and the requirement that the ACO must affirm that it will be accountable for the health outcomes, quality, cost, and access to care,” the commenter is particularly concerned that there must be accountability for outcomes. The commenter also supports

compliance with HIPAA and other laws to which the commenter would add Family Educational Rights and Privacy Act (FERPA) for services in educational settings for children. Further, there must be protections in place for patient privacy, which would include issues such as joint custody, guardianship, and minor consent for mental health treatment. Lastly in this paragraph, the commenter would encourage the use of e-prescribing and electronic health records (EHRs) as research indicates that HIT is helping to eliminate medication errors. In the case of EHRs, however, interoperability remains a challenge.

RESPONSE: The Department believes that the provision at N.J.A.C. 10:79A-1.5(c)7ii, which requires the ACO to affirm that it will be accountable for outcomes, adequately addresses the issue of outcomes raised by the commenter. Further, the Department believes that the provision at N.J.A.C. 10:79A-1.5(c)7v, which requires the ACO to affirm that it will comply with all applicable State and Federal laws, rules, and regulations including, but not limited to, laws, rules, and regulations designed to protect Medicaid beneficiaries' ability to access medically necessary care and requirements protecting the privacy and security of protected health information, addresses the issues raised by the commenter addressing those issues of access, privacy, and security regarding medical records. Additionally, the Department believes that the provision at N.J.A.C. 10:79A-1.5(c)7vi, which requires the ACO to affirm that it is committed to using electronic prescribing and electronic medical records, addresses the final issue raised by the commenter. For this reason, no change will be made.

33. COMMENT: At N.J.A.C. 10:79A-1.5(c)9, regarding the language: "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." This paragraph should be clarified by adding the following sentence: "Nothing in this provision is intended to prevent the ACO from contracting with public or private payers for the ACO to provide services to its participating providers."

RESPONSE: The Department believes that adding this specific language requested could encourage anti-competitive results. For this reason, no change will be made.

34. COMMENT: The commenter suggests amending N.J.A.C. 10:79A-1.6 to include a requirement that any savings attributable to ACOs are not retained by MCOs who decline to participate in the ACO. The Department should promulgate a regulation indicating its intent to use its broad contracting powers to require disgorgement of any savings the MCO reaps due to actions taken by the Medicaid ACO. There is significant savings potential in healthcare spending due to reductions in hospitalizations of patients receiving treatment through ACOs. In order to ensure that such savings will be returned to the ACO and the community it serves, the commenter supports a claw back provision requiring any Medicaid MCO to return funds where the Managed Care Organization has experienced savings attributable to an ACO of which the plan is not a member.

RESPONSE: At this time, the Department does not believe that it would be appropriate to adopt a rule establishing, or stating an "intent" to establish, the requested disgorgement provision for non-participating MCOs. The Department will be analyzing

the results of the Demonstration Project both in an ongoing manner during the Demonstration Project and after the Demonstration Project is completed, and will consider any potential action under applicable law in relation to any savings by non-participating MCOs as appropriate and in accordance with the MCO contracts in effect at that time. For this reason, no change will be made.

35. COMMENT: At N.J.A.C. 10:79A-1.6(a)1i(3), which states that criteria to be considered in approving a gainsharing plan shall include whether the plan promotes increased patient medication adherence and use of medication therapy management services, the commenter supports these criteria and would add the use of www.mymedschedule.com, which is a free online tool for consumers with pictures of medications, their uses, a medication schedule, and checklist for filling the pill organizer. The commenter would also advise tracking of when doses change, yet doctors tell patients to split pills or pharmacies change medication strength for the same prescription (for example, half strength so take two). Another issue occurs in-patient with the use of the EPIC system when medications may “time out” (for example, most patients take antibiotics 10 days but transplant patients may need them for a year) and physicians think since they prescribed, it’s being given, and nurses only administer what’s distributed by the in-house pharmacy, and there’s no safety net. In addition, long-term use of certain medications must be monitored to avoid complications (for example, adrenal insufficiency). Lastly, drug interactions must be checked with any new prescription. Many times all of these changes can cause errors in medication compliance, which is the single largest factor in hospital readmissions.

RESPONSE: The Department does not wish to promote or endorse any specific non-State web services. The Department supports innovation to reduce medical errors, and leaves it to the ACOs to address any medication-related issues as part of their implementation of the Demonstration Project. For this reason, no change will be made.

36. COMMENT: At N.J.A.C. 10:79A-1.6(a)1i(4), which states that criteria to be considered in approving a gainsharing plan shall include whether the plan promotes use of health information technology, the commenter supports the use of HIT when done correctly. Providers must check for accuracy in records and medications. There also must be cross-referencing between disciplines, which doesn't happen. For example, if one specialty recommends a medication that could affect another condition or a procedure, which may be contraindicated by another condition.

RESPONSE: The Department supports appropriate use of HIT and inter-disciplinary communications to reduce medical errors, and expects the ACOs to address any such issues as part of their implementation of the Demonstration Project. For this reason, no change will be made.

37. COMMENT: At N.J.A.C. 10:79A-1.6(a)1i(5), which states that criteria to be considered in approving a gainsharing plan shall include whether the plan promotes use of open access scheduling, the commenter supports the use of same-day scheduling when necessary but would recommend monitoring unintended consequences, such as wait times or if urgent care cases are seen in a timely manner.

RESPONSE: The Department appreciates the comment and the support of this quality metric. Additionally, the Department notes that the timeliness of care, appointments, and information is a patient satisfaction measure, which ACOs will be monitoring. For this reason, no change will be made.

38. COMMENT: At N.J.A.C. 10:79A-1.6(a)1ii, which states that criteria to be considered in approving a gainsharing plan include whether it encourages family health education and health promotion, home-based services, telephonic communication, group care, and culturally and linguistically appropriate care, the commenter supports patient and family centered care, which includes education and wellness initiatives. The commenter supports shared-decision making such as those found at www.healthdialog.com. For children, the commenter supports the Bright Futures wellness and prevention initiatives endorsed by the American Academy of Pediatrics (AAP) at <http://brightfutures.aap.org>. The commenter supports the use of telemedicine if done appropriately. The commenter hesitates supporting group care for the reasons that there may be a range of symptoms even within the same condition and HIPAA privacy concerns. Lastly, the commenter supports cultural and linguistic competence and recommends monitoring health disparities in underserved populations.

RESPONSE: Group care is an evidence-based therapy that may be an appropriate treatment option in specific cases. The Department would like to leave this option open in order to provide clinical flexibility to health care professionals. Regarding the information contained on the website noted, the Department does not wish to promote any specific

non-State web services as is suggested by the commenter. For these reasons, no change will be made. The Department appreciates the support of the commenter.

39. COMMENT: At N.J.A.C. 10:79A-1.6(a)1iv, the inclusion of physicians in the definition of behavioral health care providers in N.J.A.C. 10:79A-1.1 means this section should refer to “non-physician behavioral health providers.”

RESPONSE: It was not the Department’s intent to limit the reference to include only non-physician behavioral health providers. For this reason, no change will be made.

40. COMMENT: At N.J.A.C. 10:79A-1.6(d)1, which requires that a gain sharing plan explain how objectives will be achieved and lists important care approaches and techniques to be included in a gainsharing plan, the commenter agrees that the gainsharing plan should include the listed care approaches and techniques. The commenter’s only concern would be allowing out-of-network exceptions as needed if care isn’t available in the ACO, as the commenter has heard of many instances of network inadequacy for primary providers, therapists, specialists, dental care, and durable medical equipment.

RESPONSE: The Department notes that beneficiaries are not limited to receiving services through an ACO. For this reason, no change will be made.

41. COMMENT: At N.J.A.C. 10:79A-1.6(d)3, which addresses quality standards and reporting requirements for the gainsharing plan, the regulations require that the ACO shall use the quality measures determined or approved by the Department to measure its

health and quality outcomes, but the regulations do not address issues relating to data access and do not provide a process by which ACOs can request required data, as well as relevant public health data from the State or the MCOs. Much of the data needed to comply with the proposed regulations is outside the ACOs' control. In order to fulfill their reporting requirements and to track their own progress and improve the care delivery, the ACOs will need timely access to this data. Under Commercial and Medicare ACO pilots/contracts the insurers or Federal government (Center for Medicare and Medicaid Services (CMS)) provide claims data and other information at least quarterly (and sometimes daily) in order to enable the ACOs to track and improve their performance and engage patients and caregivers. Data that can support the ACOs efforts is held by the State and is not easily accessible to the ACOs, such as birth and death records, and other population/public health data sets. The rules should include a process by which ACOs can easily and expeditiously request health data relating to their covered population. The following three additions should be made to the regulations to provide more flexibility for the ACOs. The third option is the way claims-based quality measures are handled in the CMS Shared Savings Program and would be very helpful to the ACOs.

First suggestion: "An ACO may request in writing an exception to its data reporting requirements if, after reasonable efforts, it is unable to obtain complete and/or accurate data from the State, MCO, or other data source that is not a participant in the ACO. The ACO may either request an extension of time to complete its data reporting requirements or an exemption from the data reporting requirements based upon the unavailability of complete and/or accurate data. The ACO's exception request must include a detailed account of the efforts it made to acquire the required data and the reason(s) the data is

not available, complete and/or accurate. The Department will review and analyze the ACO's exemption request. The Department has the authority to extend the ACO's reporting deadline or to exempt the ACO from reporting requirements when the data is not available, complete and/or accurate."

Second suggestion: "An ACO may make HIPAA-compliant data requests to the Department and the Department of Health to support the Demonstration Project. The ACO's request must include an explanation of how the requested data will support the ACO's effort to improve health outcomes, quality, access and reduce costs. The Department and the Department of Health will review and analyze the ACO's data request and provide the requested data subject to any State or Federal privacy laws. If the ACO seeks to use requested data for published research a local IRB should be designated and be the delegated IRB of record."

Third suggestion: "For all Quality Metrics which are claims-based measures, the ACOs do not need to be involved in the data collection. The Department will obtain the necessary claims and then calculate the rates for these measures for the ACO."

42. COMMENT: The proposed rules state that the ACO shall use the quality measures determined or approved by the Department to measure its health and quality income. This assumes that the ACO will have access to all needed data from either the State or the MCOs. Much of the data needed may be outside the control of the ACO. What provisions will be made to assure that the ACOs will have timely access to data sources? Without good quality data, meaningful measurement of progress made will be worthless. Will data sources be made available for all quality measures and how often?

RESPONSE TO COMMENTS 41 AND 42: The Department believes that data requests from ACOs may be appropriate in specific limited circumstances and it will review such requests individually. The Department will not revise the proposed rules as requested in the first and second suggestions because rules would not be required in order for the Department to provide data when it believes that such action would be appropriate. The Department disagrees that the Demonstration Project would or should operate as described in the third suggestion, which contemplates that the State would provide the ACOs with the data to calculate their outcome rates. The Department does not intend to provide the ACOs with all of the claims-based outcome metrics. The Department believes this is counter to the organization's commitment to become "accountable" for health outcomes, quality, cost, and access to care and believes that ACOs should have the ability to collect their own data.. For these reasons, no change will be made.

43. COMMENT: At N.J.A.C. 10:79A-1.6(d)3i(2), the ACO should be required to select at least one to two quality performance measures that directly relate to issues of behavioral health care, such as substance abuse, depression, or anxiety. This would be consistent with current National Commission for Quality Assurance recognition requirements for patient-centered medical homes. It would also ensure a focus on addressing behavioral health issues that directly impact on health and social functioning.

RESPONSE: Several necessary quality metrics that ACOs will be using relate directly to behavioral health issues, including depression screening and medication monitoring,

as well as alcohol and substance abuse treatment. For this reason, no change will be made.

44. COMMENT: At N.J.A.C. 10:79A-1.6(d)4, which requires that the gainsharing plan must explain how patient experience findings regarding the promotion of improved health outcomes will be collected, analyzed and acted upon, including the type of tools that will be used, and which states that an appropriate tool could be the “Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey or similar survey instruments,” the commenter supports the use of the CAHPS survey if it includes not just the basic questions, but states optional questions, developed with public input.

RESPONSE: The Department’s use of the CAHPS survey is updated each year with supplemental questions that are incorporated with input from the Medical Assistance Advisory Council. The Department appreciates the commenter’s support.

45. COMMENT: At N.J.A.C. 10:79A-1.6(d)5, the commenter agrees that analyzing patient and consumer feedback is the best mechanism to detect and remediate improper limitations in care and agrees with the process for complaints. The commenter would add that health literacy must be considered in the development of a “clear and easy way to make complaints.” The commenter would add to this linguistic competency, such as the use of language lines and accessibility for people with disabilities (for example, large print, screen readers, etc.).

RESPONSE: The Department agrees that ACOs should consider this factor. Under the Demonstration Project, the ACOs are allowed flexibility in determining an appropriate way to address this issue.

46. COMMENT: At N.J.A.C. 10:79A-1.6(d)7, regarding shared savings and reducing the amount of unnecessary and inefficient care that is provided to Medicaid beneficiaries, the commenter encourages eliminating inefficiencies, but wants to ensure this does not result in denials of care. Care management should not result in denial of care. Also, there is no mechanism to share earnings with consumers, which could be used in incentive programs. The commenter is concerned that ACOs and MCOs may have a vested interest in denying care to boost savings.

RESPONSE: The Department believes that higher quality health care will be the result of necessary decisions regarding medical care appropriateness. Health care quality will be monitored by the Department. While there are no financial savings benefits for consumers, the Department expects that the consumers will primarily benefit in the receipt of better coordinated quality health care. While some denials may be appropriate, care management should not lead to unnecessary or inappropriate denials.

47. COMMENT: N.J.A.C. 10:79A-1.6(d)7ii, which addresses requirements for gainsharing plans, states that "An ACO may pursue shared savings in phases. For example, an ACO may focus on shared savings in a specific spending area, such as diabetes treatment ..." Would savings calculations for phased projects be based only on the targeted population (for example, all diabetics in the designated area) or on the full

Medicaid population in the designated area? The savings calculation should be based only on the targeted population for ACOs electing a phased approach. Further, if the savings calculation is to be based only on the targeted population, then calculations should be based on a clearly defined target population of sufficient size to yield statistically stable measurement of cost and quality. The applicants would have to provide estimates of the size and specific clinical inclusion criteria for their phased target population in the form of ICD-9 diagnosis codes because, without such information, it will not be possible to identify the target population for the purpose of shared savings calculations.

RESPONSE: The Department agrees that the savings calculation would have to be based only on the targeted population for ACOs electing a phased approach, that the gainsharing applicants would have to clearly define a target population of sufficient size to yield statistically stable measurement of cost and quality, and that the applicants would have to provide estimates of the size and specific clinical inclusion criteria for their phased target population in the form of the ICD diagnosis codes in effect at the time.

48. COMMENT: At N.J.A.C. 10:79A-1.6(d)7iii(4), given the inclusion of physicians in the definition of behavioral health care providers in N.J.A.C. 10:79A-1.1, the commenter would recommend this point focus on expanding behavioral health services other than medicine.

RESPONSE: The Department believes that the proposed wording accurately reflects the intended policy, which would leave the ACOs with flexibility in addressing the issue

raised by the commenter. Behavioral health services remain an option for the focus mentioned by the commenter. For this reason, no change will be made.

49. COMMENT: At N.J.A.C. 10:70A-1.6(d)7iv, regarding the language: "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)," it would be in the best interest of the Demonstration Project for the Department to use its contracting authority to require Medicaid managed care organizations to participate in any certified ACOs.

RESPONSE: The Department will be analyzing the results of the Demonstration Project both in an ongoing manner during the Demonstration Project and after the Demonstration Project is completed, and will consider any potential action under applicable law in relation to any savings by non-participating MCOs as appropriate and in accordance with the MCO contracts in effect at that time. For this reason, no change will be made.

50. COMMENT: At N.J.A.C. 10:79A-1.6(d)8ii(1), the commenter understands that the "gainsharing plan must explain how cost savings will be calculated, using a methodology which utilizes a calculation of "expenditures per recipient by the Medicaid fee-for-service program," and which provides that "benchmark period expenditures may be adjusted for characteristics of recipients and local conditions that predict future Medicaid spending ...". The commenter would like clarification on possible adjustments based on "characteristics"

of patients (for example, disability) and “local conditions” (for example, discrimination of urban areas).

RESPONSE: Some examples of characteristics of populations are eligibility for Medicaid due to income requirements or eligibility because of age, blindness, disability, or specific diagnosis, for example, end stage renal disease. An example of a local condition that may warrant an adjustment, could be a shortage of a specific category or categories of medical providers.

51. COMMENT: At N.J.A.C. 10:79A-1.6(d)8ii(1)(A), the commenter understands that “all risk adjustments ... must be clearly documented in the ACO’s gainsharing plan” but would like clarification on the implications of this.

RESPONSE: Failure to make such adjustments would put the State at risk of sharing gains that are not real and put the ACOs at risk of not sharing in real savings that are not documented because of change in case mix.

52. COMMENT: N.J.A.C. 10:79A-1.6(d)8 and its subparagraphs require ACO gainsharing plans to explain how cost savings will be calculated. N.J.A.C. 10:79A-1.6(d)8ii(1) reads, "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." (emphasis added) The statute requires that adjustments for changes in patient case mix be conducted. Thus, the word "may" in this subparagraph is not appropriate. Failure to make such adjustments would put the State at risk of sharing gains that are not real and

put the ACOs at risk of not sharing in real savings that are not documented because of change in case mix. The above language should therefore read: "The basic benchmark period expenditures must account for changes in patient case mix and may adjust for other factors that affect Medicaid spending in ways that are unrelated to ACO activity."

RESPONSE: The Department appreciates the comment and believes that the statute, at N.J.S.A. 30:4D-8.5.c(1), does require that the basic benchmark period expenditures be subject to adjustment 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. There may also be a need to adjust for other factors that affect Medicaid spending in ways that are unrelated to ACO activity. Therefore, in response to the comment, a revision will be made in order to clarify the originally proposed language. The language at N.J.A.C. 10:79A-1.6(d)8ii(1) will be changed as follows (additions to proposal in bold; deletions from proposal in brackets): "The basic benchmark period expenditures [may] **shall** 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, **and may be adjusted for other factors that affect Medicaid spending in ways that are unrelated to ACO activity.**"

53. COMMENT: The commenter recommends adding new N.J.A.C. 10:79A-1.6(d)8iii stating: "ACO gainsharing applicants should consult the Recommended Approach for Calculating Savings in the NJ Medicaid ACO Demonstration Project by the Rutgers Center for State Health Policy in preparation of their savings calculation plan."

RESPONSE: The recommended language would not be regulatory and, therefore, will not be added . However, the Department notes that it believes that such an approach would be advisable.

54. COMMENT: At N.J.A.C. 10:79A-1.6(d)9 and 10, regarding public comment on the gainsharing plan, the commenter supports transparency and public comment, with inclusion of health literacy, cultural/linguistic competency, and accessibility for those with disabilities.

RESPONSE: The Department agrees that ACOs should consider these factors. Under the Demonstration Project, the ACOs are allowed flexibility in determining appropriate ways to address these issues.

55. COMMENT: At N.J.A.C. 10:79A-1.7(b), clarification is requested regarding the portion of the law that states that 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 ...”

RESPONSE: The exceptions to what constitutes a “government record” are contained within the Open Public Records Act, at N.J.S.A. 47:1A-1.1, definition of “government record.” The Department will be following the law in its determination of any exceptions regarding commercial rate data provided pursuant to N.J.A.C. 10:79A-1.7(c)8.

56. COMMENT: At N.J.A.C. 10:79A-1.7(d)1, the commenter generally supports the reporting requirements for ACO gainsharing plans. However, the commenter is

concerned with the feasibility of soliciting meaningful community participation and/or consumer comments in the 30-day period provided. Use of local publications and media will be required to effectively spread awareness of a plan's publication on the Department's website and, particularly given limited resources likely to be available to promote such efforts, time will be an important element in ensuring that individuals are given the opportunity to review and comment. The 30 days provided are insufficient to meet the goals of community engagement and accountability, and it should be changed to 45 days.

RESPONSE: The Department believes that the comment is reasonable and, in response to the comment, is changing the comment period to 45 days in the adoption.

57. COMMENT: N.J.A.C. 10:79A-1.8(c) requires ACOs to execute HIPAA-required business associate agreements with their providers, as needed. It would strengthen the ability of the Department to carry out its statutory duties to add language to require the ACOs to execute HIPAA-compliant data use agreements for sharing of patient-level data with the Rutgers Center for State Health Policy, for use in the annual evaluation of the Demonstration Project. The patient-level data should enable an evaluation of patient care utilization over time without providing direct patient identifiers.

RESPONSE: The Department agrees and has added the recommended language as new N.J.A.C. 10:79A-1.8(d), as modified to use the term "protected health information" instead of the term "patient-level data" for the reasons discussed in the Response to Comment 8 above.

58. COMMENT: Regarding the quality metrics to be used by ACOs, one commenter expressed concern about the ability to capture mandatory quality measures. Many of the measures can be captured through claims data, which the ACOs may not have but which the Department will have access to. The commenter urged the Department to work with the ACOs to streamline the process of capturing and sharing this data. In addition, the commenter stated that ACOs are hopeful that the MCOs will participate in the Demonstration Project and that, therefore, it hoped that the Department will only use the existing quality metrics as an example of acceptable measures and leave the measures to be set in the gainsharing plan and contracts between the ACOs and MCOs. If quality measures need to be set at this time, they should be made closer to what CMS is using in the Shared Saving Plan. Regarding CAHPS metrics, which include standard and non-standard measures, the commenter suggested that the Department choose three standard measures (which have multiple components in each measure) from the list of clinician-group surveys at the website: (www.cahps.ahrq.gov/clinician-group/cgsurvey/patientexperience). Finally, the commenter stated that it is unclear how the cost of administering the CAHPS surveys will be paid, and suggested that this should be funded through the Medicaid program.

RESPONSE: The issue of access to data is outside of the scope of the proposed rules. The Department is currently reviewing the metrics to determine which will be provided to the ACOs. The Department believes that the CAHPS metrics that will be used are an appropriate measure of patient satisfaction. Additionally, several of the CAHPS measures include standard measures. Therefore, no change will be made in response to that portion of the comment. Finally, the Act authorizing the Demonstration

Project did not provide funding to support the elements of the Demonstration Project. ACOs may use a portion of their savings to fund the activities mentioned, which are a part of the ACO Demonstration Project. For all of these reasons, no change will be made.

59. COMMENT: The commenter's understanding of the Demonstration Project was that the State wanted to see appropriately managed care, and not necessarily more care. Perhaps wording that discusses the Triple Aim would be better than saying more care is needed. The IHI Triple Aim is a framework developed by the Institute for Healthcare Improvement that describes an approach to optimizing health system performance. It is IHI's belief that new designs must be developed to simultaneously accomplish three critical objectives, which is called, the "Triple Aim:" improve the health of the population; enhance the patient experience of care (including quality, access, and reliability); and reduce, or at least control, the per capita cost of care.

RESPONSE: The Department agrees that the goal of the Demonstration Project is to encourage appropriate care, not necessarily more care. While the Department encourages the objectives of improving population health, controlling health care costs, and improving quality, access, and reliability of care, the Department prefers not to mandate the specific framework referenced in the comment, in order to allow ACOs flexibility in addressing these issues during the Demonstration Project. For this reason, no change will be made.

60. COMMENT: The commenter submits many letters of support during the year, none of those letters bind the commenter to being involved in a particular project. However, a

legally binding participation agreement is vastly different from a letter of support. At that point, there are certain expectations that the commenter's organization must meet. The Legislature used the words, "support" and "participate" in two distinct ways and the proposed rules must give meaning to those different terms in the Act. There is a vast difference between giving one's "support" to an application and agreeing to "participate" in the ACO.

RESPONSE: The Department disagrees with the conclusion reached by the commenter regarding the intent of the Act. N.J.S.A. 30:4D-8.3 specifically refers to ACOs being organized "... with the voluntary support and participation of local general hospitals, clinics, pharmacies, health centers, qualified primary care and behavioral health care providers, and public health and social services agencies ...". Both support and participation are required. For this reason, the Department believes that the rules as proposed accurately embody the intent of the Act with regard to this issue and no changes will be made.

61. COMMENT: The commenter notes the use of medical homes language. Many Federally Qualified Health Centers (FQHCs) already accredited by either the National Committee for Quality Assurance (NCQA) or the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) as a medical home. There are certain measures and standards that must be met before one can call themselves a true medical home. The ACO should have standards that must be adhered to in terms of medical home qualifications. Just loosely saying that the gain sharing plan promotes "expansion of the

medical home model and chronic care models” is not sufficient. The commenter would like the rules to read medical home model as defined by either NCQA or JCAHO.

RESPONSE: In order to maintain flexibility in the ACO program, the Department will not prescribe a specific required accreditation as suggested by the commenter. The Department’s goal is to expand the medical home model, not to prescribe the specific accrediting agency. For this reason, no change will be made.

62. COMMENT: The proposed rules state that the ACO must engage with the public. What is the definition of engagement? Should more extensive guidelines be developed? If the governing board sends out a yearly notice of a public hearing, does this satisfy the engagement requirement? What are the expectations? As you know, FQHCs must have 51 percent consumer/user board representation. Although the commenter is not calling for this percentage of consumer representation, it might be worthwhile to look at the FQHC-board requirements as a best practice for obtaining and maintaining consumer board members.

RESPONSE: The Department would like to provide the ACOs with flexibility in their determination of the appropriate means of engagement with the community, rather than being overly prescriptive regarding such means of engagement. For this reason, no change will be made.

63. COMMENT: Regarding quality measures, an important reason to align quality measures with existing/standard measures is to leverage existing data collection

processes in order to enhance the statistical validity of the Demonstration Project quality measures. Furthermore, it is essential that the CAHPS survey be available in Spanish.

RESPONSE: The Department agrees that it is important to align quality measures with existing/standard measure. The Department believes that the metrics that have been set accomplish this. Additionally, the Department notes that CAHPS is available in Spanish.

64. COMMENT: Behavioral healthcare providers must have an active role in the governance structure of ACOs because their services will result in the most significant savings. These services address mental illnesses, addictions, and co-occurring physical illnesses through supports that ensure individuals receive and adhere to needed treatment for all health conditions. Behavioral healthcare providers should receive proportionate gainsharing percentages of the savings they help to achieve.

RESPONSE: In order to maintain flexibility in the Demonstration Project, the Department will not prescribe the specific gainsharing or governance structure suggested by the commenter. For this reason, no change will be made.

65. COMMENT: The regulations should state that savings achieved must be shared only among the providers participating in an ACO, not with any entities that are external to an ACO. This would ensure that savings are reinvested into serving patients and achieving more positive health outcomes and associated savings.

RESPONSE: The gainsharing plan must be approved by the Department. The Department would not approve a gainsharing plan wherein savings are distributed to

entities that are non-participating and external to the ACO, because such distributions would not be in accordance with the requirements throughout N.J.A.C. 10:79A-1.6. For this reason, no change will be made.

66. COMMENT: The Department should include quality measures to increase beneficiary outcomes in which pharmacists can play a vital role. Healthcare outcomes should be based on measures for medication reconciliation, hospital readmissions, and immunizations. Measures related to MTM should be included to evaluate the success of the ACO. In order to accurately gauge the effectiveness of an MTM program the Department should also include proven metrics for assessing MTM and medication adherence programs. Examples of quality performance measures related to MTM include measuring the percentage of MTM-eligible members who received a comprehensive medication review, percentage of older adults who received an MTM intervention who discontinued the use of a high-risk medication, MTM interventions for persons with diabetes, medication therapy for persons with asthma, and assessments of gaps in MTM.

RESPONSE: The commenter believes that medication reconciliation, hospital readmissions, and immunizations should be included as important quality measures in the gainsharing plan to determine the contributions of pharmacists to increased beneficiary outcomes. The Department anticipates that these recognized and credible cost-saving measures may be used in the gainsharing plan to determine the extent to which MTM services, in combination with other cost-saving measures, contribute to the overall savings resulting from an ACO arrangement. It is an ACO's responsibility to

determine how an MTM and prescription network will provide access for beneficiaries to the extent needed to meet the goals of the demonstration project. In addition, depending on how an ACO's plan is developed, MTM services may be provided in settings other than a retail pharmacy, such as clinic settings. For this reason, no change will be made.

67. COMMENT: The Department should require that a primary care physician, or appropriate specialist, be a member and leader of each of the “multi-disciplinary team to coordinate patient care.”

RESPONSE: The Department notes that the primary care physician should be an active participant in a multi-disciplinary team that addresses a patient's care. However, it believes that ACOs will adhere to this approach based upon professional practice norms and so, no revision to the proposed rule requiring this will be made. If the Department becomes aware that ACOs are not acting in accordance with this understanding, the Department will propose an amendment to the rules addressing the issue.

68. COMMENT: MCO participation in the Medicaid ACO may have the unintended consequence of underestimating ACO costs. The proposed rules do not contain mechanisms to control access, such as pre-certification or other processes to deny care. However, managed MCO contracts do contain such cost controlling mechanisms. If MCO participating providers render services that are required by the ACO, but not reimbursed under the MCO contract, patients may receive services that bolster good health outcomes, but for which no payment is made (or cost incurred to either the ACO or the

MCO). This may underestimate actual costs. The Department should address this concern or clarify how costs will not be underestimated.

RESPONSE: This commenter is addressing subject matter that should be addressed in the contract between the ACO and MCO. The contract is the business agreement between the two entities and the Department will not enter into contract arrangements between the entities. For this reason, no change will be made.

69. COMMENT: Patients/consumers' feedback is an important source to evaluate access to care and whether care has been limited. However, patient satisfaction survey results are often subjective. This data must be analyzed by clinicians to determine whether the feedback is substantive on the issues of access and limits of care. Clinicians must factor out dissatisfaction that is not linked to an appropriate standard of care or clinical outcome. The Department should require that the quality committee analyze patient satisfaction surveys.

RESPONSE: The Department expects that the quality committee or medical director of each ACO will review and analyze patient satisfaction surveys. This is the reason that the CAHPS surveys are included in the quality metrics. The Department does not believe that the rule needs to be revised in order for this to be made more clear. For this reason, no change will be made.

70. COMMENT: Given that New Jersey pays physicians among the lowest Medicaid fees in the Nation, but has one of the highest costs to practice medicine, the Department should specify that ACO shared savings may be used: to reward physician performance

that results in improved healthcare outcomes; and to foster and fund coordination of care activities.

RESPONSE: N.J.A.C. 10:79A-1.6(d)7i already includes that 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. Additionally, at N.J.A.C. 10:79A-1.6(d)7v, numerous other provisions provide for distribution of savings for participating ACO members. Therefore, the Department believes that this issue has been addressed in the rules. For this reason, no change will be made.

71. COMMENT: The proposed new rules offer flexibility in regards to gainsharing methodologies and quality outcomes. The rules allow ACOs to develop a gainsharing plan that compliments the Medicaid patients in a defined geography. The rules also allow unique quality benchmarks that are meaningful to the patient population being served and allow for more appropriate care and true savings. The rules emphasize the importance of clinical and behavioral health integration. Aligning the physical and mental needs of an individual will create better quality outcomes, financial incentives, and other program benefits. Similarly, the integration of end-of-life care is a key element in care delivery. Prioritizing care at the end of life can have a dramatic impact not only on savings, but on the overall quality of care delivered. However, without legislative or regulatory action to address the real underpinning of this issue, this will be difficult to achieve. Removing barriers, such as Medicaid enrollment for socially isolated patients and medical futility can help providers operate seamlessly in the continuity of care.

RESPONSE: The Department appreciates the issues raised by the commenter offering support for the new rules. The new rules establish a Medicaid ACO Demonstration Project and, as the commenter notes, do not attempt to resolve through the new rules the underpinnings of a larger perceived issue raised by the commenter. That issue raised by the commenter goes beyond the scope of the Department's proposed new rules. For this reason, no change will be made.

72. COMMENT: In order to maintain access for services, particularly with the presence of religious entities as providers in many ACO collaborations, the commenter requests language stating that the ACO shall certify that it has the capacity to provide all Medicaid-covered services. If any ACO participant has a religious objection to providing a specific service, such objection shall not prevent or interfere with other participants in the ACO providing the service.

RESPONSE: The Department believes that access to services required under existing laws and rules is already provided for under those laws and rules and the proposed new rules. Beneficiaries have the right to seek treatment outside of the Accountable Care Organization, should they so choose. For this reason, no changes will be made.

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 adopted new rules.

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

Full text of the adopted new rules follows (additions to proposal indicated in boldface with asterisks ***thus***; deletions from proposal indicated in brackets with asterisks *[thus]*):

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:

...

“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 ***/or*** substance use disorder) services to New Jersey residents ***with mental illnesses, substance use, or co-occurring disorders***. ***[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.]***

...

[“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.]

...

*****“Protected health information” has the same meaning as set forth at 45 CFR 160.103.***

...

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

(a) (No change from proposal.)

(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.-3. (No change from proposal.)

4. The certification application must be submitted to the Department by *[(60 days after the effective date of this chapter)]* ***July 7, 2014***.

(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.-2. (No change from proposal.)

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) (No change from proposal.)

(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*; **a quality committee must include the ACO's medical director, primary care physicians, and at least one physician who specializes in chronic diseases***.

(C) (No change from proposal.)

(2) (No change from proposal.)

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;* **specifically, the governing board must include at least one primary care physician and also include representation from other physician specialties;***

(2)-(4) (No change from proposal.)

iii. (No change from proposal.)

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) (No change from proposal.)

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

(3) (No change from proposal.)

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)-(5) (No change from proposal.)

(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 policy¹******; **and***

(8) The provider's commitment to cooperate with and participate in the annual evaluation.

5.-10. (No change from proposal.)

(d)-(e) (No change from proposal.)

10:79A-1.6 Gainsharing plan submission and review

(a)-(c) (No change from proposal.)

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

1.-7. (No change from proposal.)

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

i. (No change from proposal.)

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]* ***shall*** 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 ***and for other factors that affect Medicaid spending in ways that are unrelated to ACO activity***. 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) (No change from proposal.)

(2) (No change from proposal.)

iii. (No change from proposal.)

9.-10. (No change from proposal.)

(e)-(f) (No change from proposal.)

10:79A-1.7 Annual ACO reporting requirements

(a)-(c) (No change from proposal.)

(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]* *45* days.

i. (No change from proposal.)

2.-6. (No change from proposal.)

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

(a)-(b) (No change from proposal.)

(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]* ***protected health information***. 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.

***(d) Certified ACOs shall, upon direction from the Department, execute HIPAA-compliant data use agreements for sharing of protected health information with the Rutgers Center for State Health Policy, for use in the annual evaluation of the**

Demonstration Project. The protected health information shall enable an evaluation of patient care utilization over time without providing direct patient identifiers.*