feature

An Accountable Care Organization Primer

by Gregory W. Bee

The 2010 Patient Protection and Affordable Care Act ("PPACA")[1] represents sweeping healthcare and insurance legislation that affects numerous points of interaction between and among patients, health plans, insurers, employers, healthcare providers, and governmental health programs such as Medicare and Medicaid.

Among the reforms included in PPACA are several new payment and healthcare delivery models that are designed to integrate the delivery of healthcare and align the incentives of healthcare providers, both to improve the quality of care and to create economic efficiencies to reduce healthcare costs. Chief among these new payment and healthcare delivery models established in PPACA are accountable care organizations ("ACOs"). This article gives an overview of the ACO provisions under PPACA, describes some of the background leading up to the introduction of ACOs, discusses possible structures for ACOs, and addresses certain legal and regulatory hurdles that ACO participants must navigate in designing and implementing their ACO.

Historical Background

Numerous pilots, demonstration projects, and business models, both public and private, preceded the passage of PPACA and sought to integrate the delivery and payment of healthcare. These include, most recently, the Centers for Medicare and Medicaid Services ("CMS") Physician Group Practice Demonstration Project, CMS's Care Coordination Demonstration Project, and "patient centered medical home" pilot projects.[2] The Physician Group Practice ("PGP") Demonstration Project included large physician groups (averaging 500 doctors and 22,000 beneficiaries), and the project involved participants taking joint actions to change care protocols, improve quality metrics, and constrain capacity growth. CMS's Coordinated Care Demonstration Project was designed to test whether care coordination and diseased management programs lowered costs for and improved the health of beneficiaries with chronic illnesses covered by fee-for-service Medicare.

Finally, CMS's demonstration project involving patient centered medical homes ("PCMHs") is designed to provide targeted, accessible, continuous and coordinated, family-centered care to high need populations.[3] This program has been supported by and implemented in conjunction with numerous professional medical societies, including the American Medical Association, the American College of Physicians, and the American Academy of Family Physicians. The 2009 MedPAC report describes PCMHs as practices that are paid a fixed monthly fee in addition to fee-for-service payments and furnish primary care, conduct care management, have a formal quality improvement program, have 24-hour patient access, maintain advance directives, and maintain a written understanding with each patient that is in the medical home. PCMH pilots are ongoing, and PPACA identifies PCMHs as models to be used for testing by the Center for Medicare and Medicaid Innovation[5] and in providing for grants or contracts for health teams to support medical homes.[6] Given the integrated structure of PCMHS, they may well serve as building blocks for ACOs.

PPACA and ACOs

Section 3022 of PPACA directs the Secretary of Health and Human Services ("HHS") to implement an integrated care delivery model in Medicare, the "Medicare Shared Savings Program," using ACOs.[7] The Medicare Shared Savings Program is scheduled to begin January 1, 2012. The following providers and suppliers are eligible to participate in the Shared Savings Program:

- Physicians or other professionals in group practices
- Networks of group practices
- Partnerships or joint venture arrangements between hospitals and professionals
- Hospitals employing professionals
- Other groups of providers or services and suppliers as HHS determines appropriate

ACOs eligible to participate in the Shared Savings Program must meet the following requirements:

- Willing to become accountable for quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to it
- Agree to participate in the program for three years
- Have a formal legal structure that would allow the organization to receive and distribute payments for shared savings to ACO participants
- Include primary care professionals that are sufficient in number for the number of Medicare fee-for-service beneficiaries assigned to the ACO (minimum of 5,000 Medicare beneficiaries per ACO)
- Provide the Secretary with information

concerning participating professionals to support the assignment of Medicare beneficiaries and the determination of payments for shared savings
- Have in place a leadership and management structure that includes clinical and administrative systems
- Have defined processes to promote evidence-based medicine, report data to evaluate quality and cost measures, and coordinate care
- Demonstrate that it meets patient-centeredness criteria specified by the Secretary

PPACA also sets forth reporting requirements for ACOs (e.g., reporting clinical processes and outcomes, utilization measures and quality performance standards). Perhaps most importantly, PPACA describes in broad terms the payment mechanisms to be used under the Shared Savings Program. Specifically, participants in an ACO will continue to be reimbursed under the Medicare fee-for-service methodology. However, ACOs will be eligible for additional shared savings payments if they meet quality standards and produce cost savings as compared against a benchmark to be established by HHS.

- Additional payment models for CMS to consider

As of the date of this article, CMS has not yet issued ACO regulations.

Questions and Challenges in Setting Up An ACO

Membership and Structure

While PPACA defines in fairly broad terms the boundaries within which an ACO is to be established and may operate, the devils are, no doubt, in the details. The statute permits hospitals, physicians, and other healthcare professionals in various formations to establish or join an ACO, but it requires only that there be enough primary care physicians to serve the assigned Medicare beneficiaries. So every ACO needs a core group of primary care physicians and other providers. And PPACA permits such primary care providers to participate in an ACO by themselves in a group practice, with a network of other group practices, or in partnership with hospitals (including hospitals that employer the participating physicians). However, in order to advance CMS's goal of coordination of care, an ACO may need to include specialist physicians, other institutional healthcare providers (e.g., nursing homes), as well as home health and DME suppliers. It is almost certain that ACOs will include hospitals, since hospitals will be in a position to provide invaluable infrastructure (including IT infrastructure) and administrative support necessary for the ACO to meet the objectives laid out under PPACA, not to mention other capital necessary to fund ACO operations until Shared Savings payments start rolling in.

ACOs will also need to determine what formal legal structure to use to distribute shared savings payments. Possible structures run the gamut from sole proprietorships to limited liability companies to corporations, both profit and for-profit. In choosing among these and other options, participants must bear in mind tax considerations, charitable purpose restrictions, and barriers to entry and exit.[9] Finally, participants must determine how voting rights and other membership rights and obligations will be established and allocated.

Fraud and Abuse Limitations

The federal Anti-Kickback Statute criminalizes the knowing or willful payment, solicitation or receipt of remuneration in exchange for the referral of patients for any item or service covered under a federal health care program.[10] And the federal physician self-referral law (the "Stark" law) prohibits a physician from referring a Medicare beneficiary to an entity with which the physician has a financial relationship.[11] Clearly, coordinating care among physicians and other providers who are members of the ACO and who have financial relationships between and among one another (not the least of which is that each participant stands to receive distributions of shared savings from the ACO) potentially implicates both of these prohibitions. Several HHS Office of Inspector General advisory opinions in recent years approved of shared savings programs ("gain sharing" programs) between physicians and hospitals.[12] And while CMS has not similarly blessed such arrangements under the Stark law, it may be that existing Stark exceptions

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On November 10, 2010, CMS issued a request for comments regarding aspects of policies and standards that will apply to ACOs.[8] CMS solicited comments on the following topics, among others:

- Policies or standards to ensure that groups of solo or small practice providers can participate, including payment models or financing mechanisms to increase access to capital for small practices
- Ways to attribute beneficiaries to ACOs that will enable ACOs to target care coordination strategies to those beneficiaries while remaining accountable for care provided to the beneficiaries
- "Patient-centeredness" criteria
- Quality measures to use

for "personal services" or "indirect compensation" can protect ACO arrangements. Without knowing how the final ACO structures, shared savings incentives and payment mechanisms will work, it is difficult to predict whether existing anti-kickback safe harbors and Stark exceptions will apply. The good news, however, is that PPACA specifically grants CMS the authority to waive such requirements of sections 1128A and 1128B of the Social Security Act as may be necessary to carry out the provisions of the Shared Savings Program.[13] Recent informal comments from HHS personnel (including both Officer of Inspector General and CMS personnel) indicate that the regulators are indeed open to waiving fraud and abuse laws in order to accommodate ACOs and the Shared Savings Program.[14]

Antitrust

Suffice it to say that the establishment and operation of ACOs will raise significant antitrust concerns that will need to be addressed. The Federal Trade Commission has plenty of experience in clinical integration among healthcare providers (e.g., IPAs, PHOs, hospital systems), which experience will surely apply in large measure to the analysis of ACOs. In addition, the FTC is clearly working closely with CMS and the OIG in creating paths forward for ACOs given the current regulatory hurdles.[15]

Conclusion

The prospect of ACOs and the Shared Savings Program presents us with both a potentially exciting new structure for integrated and coordinated delivery of healthcare and a headache-inducing bundle of legal, regulatory and practical business challenges for physicians, hospitals and other healthcare providers. It remains to be seen how and whether ACOs will achieve the stated goals of better care, better health and lower costs. In addition, it remains to be seen what affect the development of ACOs under CMS's Shared Savings Program will have on, for instance, physician-hospital employment trends and private payor contracting and reimbursement. It is unlikely that the dust will soon settle on any of these issues.

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[1] The Patient Protection and Affordable Care Act of 2010, H.R. 3590 (Pub. L. 111-148), as amended by the Health Care and Education Affordability and Reconciliation Act of 2010, H.R. 4872 (Pub. L. 111-152). Pub. L. 111-148, as enacted and amended by Pub. L. 111-152, is referred to throughout as "PPACA." PPACA is the subject of numerous challenges in federal courts across the county, and two federal district courts have found PPACA (or, in one case, the "individual mandate" portion of PPACA) to be unconstitutional. Such constitutional issues are beyond the scope of this article. And in any event, many PPACA-watchers believe that the ACO and Shared Savings Program parts of PPACA discussed herein will not likely be affected by the challenges to the individual mandate health insurance portions.

[2] *See* https://www.cms.gov/DemoProjectsEvalRpts/downloads/PGP_Conference_Report.pdf; http://www.mathematica-mpr.com/health/mccd.asp; https://www.cms.gov/DemoProjectsEvalRpts/downloads/MedHome_FactSheet.pdf

[3] *See* https://www.cms.gov/DemoProjectsEvalRpts/downloads/MedHome_FactSheet.pdf

[4] *See* www.medpac.gov/chapters/Jun09_Ch02.pdf. *See also* "Initial Lessons From the First National Demonstration Project on Practice transformation to a Patient-Centered Medical Home", Annals of Family Medicine Vol. 7, No. 3 May/June 2009.

[5] PPACA, §3021

[6] PPACA, §3502

[7] PPACA, §3022. Additionally, PPACA calls for a pediatric accountable care organization demonstration project starting January 1, 2012. *See* PPACA §2706.

[8] *See* "Medicare Program; Request for Information Regarding Accountable Care Organizations and the Medicare Shared Savings Program"; 75 Fed. Reg. 70,165 (November 17, 2010); CMS-1345-NC. In addition, on October 19, 2010 the National Committee for Quality Assurance published draft accreditation standards for ACOs. The draft criteria are arranged into the following seven categories: program structure operations, access and availability, primary care, care management, care coordination and transitions, patient rights and responsibilities, and performance reporting.

[9] While beyond the scope of this article, it is an open question as to whether and, if so, how an ACO may be obtain tax exempt status. *See, e.g.*, the Internal Revenue Service Exempt Organization Continuing Professional Education Technical Instruction Program Textbook for fiscal year 1995, concluding that a physician hospital organization is not exempt because it primarily benefits its members rather than the community (and citing I.R.S. Rev. Rul. 86-96).

[10] 42 U.S.C. §1320a-7b

[11] 42 U.S.C. §1395nn

[12] *See* HHS OIG Advisory Opinions 05-01, 05-02, 05-04, 05-05, 05-06, and 08-21

[13] PPACA §3022.

[14] *See* transcripts of October 5, 2010 Workshop Regarding Legal Issues Relating to Formation of Accountable Care Organizations (ACOs), as authorized by the Affordable Care Act, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty (CMP) Laws, sponsored by the Federal Trade Commission, CMS, and the OIG. http://www.cms.gov/PhysicianFeeSched/downloads/10-5-10ACO-WorkshopAMSessionTranscript.pdf; http://www.cms.gov/PhysicianFeeSched/downloads/10-5-10ACO-WorkshopPMSessionTranscript.pdf.

[15] *See* transcripts of October 5, FTC, CMS and OIG workshop, supra Note 16.