

December 3, 2010

Donald M. Berwick, M.D., M.P.P.  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Room 445-G  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

***Re: Medicare Program; Request for Information Regarding Accountable Care Organizations and the Medicare Shared Saving Program***

Dear Dr. Berwick:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations and the nearly 200,000 employed physicians within those organizations, the American Hospital Association (AHA) is pleased to offer comments in response to the Centers for Medicare & Medicaid Services' (CMS) Request for Information (RFI) with respect to the development and implementation of Accountable Care Organizations (ACOs), as described in Sections 3022 of the *Patient Protection and Affordable Care Act* (ACA), the Medicare Shared Savings Program and the activities of the Center for Medicare & Medicaid Innovation (CMMI), as described in Section 3021.

The AHA has engaged in significant outreach to its members to educate them about ACOs and to obtain their input on the development of ACO requirements. We have sought advice from policy experts on delivery reform, those working on establishing ACOs in the private sector, and the participants in the Physician Group Practice (PGP) demonstration. We also have held webcasts for our members featuring physician leaders from institutions that have begun the ACO journey. Finally, we have sought input from our governance structure, including the AHA Board of Trustees, our nine Regional Policy Boards and our Health Systems Governing Council. All told, more than 500 hospital leaders have offered their thoughts to help formulate these comments in response to CMS' RFI. Our response addresses CMS' specific questions.



***What policies or standards should we consider adopting to ensure that groups of solo and small practice providers have the opportunity to actively participate in the Medicare Shared Savings Program and the ACO models tested by CMMI?***

One way in which CMS can achieve active participation in the shared savings program, especially for solo and small practice providers, is to eliminate regulatory barriers that inhibit clinical integration. For many years, the AHA has urged federal agencies to reevaluate and adjust their requirements or interpretations to remove major impediments to clinical integration, which is the backbone of delivery reform. The most prominent barriers are the five major federal laws that affect working relationships among providers and the use of incentives to change how care is delivered – the Stark laws, Civil Monetary Penalties, anti-kickback, anti-trust and IRS restrictions on payment to physicians. The AHA participated in the joint Federal Trade Commission/CMS listening session on this issue in October and we have attached a chart that summarizes our major concerns. It is important to understand, however, that many of these barriers need to be modified not only for ACOs but for all providers to respond to the behavioral changes required to address other ACA requirements, such as reducing readmissions, adopting evidence-based medicine and payment bundling. These barriers will get in the way of providers developing the clinical relationships needed to even prepare for an ACO role.

Most office-based physicians continue to practice solo or in small groups. Moreover, to the extent that physicians are moving to larger practices, it is generally to form single specialty practices, and not the multi-specialty groups that are best able to support care coordination.

The prevailing model of hospital-physician relationships is the organized medical staff model, which does not assure the optimal level of care coordination between a hospital and independent physicians. In this model, physicians use hospital facilities and rely on hospital staff to provide their services, but the medical staff is not employed by the hospital. Additionally, an increasing number of physicians do not practice in hospitals and, therefore, are not members of the organized medical staff. As a result, hospitals and physicians have limited tools they can use to positively influence each other's practice patterns to achieve optimal patient outcomes, especially since most forms of economic incentives may run afoul of regulatory barriers such as the Stark, anti-kickback and the Civil Monetary Penalty laws that apply to Medicare and Medicaid patients.

Given this environment, for ACOs to be successful, there needs to be a way for physicians in small and solo practices to come together with other providers to form the entity required to contract with the Medicare shared savings program. The historical approach to creating such an entity is the formation of a physician hospital organization (PHO) that combines providers without physicians having to become employees of hospitals, but there are other more contemporary models, such as health networks, that could be viable.

Not every entity will be involved in a risk-based or financially integrated relationship, which means it must become clinically integrated should compliance with antitrust law become an issue. Physicians in small groups or solo practices are less likely to be able to afford the information technology to implement electronic health records and similar technologies. They

also will have difficulty in sharing “best practices” and accessing peer data for use as benchmarks. Those elements are necessary to create clinically integrated relationships with hospitals, yet antitrust agencies still look with skepticism at non-financial relationships, leaving hospitals and physicians at risk.

CMS needs to ensure that these kinds of relationships will be permitted under the shared savings program. Otherwise, the only options available to those in solo or small practices will be to become employees of the hospitals or to form large multi-specialty group practices. In a rural environment, where many solo and small physician practices exist, the viability of forming multi-specialty physician groups is limited.

CMS could facilitate the formation of ACOs in rural areas in particular by providing assistance and resources for the formation of regional networks that would meet the requirements for forming ACOs. For example, in low-population areas it will be necessary to form regional, as opposed to local, ACOs to meet the requirement of a minimum 5,000 Medicare beneficiaries. CMS could assist in providing financial support for the kind of infrastructure required to form a regional approach, such as telemedicine services and health information technology connections among rural communities. Because of the limitations of the ACO statute, it may be necessary to look to the CMMI to explore more workable models for rural areas.

***Many small practices may have limited access to capital or other resources to fund efforts from which “shared savings” could be generated. What payment models, financing mechanisms or other systems might we consider, either for the Shared Savings Program or as models under CMMI to address this issue? In addition to payment models, what other mechanisms could be created to provide access to capital?***

While popular understanding of shared savings is that there is an opportunity for a bonus without the potential for a loss (i.e., the “asymmetric” model), forming an ACO and participating in the Medicare shared savings program involves significant investment on the part of the providers. Front-end investments, such as health information technology, data and technical expertise for analytic capability, need to be covered at least in part by the expected savings to be generated under the program. Estimates from organizations preparing to become Medicare ACOs, including some from the PGP demonstration, indicate that as much as one million dollars in start-up capital may be needed even for small ACOs.

Since the Medicare program benefits from first-dollar savings, it is reasonable to expect the program to share in the investment cost to generate those savings. Too large a hurdle to share in savings to support those investments is a sure and quick means to discourage participation in the program. To better enable participation, CMS should consider recognizing and contributing toward some of the start-up costs for ACOs. This can be done in several ways. For example, initial savings from the random variation adjustment could be contributed to an investment fund to provide some funds to ACOs showing signs of potential success, or to provide periodic interim payments to ACOs to help fund infrastructure.

In addition to using the savings from the random variation adjustment investment fund referenced above, CMS, perhaps through the CMMI, could partner with states or local governments that are interested in delivery system reform. CMS also could re-prioritize the purpose of existing programs. For example, CMS could ensure that the tenth scope of work for the Quality Improvement Organization program provides specific technical assistance to ACOs.

In addition to periodic interim payments for infrastructure, CMS also could increase access to capital by relaxing the rigidity around how shared savings is calculated. We believe CMS should demonstrate significant restraint in adjusting for random variation to improve the likelihood that ACOs will experience an early return on investment. Throughout the nearly five years of the demonstration, only half of the PGP sites earned a shared savings bonus because the criteria CMS used were so rigid. We understand that CMS is currently negotiating similarly rigid criteria for the transition of the PGP sites to the ACO program. Specifically, we understand that CMS is proposing: (1) a 25 percent withhold of the bonus payment until the end of the three-year period, (2) a potential 5 percent cap on the bonus, and (3) varying the threshold amount that must be superseded, prior to sharing in savings, based on the number of assigned beneficiaries. This last proposal will vary based on the confidence interval used to estimate random variation. A 95 percent confidence interval would suggest a 2 percent threshold for 20,000 assigned beneficiaries while a 90 percent confidence interval would allow for less than 2 percent for approximately 20,000 assigned beneficiaries.

***The process of attributing beneficiaries to an ACO is important to ensure that expenditures, as well as any savings achieved by the ACO, are appropriately calculated and that quality performance is accurately measured. Having a seamless attribution process will also help ACOs focus their efforts to deliver better care and promote better health. Some argue it is necessary to attribute beneficiaries before the start of a performance period, so the ACO can target care coordination strategies to those beneficiaries whose cost and quality information will be used to assess the ACO's performance; others argue the attribution should occur at the end of the performance period to ensure the ACO is held accountable for care provided to beneficiaries who are aligned to it based upon services they received from the ACO during the performance period. How should we balance these two points of view in developing the patient attribution models for Medicare Shared Savings Program and ACO models tested by CMMI?***

In our discussions with hospital leaders, there was strong sentiment that CMS must prospectively assign beneficiaries and allow for a reconciliation of assigned beneficiaries at the end of the measurement year to account for nuances, such as beneficiaries transitioning into a Medicare Advantage Program or for beneficiaries who receive a significant portion of their care well outside of an ACO's primary service area. We recommend CMS maximize transparency around the attribution of beneficiaries. There are many unanswered questions about the implications of the various methods that could be used for patient attribution. Though the PGP demonstration provides useful experience using one kind of attribution methodology, CMS needs to extensively invest in further methodological development to determine the pros and cons associated with various approaches. We commend CMS and its support contractor, RTI, for the extensive

preparatory work that they have completed for each of the PGP sites to prepare for extension to the ACO program, including an analysis of seven different attribution rules.

We understand that each of the attribution rules varied the definition of primary care, with the broadest rule including cardiology, geriatrics, endocrinology, pulmonology and nephrology. Many of the PGP participants felt that the patient population assigned during the demonstration was not large enough and they continue to remain very interested in exploring how variations in assignment method can increase the population size. On the other hand, assigning patients for whom the ACO provided a lesser proportion of care made it more difficult to meet spending targets because their opportunity to intervene was reduced. As a result, they felt that the patient's actual use of services in the payment year should have some bearing on whether the patient was presumed to be part of an ACO.

***How should we assess beneficiary and caregiver experience of care as part of our assessment of ACO performance?***

We recommend that CMS rely on its experience with the operations, methodology and measures associated with the both the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) and Consumer Assessment of Healthcare Providers and Systems (CAHPS). CMS must recognize that hospitals already submit HCAHPS measures as a requirement of the hospital inpatient quality reporting program. To the greatest extent possible, we recommend that CMS leverage this existing requirement to assess beneficiary and caregiver experience of care. This will ensure the greatest level of consistency across the Medicare program.

***The Affordable Care Act requires us to develop patient-centeredness criteria for assessment of ACOs participating in the Medicare Shared Savings Program. What aspects of patient-centeredness are particularly important for us to consider and how should we evaluate them?***

“Patient-centeredness” is one of the six elements of high-quality care described by the Institute of Medicine (IOM) in *Crossing the Quality Chasm*, and must be understood within that context. Whether within an ACO or in any other configuration of a delivery system, providers should constantly be striving to make care safe, timely, effective, efficient, equitable and patient-centered. While patient-centered care may be defined in many ways, within the context of the IOM's list, it is the element that emphasizes the need for the patient's needs and wishes to be considered and respected, or as the IOM defined it, “providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions.”

In articulating the criteria for patient-centered care within the ACO and CMMI efforts, we urge CMS to be mindful that it is also an aspect of several other programs in the ACA including: health insurance exchanges (§1311), health insurance coverage (§2717), National Quality Strategy (§3011-3014), Medicare bundled payment pilot (§3023), Medicare Advantage payment (§3201), medical homes (§3502), workforce training (§5301, 5315 and 5405) and comparative

effectiveness research (§6301). The Secretary must take all of these areas of health reform into consideration when developing patient-centeredness criteria and using those criteria to assess ACOs. Though patient-centeredness affects many programs, we strongly recommend the Secretary define a universal set of common elements of patient-centeredness and consistently apply the common elements to all programs.

We offer the following to elaborate on the IOM definition of patient-centeredness:

1. Providers should have a process for engaging with the patient and family at each step of care to understand that patient's physical, emotional, mental and spiritual needs, and allow the patient's values to drive the care provided to the greatest extent possible.
2. Providers should deliver care that is culturally and linguistically sensitive.
3. Providers should have processes in place to enable smooth transitions in care as patients move from one part of the delivery system to the next, ensuring that information about their diagnoses, treatment plans and personal preferences are communicated to other providers as well as to the patient and family.
4. Clinicians should provide information, education and counseling to ensure maximum patient engagement and enhance shared-decision making to achieve a patient's sense of empowerment and self-responsibility.

Rather than dictate through regulation a checklist of these aspects of patient-centeredness, CMS should allow ACOs to innovate and implement novel approaches. An important element of giving ACOs some flexibility for innovation would include their ability to provide incentives for patients to engage in their care. For example, ACOs should have the flexibility to provide free supplies or services that are not covered or to waive co-payments for certain services, such as primary care services, to encourage patients to be active participants in their health care. Currently, providers are prohibited from offering these "inducements."

Because beneficiaries are free to seek care both inside and outside the ACO, it is difficult for the ACO to foster care coordination without having near real-time data on services being provided out of network. ACOs must have access to near real-time data to support the types of interventions that could address care issues as well as enable effective ACO monitoring of progress on performance measures. The PGP demonstration sites consistently experienced about 30 percent of care delivered outside their networks. They often did not know about the delivery of out-of-network care until well after it was furnished, submitted for payment and reported by CMS back to the sites months later. The lag in data about the initiation of care provides no opportunity to identify care coordination issues or transition needs or other actions they might need to take to improve care outcomes and their own performance, especially with respect to avoiding readmissions. ACOs need to receive admission notifications for ACO patients so that they can ensure adequate discharge planning, care transitions and follow-up care. The only source of data on out-of-network care cannot be limited to data that flows from claims processing, and what does flow from claims needs to be received faster—on a monthly, or even weekly, basis.

***In order for an ACO to share in savings under the Medicare Shared Savings Program, it must meet a quality performance standard determined by the Secretary. What quality measures should the Secretary use to determine performance in the Shared Savings Program?***

The quality measures that are required for an ACO will ideally serve a dual purpose—to monitor the performance of the ACO *and* to provide the ACO with information for effectively managing the efficiency of caring for its population. The measures used under the PGP demonstration program compelled participants to establish separate quality and utilization internal tracking systems. There are some rigorously tested, fully-endorsed National Quality Forum (NQF) measures that will allow ACOs to monitor performance and manage their population within one tracking system and eliminate the duplicative need to track quality and utilization separately.

Though we recognize there are a limited number of NQF-endorsed measures that speak to both quality and utilization, we do not foresee a problem. Focusing on a small set of core measures is the right approach for early phases of ACOs, and it may be that CMS should select this small core set and not alter it during the first three years of the program as the participating organizations and the agency are learning. With a couple of years' experience, CMS may be able to determine which additional measures are essential to achieve the program's goals or are necessary to monitor for unintended consequences. If CMS chooses to expand the list of quality metrics annually, it needs to strike a balance between the current state of readiness for population-level quality measures and pushing the field further for rapid development in this area. This can best be achieved by beginning the program with a small core measure set *and* laying out an action-oriented strategic plan for implementing quality measures for future phases. Recently in the Inpatient Prospective Payment System (IPPS) and the Outpatient Prospective Payment System, CMS articulated three-year plans for implementation of quality measures. We strongly recommend that CMS follow this approach and preview a minimum of three years of quality measures that will be targeted in the ACO program.

In addition to using NQF-endorsed measures, we recommend that CMS carefully consider the evolving quality measurement environment when selecting ACO measures. Currently, IPPS hospitals are required to submit 54 quality measures to the hospital quality reporting program on an annual basis. By 2014, this number will increase to 60 measures. There are several measurement areas within the hospital reporting program, including readmissions, which are also useful for the ACO program.

There are NQF-endorsed measures that are not currently being utilized in any of CMS' quality reporting programs that may be appropriate for the ACO program. For example, many health systems have long recognized the benefit of the ambulatory care sensitive measures that have been developed by the Agency for Healthcare Research and Quality. Yet, these measures are not used in any of CMS' quality programs. Though these may be more appropriate for the type of population management needed within an ACO, CMS must recognize that providers will need a considerable amount of technical assistance to use these measures, as they have not been used within the context of a national payment program. To avoid creating unnecessary additional reporting burdens, we recommend that CMS utilize existing measures wherever possible without

change, discard existing measures that are not relevant for an ACO, and adopt ACO-specific measures only after thorough testing.

We also strongly recommend that CMS promote the collection of all-payer data to populate ACO quality measures. Since the inception of the hospital inpatient reporting program, all-payer data have been collected, but not in other settings. It is essential to aim for collection of all-payer data to achieve alignment of quality measures across all-payers and to be responsive to the National Quality Strategy that is currently being developed by the Secretary of the Department of Health and Human Services.

***What additional payment models should CMS consider in addition to the model laid out in Section 1899(d), either under the authority provided in 1899(i) or the authority under the CMMI? What are the relative advantages and disadvantages of any such alternative payment model?***

The AHA supports using maximum flexibility in both the shared savings program and the CMMI projects to test a variety of payment and delivery models that can support changing the volume-driven incentives of the fee-for-service system to one based on value-driven incentives. We also urge the CMMI to work with providers who have already established innovations with private payers in their communities so that providers can transition quickly from the old fee-for-service incentives to new structures. For our members already on the transition path, straddling payment systems with both types of incentives is extremely difficult.

With respect to specific approaches that we believe CMS should undertake, we recommend that the agency focus on partial risk approaches that look to providers to bear the risk associated with the delivery of high quality, efficient care. Most payers, including Medicare, are moving to payment approaches that shift the consequences of provider performance to the provider. We do not believe that payment approaches should expect providers to bear the insurance risk of a covered population (i.e., how many of the covered individuals will be sick or injured). Insurance risk requires covering large populations where the law of averages works to spread the risk, which is the primary purpose of insurance. The Medicare program is the best place to cover insurance risk so that it is spread across the largest possible risk pool.

A wide range of approaches should be considered, including:

- Partial capitation, where only some of the services covered are paid on a capitated basis;
- Risk corridors, where placing limits on both rewards and losses are used to approximate provider performance risk;
- Per member per month care coordination models, where different payment approaches are used to support care coordination costs that utilize a variety of accountability measures;
- Rural delivery models, where for example a medical home approach could be combined with a transitional care model to support rural hospitals and physicians working together to build the infrastructure needed to broaden the base of care coordination; and

- Condition-specific capitation, where capitated payment is focused on individuals with specific, often chronic, conditions. This differs from bundling in that it covers more than an episode of care, focusing instead on managing long-term or chronic conditions for a year. Since most individuals with chronic conditions generally have more than one chronic condition, it would be especially important to define clearly the scope of the obligation.

We are certain that there are a variety of other approaches that could emerge. It is in the area of partial risk, however, where there are no payment alternatives under the current Medicare program. It is basically fee-for-service or a full-risk Medicare Advantage plan.

The AHA believes it is also important to address several issues under all payment approaches that might be tested or adopted. They are:

- CMS must make adjustments to the data, including adjustments for graduate medical education, disproportionate share and wages, to ensure an accurate assessment of the use of resources. Removing the effect of the adjustments, commonly referred to as unit cost standardization, should be performed annually to reflect frequent changes in those adjustments.
- The need to ensure that providers are able to evolve in forming the needed relationships with other providers to form the care systems capable of accepting accountability for quality and efficiency. That means removal of barriers to clinical integration.
- The need to track the strategies and techniques used to accomplish the accountability objectives of quality and efficiency, and their costs so that:
  - CMS can evaluate the effectiveness of those strategies and techniques.
  - CMS can appropriately reflect the cost of care coordination under new payment methods, given the historic lack of Medicare coverage of care coordination.
  - Providers can examine the most effective ways to meet the challenges of delivery and payment reform.

Finally, we strongly encourage the CMMI to make a robust investment in testing bundled payment approaches. The ACA requires CMS to implement a Medicare bundled payment pilot, Medicaid bundled payment demonstration and a Medicaid global payment demonstration. Early successes from CMS' Acute Care Episode demonstration prove that bundled payment is a viable approach for reducing unnecessary costs and improving or maintaining quality of care.

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The AHA strongly supports the need for delivery reform and we appreciate your consideration of our recommendations. If you have any questions, please contact me or Lisa Grabert, senior associate director of policy, at (202) 626-2305 or [lgrabert@aha.org](mailto:lgrabert@aha.org).

Sincerely,

//s//

Linda E. Fishman

Senior Vice President

Public Policy and Data Analysis

cc: Jonathan D. Blum  
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Richard J. Gilfillan, M.D.

Acting Director, Center for Medicare and Medicaid Innovation

Attachment

## Chart of legal barriers to clinical integration and proposed solutions

Law	What Is Prohibited?	The Concern Behind the Law	Unintended Consequences	How to Address?
<b>Antitrust (Sherman Act §1)</b>	Joint negotiations by providers unless ancillary to financial or clinical integration; agreements that give health care provider market power	Providers will enter into agreements that either are nothing more than price-fixing, or which give them market power so they can raise prices above competitive levels	Deters providers from entering into procompetitive, innovative arrangements because they are uncertain about antitrust consequences	Guidance from antitrust enforcers to clarify when arrangements will raise serious issues. DOJ indicated it will begin a review of guidance in Feb. 2010.
<b>Ethics in Patient Referral Act ("Stark Law")</b>	Referrals of Medicare patients by physicians for certain designated health services to entities with which the physician has a financial relationship (ownership or compensation)	Physicians will have financial incentive to refer patients for unnecessary services or to choose providers based on financial reward and not the patient's best interest	Arrangements to improve patient care are banned when payments tied to achievements in quality and efficiency vary based on services ordered instead of resting only on hours worked	Congress should remove compensation arrangements from the definition of "financial relationships" subject to the law. They would continue to be regulated by other laws.
<b>Anti-kickback Law</b>	Payments to induce Medicare or Medicaid patient referrals or ordering covered goods or services	Physicians will have financial incentive to refer patients for unnecessary services or to choose providers based on financial reward and not the patient's best interest	Creates uncertainty concerning arrangements where physicians are rewarded for treating patients using evidence-based clinical protocols	Congress should create a safe harbor for clinical integration programs
<b>Civil Monetary Penalty</b>	Payments from a hospital that directly or indirectly induce physician to reduce or limit services to Medicare or Medicaid patients	Physicians will have incentive to reduce the provision of necessary medical services	As interpreted by the Office of Inspector General (OIG), the law prohibits any incentive that may result in a reduction in care (including less expensive products)...even if the result is an improvement in the quality of care	The CMP law should be changed to make clear it applies only to the reduction or withholding of medically necessary services
<b>IRS Tax-exempt Laws</b>	Use of charitable assets for the private benefit of any individual or entity	Assets that are intended for the public benefit are used to benefit any private individual (e.g., a physician)	Uncertainty about how IRS will view payments to physicians in a clinical integration program is a significant deterrent to the teamwork needed for clinical integration	IRS should issue guidance providing explicit examples of how it would apply the rules to physician payments in clinical integration programs
<b>State Corporate Practice of Medicine</b>	Employment of physicians by corporations	Physician's professional judgment would be inappropriately constrained by corporate entity	May require cumbersome organizational structures that add unnecessary cost and decrease flexibility to achieve clinical integration	State laws should allow employment in clinical integration programs
<b>State Insurance Regulation</b>	Entities taking on role of insurers without adequate capitalization and regulatory supervision	Ensure adequate capital to meet obligations to insured, including payment to providers, and establish consumer protections	Bundled payment or similar approaches with one payment shared among providers may inappropriately be treated as subject to solvency requirements for insurers	State insurance regulation should clearly distinguish between the risk carried by insurers and the non-insurance risk of a shared or partial risk payment arrangement
<b>Medical Liability</b>	Health care that falls below the standard of care and causes patient harm	Provide compensation to injured patients and deter unsafe practices	Liability concerns result in defensive medicine and can impede adoption of evidence-based clinical protocols	Establish administrative compensation system and protection for physicians and providers following clinical guidelines

The table above comes from the new *AHA TrendWatch* report "Clinical Integration – The Key to Real Reform." For more information on the report, click on the "Research and Trends" section of [www.aha.org](http://www.aha.org).