

**AWAITING THE MEDICARE SHARED SAVINGS PROGRAM REGULATIONS:  
PROGRESS ON THE ROAD TO ACCOUNTABLE CARE?**

February 17, 2011

**IMPORTANT DATES****January 1, 2012**Medicare Shared Savings  
Program begins.**RESOURCE LINKS****The NCQA 2011 ACO  
Criteria and Implications  
for ACO Governance**[http://www.ebglaw.com/show  
article.aspx?Show=13691](http://www.ebglaw.com/show/article.aspx?Show=13691)**Accountable Care  
Organization Regulation  
and Enforcement:****Coordinated or Siloed?**  
[http://www.ebglaw.com/show  
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According to the Administrator of the Centers for Medicare & Medicaid Services (“CMS”), Dr. Donald M. Berwick, the long-awaited proposed regulations implementing the Medicare Shared Savings Program<sup>1</sup> should be out soon. Given the incredible proliferation of policy, business, and legal thinking about accountable care organizations (“ACOs”) that has taken place since the passage of the Affordable Care Act (“ACA”) less than a year ago, CMS’s initial effort to describe a program of payment and delivery reform built around the ACO “model” will contribute importantly to the national dialogue on accountable care and will give providers a first look at CMS’s detailed requirements for the Medicare Shared Savings Program.

In recent remarks, Dr. Berwick also signaled that there may be simultaneous guidance from the Center for Medicare and Medicaid Innovation (“CMMI”)<sup>2</sup> regarding ACO demonstrations to be sponsored under CMMI’s jurisdiction as well as guidance from the antitrust enforcement agencies (the Department of Justice (“DOJ”) and the Federal Trade Commission (“FTC”)) on how antitrust and market power issues will be addressed in the ACO context, presumably in the private market as well as in connection with Medicare ACOs.

Submissions to CMS in advance of the issuance of these regulations have been voluminous, reflecting the huge interest in this subject among health care providers, purchasers, payers, and consumers across America. An additional opportunity for comments will exist after the proposed rule is issued.

<sup>1</sup> Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3022, as amended by § 10307 (2010) (the regulations were submitted to the Office of Management and Budget for review on February 14, 2011).

<sup>2</sup> *Id.* at § 3021, as amended by § 10306 (2010).

## RESOURCE LINKS

### **Constructing Accountable Care Organizations: Some Practical Observations at the Nexus of Policy, Business, and Law**

<http://www.ebglaw.com/showarticle.aspx?Show=13162>

### **The Timeline for Accountable Care: The Rollout of the Payment and Delivery Reform Provisions in the Patient Protection and Affordable Care Act and the Implications for Accountable Care Organizations**

<http://www.ebglaw.com/showarticle.aspx?Show=12639>

### **Payment and Delivery System Reform: It's Only a Matter of Time**

<http://www.ebglaw.com/showarticle.aspx?Show=12478>

### **Is Your Organization Ready to Become an Accountable Care Organization? Here Are 10 Questions to Ask**

<http://www.ebglaw.com/showarticle.aspx?Show=12260>

### **Accountable Care Organizations and Bundled Payments in Health Reform: Observations and Implications**

[http://www.ebglaw.com/files/37716\\_BNA%20Article%20-%20Accountable%20Care%20Organizations%20and%20Bundled%20Payments%20in%20Health%20Reform.pdf](http://www.ebglaw.com/files/37716_BNA%20Article%20-%20Accountable%20Care%20Organizations%20and%20Bundled%20Payments%20in%20Health%20Reform.pdf)

Dr. Berwick had the following things to say about ACOs and the proposed rule in a speech at the Brookings Institution on February 1, 2011:

The ACO proposed rule isn't out yet, it will be out very soon. I can't tell you what's in it yet because I'm not supposed to. But you'll see it very soon. There will be a comment period that I hope you will all take seriously. But of course you know this issue, as we engage in this expedition toward integrated care. What will risk look like? Shared savings only? Upside/downside? Partial cap, full cap? What would work and for whom? Who can play in each of those different conditions?

The proposed rule will be a core model. It will be what anybody can play with. But we all know there are places out there that are ready to surge ahead to a completely different level of integration. They've been there already or are en route. Wouldn't it be nice if we had made a space for a vanguard, who can move ahead of the pack and teach us all the way to go? Maybe the Innovation Center can be a home for that kind of pioneering element on our behalf, on everyone's behalf. Not specialty entitled players, but our scouts.

The core to me is authenticity. As I said, I think there will be parties out there who wish to take advantage of the law and the vocabulary to re-label what they already do. To repackage the status quo. I don't think that will be enough. Not at scale. We are going to have to find a way to deliver care better. And that means change.

What, then, are some of the key issues that the regulations are likely to address by which we can evaluate the Medicare Shared Savings Program's potential progress on the road to accountable care? The way CMS further defines ACOs and structures the Medicare Shared Savings Program, including possible risk sharing features, will not only ultimately determine the success of the Medicare ACO program but will also no doubt affect the shape of burgeoning ACO efforts at the state level for Medicaid programs and in the commercial market. Here are five issues that I think are key:

#### **I. Does the proposed rule advance our understanding of value in health care?**

If there is consensus around any single concept in payment and delivery reform, it is that we must move from volume-based to value-based payment. The goal of accountable care is to simultaneously

## RESOURCE LINKS

### Health Care Delivery System Reform Provisions in the Baucus Bill: A Substantive Set of Provisions

[http://www.ebglaw.com/files/31972\\_Health%20Law%20Reporter.pdf](http://www.ebglaw.com/files/31972_Health%20Law%20Reporter.pdf)

### Addressing the Legal Issues in Achieving Quality and Cost Efficiency: The Need for a Rebuttable Presumption

[http://www.ebglaw.com/files/29305\\_PDFArtic.pdf](http://www.ebglaw.com/files/29305_PDFArtic.pdf)

improve patient outcomes, patient satisfaction, and cost efficiency. Thus, one key element of the Medicare ACO program will be how it goes about measuring quality and cost efficiency and how it seeks to incent providers to deliver improved value. There is widespread agreement that evidence-based medicine and performance measurement have advanced greatly, but disagreement as to whether current data and measures are sufficient to judge ACO performance and to fairly drive both improved quality and cost savings.<sup>3</sup> So the measures that CMS chooses to use at the outset are important. Will it use a fairly simple “starter set?” Will it provide for different or additional measures for more advanced ACOs, accompanied by different payment mechanisms? The Medicare Shared Savings Program regulations inevitably will set forth CMS’s vision for accountable care through ACOs. We should all be interested in whether, in so doing, CMS advances the definition and measurement of value in health care in a way that triggers broad agreement and, thus, helps achieve similar consensus for purposes of Medicaid and commercial market ACOs.

## II. How well do CMS’s requirements for ACO structure and governance and ACO infrastructure balance the need for both flexibility and real change?

The diversity of type, circumstance, and capability of providers that might form or participate in ACOs is immense. There is a clear challenge in balancing the goal of incenting the development of new ACOs, particularly involving currently independent providers and smaller physician practices, while also incenting further advancement and improvement by existing, more experienced integrated delivery systems. There will need to be minimum requirements with real teeth in order to drive real change. As Dr. Berwick indicated, repackaging the status quo will not be good enough. Having serious performance and clinical integration requirements will lessen the anticompetitive potential of ACOs. At the same time, providing for multiple ACO types and payment models should enhance ACO competition in many markets while also bringing increased levels of care coordination to a greater number of health care consumers. Will CMS provide loans against future savings, start-up capital (perhaps through CMMI), or other means to help start-up ACOs? Will the Medicare Shared Savings Program start with bonus payments only or allow for tiers of participation, including risk arrangements, based on different levels of accountable care capability? The skill of CMS in providing flexibility to accommodate multiple models, experimentation, and continued progress over time, while also assuring progress in the short run, is a second key issue in assessing the proposed rule.

## III. Will the nature of the ACO-beneficiary relationship established under the proposed rule help avoid another backlash?

The method by which Medicare beneficiaries should be assigned or attributed to ACOs has been greatly debated and has been the subject of many comments submitted to CMS. Proponents of both prospective and retrospective attribution argue that their approach is in the best interest of patients

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<sup>3</sup> Robert A. Berenson, M.D., “Moving Payment from Volume to Value: What Role for Performance Measurement?” The Urban Institute (Dec. 2010).

and will lessen the likelihood of patient backlash. The ACA puts a priority on patient choice. Would open interaction between ACOs and their assigned beneficiaries contribute to more informed consumers actively participating in their health care and, thus, better health, or will it lead to a perception of “bureaucratic control” and resistance from patients? Would retrospective attribution result in fairer treatment of all ACO patients and avoid the creation of two classes of patients – those attributed to the ACO and those not attributed to the ACO? MedPAC, in its comments to CMS,<sup>4</sup> supports the prospective approach, as do most providers, but MedPAC’s discussion of a potential “opt out” for beneficiaries shows the kind of complex issues that arise. How CMS addresses attribution and how Medicare beneficiaries react when the program commences in 2012 will be a key factor in its success.

#### **IV. How will provider risk be handled?**

No one wants a repeat of provider-sponsored organizations (“PSOs”).<sup>5</sup> There are a number of good ideas circulating regarding risk corridors, two-sided risk, partial capitation, and so forth, all of which may help lessen the potential financial failure of ACOs that take on insurance-type risk. But this remains an area of potential concern given the widespread and widely publicized failures of the 1990s. It also raises the issues of capital, reserves, reinsurance, and state insurance licensure in connection with provider risk that have not been resolved in the interceding years. Absent some form of federal preemption – perhaps through the new Center for Consumer Information and Insurance Oversight at CMS – risk-bearing ACOs will likely be subject to a patchwork quilt of state laws and interpretations. Some guidance or signal from CMS on this question would be very helpful.

#### **V. How will CMS balance the need to incentivize positive collaboration among providers to form effective ACOs, while also coordinating with the Office of the Inspector General (“OIG”) and the antitrust enforcement agencies to assure appropriate enforcement of the fraud and abuse and antitrust laws?**

This is another question that has triggered voluminous commentary, which I have written about elsewhere.<sup>6</sup> The October 5, 2010, workshop co-sponsored by CMS, OIG, DOJ, and FTC featured lengthy discussion, debate, and commentary. The agencies have signaled that the internal distribution of shared savings among ACO providers is likely to be protected in connection with the fraud and abuse laws and that qualification as an ACO under the Medicare Shared Savings Program likely will result in deeming provider networks and other collaborative arrangements as clinically integrated and, therefore, subject to review under the rule of reason for antitrust purposes. But serious questions remain as to fraud and abuse issues in connection with ACO formation and capitalization and as to antitrust issues in connection with ACOs that have market power in commercial markets. To me, the question is whether we can use ACO criteria, including quality measurement and reporting, to find positive resolution to these issues, rather than simply seeking ways to avoid exacerbating existing problems. Where ACOs can demonstrate that patient outcomes are improving, patients are satisfied, and costs are going down or at least cost efficiency is

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<sup>4</sup> Letter from MedPAC to Donald M. Berwick, CMS Administrator (Nov. 22, 2010).

<sup>5</sup> 42 U.S.C. § 1395w–25(a) (requiring a PSO to be licensed by a state as a risk-bearing entity).

<sup>6</sup> See e.g., Douglas A. Hastings, “Addressing the Legal Issues in Achieving Quality and Cost Efficiency: The Need for a Rebuttable Presumption,” *BNA’s Health Law Reporter*, Vol. 18, No. 22 (June 4, 2009); Douglas A. Hastings, “Accountable Care Organization Regulation and Enforcement: Coordinated or Siloed?” *BNA’s Health Law Reporter*, Vol. 19, No. 37 (Sept. 23, 2010).

improving, we ought to be able to find an appropriate basis to determine legality. CMS, in its Medicare Shared Savings Program regulations, and in conjunction with related pronouncements of the other agencies, could advance the ball greatly in this important area as well.

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The Medicare ACO regulations should be out shortly. If the Medicare ACO program is successful, it will represent a crucial step in the continued progress on the road to accountable care for not only Medicare but also Medicaid and private pay. There will be opportunity to comment on the regulations. Here's to hoping that the proposed rule provides a very strong start to laying out a program that can succeed and that comments received are constructive and add improvements. This is too important for there to be any other outcome.

For more information about this issue of *IMPLEMENTING HEALTH AND INSURANCE REFORM*, please contact the author below or the member of the firm who normally handles your legal matters.

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