



**American Hospital
Association**

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Jonathan D. Blum
Deputy Administrator
Center for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Mail Stop: 314G
Washington DC

Dear Mr. Blum:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, our nearly 40,000 individual members and our 199,000 employed physicians, the American Hospital Association (AHA) is pleased to offer our comments on the development and implementation of Accountable Care Organizations (ACOs), as described in Section 3022 of the *Patient Protection and Affordable Care Act* (ACA), the Medicare Shared Savings Program. The AHA intends these comments to be constructive and helpful so that the program can be successful in promoting delivery reform. We also look forward to commenting on the just-released “request for information” on specific questions and on the forthcoming proposed regulation on ACO requirements.

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 us formulate these comments. This letter captures the primary points emphasized by our members, and we provide these comments as follow-up to our November 12 meeting with you and your staff.

The AHA agrees with Administrator Berwick that with ACOs “no one size will fit all.” The ACA allows for considerable flexibility in which providers may organize as ACOs. We believe CMS should allow different configurations of provider organizations to enter the shared savings program to see what works and what does not work well.



Many different models need to be tested in the first phase of the national program. We feel it is especially important to find a way to foster delivery reform in rural areas and we are concerned that the statutory requirements for ACOs limit the ability of rural providers to participate in the shared savings program. We encourage CMS, perhaps through the Center for Medicare and Medicaid Innovation, to explore opportunities to extend similar arrangements to rural providers who are interested in adopting delivery reforms.

We also urge CMS to start the program slowly, perhaps limiting the number of ACOs in the early years and establishing mechanisms for ongoing evaluation so that successes can be communicated and, hopefully, replicated throughout the health care system. We also recommend a mechanism to make mid-course corrections in the administrative requirements and methodologies. To date, there are a number of private-sector efforts to form ACOs. The AHA encourages CMS to partner with these early adopters to maximize the potential for success.

CARE TRANSFORMATION

The overarching goal of ACOs needs to be delivery reform that improves quality, efficiency and the patient experience through accountable care: ACOs are about creating systems of care with providers acting in concert to keep the whole patient at the center of their attention. Currently, providers are operating in silos of payment, standards and care delivery. To transform care delivery, we need to bridge the silos, meaning we need to change our relationships across the silos. For example, we know from the PGP demonstration that a primary source of savings comes from avoiding admissions and reducing readmissions. Hospitals are being very creative with strategies to address readmissions, such as sending social workers or nurses to patients' homes, or providing scales to heart failure patients in their homes – all free of charge. Some hospitals have been advised by their lawyers that they cannot provide free services to patients who leave their hospital because it is viewed as an inducement to provide potentially unnecessary services.

Federal agencies that regulate the silos must similarly bridge their regulatory silos to support care transformation. An example is the need to coordinate among all the federal agencies (CMS, the Office of the National Coordinator for Health Information Technology, the National Committee on Vital Health Statistics, the Agency for Healthcare Research and Quality) on the data required for monitoring both operations and quality measures. We currently are implementing meaningful use rules, the ICD-10 classification system, the current 5010 revisions to standardized transactions and other administrative simplification initiatives. All of these agencies need to be coordinated, consistent and supportive of the kinds of changes we are trying to accomplish to transform care.

A careful balance also must be struck between the goal of care coordination to improve quality and efficiency and the desire to maintain beneficiary choice. The ACA does not allow for restructuring the benefits or cost sharing for ACO-attributed patients. The statute guarantees beneficiaries their free choice of providers, but there is no provision for incentives for beneficiaries to stay within the ACO network. This construct is difficult for implementing

greater care coordination. CMS should look for ways to meet the requirements of the statute while achieving greater balance. For example, CMS should waive the hospital discharge condition of participation (CoP) that prohibits recommending specific sources of post-acute care to beneficiaries so that ACOs can demonstrate why it would be advantageous to stay within the ACO network where all providers participate in a common quality improvement process.

ELIGIBILITY CRITERIA

The AHA supports the full use of the flexibility provided in the ACA with respect to how ACOs are structured and governed. We recommend that CMS defer details of the organization, such as the leadership and management structure, to each ACO and to focus instead on what is required by the statute for each ACO, e.g., a formal legal structure enabling the ACO to accept and distribute shared savings to participating providers.

DATA

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 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.

QUALITY MEASUREMENT

The quality measures required for an ACO will help the ACO monitor its performance and provide information to manage the population effectively. There are some measures endorsed by the National Quality Forum (NQF) that comply with the triple aim of better care, healthy communities and more affordable care. We recommend that CMS choose only those measures for the ACO program that meet these three criteria. Focusing on measures that meet the triple aim will allow ACOs to monitor performance and manage their population within one tracking system and eliminate the duplicative need to track quality and cost separately, as was done by the PGP participants.

Focusing on a small core measure set is the right approach for early phases of ACOs. CMS needs to strike a balance between the current state of readiness for population-level quality measures and pushing the field toward rapid development in this area. This can best be achieved by beginning the program with a small core measure set and laying out a strategic plan for implementing quality measures for future phases of the program. In addition to using NQF-

endorsed and triple aim criteria for selecting ACO measures, we recommend measures beyond the inpatient setting, including post-discharge place of service information.

SUPPORT FOR DETERMINING ACO VIABILITY

It is important to recognize that forming an ACO and participating in the Medicare shared savings program involves significant investment on the part of the providers who form the ACO. Those front-end investments need to be covered at least in part by the expected savings to be generated under the program. In order to assess the viability of entering the program, providers need all of the methodologies that CMS will use to attribute beneficiaries to their ACO, to determine what their performance quality and efficiency targets will be, the percentage savings that CMS will attribute to random variation before the agency attributes savings to the ACO, how the savings will be calculated and when the savings will be distributed to the ACO. Some of the PGP demonstration sites held back on some infrastructure investments due to the uncertainty regarding shared savings and the inability to model performance.

Lack of transparency and too large a hurdle to share in savings to support those investments is a sure and quick means to sabotage the success of the program. There are potential ways to ease the problem. 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. 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.

FLEXIBLE IMPLEMENTATION

CMS needs to delineate carefully between what must be “guaranteed” in the regulations to enable providers to make a three-year commitment and what needs to remain flexible for negotiation in their contracts with CMS so that organizations can reflect their operating environments and communities. Our discussions with AHA members illuminated several elements of the program that are “must-haves” and several that are “must-not-haves.” Elements that must be part of a rulemaking include “must-haves,” such as:

- Prospective knowledge of the ACO’s responsibilities, including:
 - Assignment of beneficiaries, including how “snowbirds” will be treated by the attribution model;
 - Spending and quality targets or benchmarks against which the ACO’s performance will be judged, and the associated IT requirements that may affect start-up infrastructure costs or timing; and
 - Transparent methodologies and past data that can be used to model whether the Medicare ACO program is a viable option for that organization.

- Prospective knowledge about how current or past Medicare expenditures will be used in calculating both the spending targets and performance evaluation, including:

- Treatment of fee-for-service prospective payment system adjustments in both the ACO and the comparison group, including adjustments for graduate medical education, disproportionate share and wages to ensure an accurate assessment of the use of resources. Removing the effect of these adjustments, commonly referred to as unit cost standardization, should be performed annually to reflect frequent changes in those adjustments.
- A method for ensuring that historically low-cost providers who form ACOs are not disadvantaged in becoming successful ACOs.
- Waiver of barriers to clinical integration, both the gateway barriers and other regulatory barriers. For many years, 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 gateway 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 AHA participated in the joint Federal Trade Commission/CMS listening session on this issue in October and we have attached a chart that summarizes many of these issues.

Other regulatory issues also impede clinical integration, such as the example noted above regarding preferential referrals for post-acute care. It is important to understand, however, that many of these barriers need to be waived 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.

- The need for beneficiary education and outreach to understand the benefits of receiving care from an ACO, as well as the ability to provide some beneficiary incentives to encourage engagement with their care teams in managing their conditions and to stay within the ACO's network.

“Must-not-haves” include:

- Rigid organizational/governance rules that could inadvertently act as barriers to many providers. There are a variety of complex state and federal requirements that dictate how providers come together based on whether some are tax exempt, publicly owned or governed, and so on.
- Rules on the distribution of shared savings within an ACO. Building the necessary relationships within an ACO will require a great deal of flexibility to ensure that performance targets are met.
- Rules on the specific services that must be provided directly by the ACO, other than adequate primary care capacity as required by the ACA. The resources available in any

given community differ. ACOs will have strong incentives to build the relationships necessary to have as many of the needed services delivered within the ACO. Rigidity in this area of the rules could pose barriers to ACOs, especially in rural areas.

CONCLUSION

In summary, AHA believes there are several themes or principles that should guide CMS' approach to implementing the ACO program. They are:

- The need for clarity about the purpose of ACOs, including what they can and cannot be expected to deliver. ACOs start from the premise that systems of care are preferable to non-systems of care. A central purpose of the program should be to devise a path that moves more providers toward forming or joining systems of care.
- The desire to generate Medicare program savings. The need for savings should not be so dominant that it discourages this type of delivery reform, killing it in the early stages. The requirement that participants contribute two percent "off the top" before shared savings can occur (as in the PGP demonstration) could be a disincentive for formation of ACOs.
- The importance of flexibility in how the rules are developed. Even though ACOs were enacted as a program without any sunset provision, the program needs to be treated as a pilot initially so that mid-course corrections can be implemented to reflect what is learned in the early years of the program.
- The need for a careful delineation of which provisions and details need to be in the implementing regulations to enable enough certainty for organizations to make a three-year commitment, and which provisions and details should be left to the negotiation of an individual agreement between CMS and a potential ACO to enable some flexibility.
- The need to preserve some CMS discretion in deciding which organizations and how many organizations initially enter into the program so that there is a greater ability to adjust the approach as the agency expands the number of ACOs. There also will need to be a cross-section of levels of ACO risk-taking and size, in order to identify factors that can cause the program to fail.
- The need to recognize that there are some "must-have" elements in the program and some "must-not-have" elements in implementing the program to ensure success and to avoid premature failure.

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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 at (202) 626-4628 or lfishman@aha.org, or Lisa Grabert, senior associate director of policy, at (202) 626-2305 or lgrabert@aha.org.

Sincerely,

Linda E. Fishman
Senior Vice President
Public Policy and Data Analysis

cc: 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?
Antitrust (Sherman Act §1)	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.
Ethics in Patient Referral Act ("Stark Law")	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.
Anti-kickback Law	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
Civil Monetary Penalty	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
IRS Tax-exempt Laws	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
State Corporate Practice of Medicine	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
State Insurance Regulation	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
Medical Liability	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.