



June 6, 2011

Donald M. Berwick, MD, MPP
Administrator
Centers for Medicare and Medicare Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

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

Submitted Electronically

Dear Dr. Berwick:

On behalf of the American Medical Group Association (AMGA), thank you for the opportunity to comment on the notice of proposed rulemaking (NPRM) regarding the establishment of a new Medicare health care delivery model and its reimbursement framework, the shared savings program, commonly referred to as Accountable Care Organizations (ACOs).

AMGA represents multi-specialty medical groups and other organized systems of care, including some of the nation's largest, most prestigious integrated health care delivery systems. AMGA represents the interests of 390 such groups and systems that employ approximately 117,000 physicians who provide services to an estimated 110 million patients. As such, we have a strong interest in ensuring that the implementing regulations for the ACO program are workable, and will inspire the voluntary participation of medical groups.

Without dramatic changes to the proposed rule, it is our considered opinion that ACOs will be unsuccessful from inception and that the best opportunity for health care delivery reform in decades, and its potential for attendant improvements in care for millions of Americans, will have been squandered. Having said that, we acknowledge and applaud CMS for its noteworthy activities in providing information about ACOs by broadly inviting comments and suggestions, holding national conference calls, making much information readily available on its website, and dispatching senior CMS officials to talk to stakeholders and interested parties. Furthermore, we hope that CMS will incorporate ideas submitted during the rulemaking process into the final version of the regulation to recast the ACO framework, as we will suggest with specifics in the paragraphs that follow.

Background and Introductory Remarks

Determining attractiveness of ACO participation is a function of the sum of all of the requirements and conditions of participation measured against the likelihood of financial benefit, assessed in the context of meshing program and institutional goals. CMS has created a design specification encompassing onerously complex application and participation requirements coupled with unbalanced risk/reward criteria, overwhelmingly disadvantaging ACO entities. We offer many suggestions, which, if incorporated into final program design, may make the ACO program attractive enough to garner enough voluntary participants to set the stage for delivery system transformation from its fragmented state to one of greater effectiveness and efficiency, over time.

AMGA's tireless advocacy efforts were rewarded when Congress included Section 3022 the Patient Protection and Affordable Care Act (PPACA). Section 3022 creates Accountable Care Organizations (ACOs), a clear recognition by the legislators that our health care system needed restructuring and reordering to move it toward greater clinical integration while delivering high quality care efficiently.

The strongest underpinning of clinically integrated health care delivery systems is the multispecialty medical group or other organized system of care. ACOs were created to emulate and stimulate promulgation of the advanced practice model in which AMGA member groups have long delivered and managed the health care services they provide.

Congress made participation in the shared savings program voluntary. As such, conditions have to be attractive to garner interest and involvement. When we wrote to you last in response to CMS' request for information, we provided answers to your questions and offered an overarching suggestion on how to help guide development of regulations to that end: Align incentives to attract many participants of various sizes and configurations. Make the barriers to entry as reasonable as possible, while keeping performance standards high. We are concerned and deeply disappointed that the proposed rule falls far short of being attractive.

Determining attractiveness of ACO participation is a function of the sum of all of the requirements and conditions of participation measured against the likelihood of financial benefit, assessed in the context of meshing program and institutional goals. CMS has created a design specification encompassing onerously complex application and participation requirements coupled with unbalanced risk/reward criteria, overwhelmingly disadvantaging ACO entities. This is exacerbated by a high level of uncertainty in pursuit of inadequately set shared savings payouts, offered in a timetable that is too short to accommodate learning and adaptation of participants.

Not long after the proposed rule was published, the Center for Medicare and Medicaid Innovation issued details of its Pioneer ACO program. This is an application, not a proposed rule, so we will not comment on it, but will cite it during our more detailed remarks, because in a number of

ways, it exhibits more flexibility and casts an eye to the realities of the medical practice and medical insurance worlds, more than is shown in the proposed shared savings proposals.

We offer this summary observation about the Pioneer ACO program design. In our view, if the key elements of the Pioneer ACO program had been found in the proposed rule, we would have been much more hopeful of its evolution, after comments consideration, to becoming a framework appealing to many in the provider community.

Population Health Management

CMS has expressed concerns that data-sharing of identified patient data might lead to more than one level of care being offered. Withholding identified patient information is a bad way to assuage these concerns. CMS should instead ask ACO participants to attest and affirm, as part of the application process, that they will provide one level of care only and will not treat patients differently except as warranted by clinical circumstances.

Population health management is a cornerstone of the ACO concept and is a systems-based approach to health care delivery geared to meeting individuals' needs. It is best created on a foundation of philosophical support for the inherent components, and given the large investments needed to supply the electronic infrastructure that makes its implementation possible, is of necessity, designed to encompass the entire patient population. Population health management involves frequent and open access to patient-physician (and other caregiver) communications; easy access and free flow of information; routine preventive and scheduled follow-up care based on individuals' needs and preferences in the context of evidence-based, best medical practices; on-going monitoring of a patient's health status; timely intervention and access to care; compilation of data from the patient care experience used to analyze and improve effectiveness and efficiency of that experience and the underlying processes and procedures. In short, population health management is proactive, reactive and adaptive. More information is better. In fact, AMGA members have told us that having available patient information as close to "real-time" as possible, is the situation for which they strive. Knowing who the patients are is essential. Since population health management is the *raison d'être* for ACOs, the program design must have prospective patient alignment and identification. In NPRM terms, ACOs must have prospective assignment of patients coupled with provision of identified patient claims and other data available. Without these key provisions, the ACO model is dangerously handicapped, if not effectively nullified.

Focused and targeted interventions based on disease state, health status, and medical history, are part and parcel of population health management. CMS has expressed concerns that data-sharing of identified patient data might lead to more than one level of care being offered. Withholding identified patient information is an ineffective way to assuage these concerns. CMS should instead ask ACO participants to attest and affirm, as part of the application process, that they will provide one level of care only and will not treat patients differently except as warranted by clinical circumstances.

The Application/Process

The application process is too complex and burdensome. Attestation and affirmation of the existence of almost all of the items, plans, reports, and documentation required for submission should be part of the process, rather than physical submission.

The word “application” is used 105 times in the NPRM. CMS would require voluminous submission of data, documents, and perhaps the most burdensome, the creation of new plans about how many requirements of the ACO program are to be addressed.

Below are several examples of items to be submitted as part of the application, taken randomly, quoted nearly verbatim from the NPRM:

1. An ACO must provide in its application evidence that it is recognized as a legal entity in the State it was established and is authorized to conduct business in each State in which it operates; required to provide in its application evidence that its pre-existing governing body meets all other criteria required;
2. ACOs are required to describe how they will partner with community stakeholders as part of their application;
3. ACO documents (for example, participation agreements, employment contracts, and operating policies) that describe the ACO participants’ and ACO providers/suppliers’ rights and obligations in the ACO, the shared savings that will encourage ACO participants and ACO providers/suppliers to adhere to the quality assurance and improvement program and the evidence-based clinical guidelines;
4. Documents that describe the scope and scale of the quality assurance and clinical integration program, including documents that describe all relevant clinical integration program systems and processes, such as the internal performance standards and the processes for monitoring and evaluating performance; supporting materials documenting the ACO’s organization and management structure, including an organizational chart, a list of committees (including names of committee members) and their structures, and job descriptions for senior administrative and clinical leaders; and descriptions of the remedial processes that will apply when ACO participants and ACO providers/suppliers fail to comply with the ACO’s internal procedures and performance standards, including corrective action plans and the circumstances under which expulsion could occur;
5. CMS proposes to require ACOs to provide a description in their application of the criteria they plan to employ for distributing shared savings among ACO participants and ACO providers/suppliers, and how any shared savings will be used to align with the aims of better care for individuals, better health for populations, and lower growth in expenditures.

In addition to being intimidating to prospective participants, in particular those who are not already functioning in an ACO-like practice model, these requirements and the others, are onerous, and unnecessarily intrusive, and will not attract voluntary participation. CMS notes in

its commentary in the NRPM that nothing in the statute seeks to define how shared savings will be distributed, yet CMS heavy-handedly requires ACO participants to explain its method of shared savings distribution in number 5, above, as part of the application.

We recognize that CMS seeks to protect program and beneficiary interests. We propose a more provider friendly approach. ACO attestation to most, if not all, of the application process submission requirements and affirmation of compliance with others, would simplify and satisfy CMS' interests. Nothing in such an approach would obviate use of any of the many existing program integrity assurance tools at CMS' disposal. While some larger entities may be able and willing to apply as written, absent this simpler method, we believe that many will decline to do it, even if otherwise interested. We realize that this new reimbursement model will require submission of some documentation, and suggest that an approach similar to the application for the Pioneer ACO program would be a better one to employ. That application is 14 pages long (it does require attachment and submission of considerable documentation), but consists of many items which can simply be typed into a data box or "check off" list.

Governance

Drop the requirement to have beneficiaries on the governing body, as this is unduly intrusive into the operations and organization of a private business, is impossible for many under state law, and a heavy burden for most.

The governance requirements found in the proposed rule for ACOs are quite extensive. They represent overreaching on the part of CMS, and the creation of a separate governing body for an ACO that is currently functioning as part of a larger delivery system may prove inhibitory for many. CMS should reconsider the need be so extensively involved in the business of corporate regulation, and the details therein.

The requirement to have beneficiary representation on the ACO's governing body will prove problematic for many potential ACOs due to state corporate practice of medicine laws that require all board members to be licensed health professionals. AMGA would recommend modifying this requirement so that one of the sitting board members could be appointed as a beneficiary representative, or a better alternative would be to permit the use of a beneficiary advisory body to represent patients in the ACO. The requirement could also be modified to align with that in the recently released Pioneer ACO Request for Application, which states that beneficiary representation on the governing board is only required "in the absence of extenuating circumstances such as existing legal restrictions on their governance structure" such as state laws that in some cases prohibit non-licensed health care professionals from sitting as a director.

Many AMGA member groups currently operate with several of the requirements outlined in the proposed rule, such as quality assurance and improvement programs, evidence-based medical practice and clinical guidelines, and a commitment to clinical integration. However, we suggest that the final rule drop requirements for direct patient representation on the governing body.

Opt-Out Provision

Data-sharing is a HIPAA-covered, allowable activity. The beneficiary opt-out provision is not conducive to population health management and should be dropped as a design feature of ACOs.

CMS contemplates a framework that allows beneficiaries the opportunity to opt-out of sharing their claims data with the ACO, save for the information needed to assign them to an ACO, tracking their per capita costs, or benchmarking activities essential to the functioning of the ACO. If a significant enough number of beneficiaries chose not to share their claims data with the ACO, it could hobble the ACOs' ability to create care management processes that would adequately address the needs of their unique patient populations. In addition, the opt-out provision creates yet another cumbersome administrative process because the beneficiaries who make this choice must be tracked. As mentioned earlier, physicians from AMGA member medical groups have repeatedly asserted the importance of full and timely access to claims data to manage their patient populations. We are aware of ongoing and successful ACO projects between private payers and health care providers that allow the sharing of this data with the involved providers so that they may manage their resources effectively in the context of population health management precepts.

Since an ACO is also responsible for the per capita costs of treating its assigned beneficiaries, it is important that ACO providers know what care their beneficiaries have sought outside of the ACO, in all cases. The unimpeded flow of beneficiary claims data to the ACO is therefore important from both the care management and resource use perspectives.

In the proposed rule, CMS recognizes that data sharing is a covered use of beneficiary claims data under the current HIPAA regulatory framework. It is well within CMS's discretion to eliminate the opt-out provision and we believe that the best interests of both patients and those furnishing health care services in an ACO would be better served by doing so. We therefore recommend eliminating the opt-out provision.

Patient Assignment

Allow ACOs to elect either prospective or retrospective attribution of patients. If limited to one approach, prospective attribution is the only method compatible with population health management and its requirements.

The proposed rule states that beneficiaries will be assigned, or aligned, with an ACO retrospectively based on where they receive the plurality of their primary care services, as determined by a preponderance of allowable charges. The proposals also state that the ACO will receive some data prospectively on those beneficiaries that would have been assigned the previous year based on the primary care services they received at the ACO.

While we understand the need to promote improved care processes for all patients, and not just those assigned to the ACO in order to advance the goals of population health management, we

have been told by our members, some of whom were participants in the Physician Group Practice (PGP) Demonstration, that having prospective identification of their patients is fundamental to allowing them to redesign care processes and manage patients effectively. Members have also told us that it is more efficient to make changes to care processes on a system-wide basis, rather than targeting certain beneficiaries. The philosophical approach of large, integrated, multi-specialty medical groups is to provide a uniformly high standard of care to all patients. We therefore believe the risks of prospective identification of beneficiaries in ACOs are mitigated by the benefits that would inure to the entire patient population of an ACO, and would also make population health management more efficient.

The recently released Pioneer ACO Request for Application permits either prospective or retrospective assignment of beneficiaries in the program. AMGA therefore strongly suggests that the final ACO rules offer the same flexibility as that found in the Pioneer ACO program.

Quality Reporting/CAHPS Survey

CMS proposes reporting of 65 quality measures. This is too great a target. Measures should be harmonized with existing reporting systems and should be limited to no more than 32 measures, phased-in over 3 years as was done in the PGP demonstration project. Hospital Acquired Conditions should be dropped, as these are not fair measures of performance of ACOs that do not own hospitals—care given in the hospital is beyond the control of the ACOs physicians in most cases. The CAHPS survey is inadequate to the purpose of measuring the totality of the patient experience in a coordinated care environment, lacking means to assess the experience in terms of team care provided. More than one choice of survey instruments should be available, as long as the basic requirements CMS sets are reflected in them.

CMS proposes that ACOs will report on 65 quality measures, in five domains on day one of the program. This is an excessive number that will prove to be a significant obstacle for even those medical groups that have well-established and integrated electronic health record (EHR) systems in place and currently conduct quality improvement activities. The burden inherent in reporting on the sheer number of measures proposed is extensive, given the resources that are involved in the programming to capture information for each measure and to be certain that quality thresholds are met, in addition to the care process modifications implicit in each measure. Even with sophisticated electronic infrastructure, many of the measures will still require chart abstraction. In addition, PGP demonstration participants have estimated that, on average, its costs about \$30,000 to program a single new quality metric, making 65 quality metrics a very costly proposition.

For ACOs that do not include a hospital within their structure, the hospital measures (numbers 24 and 25) should not be a requirement. To require reporting of these measures by those ACOs that do not include hospitals would require ACOs to be accountable for care quality outside of its control. The goals of these measures are laudable from a patient safety perspective and are currently reported in separate CMS hospital quality initiatives. Therefore, they should not be a requirement for those ACOs that do not include a hospital.

For the first years of the program, CMS should require ACOs to report on a much smaller number of measures, increasing them gradually over the term of the program. In the PGP demonstration, medical groups initially reported on eight quality measures. For the second year, the number went up to 16 measures. Finally, in the third year, PGP demonstration participants reported on 32 measures. We therefore suggest that CMS adopt a phased-in approach for quality reporting in ACOs, and one that more closely mirrors the approach used in the PGP demonstration, continuing to focus on high-volume, and high-cost disease states for maximum benefit in managing population health.

We note that some measures will require reporting via a survey instrument, notably measures in the Patient Experience of Care domain. CMS proposes that the National Quality Forum-endorsed Consumer Assessment of Health Providers and Systems (CAHPS) survey be used to capture data for seven patient experience measures. Given the emphasis on collaboration among providers to treat an individual patient across care settings, AMGA believes that the proposed survey does not fully encompass patients' care coordination experience, nor does it assess the quality of preparation for care transitions. Moreover, there is a complete absence of recognition of the importance of care delivered by teams of professionals in order to achieve the desired care coordination.

AMGA therefore proposes that CMS utilize a hybrid survey that would incorporate measures already in use in the Clinician/Group CAHPS survey, especially the Patient Experience measures and the Care Coordination measures that address advanced care coordination, but also consider Supplemental Modules and concepts (see Appendix A for AMGA recommendations).

AMGA also urges that the final survey instrument that is required of ACOs take into account the burden and costs associated with administration and that the information gained through a beneficiary survey is actionable and will help providers improve their care processes. Above all, more than one choice of survey instruments should be available, as long as the basic requirements CMS sets are reflected in the instrument.

Two-sided Risk Model/Participation Option Tracks/Shared Savings Rate and Cap

Most are not willing or able to engage in loss risk, and certainly not in the short timeframe proposed. CMS should offer several tracks for participation, one of which should be a sharing risk only approach. The shared savings rate should vary depending on the risk/reward criteria in the tracks, e.g., 70 percent in track one with no downside risk and 80 percent in track two, a two-sided option. Other tracks should be considered and offered, as is the case in the Pioneer ACO program, which should also serve as the model for shared savings maximums.

The shared savings program establishes a two-sided risk model that requires repayment of losses. The PGP demonstration, the "field test" for the shared savings program, employed a one-sided risk model, with participants only at risk for shared savings. Few organizations in the country have the size, scope and experience necessary to readily assume both upside and downside risk, in particular not in what is putatively the fee-for-service (FFS) setting. The superimposition of

accountability for population health management with upside risk assumption into the FFS realm produces operational tensions and business model dissonance, as this combination is of the managed care world. However, some might be able to bear it and be willing to adapt to these tensions. Adding the additional weight of downside risk to the mix, however, is simply more risk than most are willing or able to assume, in particular, when coupled with other program requirements such as offering retrospectively determined, de-identified patient data and the other key parts of the overall methodology used to determine costs, savings, and losses.

CMS proposes a two-track system. We believe that this should continue, perhaps even be expanded to several tracks, but that track one should be offered as a one-sided risk option only with track two offering shared savings and loss risk. In recognition of the need for fundamental risk/reward balance, we suggest that track-one offer a shared savings rate of 70 percent with track-two offering 80 percent. Other tracks might offer different combinations of risks and attendant rewards, as is the case in the Pioneer ACO program.

The shared savings cap is posited at 7.5 percent for track-one and 10 percent for track-two. Pioneer ACOs may share (or lose) either 10 or 15 percent of the shared savings, depending on the payment option selected. Participation in the ACO program will be decided by potential participants, based on their overall estimation of burden and reward. The maximum payout is a very important part of that evaluation. The maximum shared savings caps are, in and of themselves, not likely to be viewed as “deal breakers,” especially if other parts of the methodology, in particular the shared savings rate, are boosted to the levels we suggest. If that is not done, based on what we have heard from our members, in particular those who were PGP participants, the maximum shared saving caps are too low and should be raised, akin to those of the Pioneer ACO program.

Risk Adjustment

Risk adjustment is critical and should be recalculated and applied each performance period. If CMS has concerns about “coding intensity”, these could be addressed by using a system of adjustment which is not based on diagnostic coding. Static risk adjustment of the sort proposed will keep many potential ACO applicants from participation in the program.

CMS proposes risk adjustment as is required in the statute, but intends to use the same risk score throughout the agreement period. CMS proposes to apply the risk adjustment factor to the annual assigned patient populations’ per capita expenditures for assigned beneficiaries, but will not incorporate changes in the assigned beneficiaries population risk score that may result from changes in the disease acuity of the patients from year to year—by CMS’ own estimate, 20-15 percent of the beneficiaries may seek care elsewhere, a meaningful population change via this permissible “leakage.” CMS justifies this as guarding against changes that result from more specific or comprehensive coding as opposed to improvements in the coordination and quality of health care. By not incorporating the effects of changes in coding intensity during the

performance years (versus the benchmark), CMS concludes that it will protect the program from costs due to greater diagnosis coding intensity in ACOs.

The purposes of risk adjustment in both benchmark calculations and subsequent reassessments should be to recognize disease severity of the population and to compute costs accordingly. Sicker patients cost more than do healthy patients, and that should be reflected in cost computations and comparisons. Employing the method CMS proposes, will indeed take out the “coding intensity” factor, but will in the process of statistically applying the risk adjustment factor, produce cost profiles not adequately reflecting realities of the beneficiary assigned population. One of the goals of risk adjustment is that its outcomes be acceptable to all stakeholders. The method proposed is not fair, and it is not acceptable.

There are alternatives which meet CMS’ concerns about “coding intensity” and address potential participants’ interest in dynamic computation of risk adjustment, and one approach is put forward in the Pioneer ACO program design: Use an historically cost-based risk adjustment mechanism. The Pioneer ACO application describes this as: “... risk adjustment through use of the actual historical expenditures for each of an ACO’s aligned beneficiaries...rather than using clinical diagnoses to adjust from an average expenditure for a geographically defined or other general population.”

While we believe that risk adjustment based on diagnostic information is preferable, we feel that recalculating, for each performance year, disease acuity of the assigned population is essential, regardless of adjustment methodology selected.

Withholds and Self-executing Mechanism to Repay Losses

These requirements are a disincentive to participation and are heavily tilted toward CMS. CMS should simplify and reduce these burdens: For on-going enterprises, those in existence for 5 or more years, an agreement to recoup losses from future Medicare revenue payments should be the loss indemnification requirement. The pay-back period should be scaled from 1 to 10 years and limited to 1 percent of operating revenues to assure no harm to the viability of the on-going enterprise.

CMS proposes withholding 25 percent of shared savings in order to reserve funds for the purpose of repaying ACO operating losses. Additionally, CMS requires that an ACO establish a self-executing method for further assurance against potential losses, sufficient to ensure repayment of losses equal to at least 1 percent of per capita expenditures for its assigned beneficiaries from the most recent year available. This combination is considerable, in particular for small to mid-sized ACOs. We suggest that the requirements be simplified and the burden reduced in the following way: For on-going enterprises, those in existence for 5 or more years of continuous operations, an agreement to recoup losses from future Medicare revenue payments should be the loss indemnification requirement. Furthermore, the repayment term for any losses should be set on a sliding scale of time in proportion to the amount of debt as a percentage of operating revenues of

the most current year results available. The terms should range from one to 10 years and in no case be greater than one percent of operating revenues, to assure no harm to the viability of the on-going enterprise.

ACO Marketing Guidelines

The requirement is a burden for participants and CMS. We suggest use of clear guidelines for most of the marketing and communications materials and model letters/forms only for a few. Much of the communication to patients in the ACO should come directly from CMS to the patients.

CMS is proposing 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 pre-approved to protect beneficiaries from false and misleading communications.

Given some past practices of aggressive and even misleading sales tactics employed in manifestations of commercial insurers in the Medicare Advantage program, we appreciate CMS' role in beneficiary protection and program integrity. However, we are concerned about the breadth of the proposed pre-approvals. Should more than a small number of ACOs come into being, we cannot imagine that CMS could manage to review and approve the myriad communications typically flowing between large practices and their patients.

There are ameliorating factors to concerns about the excesses mentioned which pertain in ACOs:

1. Abuses occurred at the insurer level; not the provider level.
2. The program design already requires patients to be informed that they are in an ACO.
3. Sales, and marketing in that regard, are nowhere a feature of the program.
4. Allowing patients to opt-in is discussed but not proposed.
5. This is a new, different kind of program, and the past isn't necessarily prologue here.

There are two approaches to make this manageable. First, the model employed in Medicare Advantage is plausible, i.e., essentially the use of model forms, letters, etc. This might be most acceptable if the scope of communications covered were narrow. As the NPRM describes the communications/marketing materials, the scope is extensive. Secondly, perhaps clear and comprehensive guidelines rather than pre-approval, would be sufficient to meet the needs. Naturally, all available CMS' monitoring and review tools already extant, stand ready for deployment as necessary, should the agency wish to undertake routine audits or targeted reviews. Giving ACOs the choice of using model documents and text or following guidelines, or better yet, blending the use of both approaches, would be ideal. Further, we would suggest that CMS be responsible for notifying patients that they are in an ACO as a way of reducing that particular communication burden to ACOs, while at the same time, ensuring consistent communication.

Minimum Savings Rate (MSR)

The MSR as proposed is a “deal breaker” for small to mid-sized potential ACO applicants. It is asking too much and they cannot attain this level of savings. The same can be said for those operating in an ACO-like manner today but who are already highly efficient—achieving a minimum 2 percent MSR is problematic. We propose setting the MSR at 1 percent as proposed in the Pioneer ACO program.

The MSR is designed to assure that shared savings are the function of operations and clinical interventions, not random variation. CMS goes to great pains to explain its use of inferential statistics and related assumptions to justify its proposal. While somewhat valid, the fact remains that setting an MSR too high will severely dampen interest in participation for a host of reasons. In the case of organizations already highly efficient, setting the floor of the MSR at 2 percent simply sets the bar too high, and this was true in the PGP demonstration for several of the participants. They delivered excellent quality care, but ended up receiving no shared savings, the victims of their own efficient operations. Again, we refer to the Pioneer ACO model in which the MSR is set at 1 percent across the board. It is true that the minimum number of beneficiaries in the Pioneer ACO program is 15,000, compared to 5,000 in the NPRM design. However, the average number of patients in the PGP demonstration was around 20,000. It is also true that the size and scope and risk/reward calculus in the Pioneer ACO program differs from that of the NPRM.

The determination of the MSR is ultimately not a statistical exercise or mathematical problem with one right answer, but rather an administrative determination. In furtherance of broader national policy goals, the MSR as envisaged in the NPRM is a fatal impediment to program success. Smaller potential ACOs are essentially barred from earning any shared savings as the MSR will dissuade almost all of them from participating to begin with, but should some still enroll, will by design prevent them from garnering any savings. For example, a 3.9 percent MSR for an ACO of 5,000 beneficiaries will exist only in theory. That is largely true for the rest of the sliding scale proposal also.

ACO aspirants are asked to accept uncertainty for a relatively small “reward” and must be prepared to make considerable investments to prepare to become ACOs. The PGP demonstration, with participants hand-picked by CMS and large by definition (200 or more physicians was the size criterion), reported an average “investment” cost to gear up of \$400,000, with no provisions in the methodology to compensate them for that cost. In its own Regulatory Impact Statement, CMS’ actuarial estimate for start-up and first year operational costs is approximately \$1.76 million per ACO.

CMS heavily tilts the design to its favor in ways that make participation burdensome and unappealing to ACO participants. In order to make the ACO concept work, CMS needs to simplify and make more realistic the MSR requirements. There should be a flat 1 percent MSR for all participants and CMS should bear the risks of this administrative determination and consider it as part of its “investment” in the concept. Without serious realignment and readjustment of the MSR, many will view the MSR portion of the proposal as a “deal breaker.”

Antitrust Issues

The assurances offered are not strong enough to convince many to enter the shared savings program without seeking agency review. We are concerned that the expedited process might be a strain if large numbers of applicants make requests. This will surely have a dampening effect on the numbers of organizations becoming ACOs. We urge CMS to work with DOJ and FTC to reach concordance on antitrust matters allowing CMS to “deem” those approved as presumed to be in compliance. We recognize that legislative changes may be required if voluntary agreement is not achieved.

We do not see how any behavior, anti-competitive or not, can have an impact upon Medicare reimbursements. Reimbursement rates are determined by Congress and CMS, and no amount of collusion will change Medicare rates. Consequently, we struggle to understand why antitrust issues are considered in the scope of proposed regulations that impact Medicare. That said, we support using the “rule of reason” approach that evaluates whether collaborations between health care providers are likely to have substantial anticompetitive effects, and whether the pro-competitive collaboration’s efficiencies are likely to outweigh the risks. However, this analysis is a complex one that may prove too subjective to offer potential ACOs the necessary assurance to move forward with the substantial financial investments to form a successful ACO. We suggest that if an ACO meets the CMS indicators for clinical integration and the extensive requirements for application, vetting, and approval in order to become an ACO, that these actions represent presumptive compliance with the FTC and DOJ’s antitrust guidelines. If it has not already done so, CMS should seek interagency concordance with the FTC and DOJ that would permit ACOs accepted into the program to be “deemed” to be in compliance by virtue of being accepted by CMS. Further, the application process could serve as an opportunity for ACOs to provide an attestation that they are not engaging in anticompetitive activities within their markets. We recognize that legislative changes might be necessary to act on all of these ideas.

No CEO of a large medical enterprise is likely to commit his organization to the large investments and systems changes necessary to become an ACO with the insufficient protections provided in the DOJ and FTC assurances. Most will either decline to participate or will insist on a review before taking additional steps forward to be ACOs. Although we support, and appreciate, the commitment behind the 90-day expedited review process for those entities that have determined their market share of their primary service area (PSA) to be greater than 50 percent, we are concerned that the FTC and DOJ may not be able to meet the 90-day timeframe for all potential ACOs.

Waiver of Stark Law/Anti-Kickback Statute/Civil Money Penalties

The Secretary of Health and Human Services and the Office of Inspector General (HHS OIG) should adopt a position granting ACOs presumed compliance with Stark and anti-kickback laws, given the extensive application and vetting procedures, documentation, and attestations that are necessary to form an ACO.

The Secretary of HHS proposes to waive applicable Stark self-referral prohibitions to an ACO's distributions of shared savings received from CMS under the Shared Savings Program under these circumstances: 1) to ACO participants and providers/suppliers during the year in which the shared savings were earned by the ACO, and 2) to others as "necessary for and directly related to" participation as an ACO under the shared savings program, with waiver limited to distribution of its shared savings.

The proposed rule does not go far enough in granting waivers by only addressing the sharing of savings among the ACO participants. No assurances are given to an ACO as it organizes, before it is accepted into the shared savings program. Given the significant start-up costs found in the PGP demonstration, which will be mirrored in newly forming ACOs, these considerable advance investments should also be included in the waiver of Stark Law applicability, as should all activities reasonably related to the ongoing operation of the ACO, and its activities directly related to organizing as an ACO in advance of acceptance into the shared savings program.

Existing program integrity mechanisms for oversight, both prospective and retrospective in nature, coupled with the extensive application vetting procedures, documentation, and attestations necessary to become an ACO, are strong and effective. For this reason, we believe that the HHS OIG should adopt a position granting ACOs in the shared savings program presumed compliance with Stark and anti-kickback laws. This presumption should extend and apply to the ACOs activities directly related and necessary to organizing to become an ACO, undertaken in a period of reasonable duration, in advance of acceptance into the shared savings program.

Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs)

CMS should make provisions and make changes to data gathering which will allow FQHCs and RHCs to become ACOs on their own.

While the ACO proposals permit FQHCs and RHCs to be included in ACOs, they do not permit these entities to form their own ACOs. These entities, in many cases, are already clinical integrated, coordinate the care of their patient populations, and most importantly, perform an important role in the nation's health care delivery system by serving as safety net providers of primary care and other health care services in rural and other underserved areas, and for low-income Medicare beneficiaries. CMS states in the proposed rule that, at this time, FQHC and

RHC claims do not include the Health Care Procedural Coding System (HCPCS) codes for services that identify the specific service provided. For RHCs, the claims contain limited information about the rendering practitioner, and thus insufficient data for beneficiary assignment, benchmarking, and determination of shared savings.

However, we have learned that the UB-04 claim forms utilized for FQHCs and RHCs do in fact contain HCPCS codes, national provider identifiers (NPIs) and tax identification numbers (TINs), and thus the data is available that would enable these entities to form their own ACOs. This suggests that there is an issue with the collection of this information, not its availability. AMGA therefore recommends that CMS partner with FQHCs and RHCs to find and implement a solution which permits these entities to collect needed data in a workable form to eliminate the barrier to their becoming ACOs directly.

Final Comments

Let me close by reiterating AMGA's unwavering endorsement of Accountable Care Organizations. However, we believe that without significant changes, the proposals represent a missed opportunity to transform the health care delivery system from its current fragmented and unsustainable state, to one that rewards accountability for patient care in an effective and efficient manner.

Our members have been delivering accountable care long before it was known as such, some of them for decades. They will continue to do that regardless of the CMS final shared savings program regulations. However, because we feel that this advanced practice model of delivery has long-term potential to redirect and reshape the nation's fragmented health care delivery system, we urge you to significantly change the program design. If this does not happen, participation will be scant and the ACO national implementation runs the risk of ending up inconsequential.

Should you have any questions, please do not hesitate to contact these members of my staff, George Roman at groman@amga.org or Karen Ferguson at kferguson@amga.org.

Sincerely,



Donald W. Fisher, Ph.D.
President and CEO

Suggested Supplemental Survey Modules

- **Coordination of Care**
 - My Care Provider talks with me following any treatment I have outside of his or her office
 - If my Care Provider recommend I see a specialist/another doctor, they explain the reason
 - My health care is well-coordinated between all of the providers who care for me
- **Care Teams**
 - Without the help of my Care Team I would not be as healthy as I am today
 - Someone from my Care Team discusses with me how to handle health problems that may arise between visits
 - My Care Team makes me aware of any additional resources that are available to help me improve my health
- **Information Use and Sharing**
 - I feel comfortable asking my Care Provider questions about any health issue I do not understand
 - I understand the purpose and schedule of my medications
 - I am interested in increasing the amount of communication I have with Care Provider, outside of a scheduled visit
- **Compliance**
 - I take my prescribed medications as directed
 - There are issues that keep me from taking my prescribed medications as directed (cost, transportation, other)
 - If my Care Provider recommends additional medical visits, I make sure I go.