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Accountable Care Organization Regulation and Enforcement: Coordinated or Siloed?

By Douglas A. Hastings

There are positive signs of significant efforts at interagency coordination around the development of regulations for accountable care organizations (ACOs) under the Affordable Care Act (ACA). Such coordination will be important in developing a regulatory framework that will promote the many related but complex goals of payment and delivery reform—care coordination, patient-centeredness, improved health outcomes, patient satisfaction, cost-efficiency, and transparency, among others. All of this is to be accomplished by providing affirmative financial incentives through Medicare and Medicaid payments to diverse providers in various stages of integration while maintaining aggressive enforcement against fraud and abuse and restraints of trade. Success in this endeavor will require a careful precision in distinguishing between ''good'' care coordination—provider collaboration that improves quality and cost-efficiency—and ''bad'' payments for referrals or agreements that violate antitrust laws. Finally, all of this needs to be done in a way that creates a level playing field that operates in a consistent manner in both the public and private sector.

As we await formal guidance, hopefully this fall, regarding ACOs from the Centers for Medicare & Medicaid Services (CMS), the Department of Health and Human Services's Office of the Inspector General (HHS OIG), the Federal Trade Commission (FTC) and perhaps the Department of Justice (DOJ), there are a number of key areas to be addressed that will determine the shape of the federal health programs and also signifi-

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cantly influence the private sector. It seems clear that these agencies are interested in listening to the private sector and are communicating with each other in developing ACO program guidance. Various meetings among agency representatives have been taking place all summer in Washington. In addition, on June 24,[1] CMS held an Open Door Forum on ACOs in which certain key questions were posed and a variety of organizations gave comments to CMS regarding the shape of shared savings program under Section 3022 of the ACA. On Oct. 5,[2] the FTC, CMS, and HHS OIG will be hosting a workshop, open to the public, on ACO legal issues in order to ''facilitate providers' efforts to develop ACOs that will provide high quality, lower-cost care to their patients.'' This kind of interagency collaboration is a positive sign and indicates the importance the agencies are placing on having a coherent policy relating to ACOs that will help assure that the benefits of improved quality and greater cost-efficiency can be realized.

Following are some of the key questions that coordinated regulatory guidance could help answer to assist provider organizations, payers, purchasers, and consumers in understanding how the implementation of the ACA's accountable care provisions will affect all of them and will change health care in the United States.

How will Medicare beneficiaries be assigned or attributed to ACOs?

- Will the ACO or the patient know of the assignment?
- To what degree will ACOs be allowed to track and communicate with their assigned beneficiaries?
- Will the answer to these questions differ in a simple shared savings program as compared to a bundled payment or partial or fully capitated program?

At the Open Door Forum on June 24, there was much discussion of this assignment/attribution question as well as discussion regarding the ability of ACOs to communicate with beneficiaries, patient freedom of choice and the right of the patient to know the types of incentives providers are receiving. There is a widespread view in the health care industry that ACOs will need the active engagement of their assigned patients to be successful and, therefore, that beneficiaries should be assigned prospectively rather than retrospectively. In addition, there are debates taking place in Washington about how much impact a simple shared savings approach, even if implemented on a broad scale, will have on improving quality and bending the cost curve. For ACOs, the answers to these questions will help guide how and at what pace to invest in ACO infrastructure. The debate also reflects consideration of to what degree ACO implementation will look like provider risk sharing and managed care of the 1990s or whether we will be able to implement a new generation of coordinated care techniques and payment methods that do not trigger a similar backlash against managed care. Put another way, can the regulations implementing ACOs thread the needle to allow for true care coordination and the consistent application of evidence-based measures, including efficiency measures, thus better managing patients and patient populations while also increasing patient satisfaction and not alienating both patients and physicians through new rules, requirements, and limits on choice? Not easy!

How will the ''shared governance'' and ''formal legal structure'' requirements of Section 3022 of the ACA be interpreted and implemented?[3]

- Will most organizations engaged today in some level of coordinated care and clinical integration be eligible in their current form or will new structures or structural changes be required?
- Will the regulations recognize different levels of capability to coordinate care and to measure and report on outcomes, patient satisfaction and cost-efficiency and apply different payment approaches accordingly?[4]
- Will there be specified governing board requirements for ACOs?

The real world of health care providers consists of some organizations that are comprised of both payer and provider components, some with both hospital and physician components, others with physicians only, others that include post-acute providers and many other variations. Some organizations are bound together through common ownership and/or common employment in a single entity or family of entities, others are joint ventures, joint operating companies or virtual forms of organizations and still others are made up of independent providers bound together by contract. Many of the organizations under one corporate umbrella function in an integrated fashion, but there is not necessarily a complete correlation between the degree of corporate integration and the degree of clinical integration. So guidance will need to integrate the government's vision of promoting evidence-based medicine, reporting on quality and cost measures and coordinating care with its vision of formal legal structures and necessary administrative systems. How the federal regulators choose to articulate the necessary structural and governance components of ACO entities for the purpose of contracting with them under Section 3022 will have a significant impact on the future shape and structure of health care delivery organizations, not only in the public programs but in the private sector as well.

How will ACO financial risk be regulated?

- Will risk sharing be handled in a way that facilitates or inhibits provider entry into ACO arrangements?

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[1] Centers for Medicare & Medicaid Services Special Open Door Forum: Medicare Shared Savings Program: Accountable Care Organizations (ACOs) (June 24, 2010) (*announcement available at* https://www.cms.gov/OpenDoorForums/Downloads/rACO062410r.pdf).

[2] FTC, HHS Office of Inspector General, and Centers for Medicare & Medicaid Services Announce Workshop on Issues Related to Accountable Care Organizations (Oct. 5, 2010) (*announcement available at* http://www.ftc.gov/opa/2010/09/healthcare.shtm); 75 Fed. Reg. 57,039 (Sept. 17, 2010).

[3] ACA §§ 3022(b), (b)(2)(C).

[4] For helpful discussions of matching different levels of provider integration to different levels of payment reform in the ACO context, *see* Stephen M. Shortell and Lawrence P. Casalino, ''Implementing Qualifications Criteria and Technical Assistance for Accountable Care Organizations,'' *Journal of the American Medical Association*, Vol. 303, No. 17, May 5, 2010; Mark McClellan, Aaron N. McKethan, Julie L. Lewis, Joachim Roski, & Elliott S. Fisher, ''A National Strategy To Put Accountable Care Into Practice,'' *Health Affairs*, Vol. 29, No. 5, May 2010.

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- To what degree will state insurance laws apply or not apply to ACOs?
- Will the way the federal program addresses these issues be designed to function similarly in the private sector?

There is a broad consensus that we need to move away from a fee-for-service payment system in order to improve quality and reduce costs. Moving to bundled and global payments necessarily means some degree of shared financial risk between the purchaser or payer and the delivery organization. How this sharing is structured and regulated is critical to finding the right balance in encouraging care coordination through financial incentives and new payment models on the one hand and in protecting the consumer from underfunded ACOs on the other. Many providers are again looking at acquiring state insurance licenses. Many already have them. We will need new thinking on capital and reserve requirements and ways of structuring the payments to ACOs to avoid the problems faced under the provider sponsored organization (PSO) program in the 1990s—i.e., such onerous HMO-like regulations that relatively few PSOs were formed or sought qualification. It may be that the initial shared savings program under Section 3022 will include no provider risk sharing. But as payment reform evolves into bundled and global fees, these questions as to capital and reserves and state insurance regulation will be relevant and important.

Will the secretary of HHS use the waiver authority under Sections 3021, 3022, and 3023 of the ACA to address legal barriers created by the current fraud and abuse laws?

- Do we need a new definition of fraud and abuse?
- How can CMS and the OIG best balance necessary ongoing enforcement and the new enforcement tools in the ACA with the coordinated care incentives also prominently featured in the ACA?
- If an organization is recognized by CMS as a qualified ACO, and remains so by achieving targeted quality measures, should it not benefit from a presumption of compliance with the fraud and abuse laws?

The fraud and abuse laws (anti-kickback, Stark, civil monetary penalties)[5] were passed with fee-for-service and diagnosis-related group (DRG) payments to providers in mind. Thus, these laws seek to make illegal practices that would lead to overuse or underuse of appropriate medical services, based on certain assumptions about the impact of financial incentives on provider behavior in an era prior to widespread understanding of evidence-based measures. Today we have at our disposal measures that can determine proper use and identify overuse, underuse, and misuse. ACOs will be subject to such measures. It would seem logical, then, that the definition of fraud and abuse would evolve along with enforcement techniques. Financial incentives to drive provider collaboration to bring about coordinated care need to be affirmatively protected.

The ACA calls for cost savings in health care through both enhanced provider collaboration and enhanced fraud and abuse enforcement. The enforcement agencies will need to re-define their approach to financial incentives related to collaboration, I would argue, to move away from the presumption that such incentives are illegal but subject to available safe harbors and exceptions to a presumption that they are legal and, indeed, desirable. That's what the ACA says. HHS, in its dual role as both purchaser and regulator, understands this challenge. The ACA grants the secretary significant waiver authority relating to the fraud and abuse laws. At the very least, financial relationships related to funds flow within a federally recognized or certified ACO—that is, internal allocation or distributions of federal programs funds paid to such ACO—should, through waivers, regulation or other program guidance, be presumed or deemed to be compliant with the fraud and abuse laws.[6]

How will the antitrust laws be applied and enforced to help facilitate ACO development and operational success?

- How helpful is the current guidance?
- Can CMS's ACO program design help stimulate competition?
- How might market power concerns be addressed?

Antitrust will be a complex but vital aspect of the regulatory oversight of ACO implementation. These questions revive the decades long health planning versus competition debate, as well as the public utility model versus market model debate. Without commenting further here on those macro considerations, suffice it to say that providers seeking to form and operate ACOs are going to need to be very mindful of the antitrust implications of their actions and further guidance would help. Thus, it is encouraging that the FTC is actively in dialogue with CMS about ACOs.

The clinical integration concept, as it has evolved in guidance[7] and in the market, is a very helpful starting point. From a practical standpoint, independent providers, particularly those seeking to implement physician-hospital organization and independent practice association-type models,[8] should be able to move forward with ACO development without undue concern as to Section 1 issues,[9] if current regulatory guidance is followed. The ACO provisions in the ACA, and, indeed, the entire range of payment and delivery reform provisions in the ACA support clinical integration as the appropriate pathway to improved patient outcomes, patient satisfaction, and cost efficiency. Moreover, if a greater number of less integrated provider organizations can make progress on the road to more coordinated care and can qualify for ACO recognition by CMS, competition in individual markets generally should be enhanced to the benefit of all.

The bigger challenge for all concerned—providers, payers, purchasers, consumers, and regulators—is the market power question. It is a big and complex topic

[5] 42 U.S.C. § 1320a-7b(b); 42 U.S.C. § 1395nn; and 42 U.S.C. 1320a–7a.

[6] I have argued elsewhere for the establishment of a rebuttable presumption in favor of ACO-like entities. *See* 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.

[7] FTC Statements of Antitrust Enforcement Policy in Health Care (*available at* http://www.ftc.gov/bc/healthcare/industryguide/policy/index.htm).

[8] *Id.*

[9] 15 U.S.C. § 1 (restricting contracts in restraint of trade).

featuring sophisticated questions related to geographic and product market definition, provider pricing, defining and proving quality, exclusivity and so forth. The antitrust agencies and numerous representatives of purchasers and payers have indicated concern as to the market power implications of ACO development, at least in some markets. Much more dialogue on this topic will be forthcoming, including at the October FTC, CMS, and HHS OIG event. To me, there are a few key points at the crux of this critical debate:

- Aggregation does not equal accountability; some size and scale is necessary for effective care coordination and quality reporting; applying nationally recognized measures of quality and cost-efficiency will help define ''quality.''
- As long as the payment system rewards volume, unit pricing, and billable transactions, this issue will be difficult to resolve.
- New forms of contracting (rather than mergers) among competing providers with market power to accomplish accountable care goals through bundled and global payments may help create antitrust-acceptable pathways in some situations.
- The private sector would benefit from greater payer-provider collaboration and acceleration of the movement to accountable care.
- Failure to do so will put more onus on government to regulate both provider and payer prices and to regulate contract provisions.
- If the promise of accountable care is realized, purchasers, providers, and consumers all will benefit.

Conclusion

These are challenging questions, the answers to which will determine the nature of health care payment and delivery in the United States for a long time. There is great consensus as to the goals of accountable care. Coordinated and well-balanced regulatory implementation will serve both the federal programs and the private market well. Let the dialogue continue!

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