



June 6, 2011

Donald Berwick, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1345-P, Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Proposed Rule, March 31, 2011

Dear Dr. Berwick:

On behalf of the North Carolina Medical Society (NCMS) and our over 12,000 physician and physician assistant members, I am writing to provide our feedback on the CMS proposed rule on Medicare Shared Savings Program: Accountable Care Organizations (proposed ACO rules). We appreciate the level of thoughtfulness and coordination of each of the agencies that had a role in the development of the proposed rules and related documents, and we value the opportunity to share our comments on this important program.

While the NCMS strongly supports the goals of the Shared Savings Program to improve health and quality and to control costs, we are convinced that the proposed ACO rules are seriously flawed and that, as currently structured in the proposed rule, the Shared Savings Program is likely to fail. The NCMS would very much like to see the Shared Savings Program succeed, and so we are submitting this comment today to implore you and the other agencies to make substantive changes to the proposed ACO rules that will encourage participation in the Shared Savings Program. We join numerous organizations in expressing our grave concerns about the proposed ACO rules, including the American Medical Association (AMA), the American Medical Group Association (AMGA), the Medical Group Managers Association (MGMA), the American Hospital Association (AHA), and numerous national specialty societies.

Without going into the level of detail provided by the AMA, AMGA, MGMA, AHA and others, we will highlight our concerns and make suggestions that we firmly believe will encourage participation in the Medicare Shared Savings Program.

General

- The proposed rules are far too onerous for even the more sophisticated physician practices and health care organizations. In order to encourage physician practices to move forward and incorporate the

principles, tools, and improvements needed to provide more accountable care, more options will be needed that are less intrusive, costly, and risky.

Assignment

- Rather than having retrospective assignment and giving potentially assigned beneficiaries the right to opt-out of data sharing, we believe that in order to maximize care coordination, patient engagement, and mutual provider and patient accountability and trust, prospective assignment with beneficiary choice of ACO participation, with data sharing, will promote the most conducive environment for achieving the Three-Part or Triple Aim.

Benchmarking and Beneficiary Risk Adjustments

- The proposed beneficiary risk adjustment methodologies for establishing the benchmark and risk adjustments applied during the agreement period are inadequate. The benchmark should be risk adjusted for each year, and the risk adjustment methodologies generally need to be explored further.

Shared Savings and Risk Assumption

- We urge you to consider providing at least one track with no down-side risk for a new ACO, and we further recommend that ACOs be given the option of participating in that track for at least two three-year agreement periods, so that fledging ACOs are not forced to take on down-side risk before they are ready. We believe that many ACOs will not realize savings within a three-year period particularly with a retrospective attribution of beneficiaries. This is a lesson learned from several prior savings-based programs under Medicare and Medicare Advantage. Successfully changing work flow, care processes, alignment, and patient treatment and behavior takes substantial time, investment, and effort on the part of the care team, and the patient. In many cases, three years will not be adequate to recoup initial investment and produce actual savings under the methodology proposed by CMS.
- Eliminate the minimum savings rate (MSR) or cap it at one or two percent. The current proposal, which subjects the smaller ACOs to higher MSRs, is a huge disincentive for smaller entities.
- Eliminate the 25 percent withhold of all shared savings bonuses. Those funds will need to be reinvested in the ACO to support the infrastructure and maintain momentum.
- Increase the shared savings rate closer to the Physician Group Practice (PGP) demonstration amount so that there is a greater chance that the ACO will recoup some of the significant start up and maintenance costs. Further, consider creating a minimum shared savings rate to reward ACOs for efforts to redesign processes and align with other providers to improve quality, efficiency, and coordination of care. Simply put, the proposed ACO rule does not provide adequate incentives for physician practices and others to take the risk of changing current work flow and undertaking significant practice redesign and alignment with others needed to improve quality and control costs.

Quality

- Reduce the number of quality measures and gradually phase in more each year as was done with the PGP demonstration, starting with a number significantly smaller than 65. Also, consider allowing the ACO to choose from a menu of options similar to the Meaningful Use incentive program.
- Consider the inclusion of registries as a mechanism for reporting quality data, at least initially.

- Reduce and gradually phase in an increasing percentage of ACO Participants, as opposed to just primary care providers, who are eligible to be and are Meaningful Users of EHR. The current 50 percent threshold for primary care providers could be a significant hurdle for many organizations. We believe that there are adequate incentives for meaningful use adoption and that the exchange of health information will be key to true integration. We caution that the current proposed threshold could lead to poor choice of EHR and wasted investment. The ACO Participants should be allowed to adopt when ready, and the focus should be on redesigning care processes and integration efforts generally.
- Assessing an ACO's performance improvement should be based on a combination of factors, including: the ACO's own baseline performance, its performance relative to a national standard, and the maturity of the ACO. Initially, for less mature ACOs, performance improvement should be based on its own baseline and not on a national standard. Expecting a nascent organization to meet a national standard is intimidating and provides a disincentive to smaller, less sophisticated entities to participate in the Shared Savings Program. The more mature the ACO, the more it makes sense to hold them to a national standard. The goal should be to encourage continued improvement by all. Over time, the bar would be raised for all. Organizations already performing above the national standard should not be expected to necessarily have the same relative annual improvements as those below, as incremental improvements may become more difficult.
- While the Consumer Assessment of Health Providers and Systems (CAHPS) survey is an industry standard and covers seven patient experience measures, the existing survey does not give sufficient emphasis to communication, the patient's role in care, care coordination, and the quality of transitions of care. For the purpose of ACO evaluation and reporting, we recommend the addition of questions related to these areas.
- Advanced care planning for end of life is extremely important. We urge the incorporation of incentives for activities related to advanced care planning and follow-up. Conversations addressing beneficiary wishes about care and treatment at the end of life are critical to ensuring that our beneficiaries get the level of care they want in the setting they desire to the greatest extent possible. The use of advance directives and POLST paradigm forms are tools that can be utilized and should be encouraged.

Governance, Leadership, and Administrative Considerations

- The proposed requirement that 75 percent control of the governing board by ACO Participants is strong and should be retained.
- ACOs should be organized as separate legal entities. The NCMS supports the concept that health care reforms and improvements are best accomplished if they are physician-led and are designed for the purpose of improving quality, coordination, and efficiency. The NCMS acknowledges that the need to set up a new legal entity might be a disincentive to creating an ACO, but we believe that if an ACO is going to devote itself to proper reforms, the leadership and governance should be focused on those objectives and not subject to the distractions and conflicts of other business and professional obligations.
- Beneficiary and other representation on the governing board, however, could run afoul of state laws (as in North Carolina) that prohibit the corporate practice of medicine. A beneficiary / community advisory panel requirement would address concerns about beneficiary and community input.

- We strongly agree that ACO's clinical management and oversight should be managed by a senior-level medical director licensed and present in the state where the ACO is located. And while we generally support a board certification requirement, we urge you to consider additional alternatives such as the Certifying Commission on Medical Management, which is the American College of Physician Executives body to certify physician executives, as well as the American College of Medical Quality's certification in quality. Physicians who have focused on public health and have MPH degrees or Masters in Medical Management, Masters in Health Care Administration, and appropriate experience also should be considered.
- Given that care in the last months of life is particularly expensive and challenging to manage, NCMS believes that CMS should provide incentives for including long term care providers, home health providers, and hospice providers in ACOs.

Legal Considerations

- The CMS and OIG proposal to waive Stark Law, Anti-Kickback Statute and Civil Monetary Penalties Law for distribution of shared savings among ACO Participants and providers/supplier should be extended to allow additional collaborative activities beyond the Medicare Shared Savings Program and other CMS-sponsored programs.
- As a state level organization operating in a state with restrictions on the corporate practice of medicine and with robust fraud and abuse laws, NCMS is very concerned that ACOs would run afoul of local law and regulations. We strongly recommend that CMS and the OIG act to preempt the corporate practice of medicine doctrine and the state equivalents of the federal Civil Monetary Penalties Law, Anti-Kickback Statute, and Anti-Referral (Stark) Law, but only insofar as these state laws might otherwise apply to properly organized and operated ACOs.

Other

- While we applaud the additional incentives for including Federally Qualified Health Centers (FQHCs) and/or Rural Health Centers (RHCs) as part of an ACO, we believe that in a largely rural state such as NC, these entities should not be precluded from forming their own ACO.
- ACOs whose beneficiary count drops below 5,000 should be allowed to remain in the Shared Saving Program absent inappropriate conduct. As long as the ACO is moving toward more accountable care, allowances should be made for ACOs that drop below the 5,000 beneficiary threshold. Further, while an ACO can drop ACO Participants during the agreement period, it cannot add ACO Participants, which further compounds this problem. If this concern is not addressed, smaller entities will not undertake the substantial effort and investment needed to form an ACO.
- The requirement that all marketing materials must be approved by CMS prospectively is unworkable. We suggest that CMS provide guidelines or criteria for the materials, and develop a secondary process to address serious issues as they are discovered.
- We urge CMS to adopt a more graduated approach to participating in the Shared Savings Program on multiple levels, so that all providers regardless of size and resources, who are willing to make the needed investments, will feel comfortable doing so.

Again, thank you for the opportunity to comment on the proposed ACO rules. The NCMS would like to see the Shared Savings Program succeed as we believe it can serve as a positive first step to changing our healthcare delivery system for the better. We urge you to make the substantial modifications needed to encourage participation.

Sincerely,

A handwritten signature in black ink, appearing to read "John R. Mangum". The signature is fluid and cursive, with a long horizontal stroke at the end.

John R. Mangum, MD
President

Copy: Steve E. Wegner, MD, Chair, NCMS Accountable Care Task Force
Robert W. Seligson, Executive Vice President, CEO