July 8, 2013

James M. Murphy
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Submitted via email and fax to James.M.Murphy@dhs.state.nj.us
RE: Comments on Proposal Number PRN 2013-054; Proposed New Rules N.J.A.C. 10:79A; 45 N.J.R. 1080(a): proposed rules for Medicaid Accountable Care Organization Demonstration Project.

Dear Mr. Murphy:

We submit the comments sets forth herein on behalf of the Affiliated Accountable Care Organizations ("AACO"), an initiative of the New Jersey Health Care Quality Institute ("Quality Institute"). The AACO's membership includes the Camden Coalition of Healthcare Providers, the Trenton Health Team, and the Greater Newark Healthcare Coalition (hereinafter referred to as "Health Care Coalitions").

The Quality Institute is a non-profit membership organization whose purpose is to undertake projects that will ensure that safety, quality, accountability and cost containment are all closely linked to the delivery of health care services in New Jersey. The Quality Institute fosters collaboration amongst all stakeholders in the State's health care delivery system so that purchasers and health care consumers more fully realize the benefits of the linkage between quality, accountability and cost containment. The AACO is a learning and resource network for Accountable Care Organizations ("ACOs"), particularly those focused on the Medicaid population.

The Quality Institute supported the enactment of the Medicaid Accountable Care Organization Demonstration Project (the "Act") and sees great promise in the Health Care Coalitions' current activities to improve access to care and the health of their communities. The Department, the Health Care Coalitions, the Medicaid Managed Care Organizations ("MCOs") and the entire Medicaid eligible population will each, in its own way, experience great change due to the

Comprehensive Waiver and the expansion of Medicaid eligibility. The management of the Medicaid program and of the Demonstration Project under this Act is going to be challenging for both the Department and the ACOs in the face of so much external change. Therefore, being flexible to various models and open to collaboration with the ACOs and the MCOs will be crucial to the success of the Demonstration Project. We offer these comments in the spirit of collaboration and with an eye towards flexibility. We look forward to working with the Department and doing whatever we can to assist the Department in making the Demonstration Project a success for potential Medicaid ACOs and their communities across New Jersey.

1. Under 10:79A-1.1, Definitions:

   For the definition of "Demonstration Project Year" we suggest that you change from it "an annual 12-month period specified …" to "a 12 month period as described in the Gainsharing plan".

   We suggest this change because the phrase "an annual 12-month period" is confusing and could lead to an interpretation that a Gainsharing plan must be tied to a January to December schedule. Changing the definition makes it clear that the 12 month period will be defined in each applicant's Gainsharing plan and allows for flexibility in designing a plan.

   For the definition of "patient-level-health data" we suggest that you replace that term with "protected health information" as defined pursuant to 45 C.F.R. 160.103. Use of a HIPAA term will make privacy and security obligations and business associate agreements consistent with the federal law and, thereby, less complicated for the ACOs.

2. Under 10:79A-1.2, Statement of purpose and goals:

   We suggest that a portion of the Statement be modified to make it more consistent with the purpose of the Demonstration Project, which is not to necessarily provide more care, but rather to provide more appropriate care and other social services and community supports. Therefore, we suggest:

   At (b), change to **delete** bracketed words as indicated: "The Demonstration Project encourages [additional] appropriate care [not reduced care] for the most vulnerable beneficiaries; …"

   The ACOs' goal is to provide appropriate care and improved quality and access. Those goals do not mean that there will necessarily be "additional" care. In fact, the ACOs aim to reduce unnecessary emergency room visits and increase primary care and behavioral health care. It is important to emphasize that more care is not necessarily better and in many cases is worse for the patient.

3. Under 10:79A1.5(b)(1), Application process for approval of Medicaid ACOs in the Demonstration Project:

   We are extremely concerned about the 60 day application period restriction created under these rules. The law does not provide that the project would have a limited application window. N.J.S.A. 30:4-D-8.4(a) states that "the department shall accept applications for certification from demonstration applicants beginning 60 days following the effective date of this act …" We read the law to allow for a rolling application and for maximum flexibility for applicants to submit their three year or longer Gainsharing plans within one year of their certification as a Medicaid ACO. See N.J.S.A. 30:4-D-8.4(c)(6) and 8.5(a). A one-time 60-day deadline for participation in the demonstration project will exclude potential participants from the project and, as a result, limit the models that can be tested and the potential of the entire law. In the findings and declarations section of the law, the Senate and General Assembly recognize the potential for the ACO model to improve health outcomes, quality, access and reduce costs. This potential can best be recognized through the participation of as many qualified ACOs as possible. Rather than a one-time, 60-day deadline, the certification application process should allow for applications to be submitted at any time.

   Therefore, we request that this section be revised as follows:

   "The certification application may be submitted to the Department at any time during the demonstration period."

4. Under 10:79A1.5(c)4, Application process for approval of Medicaid ACOs in the Demonstration Project:

   This section addresses the required content of each letter of support. As proposed, the 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 …; (4) The provider's commitment to share patient medical information with participating ACO members …;"

This proposed language 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% 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-8.4c (3) (emphasis added). 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) (emphasis added).
The Legislature used the words, "support" and "participate", in two distinct ways and the Department 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 and gainsharing plan. The Act requires the ACO to have the support of its application by 100% 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 of proposed regulations 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. Moreover, adding this requirement will have a negative impact on the Demonstration Project. The proposed 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. This is a Demonstration Project where different models will emerge. Experimentation should not be limited by the imposition of new regulatory constraints. We suggest that the proposed regulation at 10:79A1.5(c)4 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. We suggest 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 …"

Under this proposed revision, the Department still has the authority to review the application and the Gainsharing plan to make sure that each submission complies with all aspects of the Act and regulations.

In addition, under this section of the proposed regulations, we request that the word "qualified" be added in front of "provider" at 10:79A-1.5 (4) (c)4.i.(2). The word "qualified" seems to be inadvertently omitted. 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 NJSA 30:4D-8.4 (c)(3). We ask that the regulations be consistent with the defined terms in the Act.

5. Gainsharing plan submission and review, 10:79A-1.6:

Regarding quality standards and reporting, 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 ACO's 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, hereinafter referred to as "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. Timely access to usable data is essential to an ACO's success. Therefore, we recommend that the following three additions 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.[1]

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

[1] See http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO-NarrativeMeasures-Specs.pdf

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."

6. Application cover sheet, form and list of Quality Measures:

   The Application Cover Sheet, Application form and List of Quality Metrics were not published in this Notice of Proposed Rulemaking, but were posted on the Department's website. Therefore, we respond to them here to provide suggestions and raise concerns.

   Cover Sheet and Application: As stated above, the application period should not be limited to 60 days but should be an open rolling period throughout the Demonstration Project.

   List of Quality Measures:

   The State is proposing 27 mandatory quality measures. Our members are concerned about their ability to capture these measures. We raised three suggestions above that may assist with some of those concerns. In particular, many of these measures can be captured through claims data. For instance, 9 of the 14 mandatory measures, other than

the 7 CAHPS measures, can be captured through claims data, which the ACOs may not have but which the Department will have access to. We urge the Department to work with the ACOs to streamline the process of capturing and sharing this data for the purpose of improving care.

In addition, the ACOs are hopeful that the MCOs will participate in this Demonstration Project. Therefore, we suggest that the Department not lock into the quality metrics posted on the website, but use those 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 the Department needs to set the quality measures at this time, we suggest that they be made closer to what CMS is using in the Shared Saving Plan.[2] Moreover, the proposed list of CAHPS metrics includes a mix of standard and non-standard measures. We suggest that the Department choose three standard measures (which have multiple components in each measure) from the list of clinician-group surveys at the AHRQ website (www.cahps.ahrq.gov/clinician-group/cgsurvey/patientexperience). Finally, it is unclear how the cost of administering the CAHPS surveys will be paid. We respectfully suggest that this should be funded through the Medicaid program.

The Quality Institute and AACO appreciate your consideration of these comments. The New Jersey Medicaid ACO Demonstration Program holds great promise. We look forward to working with you to make the program a success.

Sincerely,

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Allison DeBlois
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[2] See id.

Affiliated Accountable Care Organizations

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