Cleveland Clinic

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May 26, 2011

Donald M. Berwick, M.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, ME 22114-8013

Re: CMS-1345-P, Medicare Shared Savings Program: Accountable Care Organizations

Dear Dr. Berwick:

Cleveland Clinic, a not-for-profit, integrated healthcare system dedicated to patient care, teaching and research, has reviewed your proposed rule (Proposed Rule) governing payments to providers of services and suppliers participating in Accountable Care Organizations (ACOs). Our healthcare system is composed of a main campus, nine community hospitals and 14 family health centers with over 3,000 salaried physicians and scientists. Last year, our system had more than five million patient visits and over 165,000 hospital admissions.

We support the concept of ACOs as envisioned in the Patient Protection and Affordable Care Act (PPACA) because of the need to ensure that patients, over time, receive the best and most efficiently delivered care possible. To do so requires more coordination and collaboration among providers and suppliers than is generally the case today.

We appreciate the dedication and hard work of CMS staff in its efforts to move from PPACA to implementation. Further, we appreciate the patience and openness of CMS staff to the myriad of comments offered about how to structure the Proposed Rule. Unfortunately, after reviewing it, we are disappointed generally with its content. Rather than providing a broad framework that focuses on results as the key criteria of success, the Proposed Rule is replete with (1) prescriptive requirements that have little to do with outcomes, and (2) many detailed governance and reporting requirements that create significant administrative burdens. Further, we have concluded that the shared savings component (Shared Savings) is structured in such a way that creates real uncertainty about whether applicants will be able to achieve success. The combination of these factors creates significant barriers to potential applicants and, in our opinion, will discourage their engagement with this innovative concept. The comments below provide the detail of our concerns and offer what we hope will be construed as constructive recommendations to improve the Proposed Rule.

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Governance

- **Board Composition and Relationships**
  CMS would allow existing provider organizations to be an ACO, although it has some reservations about this because of the fact that the provider organizations have other ongoing relationships with the Medicare program which may create the potential for confusion between roles. CMS also would require that (1) ACO participants (providers and suppliers) hold at least 75% control of the Board of Directors, and (2) patients be involved in ACO governance by having a representative on the Board. The rights and obligations of the various provider and supplier participants also must be detailed.

  We think CMS has exceeded legislative intent as reflected in the PPACA in its detail of Board organization and authority. CMS appears to rely on the patient centeredness concept as justification, but when this language in the law is reviewed, it refers to the quality of care provided to patients, not to organizational issues.

  Recommendation: We recommend that CMS drop its specific Board composition and relationship requirements, that CMS state what the goals of an ACO should be that could be incorporated into any mission statement, and that CMS require the ACO to be licensed, as they do other provider entities, under State law. CMS has made clear elsewhere in the Proposed Rule that ACOs are accountable to other Medicare requirements, and it make sense to apply these requirements in this particular instance as well, rather than attempting to create a whole new set of requirements.

- **Application Requirements**
  CMS proposes a host of requirements for the Application which must be filed to qualify an entity as an ACO. Among them are the following:
  - The ACO is required to describe evidence-based guidelines it intends to establish, implement and periodically update.
  - The ACO is required to describe the patient engagement process it intends to establish, implement and periodically update.
  - The ACO is required to describe its process to report internally on quality and core measures and how it intends to use that process to respond to the needs of its Medicare population and to make modifications in its care delivery.
  - The ACO is required to define processes to coordinate care.
  - The ACO is required to show a degree of interactions and interdependence among providers in their provision of medical services that enable them to achieve jointly both cost effectiveness and quality improvement in the care provided to assigned Medicare beneficiaries.
  - The ACO is required to explain (1) how Shared Savings would be distributed among ACO participants and ACO providers/suppliers, and (2) how these savings will be used to achieve the program's goals.
  - The ACO is required to describe how the ACO will use the Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CHCAHPS) survey results to improve care over time.

  While there is merit in addressing these items, we believe it is an unnecessary administrative burden to provide all this detail in an Application, particularly when there is no evidence as

to how, if at all, the information might be used. The ACO demonstration, unlike traditional Medicare demonstration projects, is not so much focused on processes of care as it is in achieving savings and improving quality. One will never be able to backtrack from an Application to a result in these projects. There will be intense scrutiny of the projects, and there will be much attention paid to those who are successful, and the results predictably will spread because they work, not because there will be some federal report based on what was filed as an Application. ACOs are live experiments, and projects will be constantly evolving. Moreover, it would appear that anytime a protocol is modified or a care coordination process is adjusted, further written submissions to CMS would be required which will exacerbate the administrative burden.

Recommendation: It is reasonable to require a work plan from an applicant, but the work plan should address the overall approach to achieving the project's goals, not day-to-day operations as required in the Proposed Rule. We would urge CMS to pull back from this level of detail and, instead, create a more generic outline that would allow the applicant flexibility in describing its approach.

- **ACO Marketing Guidelines**
  As detailed further below, CMS proposes prior approval of any ACO marketing materials or related communications to beneficiaries. CMS acknowledges that there is no explicit provision in the law related to marketing activities and, as a result, links its authority to control any marketing activity through the phrase "patient-centeredness criteria." However, this linkage is an extraordinary stretch, given that the phrase in large part refers to how a patient is treated and cared for when sick. The narrative then goes well beyond marketing to include any beneficiary communication "related to the ACO operations or functions as well..." CMS then specifies that "...all ACO marketing materials, communications, and activities related to the ACO and its participation in the Shared Savings Program, such as mailings, telephone calls or community events, that are used to educate, solicit, notify or contact Medicare beneficiaries or providers/suppliers regarding the ACO and its participation in the Shared Savings Program, be approved by CMS before use to protect beneficiaries and to ensure that they are not confusing or misleading."

  We disagree that there is any significant potential for beneficiaries to be misled about Medicare services available from an ACO or about the providers and suppliers from whom they can receive those services. We realize that the CMS experience with Medicare Advantage (MA) and Part D marketing practices has increased CMS' sensitivity to this concern, but an ACO is neither an insurance company nor a drug supplier. Providers have long standing relationships in their respective communities, and their honesty with their patients and families is crucial in maintaining open, positive relationships. Providers have far more to lose than to gain in any attempt to mislead. We believe that this proposal goes beyond the PPACA's intent and is very impractical. The proposal, in the guise of beneficiary protection, exemplifies micromanagement. Beneficiary communications tend to be time sensitive and framed specifically to a locality. It is difficult to imagine that CMS can be sensitive to local conditions or respond in a timely manner. The proposal does not protect beneficiaries; rather, it puts them at risk of not receiving timely information when needed.

  Recommendation: If CMS is concerned that it needs some accountability regarding beneficiary communications, we recommend that CMS establish a framework for what would

be the appropriate criteria for beneficiary communications and then monitor ACO behavior as part of its ongoing evaluation of performance by an ACO.

Shared Savings

To be eligible for Shared Savings, the ACO must first meet all of the prescribed quality criteria. A savings calculation is then made, and the ACO is eligible for savings "...only if the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries for Parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark... ."

The Proposed Rule then sets forth whether there should be first dollar sharing or some threshold of savings that must be achieved before sharing begins. CMS proposes, at a minimum, a 2% threshold, based on randomness in the data which may lead to getting credit for unearned savings.

The benchmark would be based on a three-year compilation of expenditures for patients who would be assigned to the ACO had an ACO been in existence. The expenditure information will be risk adjusted by the risk model currently used in the Medicare Advantage Program. The risk adjustment identified through the three-year historic profile will be maintained for the duration of the three-year period. CMS argues that this approach is essential because of the incentive which an ACO may have to manipulate risk adjustment to increase its savings opportunities. The benchmark and the savings calculations during the three-year period would also include IME and DSH payments.

CMS proposes two models: one with no downside risk until year three and the other with downside risk from the outset. If an ACO is willing to assume risk in all three years, the cap on potential Shared Savings will be increased.

CMS also proposes to withhold 25% of Shared Savings each year as a reserve in case an ACO has losses it cannot cover thereafter.

General Recommendation: We believe the Shared Savings formula is structured in a way that makes Shared Savings difficult to accept. If CMS is concerned about potential losses, we recommend that CMS consider the insurance model where certain reserves would be required of ACOs in order to participate, rather than holding back earned savings on the front end with no discussion as to how the holdback might ultimately be paid to the ACO. We support first dollar Shared Savings over the threshold approach because randomness in data works both ways, not just downward as implied in the CMS narrative. Additionally, we believe CMS would incent ACO participation if (1) it were more generous in the split of Shared Savings, and (2) it allowed the one-sided model to run for three years, not two.

- **Risk Adjustment**
  CMS has noted that there is considerable beneficiary movement among providers from year to year. For this reason, we are concerned that using a benchmarked risk adjustor may be seriously inaccurate. Rather, we would recommend that there be a sampling of assigned beneficiaries audited to construct a more relevant risk adjustment. CMS could do this just as easily as constructing a benchmark risk adjustment, and it would be more relevant to an ACO's current situation.

- **Inclusion/Exclusion of Indirect Medical Education (IME) and Disproportionate Share Hospital Payments (DSH)**
  We also have reservations about the inclusion of IME and DSH payments in both the benchmark and the demonstration. The IME/DSH funds are for special missions not relevant to this demonstration and should be excluded. Their inclusion builds in a major bias against referring patients to academic medical centers, the places that may be best suited to treat complex cases. We understand that CMS has sufficient authority under section 1899(i) of the Social Security Act, as amended, to do this, and we urge CMS to exercise its authority in this manner.

- **Use of the Individual ACO Benchmark**
  Finally, we are concerned with measurement against the individual ACO's risk adjusted benchmark rather than a national or regional benchmark. We believe that being measured against one's own performance is biased against providers who already manage care effectively and biased in favor of those who historically have done a poor job of care management. We recognize and appreciate that CMS has attempted to mitigate this bias through the use of a national update factor. However, we believe it is insufficient. While we recognize CMS is limited in its measurement options due to the PPACA requirements, we urge CMS to review the statutory language to enable it to provide for more relevant measures of financial performance results much as it has in quality measurement and hospital value-based purchasing.

Assignment of Medicare Fee-for-Service Beneficiaries

- **Operational Definition of an ACO**
  CMS proposes an operational definition of an ACO as a collection of Medicare-enrolled tax identifier numbers (TIN). CMS also proposes that ACO primary care physicians be exclusive to one ACO and that primary care physicians are only those with a designation of internal medicine, geriatric medicine, family practice, or general practice.

- **Definition of Primary Care Services**
  CMS proposes three options with respect to defining primary care services: (1) assignment of beneficiaries based on a predefined set of primary care services, (2) assignment of beneficiaries based on both a predefined set of primary care services and a predefined group of primary care providers, or (3) assignment of beneficiaries in a step-wise fashion. Under the proposal there would be a basic set of evaluation and management (E&M) services, including G-codes associated with the annual wellness visit and "Welcome to Medicare" benefit. Of the three options, CMS proposes to adopt option (2), which would assign beneficiaries to physicians designated as primary care providers (internal medicine, general practice, family practice, or geriatric medicine). It would exclude primary care services delivered by specialists.

  Recommendation: We believe that the exclusion of primary care services provided by specialists is a serious error. As CMS acknowledges, for many patients with chronic illness the specialist is the glue for care continuity, not the primary care physician. Because the focus of this ACO project is on improving the quality and efficiency of care for the chronically ill, we believe the definition of primary care services should include those defined services provided by specialists as well as primary care physicians.

- **Prospective vs. Retrospective Beneficiary Assignment to Calculate Eligibility for Shared Savings**
  CMS proposes to assign beneficiaries retrospectively for purposes of determining eligibility for Shared Savings. CMS also notes that few of those who commented in its listening sessions supported retrospective assignment. The balance which CMS seeks is to provide the ACO with information on its beneficiaries gleaned from each ACO's benchmark data.

  CMS argues that a prospective process would be inaccurate because beneficiaries often see many providers, some of which would not be part of an ACO. However, CMS does not discuss how such prospective assignment might be adjusted in the first quarter of ACO operations to provide a more accurate assignment. While acknowledging that there are strong arguments from a care practice perspective for prospective assignment of beneficiaries, CMS opts for a retrospective assignment model that is more convenient to itself.

  Recommendation: We disagree with the CMS rationale for retrospective assignment and urge the Agency to assign beneficiaries prospectively, with an adjustment period in the initial stages of the three-year period. Retrospective assignment drastically undercuts the ability of the ACO to manage care efficiently and is counter to the intent of the demonstration project.

- **Majority vs. Plurality Rule for Beneficiary Assignment**
  CMS is given wide discretion regarding how to assign beneficiaries to an ACO on the basis of their primary care utilization. While acknowledging that a certain percentage could be used, CMS discusses two utilization options—majority vs. plurality. CMS opts for a plurality standard on the grounds that a majority standard would exclude too many beneficiaries. CMS recommends that there be a minimum floor of at least one visit for assignment, and it asks for comment as to whether this floor is too low. Plurality would be determined not by the number of services but on the basis of allowed charges.

  Recommendation: Given beneficiary variability in choosing primary care providers, we understand and support the plurality concept but believe that the threshold of just one visit is too low. We would recommend that CMS establish a threshold of at least three visits which would provide more assurance of continuity with the ACO and more patients who have continuing needs.

- **Beneficiary Information and Notification**
  CMS proposes to develop a communications plan, including educational materials and other forms of outreach, to provide beneficiaries in a timely manner with accurate, clear and understandable information (1) about the Shared Savings Program in general, (2) about their utilization of services furnished by a provider or supplier participating in an ACO, (3) about the possibility of their being assigned to an ACO for quality and Shared Savings purposes, and (4) about the potential that their health information may be shared with the ACO and their ability to opt-out of that data sharing. CMS proposes that a beneficiary will be notified by the ACO at the time a beneficiary seeks services from the ACO.

Recommendation: We support this general approach to beneficiary communication. In this light, we urge CMS to review its section concerning marketing guidelines to be consistent with this provision.

- **Provider Participation**
  CMS proposes that participating providers must be declared at the outset of an ACO's three-year commitment to the demonstration project and that additional providers cannot be added thereafter. It is not uncommon for primary care physicians to leave practices for a variety of reasons. In the event that a participating provider leaves an ACO in the course of the three years, the Proposed Rule would preclude adding a new provider to the ACO which would assume responsibility for a departing provider's panel of patients. This aspect of the rule would be particularly onerous for small provider groups which would have to divide a potentially large panel of patients among a small number of individual providers. Additionally, CMS does not address how primary care physicians are often supplemented in their work by the use of advanced practice nurses and physician assistants and how they might be affected by this requirement.
  Recommendation: We suggest that CMS modify the proposed rule to allow the addition of new providers to an ACO in the event that enrolled providers depart during the three-year demonstration project.

  We also believe that CMS should use the opportunity to encourage the use of allied health professionals, such as advanced practice nurses and physician assistants, in the formulation of care delivery and management models. Much has been learned over the years regarding the utility of using these professionals in improving care delivery and coordination.

Quality

- **Number of Measures to be Reported**
  CMS proposes that for the first year achievement will be defined by merely reporting all measures, and in the second year standards/benchmarks will be developed which must be met. CMS would require achievement on all measures in order to be eligible for Shared Savings. The quality list consists of 65 measures.

  We believe the proposed number of measures to be reported is excessive, and the large number would be practically impossible to meet successfully. A number of the measures are ones physicians and hospitals have not been reporting. A learning period is warranted.

  Recommendation: We recommend that CMS reduce the list to a more manageable size and that additional thought be given to which measures to include. We discuss this point further below.

- **Which Measures to Report**
  The CMS quality measure list contains both ambulatory-sensitive and inpatient-sensitive measures, but if an ACO does not have a hospital as part of its organization, it seems unfair to require reporting on what are essentially inpatient measures. Additionally, the list contains some measures not approved by the National Quality Forum (NQF). Finally, many of the measures are process measures.

Recommendation: We recommend that measures which are largely dependent on hospital performance should be excluded. This includes measures 8, 9 and 10--readmissions, 30-day post-discharge physician visit, and medication reconciliation after discharge from an inpatient facility. These measures are addressed in the IPPS regulations, and it is duplicative to include them here. For the same reason, we recommend that hospital acquired condition (HAC) measures be excluded and that the prevention quality measures be delayed for further study. Finally, the overwhelming majority of measures are process measures. We recommend that the emphasis be placed on outcome measures instead.

- **Beneficiary Experience of Care Survey**
  CMS proposes that ACOs use the CAHPS survey instrument to measure patient satisfaction. CMS comments that CAHPS is nationally recognized and widely used. CMS acknowledges that it represents an increased administrative burden for ACOs currently not using the survey instrument, and it considers, but rejects, whether other survey instruments could be used in its place.

  Recommendation: We agree with CMS that it is reasonable to use a single instrument. However, the administration of the CAHPS survey is not only administratively burdensome but also expensive. We recommend that CMS provide for a sampling approach to mitigate both administrative and financial concerns regarding its administration.

Legal-Technical Concerns

Scattered throughout the proposed rule are a number of terms that are used interchangeably but have differing requirements and/or obligations. Below we highlight some of the terminology in question.

- **ACO participant and ACO provider/supplier**—These two terms are often used as if they are the same, but there are differing requirements for each. Care needs to be taken to clarify the definitions and then to use them discretely in the Proposed Rule. Otherwise, there will be unnecessary confusion in the field.

- **Contractual obligations**—It is clear that an ACO is to contract with CMS. However, there appears to be a requirement for "ACO participants" (meaning those physicians to which beneficiaries are assigned) to also contract directly with CMS. It is not clear as to whether this participant requirement refers to physician participation in Medicare in general or to the ACO demonstration specifically. If it is the latter, we question its purpose. It is our belief that such a requirement undercuts the authority and responsibility of the ACO for outcomes and savings related to the assigned beneficiaries.

We thank you for the opportunity to provide these comments, and we look forward to continuing to work with CMS in providing the best care possible at a reasonable price for our nation's Medicare beneficiaries.

Sincerely,

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Chief Executive Officer and President

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