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Submitted via Electronic Submission

Dr. Don Berwick
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1325-P
P.O. Box 8020
Baltimore, MD 21244-1820

Comments to CMS-1345-P: Medicare Program: Medicare Shared Savings Program: Accountable Care Organizations

Dear Dr. Berwick:

Quincy Medical Group (Quincy) is pleased to provide the following comments in response to the above captioned proposed rule published by the Centers for Medicare and Medicaid Services (CMS) in the *Federal Register* on April 7, 2011.[1]

Quincy is one of the leading multi-specialty group practices in the Midwest. With over 130 physicians and providers practicing in 26 medical and surgical specialties, Quincy provides quality healthcare services to over 250,000 people annually in the tri-state area of Illinois, Missouri and Iowa. Quincy is comprised of approximately 50% primary care providers and 50% specialty providers. All of Quincy's primary care providers practice exclusively in certified Rural Health Clinics (RHCs). In the 50 mile radius around Quincy there are a total of 165 primary care providers of which 136 practice in RHCs. In addition, over 50% of Quincy's business is provided to Medicare and Medicaid patients accounting for over 70,000 annual primary care encounters and total Medicare and Medicaid encounter clinic-wide of nearly 150,000.

Quincy supports the Agency's broader goal of increased innovation in health care delivery under the Medicare Shared Savings Program in section 3022 of the Patient Protection and Affordable Care Act (PPACA). We feel strongly that regulators and providers need to work together to better align payment incentives to achieve the triple aim of better care for individuals, better health for populations, and lower growth in

[1] Medicare Program: Medicare Shared Savings Program: Accountable Care Organizations, *Federal Register*, Vol. 76, No. 67; April 7, 2011. Also referred to as the "ACO NPRM" in this letter of comment.

expenditures. However, the ACO NPRM is not only a step too far but also seemingly off course from Congressional intent.

Of major concern to Quincy is how RHCs are treated in the ACO NPRM – RHCs need to be independently eligible to be ACOs and how beneficiaries would be attributed to RHCs needs to be clarified regardless if RHCs can independently become ACOs. Quincy also seriously questions the financial viability of the two risk models in the proposed regulation and believes few if any potential ACOs will be able to participate financially with low caps on savings and low sharing percentages.

Quincy appreciates the opportunity to specifically comment on provisions in the proposed rule and its potential impact on Quincy. Our more detailed comments pertain to each of the following sections: (I) Eligibility and Governance; (II) Assignment of Medicare Fee-For-Service Beneficiaries; (III) Quality and Other Reporting Requirements; (IV) Shared Savings Determination; (V) Monitoring and Termination of ACOs; and (VI) Coordination with Other Agencies.

I. Eligibility and Governance

Section 3022(b) of PPACA (section 1899(b) of the Social Security Act) provides that the following groups of providers are eligible to form ACOs:

- ACO professionals in group practice arrangements;
- Networks of individual practices of ACO professionals;
- Partnerships or joint venture arrangements between hospitals and ACO professionals; and
- Hospitals employing ACO professionals.

The ACO statute also gives the Secretary the authority to make other providers eligible to form ACOs. Quincy believes that the Secretary should use her discretion to allow and encourage RHCs and FQHCs to participate independently in ACOs, as they typically emulate the type of team based care and help address the physician shortage issues that the broader PPACA attempts to promote. CMS itself discusses the importance of teams in the Preamble to the rule.

A. Eligibility of RHCs and FQHCs

In the ACO NPRM, the Secretary declined to allow RHCs and FQHCs to form their own ACOs. The Secretary reasoned that CMS must be able to obtain sufficient data in order to carry out the necessary functions of the program, including assignment of beneficiaries, establishment and updating of benchmarks, and determination of shared savings. CMS asserts that FQHC claims for services furnished prior to January 1, 2011 do not include HCPCS codes that identify the specific service provided and do not currently provide data for associating the rendering provider with the specific services furnished to the beneficiary. CMS also asserts that while RHC claims distinguish general classes of services by revenue code, the beneficiary to whom the service was provided,

and other information relevant to determining whether the all-inclusive rate can be paid for the service, these claims do not include HCPCS codes that identify the specific service provided. CMS asserts in the ACO NPRM that RHC claims also contain limited information concerning the individual practitioner, or even the type of health professional who provided the service. For FQHCs and RHCs, therefore, CMS asserts that it currently lacks the requisite data elements (service code, physician, physician specialty, and specific attribution of services to the rendering health care professionals) in the claims and payment systems to enable CMS to determine (1) beneficiary assignment and (2) expenditures during the 3-year look-back period for calculating the benchmark.

Quincy disagrees with CMS's analysis of the information available in FQHC and RHC claim forms. The UB-04 claim forms include HCPCS codes, national provider identification (NPI) numbers, and tax identification numbers (TINs). In addition Quincy's Medicare Administrative Coordinator (MAC) has shared that while some of the data elements are not retained in the database, they are routinely submitted by RHCs. This fact does not seem to suggest that FQHCs and RHCs should be excluded from participation as the process for data submission is in place. The real issue likely is that CMS does not have a method for meshing the databases of HCFA 1500s and UBs. This is a technological problem rather than a data submission or claim form problem. CMS could partner with RHCs and FQHCs to institute a technology solution to gather the information needed for attributing beneficiaries and developing benchmarks. Furthermore, if FQHCs and RHCs wish to submit the data independently, they should be allowed to do so solely for the purpose of participating in the shared savings program.

B. Restriction on Adding New ACO Participants

Not being able to add ACO provider participants during the 3-year term seems counter to the idea of encouraging more integrated models and thus greater coordination of care. For example, if larger integrated organizations are active in merger and acquisition activity they will most likely want to incorporate those new participants (such as acquired hospitals and medical groups) into the larger ACO that already has the core infrastructure in place. Perhaps adding new participants could be done just on any January 1 during the ACO 3-year term. This would seem consistent with further promoting clinical integration and improving coordination across the care continuum.

II. Assignment of Medicare Fee-For-Service Beneficiaries

In the ACO NPRM, CMS asserts that the ACO statute requires that CMS consider only beneficiaries' utilization of primary care services provided by ACO professionals who are physicians when determining a methodology for beneficiary assignment. CMS proposes to identify an ACO operationally as a collection of Medicare enrolled TINs (rather than NPIs) of physicians who are primary care physicians (defined as internal medicine, geriatric medicine, family practice, and general practice). This collection of TINs would be permitted to associate with only one ACO. TINs associated with FQHCs and RHCs would be permitted to be associated with more than one ACO. This proposed operational definition of an ACO would exclude primary care services provided by

physician extenders such as nurse practitioners and physician assistants who are supervised by physicians – only primary care services by physicians in the fields of family medicine, internal medicine, geriatrics, and general practice are included.

A. Inclusion of Mid-Level Practitioners

Quincy disagrees with this proposal and suggests that beneficiaries be allowed to be assigned to the supervising primary care physician of a nurse practitioner or physician assistant operating within or outside an RHC even if the plurality of care is provided by a mid-level practitioner such as a nurse practitioner within either setting. Quincy believes that primary care services provided by mid-level practitioners should be included in the definition of "primary care services" because, as pointed out in a recent George Washington University School of Public Health issue brief, [2] without including these services in the definition of primary care, the poorest beneficiaries and highest health risk patients will be excluded from ACOs.

CMS seems to have taken the liberty to restrict the statute's definition of "provided" to "directly provided" by a physician. Not only does this seem to neglect the role of nurse practitioners and physician assistants practicing team based care in collaboration with primary care physicians but it also is confusing as to why the statute would allow nurse practitioners and physician assistants to be included in the definition of "ACO Professionals," but not allow patients to be attributed to them directly or to their collaborating physician. The statute does not require that services be "directly provided" by a physician, but only that physicians provide care, which can be done in a variety of ways. Quincy believes that Congress recognized that physicians can provide care both directly and indirectly via a collaborating primary care physician and accordingly the Secretary should use her discretion to meet Congress' intent by relaxing the proposed rule's interpretation of "provided" so that nurse practitioners and physician assistants, when they are collaborating with a primary care physician, can be included. This step would further promote team based care in the primary care setting as well as the Patient Centered Medical Home model than many consider foundational to ACO success. Quincy also believes Congress intended to allow robust participation in rural America that regularly provides care in the team based approach and thus relaxing the proposed interpretation of "provided" must also be extended to RHCs.

Furthermore, CMS' use of "directly" is in conflict with state law that recognizes physicians as providers of health care who are accountable for the quality of health care, whether provided directly or by supervising the indirect provision of that care by other professionals such as nurse practitioners and physician assistants. Finally it is important to note that RHCs are required by law to provide primary care services by a nurse

[2] Sara Rosenbaum and Peter Shin, Medicare's Accountable Care Organization Regulations: How Will Medicare Beneficiaries who Reside in Medically Underserved Communities Fare?, George Washington University School of Public Health Policy Brief #23, available at http://www.gwumc.edu/sphhs/departments/healthpolicy/dhp_publications/pub_uploads/dhpPublication_6EFAAA15-5056-9D20-3DBE579D20C06F05.pdf.

practitioner or physicians assistant further illuminating CMS' current recognition of the value of the team based care approach.

B. Attributing Beneficiaries to RHCs

Under the ACO NPRM, RHCs are not able to have beneficiaries attributed directly to them and as such are not on a level playing field with their primary care physician counterparts in urban practices. This pattern seems to repeat itself in various quality initiatives by CMS including PQRI, ERx, Meaningful Use, and now ACOs: where RHCs are presented with either no ability to participate or face rules making them effectively unable to participate. CMS was correct in noting there are differences in billing for RHCs. However, the UB-04 claim forms that RHCs submit to the Medicare Administrative Contractors require us to include TINs, NPIs, and CPT/HCPCS codes. If this data is omitted, the claims are denied. It would seem that if the data is being submitted electronically that it could be cross walked accordingly for ACOs, not to mention the other aforementioned initiatives. RHCs need an "equal" opportunity to participate.

It is also important to understand how the proposed rule for beneficiary allocation in rural communities might create inappropriate beneficiary attribution. For example, envision a large physician multispecialty group whose primary care base provides the vast majority of a rural region's primary care under RHC status within the multispecialty group. The multispecialty group meets all the ACO requirements except for the attributed beneficiary threshold of 5,000 because its 20,000+ Medicare beneficiaries are provided services within the RHC. Across town a competitor which employs a few primary care physicians that do not operate under the RHC status is also partnered with a larger ACO operating primarily outside of the immediate service area. If a beneficiary is seen a plurality of time by the large RHC multispecialty group, but also has even one primary care visit to the non-RHC across town, it seems the patient will be attributed to the non-RHC ACO. Due to the real possibility of this type of inappropriate random variation in mid-sized rural communities, RHCs need an immediate mechanism to have beneficiaries assigned to them within an ACO. CMS seems focused on limiting random variation, particularly in measuring savings by setting a Minimum Savings Rate (MSR). Quincy believes the care should be taken to eliminate the potential random variation of beneficiary attribution in rural communities. In this example the large multispecialty group with an RHC component, desiring to be an ACO, needs to be able to submit the data necessary for accurate and appropriate beneficiary attribution.

C. At Risk Beneficiaries

The ACO NPRM includes specific provisions for monitoring ACOs to assure they do not attempt to avoid "at risk" beneficiaries. Included in the definition of "at risk" is dually eligible Medicare and Medicaid beneficiaries. By excluding RHCs and FQHCs, CMS is actually doing what the specific monitoring provision are attempting to deter, excluding a large number of dually eligible beneficiaries. As the PPACA significantly expands Medicaid enrollment in 2014, this important issue would seem to be only exacerbated.

III. Quality and Other Reporting Requirements

Section 1899(b)(3)(A) requires CMS to determine the appropriate measures to assess the quality of care furnished by ACOs. In the ACO NPRM, CMS proposes that an ACO be considered to have met the quality performance standard if ACOs report quality measures and meet the performance criteria in accordance with the requirements detailed in rulemaking for each of the three performance years. The quality performance standard for the first year is simply to report and in subsequent years to meet measure scores with a minimum attainment score. CMS proposes 65 different measures for evaluating quality.

Quincy notes that of the 65 measures, 11 are derived from claims by CMS (ACOs have to do nothing for these, CMS will extract) in one year. The burden to gather the information on the other 54 measures is significant. A one year ramp up for reporting is likely not enough time for the organizations beginning this program to invest in the necessary infrastructure to capture this data and make the necessary compliance changes. Quincy suggests that the quality measures focus initially on high-cost and high-volume chronic disease states or those that have a demonstrable connection to outcomes, and not simply be reporting for reporting's sake. One option might be to phase in the quality measures over a three-year period to reduce the administrative burden, similar to the process used in the Physician Group Practice Demonstration Project. Another option is to allow individual ACOs some flexibility to select their own metrics, perhaps from a broader defined set, so that they can be tailored to the needs of the patient population that they serve. Quincy also suggests that there should be a pathway spelled out for CMS to work with ACOs to develop new measures and survey questions over time that are more reflective of the pattern and practice of medicine. Because seven of the quality measures are for hospitals, and many large multi-specialty groups like Quincy do not have hospitals in their organization, it appears that many multispecialty groups, one of the main participants enumerated by the statue as eligible to develop an ACO, will be unable to meet the quality reporting requirement on all 65 measures the first year. CMS needs to make an exception to the reporting requirement on quality measures for ACOs without hospitals for all three years.

IV. Shared Savings Determination

A. Assuming Risk

CMS proposes two models for assuming and sharing risk: a one-sided model with downside risk in year three only and a two-sided model with downside risk in all three years. Because each of the two paths for shared savings carries some eventual burden of downside risk, Quincy believes that potential ACOs will have diminished interest, perhaps significantly, and particularly in markets not accustomed to taking downside risk. While the ACO statute gives the Secretary the authority to use risk-models, CMS should not use risk as the backbone in the ACO NPRM. Quincy believes it is too early in the evolution toward value based payment to have both models have down-side risk. It

would seem more reasonable and attractive if one of the paths had no downside risk for the first three years and also had an option to renew the contract for a maximum of an additional 3 years with no downside risk. Also allowing those in a "no downside risk" path to convert to downside risk at the beginning of any calendar year would continually dangle the greater incentive but also allow organizations to move there at a time their operations can support.

B. Benchmarks

CMS proposes to estimate the benchmark for an ACO based upon the assigned beneficiaries' claims of the prior three most recent available years using the per capita Parts A and B fee-for-service (FFS) expenditures, which are adjusted for overall growth and beneficiary characteristics, including health status using prospective HCC (Hierarchical Condition Category, the risk adjustment methodology used in Medicare Advantage (MA)). The benchmark will be updated annually based on the absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program.

Quincy is concerned that this methodology will disadvantage ACOs that operate in underserved areas where patients are traditionally poorer and have higher health risk. As more of these higher-acuity patients become eligible for Medicare, and coincidently dual eligible for Medicaid when the eligibility expands in 2014, the national benchmark may not keep pace with the ACOs actual increase in overall beneficiary population acuity. Quincy suggests that the base risk scoring methodology needs to change each year over the three years.

C. FQHC/RHC Incentive

Because FQHCs and RHCs are unable to participate independently as an ACO under the ACO NPRM, CMS proposes to provide incentives to ACOs that include FQHCs and/or RHCs as ACO participants. CMS believes FQHCs and RHCs will promote care coordination and the delivery of efficient, high-quality health care. CMS proposes, for the one-sided model, up to a 2.5 percentage point increase in the sharing rate for ACOs that include these entities as ACO participants. (CMS proposes up to 5 percentage points for the two-sided model). Specifically, CMS proposes establishing a sliding-scale payment based on the number of Medicare FFS beneficiaries with one or more visits at an ACO's participant FQHC or RHC during the performance year.

Allowing ACOs that use RHCs to earn a greater savings amount is a noteworthy attempt to recognize the importance of RHCs to the health care system. However, at the same time it creates an incentive to treat RHCs as something to be "latched on" in an attempt to achieve a greater share of any savings. What is most concerning is that the beneficiary attributed data needs to be provided to be able to determine if the RHC is providing value to the ACO, and in turn CMS. Because RHCs, just like their urban counterparts, will provide varying levels of quality at varying costs, the data will be imperative to be used as feedback to affect change in practice patterns. Also of marked concern is that the

RHC risks getting lost within the larger ACO system. Without the appropriate data the larger ACO is likely to distribute savings in a manner that does not realize the benefit provided by the RHC. Consequently, Quincy believes this could generate a result opposite that which CMS appears to be seeking, by actually disincentivizing independent RHCs from participating because they will have no ability to have direct attribution. For these reasons it is imperative that RHCs have options to submit the necessary data and be able to become ACOs both independently and within larger systems of care.

Quincy is also concerned that the structure of the incentive payments could lead to gaming by ACOs. For instance, an ACO near a RHC, perhaps even in the same community, could schedule its beneficiaries to have at least one visit to a RHC each year, in order to be counted as a RHC beneficiary, when in reality the beneficiary is not a RHC patient. Any such gaming could prove to be disruptive to normal RHC operations and compromise access to care for primary RHC patients. This simply further illustrates the need for direct beneficiary attribution to RHCs.

D. Minimum Savings Rate

In the ACO NPRM, CMS proposes a Minimum Savings Rate (MSR) or percentage that expenditures must be below the applicable benchmark to account for normal variation in expenditures, based upon the number of Medicare fee-for-service beneficiaries assigned to an ACO. The MSR in combination with the savings rate will determine the amount of shared savings that an ACO can receive. CMS proposes a waiver of the MSR in certain circumstances such as rural areas.

Quincy supports this waiver of the need to have the 2% savings threshold in underserved areas because it appropriately recognizes the financial challenges of setting up ACOs in rural areas. However, the larger issue will be reaching minimum assigned beneficiary levels due to how much primary care in these areas is being delivered by RHCs. Thus for the benefit of the 2% threshold waiver to be effective, RHC beneficiaries need a means to be assigned to RHC physicians within both larger and independent RHC ACOs.

Quincy notes that setting the shared savings threshold as high as 3.9% will likely cause many to pass on the ACO model. Even the 2% threshold was difficult for PGP demo groups to achieve. It would seem the use of a common threshold rather than a sliding scale threshold as CMS proposes would make the program more attractive in early years and perhaps more effectively move more of the industry toward a focus on value. The forest through the trees here is that providers are engaging in transforming the model; difficult to do if no guests show up to the party.

E. Cap on Shared Savings

CMS proposes to place a 7.5% of an ACO's benchmark as maximum sharing cap under the one-sided model, and a 10% maximum sharing cap on the two-sided model. Quincy questions whether these caps make for low financial viability of becoming an ACO. Furthermore, while Quincy believes that ACOs hold much promise, limiting the

maximum savings share to as low as 50% also mutes the financial attractiveness to many providers that must consider high levels of investment toward infrastructure affecting operational change to improve quality. Perhaps starting maximum savings in the early years at a higher level, say 75%, and then have it taper off in an ACO's subsequent contract years would be more realistic from the perspective of financial viability.

V. Monitoring and Termination of ACOs

The ACO statute allows CMS to impose sanctions against ACOs and to terminate them from the shared savings program. For example, if an ACO does not meet an established quality performance standard, CMS may terminate it. In the ACO NPRM, CMS proposes to use many of the methods developed in Medicare Advantage and the prescription drug program to monitor and assess ACOs including analysis of financial reports, site visits, investigation of beneficiary complaints, and audits. CMS proposes to have the sole discretion to decide whether to provide warning notices, request corrective action plans, and special monitoring plans. The ACO NPRM enumerates a number of situations whereby CMS may terminate ACOs and result in a loss of the 25% withhold of shared savings. CMS proposes that ACO must give 60 days notice of their intent to terminate from the shared savings program.

Section 1899(g) of the statute states that there shall be no judicial or administrative review of a limited number of events:

- Specification of criteria for meeting quality performance standards
- Assessment of quality of care furnished by an ACO and the establishment of quality performance standards
- Assignment of Medicare FFS beneficiaries to an ACO
- Determination of whether an ACO is eligible for shared savings, the amount of shared savings, including the average benchmark
- Percent of shared savings and any limit on the total amount of shared savings.
- Termination of an ACO for failure to meet quality performance standards.

CMS proposes to set forth an administrative process to request review of all other decisions. Quincy believes that the statutory exceptions to administrative review should be construed narrowly and that proposed review process (15 days to request a review) is too quick. Quincy also believes that ACOs should not have to forfeit their 25% withhold at the time of termination. This penalty is too severe.

VI. Coordination with Other Agencies

The ACO statute allows waiver of the fraud and abuse laws so that the laws do not unduly impede the development of beneficial ACOs. In its proposed rule,[3] the Office of Inspector General (OIG) proposes a limited exception from the anti-kickback and self-

[3] Medicare Program: Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center, Federal Register, Vol. 76, No. 67; April 7, 2011.

referral statutes for the shared savings that an ACO generates under two conditions: (1) the savings are paid to among ACO participants during the year in which the shared savings were earned by the ACO; or (2) for activities necessary for and directly related to the ACO participation in and operations under the Medicare Shared Savings program.

Quincy believes that this exception is the minimum necessary to allow ACOs to operate. For instance, the OIG needs to broadly permit the furnishing by ACO providers of free or discounted items and services to assigned beneficiaries that promote coordinated care and other population health objectives of ACOs. Furthermore, ACOs should have the flexibility to waive co-payments for certain services, such as primary care services, to encourage patients to be active participants in their health care and to comply with treatment protocols. By allowing this flexibility for both ACO providers and providers outside the ACO if the beneficiary receives services from the outside provider, ACOs can improve health. Quincy also believes that ACO participants should be permitted to support other ACO participants who may be in a position to refer Medicare business to the funding group through the coverage of infrastructure costs such as information technology acquisition and operation and training of providers on the new quality measures.

Again, we appreciate the opportunity to submit these comments. Should you have any specific questions, or wish to discuss our comments further, please contact me at 217-222-6550.

Sincerely,

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Chief Executive Officer

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