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

By Douglas A. Hastings

Introduction

We are at an interesting transitional juncture in the payment and delivery reform process in the United States. There is a lot of planning, thinking, positioning, and strategizing going on, but also a lot of waiting and watching. Among other factors, more specific guidance from the Centers for Medicare & Medicaid Services (CMS) on the requirements of Section 3022 of the Patient Protection and Affordable Care Act (PPACA) will assist health care provider organizations in making decisions as to a variety of structural, governance, legal, and financial variables relating to possible participation in the Medicare shared savings program. At the same time, organizations assessing accountable care organization (ACO) development want to be able to deliver services using reasonably similar structures, provider components, financial arrangements, and clinical pathways in both the public and private sectors—to warrant the investment and do the most good. And, from a policy perspective, both sectors need to be reasonably aligned. Despite the inevitable uncertainty that is present in a period of transition, ACO construction is moving forward in diverse ways across the country.

Hastings is partner and chair, Epstein Becker & Green PC; member, Board on Health Care Services, Institute of Medicine; past president, American Health Lawyers Association; and member, BNA's Health Law Reporter Advisory Board. He can be reached at dhastings@ebglaw.com or (202) 861-1807. *The author gratefully acknowledges the assistance of Shawn Gilman, Esq. in the preparation of this article.*

Structural Considerations

The three basic structural approaches to provider integration—fully integrated structures, virtual or partially integrated structures, and contractual

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structures—all are in play. Full-integration, meaning common ownership and common employment in a single entity or corporately related family of entities (being ''Copperwelded'' for antitrust purposes), has many advantages: greater size and scale to invest in accountable care tools, tighter decision making, clearer control over clinical activities in order to drive quality and cost-efficiency and better legal protection under the fraud and abuse and antitrust laws. The exception to the latter is where an organization achieves a significant degree of market power, thus making further growth through acquisitions subject to greater scrutiny and possible challenge. In addition, there are other practical limits to the ability and desirability of trying to put every provider component of a potential ACO under the same corporate umbrella—including cost limitations, charter restrictions, and the willingness of potential partners to be acquired.

Virtual or partial integration, while often more complex, creates a pathway to greater clinical and financial integration without requiring a complete change of control. Joint ventures, joint operating agreements, and virtual parent governing bodies are all forms of virtual or partial integration. Inherent in the concept is some degree of financial integration as well as fairly robust clinical integration that can be achieved initially and over time. There is legal recognition of the appropriateness of the financial relationships and procompetitive potential of these kinds of joint arrangements, yet there generally also is a greater burden on the parties to demonstrate the benefits than in fully integrated structures.

Contractual structures may be short or long-term, but at their core, they contain elements of integration not through corporate structure but through language in an agreement. This is not to say that contractual models cannot achieve financial or clinical integration—a physician-hospital organization (PHO) meeting Federal Trade Commission (FTC)/Department of Justice (DOJ) guidelines for clinical integration would be an example of a successful contractual model—but the agreements among the parties need to be strong enough and long enough to achieve the degree of sufficient integration sought. Given the constantly changing reality of health care financing and delivery, it remains likely that contractual approaches will be utilized to some extent in ACO development even by the largest and most integrated health systems.

Ultimately, there is a need for flexibility as to structural models and caution as to the urge to find the ''best'' model to adopt wholesale. Each of the above approaches will be necessary for ACOs currently in different stages of development and all may be necessary for the same ACO as it addresses different levels of payment reform.

The Challenge of Governance

The boards of directors of ACOs and their provider components will have a critically important role to play in the future of health care delivery. First, they will have the fiduciary responsibility to oversee the enhanced coordination of care required in the accountable care era. Board composition will evolve as new, expanded ACO entities combine hospital components, physician components, post-acute components, payer components, and other elements to meet changing payment arrangements and delivery responsibilities. So there will be a challenge to get the balance on the board right.

Second, ACO boards will have new and expanded oversight responsibilities in the accountable care era—financial and audit, fraud and abuse compliance, antitrust compliance, and quality compliance, among other areas. We know that the upcoming transition from fee-for-service payments to more value-oriented forms of payment will be challenging for providers to manage financially. We also know that, notwithstanding useful dialogues going on now with the regulatory enforcement community—especially CMS, Office of Inspector General (OIG), DOJ and the FTC—compliance with the fraud and abuse and antitrust regulatory schemes will at times be challenging and will require careful oversight and diligence at the board level.

In addition, new quality measurement and reporting requirements will open up a significantly expanded area of compliance. Poor quality outcomes may reduce public and private reimbursement and even trigger both false claims and tort liability. Inability to measure may lock some providers out of some payment streams. Incorrect reporting may trigger paybacks and penalties. Effective board oversight of quality compliance as it continues to be defined will be essential.

Governance in the accountable care era will be increasingly important and complex. It will be challenging, but for directors of ACOs, it is an opportunity to make a profound contribution to health care in the United States through improved patient outcomes, patient satisfaction and cost efficiency.

Paying for ACO Development

As many of the pioneers in the field can attest, the investment in developing coordinated care systems generally is not rewarded financially in a fee-for-service reimbursement environment and, in fact, may be penalized. The rollout of change under the PPACA, in Sections 3021, 3022, 3023, as well as other related provisions,[1] takes place over time and is uncertain as to its degree of potential positive economic impact. There are a number of efforts taking place in the private market to test new payment arrangements to better reward more coordinated and accountable care delivery. But it naturally is a piecemeal process without, as Atul Gawande pointed out, ''all the answers up front.''[2]

So every ACO will have to decide how much to tackle over what timeframe, how big to get, and how fast and whether to build, buy, or join someone else. In particular, the pace at which ACOs can move through shared savings to various forms of episode or bundled payments to partial or full capitation will vary dramatically from ACO to ACO and market to market.[3]

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[1] *See* Douglas A. Hastings, ''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,'' *BNA's Health Law Reporter*, Vol. 19 No. 12, March 25, 2010.

[2] Atul Gawande, ''Testing Testing,'' *The New Yorker*, Dec. 14, 2009.

[3] 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, and Elliott S. Fisher, ''A National Strategy To Put Ac-

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Finding seed money and opportunities to pilot test coordinated care is as important an issue in constructing an ACO as are the structure, governance and legal issues. Providers are again looking at owning or joint venturing health plans. Payers and providers are assessing carefully this new era in their relationships with each other to determine what degree of cooperation in ACO development best serves their strategies. And ACOs should not overlook – and in some cases should put at the front of the list – opportunities for developing new payment arrangements with their state governments for Medicaid patients.

Clinical Transformation

The heaviest lifting, and most important component, in all of this is the day-to-day labor intensive process of driving care coordination through clinical pathway implementation, quality measurement, and ongoing monitoring. It takes strong physician and organizational leadership, information and management capabilities, and the time and commitment of clinicians.

While others are far more qualified to assess and comment on the practical challenges of clinical transformation, what is important to emphasize here is that there is confluence between the clinical component and the legal component. Where true progress toward clinical integration is being made by an ACO—and measures can demonstrate proper care and improved patient outcomes, patient satisfaction and cost-efficiency—there is greater legal protection under current law, which, I would argue, will only grow stronger as the PPACA provisions are implemented, whether or not the Department of Health and Human Services (DHHS) grants formal fraud and abuse waivers or the antitrust enforcement agencies issue further formal guidance.

Achieving Sufficient Regulatory Comfort to Move Forward

We are in the midst of a very important time of change in health care with an opportunity to achieve very positive results. With change comes risk, including legal risk. The lack of clarity in fraud and abuse and antitrust guidance, privacy laws, state corporate practice of medicine laws and state insurance laws (as providers take on insurance-type risk), and new exposure related to quality measurement and reporting all create legal uncertainties for ACOs. Will complete clarity be achieved before ACOs and their provider components need to move forward? No. Can ACOs get sufficiently comfortable to move forward? Yes. What are the keys to obtaining such comfort? Having the right goals, proper and effective planning and careful attention to legal compliance in implementation and operations.

In my opinion, it will not be possible for ACOs to accomplish everything that needs to be accomplished to achieve the goals of accountable care in connection with every possible legal issue within a safe harbor or with a government-issued opinion in hand.[4] While formal and informal guidance from federal and state regulatory agencies can be helpful and in limited circumstances may be dispositive, compliance will require an ongoing combination of doing the right thing in principle, carefully following regulatory developments, and determining, with good counsel, that the ACO's actions meet legal requirements, even where there are no directly applicable safe harbors or fact-specific governmental guidance.

Monitoring Regulations and Guidance to Come

The first CMS open door forum on ACOs is taking place this week.[5] In addition, DOJ and FTC antitrust regulators have been speaking about ACO development publicly in recent weeks.[6] These agencies, as well as those in many states, have welcomed commentary from the private sector as PPACA regulations and guidance are developed. This is an opportunity (I would argue obligation) that we must take seriously. PPACA is important and complex legislation. We have a mixed public-private health system for powerful historical reasons. Accountable care will not be effective if it fails to develop in a reasonably balanced and simultaneous way in both the public and private sectors. We should be providing our constructive thoughts to the agencies on benchmarks to be set, measures to be used, savings allocation methodologies, waivers of current law, and many other applicable areas.

Conclusion

As one speaker said at the recent ACO Summit in Washington, D.C., ''PPACA provides a tremendous opportunity to improve health care outcomes while achieving greater cost-efficiency. We cannot afford to blow it.'' Well put. We need to be actively constructing ACOs, paying attention to structure and governance, considering what components to develop and how fast, paying careful attention to current legal compliance, all while seeking to constructively influence both public and private sector payment methodologies and regulatory requirements. Success will require strong leadership at the board and management levels. Success also will require the nerve to act even in the face of financial and legal uncertainty. There is a lot to do, but much good can result from the effort.

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countable Care Into Practice,'' *Health Affairs*, Vol. 29, No. 5, May 2010.

[4] 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.

[5] CMS Special Open Door Forum, Medicare Shared Savings Program: Accountable Care Organizations (ACOs), June 24, 2010 (information *available at*: https://www.cms.gov/OpenDoorForums/Downloads/rACO062410r.pdf).

[6] Assistant Attorney General Christine Varney, Antitrust and Healthcare, Remarks as Prepared for the American Bar Association/American Health Lawyers Association Antitrust in Healthcare Conference, May 24, 2010, *available at*: http://www.justice.gov/atr/public/speeches/258898.htm; FTC Chairman Jon Leibowitz, A Doctor and a Lawyer Walk into a Bar: Moving Beyond Stereotypes, Remarks As Prepared for Delivery for the American Medical Association House of Delegates, June 14, 2010, *available at*: http://ftc.gov/speeches/leibowitz/100614amaspeech.pdf.