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Hospital-Physician Relationships in the Post-Reform World: Does One Size Fit All?

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Introduction

Integrated delivery systems widely used in the 1990s were primarily developed to foster managed care contracting positions of institutional and physician providers. Organizations such as physician-hospital organizations and independent practice associations were developed in hopes of gaining advantage in contract negotiations. Some effort was made to show that such organizations and affiliations achieved some level of clinical and/or financial integration to pass antitrust scrutiny from the Federal Trade Commission (FTC) and the U.S. Department of Justice (DOJ). However, with passage of the Patient Protection and Affordable Care Act (ACA),[1] new models of integration will be required to focus primarily on enhanced coordination of care across the full continuum (primary care, acute care, long term care, and palliative care) to improve the quality of care and patient outcomes while at the same time controlling the cost of healthcare. This article reviews some of the pilot programs contemplated by the ACA and models currently being used and developed by providers and payors to secure long-lasting relationships that are mutually beneficial and designed to achieve the objectives of coordination of care, improved quality, and reduced costs.

Section 3021 of ACA states that selection of innovative payment and service delivery models should "give deference to models that also improve the coordination, quality, and efficiency of health care services." While previous integration strategies were mostly defensive aimed at maintaining or expanding market shares, new integration strategies can create value for high-performing provider organizations by responding to patients and payors who are demanding accountability and demonstrated results. The ACA contains many pilot projects, such as accountable care organizations (ACOs), patient-centered medical homes, bundled payment programs, and gainsharing arrangements. In addition, providers continue to utilize more traditional forms of integration, such as physician employment, physician practice subsidiaries, and co-management agreements.

The Medicare Shared Savings Program and Other CMS Initiatives

ACOs typically involve a core group of medical and institutional providers and suppliers that accept responsibility for providing or arranging care for a defined group of patients under a payment arrangement that allows net profits payments to participants for achieving reduced costs and improved or enhanced quality of care. Section 3022 of ACA required the U.S. Department of Health and Human Services (HHS) to establish by January 1, 2012, the Medicare Shared Savings Program. On April 7, 2011, the Centers for Medicare & Medicaid Services (CMS) released draft regulations related to the Shared Savings Program.[2] These regulations were intended to provide the framework for an accountable care model whereby providers would take on some of the responsibility, and receive some of the reward, for reducing Medicare costs for defined populations. The Shared Savings Program was designed to provide: (1) a mechanism for the delivery of integrated and coordinated care by providers and suppliers, (2) measurable improvements in quality of care, (3) lower costs to the Medicare program, and (4) performance incentives to achieve the stated goals.

The Shared Savings Program is intended to incentivize providers, organized into ACOs, consisting of primary care physicians, specialists, and other healthcare providers and suppliers, with reducing overall Medicare costs incurred by patients who have been assigned to the ACO. If the ACO is successful in reducing costs, Medicare would share a percentage of the savings with the ACO. If Medicare costs for patients assigned to the ACO increased, however, the ACO could be responsible for a portion of the increased costs.

Reaction to the draft regulations was strongly negative. Industry groups generally believed the draft regulations placed too much risk on the ACOs, without giving them the tools they would need to ensure they could actually reduce costs. Additionally, potential participants felt the cost of starting up an ACO outweighed any potential gain that could be realized by participating in the program. High-profile healthcare institutions like the Cleveland Clinic, Mayo Clinic, Intermountain Healthcare, and Geisinger Health System, thought to be the model for the ACA's ACO demonstration project, indicated they had so many concerns about the draft regulations that they doubt they would participate.[3] In addition, provider groups such as the American Hospital Association, American Medical Association, and the Medical Group Management Association weighed in with detailed comments and concerns about the draft regulations.

On October 20, 2011, CMS issued an interim final rule concerning the Medicare Shared Savings Program.[4] At the same time, CMS and the HHS Office of Inspector General issued a series of waivers from the fraud and abuse laws,[5] and the FTC and DOJ issued revised antitrust guidance concerning ACOs.[6] The Center for Medicare and Medicaid Innovation (CMMI) also announced the testing of an "Advance Payment ACO Model," which is designed to provide selected participants with advance payments to invest in infrastructure necessary for ACO operations.[7] CMS will recoup the advance payments from the shared savings generated by the ACO.

The agencies sought to address stakeholder concerns and provide a flexible approach to accountable care, foster a better understanding of the requirements for participation, and indicate how enforcement agencies will view ACO activities in governmental

and commercial programs. The preamble to the interim final rule also describes the options that commenters suggested and should be instructive to other types of accountable care programs.

Previously, on May 17, 2011, CMS announced the Pioneer ACO Program.[8] The Pioneer ACO is an initiative out of CMMI, and it differs significantly from the Shared Savings Program under Section 3022 of ACA. Pioneer ACOs must have at least 50% of their total revenues derived from outcomes-based contracts and sufficient primary care physicians to assign at least 15,000 beneficiaries (not including beneficiaries aligned through specialists). The core payment arrangement is based on escalating shared savings and losses and a transition to population-based (i.e., capitated) payment in the third year (50% fee for service plus monthly payment of ACO's projected fee for service revenue as a per-member per-month payment). The Pioneer performance metrics will be the same as those contained in the *final* Shared Savings Program regulation (where CMS substantially simplified the quality metrics).

CMS also recently released information concerning the Bundled Payments for Care Improvement Initiative (Bundled Payment Initiative).[9] Section 3023 of ACA authorized the Bundled Payment Initiative. On August 23, 2011, CMS released requests for applications to participate in the Bundled Payment Initiative. The Bundled Payment Initiative provides four different payment models that providers will test and develop. CMS hopes to design a new payment system based on services delivered across an episode of care to replace the current system of separate fee-for-service payments. The goal of the Bundled Payment Initiative is to increase efficiency, improve quality of care, and lower costs through the coordination of care across settings. There are three retrospective models, under which providers would be paid under a Medicare fee-for-service system, but at a discounted price, and one prospective model. A provider would use historical data to establish a target price for an episode of care (such as cardiac bypass surgery). If total payments are less than the target, the provider would be eligible to share in the savings. There are different models for an inpatient stay, an inpatient stay and post-acute care for a minimum number of days following discharge, and a period of time beginning with discharge and ending no later than thirty days after discharge.

The Development of Commercial ACOs

Negative initial reaction aside, some of the elements of the Medicare Shared Savings Program are likely here to stay. Both Medicare and commercial insurers are continuing to look for ways to control costs and are looking to providers to partner with them in meeting those goals. Commercial insurers already have begun to implement ACO-like programs in some of the nation's largest markets. One recent trend is for commercial insurers to seek to set up ACO-like relationships with hospitals and health systems and physician groups. As more and more insurers move to this model, hospitals and physician groups that are not prepared may find themselves at a competitive disadvantage. These models, like the Medicare Shared Savings Program, will require providers to monitor and report quality data and control costs. Physician integration and buy-in to the goals and objectives of these programs are critical to successful implementation of commercial ACOs.

Commercial ACO programs are designed to increase access to quality patient care, provide better care coordination, and lower medical costs. Examples of performance goals include reducing readmission rates and unnecessary emergency room visits. In some cases, a team of clinical care coordinators and health coaches manage the ACO pilot programs, and these positions are often funded by the payor. The success of the ACO is dependent on information, clinical collaboration, and consultation. CIGNA has developed a Collaborative Accountable Care Model that involves a large primary care physician group, a multi-specialty group, and an integrated delivery system or physician-hospital organization. There are rewards for improving quality, cost efficiency, and patient experience and ensuring that care is delivered in the right setting.[10]

Related to the ACO model is the Patient Centered Medical Home (PCMH). ACOs and PCMHs are not necessarily competing models and could merge into a single model over time. PCMHs are the primary means by which patients are placed into the delivery system. They ensure a conscious and comprehensive series-of-care encounters that are coordinated by a team of primary care providers.

The National Committee for Quality Assurance has established a program to recognize PCMHs that meet its standards.[11] These standards describe clear and specific criteria about organizing care around patients, working in teams, and tracking care over time. The PCMH is designed to operate much like a gatekeeper with the goal of structured, proactive, and coordinated care rather than episodic treatments for illnesses by paying for not just face-to-face encounters but also consultations and administrative services required to coordinate care.

Because of this continued industry trend, it is important for hospitals, health systems, and other interested providers to consider how these trends will affect their businesses. Going a step further, many providers have begun to take steps to position themselves to be able to react to any future changes, both to the Medicare system of payment and to the increasing demands of commercial insurers to participate in ACO-like reimbursement models. Nearly any model will require greater cooperation and closer integration between hospitals and physicians. Hospitals and health systems that have begun to better integrate with their physicians will undoubtedly be better positioned to adapt and respond to changing market pressures.

Physician Integration Models for Achieving the Goals of Accountable Care

There is no one-size-fits-all model for the physician integration needed to accomplish the goals of accountable care. Any physician integration model must be tailored to the culture, goals, and market in which a particular hospital and its medical staff operate. Market conditions and the structure and independence of the physician community will be key considerations in selecting the model of integration best suited to accomplish the stated goals. Just because one model works for one system does not mean that it will work for all systems.

Direct Employment

Direct employment of physicians is the most common model of hospital-physician integration. The upside of employment is that it allows a lot of flexibility to the physician and the hospital in structuring the relationship (such as compensation) and gives the hospital or health system a high-degree of control over the relationship. It also allows for the hospital to subsidize the practice of a physician or a specialist that the community otherwise might not be able to support. The major downsides to employment are that it does not allow physicians to share in ancillary revenue and it removes control of the day-to-day operations of the physician's practice from the physicians. The traditional independence enjoyed by physicians can make it difficult for employment to spur true engagement. Physicians have been trained to be individual leaders and they come to meetings as leaders and not participants. Physicians and hospital administrators also solve problems in different ways. Hospital administrators are accustomed to taking data and using it to come up with alternatives. To address these issues, goals and objectives for the relationship must be stated clearly upfront.

Group Practice Subsidiaries

One alternative to direct employment are so-called group practice subsidiaries or hospital-operated group practices. The benefits of these organizations is that they operate almost like self-contained group practices, and allow the physicians practicing in them to maintain some control over their practices, while providing the physicians with the benefits of being closely affiliated with a hospital or health system. These entities can be set up to incorporate several groups or different specialties, and allow the physicians, with some limitations, to generally structure their compensation relationships among each other as they choose and to have input in other key decisions. These organizations often are governed by a board of directors with both hospital and physician representation.

Physician Co-Management

Another alternative form of integration is physician co-management. A contractual relationship is created whereby the physician or physicians group is compensated for various administrative and management services provided to the hospital, typically involving a particular service line such as cardiology or orthopedics. Regardless of form, these arrangements are intended to increase the physician's connection to the hospital and align the physician and the hospital's interests by providing leadership of a program through development and enforcement of clinical guidelines and teaching of other physicians and support staff. Physician leadership is key to clinical performance improvement.

Development of Health Information Technology Infrastructure

Before any system of providers is ready to travel down the road to accountable care, it must invest in the information technology infrastructure needed to provide detailed cost and quality data. To meaningfully implement an ACO-like model, the hospital or health system must be able to track and control cost and quality data. Many ACA provisions emphasize the importance of health information technology and the reporting of achievements in quality and clinical and cost effectiveness of various initiatives and strategies. For example, HHS is authorized to incorporate into the existing Physician Quality Reporting Initiative reporting and incentive payments related to electronic prescribing and meaningful use of electronic health records. HHS also is directed to develop a national strategy for the improvement of care, including the use of data to improve quality, efficiency, transparency, and outcomes, and the improvement of research and dissemination of "best practices" to improve patient safety and reduce medical errors, preventable readmissions, and healthcare-associated infections.

Legal Impediments to Hospital-Physician Integration

The Stark Law

The Stark Law prohibits a physician from referring a Medicare patient for certain "designated health services" to an entity with which the physician, or a member of the physician's immediate family, has a financial relationship unless an exception applies.[12] A financial relationship includes an ownership interest or a compensation arrangement. The Stark Law and regulations promulgated pursuant to the Stark Law contain a number of exceptions, such as bona fide employment relationships and personal services agreements. These exceptions contain many elements and requirements that can be difficult to meet and therefore do not provide a great deal of latitude in the ways hospitals can compensate physicians. There appears to be tension between the government's encouragement of pay-for-performance initiatives and the Stark Law's direct prohibition on payments based on the volume or value of referrals.

In the preamble to the Stark II Phase III regulations, CMS stated that payments based on preventative care or quality measures or other quality measures could pass muster under the personal services agreement exception. Of course the payments must be at fair market value and meet the other requirements of the relevant Stark exception. With respect to pay-for-performance or other incentive payments that relate to cost or volume of services, the options are more limited. Pay-for-performance or other incentives may be permissible if paid to employed physicians or through use of the "shared risk" exception, but great care should be paid to the regulatory requirements when structuring such payments.

Federal Anti-Kickback Statute

The federal Anti-Kickback Statute prohibits the knowing and willful solicitation, offer, payment, or acceptance of any remuneration for referring an individual for a service or item covered by a federal healthcare program or purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any good, facility, service, or other item reimbursable under a federal healthcare program.[13] The Anti-Kickback Statute is an intent-based statute, and the courts have struggled to define the correct standard of intent. Some courts have adopted the restric-

tive "one purpose" test, which provides that if one purpose of the payment is to induce referrals, the statute is violated, notwithstanding other legitimate bases for the payment.[14]

The Anti-Kickback Statute contains a statutory exception for payments made to bona fide employees and a "safe harbor" also has been adopted for employees. Amounts paid to bona fide employees do not constitute "remuneration" and therefore do not constitute a violation of the Anti-Kickback Statute. OIG has suggested that payments in excess of fair market value to employees will not be protected by the safe harbor.

The Civil Money Penalties Law

In 1986, Congress enacted the Civil Money Penalties Law (CMP Law) as part of the Social Security Act.[15] Under the CMP Law, it is illegal for a hospital to make a payment to a physician "as an inducement to reduce or limit services provided with respect to individuals who are entitled to Medicare and Medicaid benefits and who are under the care of the physician." Under the CMP Law, both the hospital and the physician are subject to penalties under such circumstances.

In 1999, OIG issued a Special Advisory Bulletin outlining its concerns with "gainsharing programs." Gainsharing typically refers to a program in which a hospital gives a physician a share of any reduction in the hospital's costs attributable in part to the physician's efforts. OIG stated that such programs violate the CMP Law.

In subsequent advisory opinions, OIG has somewhat relented from the position announced in the Special Advisory Bulletin, but the opinions may not be relied upon by other parties and gainsharing programs still risk violation of the CMP Law.

Fraud and Abuse Waivers

ACA authorized the HHS Secretary to waive the fraud and abuse laws as necessary for the implementation of ACOs. On October 20, 2011, CMS and OIG issued guidance that included five specific waivers: (1) a pre-participation waiver; (2) a participation waiver; (3) a patient incentive waiver; (4) a shared savings distribution waiver; and (5) a compliance under the Stark Law waiver. The waivers apply only to the Shared Savings Program and participating ACOs. The waivers are self-implementing, and no application is required. The waivers are more flexible than anticipated and provide opportunity for creative arrangements. The waivers apply only to the Stark Law, Anti-Kickback Statute, and the CMP Law, and do not, for example, apply to the Internal Revenue Code or the antitrust laws.

Antitrust Issues

DOJ and FTC issued a proposed Antitrust Policy Statement applying to collaborations (not including mergers) among otherwise-independent providers that seek to participate in the Shared Savings Program.[16] The proposed Policy Statement describes a "safety zone" for certain providers that participate in the Shared Savings Program. To fall within the safety zone, independent ACO participants that provide a common service must have a combined share of 30% or less for each common service in each participant's primary service area, whenever two or more participants provide that service to patients from the primary service area.

The revised Antitrust Policy Statement issued on October 28, 2011, eliminated the requirement that an ACO participant that has a share of 50% or more for any common service that two or more participants provide in the same primary service area must obtain a letter from one of the antitrust enforcement agencies advising the reviewing agency has no present intent to challenge or recommend challenging the ACO. The revised Antitrust Policy Statement also provides that rule-of-reason analysis will be provided to ACOs that meet CMS eligibility requirements. The eligibility requirements are sufficient to support a finding of adequate clinical integration such that joint negotiation of prices with a commercial plan would not constitute unlawful price-fixing.

Conclusion

ACA and the current market for healthcare services, coupled with economic pressures associated with ever-rising healthcare costs, have forced providers and payors to evaluate different models for the delivery of care. The days of sole reliance on fee-for-service appear to be gone, and the focus is turning to payment for care based on quality, efficiency, and outcomes. To succeed in this environment, hospitals and physicians must be able to align their interests and provide coordinated care focused on quality and transparency.

Numerous strategies are available to providers prepared to work together to secure these goals. However, it remains incumbent on Congress and the regulatory agencies to remove the regulatory barriers to achieving the goals of accountable care: delivering care that is integrated and patient-focused.

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1 Pub. L. No. 111-148, 124 Stat. 119 (2010).
2 76 Fed. Reg. 19528-19654 (Apr. 7, 2011).
3 Model ACO Health Centers Skeptical of Proposed Rule, The Commonwealth Fund, May 6, 2011, *available at* www.commonwealthfund.org.
4 76 Fed. Reg. 67802-67990 (Nov. 2, 2011).
5 76 Fed. Reg. 67992-68010 (Nov. 2, 2011).
6 76 Fed. Reg. 67026-67032 (Oct. 28, 2011).
7 76 Fed. Reg. 68012 (Nov. 2, 2011).
8 Center for Medicare & Medicaid Innovation, Pioneer ACO Model, *available at* http://innovations.cms.gov/areas-of-focus/seamless-and-coordinated-care-models/pioneer-aco/.
9 Center for Medicare and Medicaid Innovation, Bundled Payments for Care Improvement, *available at* http://innovations.cms.gov/areas-of-focus/patient-care-models/bundled-payments-for-care-improvement.html.
10 Collaborative Accountable Care: CIGNA's Approach to Accountable Care Organizations, *available at* http://newsroom.cigna.com/knowledgecenter/aco.
11 *See* National Committee for Quality Assurance, Guidelines: Physician Practice Connections. Patient Centered Medical Home, *available at* www.ncqa.org.
12 42 U.S.C. § 1395nn.
13 42 U.S.C. § 1320a-7b(b). A kickback violation may also serve as a basis for liability under the federal False Claims Act.
14 *See United States v. Katz*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greben*, 760 F.2d 668 (3d Cir.), *cert. denied* 474 U.S. 988 (1985).
15 42 U.S.C. § 1320a-7a(a).
16 76 Fed. Reg. 21894-21902 (Apr. 19, 2011).