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Antitrust, Antifraud Barriers to Entry for Accountable Care Organizations


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The Patient Protection and Affordable Care Act of 2010[1] (PPACA or Affordable Care Act) seeks to advance quality of care while reducing cost by creating new opportunities for Medicare to test innovative payment and delivery models to more closely link health care provider payments to improved quality and value.

It requires the secretary of health and human services (HHS) to establish the Shared Savings Program, under which accountable care organizations (ACOs) are eligible to receive additional payments if the ACO meets certain quality performance standards and cost savings benchmarks.

ACOs are groups of health care providers such as primary care and specialty physicians, hospitals, and suppliers that share governance and accountability for the quality and cost of care for the Medicare patients that they serve. The stated purpose of the ACO model is to better coordinate and manage care. The model purports to incentivize and reward quality and efficiency by creating a mechanism for ACOs to share in the resulting savings to the Medicare program.

There are, however, potential hurdles and conflicts between the goals of the ACO model and existing health care antifraud and antitrust laws. Within HHS, the Centers for Medicare & Medicaid Services (CMS) is devel-

[1] The Patient Protection and Affordable Care Act of 2010, P.L. 111-148 (March 23, 2010).

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 ISSN 1092-1079

oping regulations that specify the criteria for ACOs and eligibility for increased payments through participation in the Shared Savings Program.

CMS, the HHS Office of Inspector General (OIG), and the Federal Trade Commission (FTC) are exploring ways to fulfill the goals of improved quality and cost effectiveness through the ACO model while also protecting the programs from fraud and market abuse.

Some providers are not waiting for the government to issue regulations to move forward with developing their ACOs. In October, the Medical Society of the County of Queens in New York announced that it had established one of the largest physician ACOs in the state (hereinafter Queens County ACO).

The new ACO consists of approximately 700 physician members who will own and manage the organization. The goal of the ACO is to encourage independent local physicians to work together to provide high quality, efficient care to the ACO's patients at a lower cost, and to allow those physicians to share with Medicare in the resulting savings.

The physicians plan to eliminate inefficiencies and reduce costs by improving coordination of care, implementing ''best practices,'' and increasing the use of health information technology.

Physician-operated ACOs may offer advantages. For example, the physician-based model appears to assuage some concerns that relaxed antitrust and antifraud laws may lead to decreased access to and quality of care. Recent ACO announcements have generated reports of public concern over the risks associated with market consolidation and that ACOs might withhold expensive care.[2] Notwithstanding these reports, the public appears to respond favorably to the idea that physicians, rather than insurers, retain control over cost-related decisions about care.

Other ACO models are emerging that offer additional advantages. In November, Norton Healthcare and Humana Inc., announced their partnership in forming an ACO to participate in the ACO Pilot Program. The partnership of Norton Healthcare's provider facilities with Humana offers a unique opportunity to test an insurer managed model. In addition, Humana announced its acquisition on Concentra on Nov. 22, 2010.

Like the physician-based model, the Humana Norton alliance aims to transform current fee-for-service payments into a more cost-efficient, patient-centered care system. Humana's experience in collecting and analyzing data is expected to be integral to establishing and utilizing indicators necessary to benchmark cost-savings and quality.

While ACOs face significant legal and regulatory issues, outlined below, PPACA creates an environment with new opportunities and challenges.

Opportunities include the promise of a coordinated and professional practice environment, improved health care delivery and outcomes, and the potential not only to share in the savings but to impact the growth of health care spending. Unlike previous efforts, the advantages for the Medicare program are clear and the risks low given that only true savings to the programs are shared.

Challenges include developing effective quality and efficiency benchmarks designed to measure success and transform care. One of the key undefined questions is how the government will choose to define, create, regulate, and enforce the benchmarking process.

1. Overview

a. Affordable Care Act

Section 3022 of PPACA requires CMS to establish by Jan. 1, 2012, a Medicare ''Shared Savings Program'' that promotes accountability for Medicare beneficiaries and encourages better care coordination, higher quality, and more efficient service delivery.

Specifically, the law requires the HHS secretary to establish a program that coordinates the items and services furnished under Medicare Part A and Part B, and encourages investment in the health care payment and delivery models that promote high quality and efficient delivery of care.

Under the Shared Savings Program, groups of providers and suppliers that meet criteria, to be defined by the secretary, are encouraged to work together to manage the care of Medicare fee-for-service beneficiaries through ACOs that meet quality performance standards for eligibility for shared savings payments, discussed below.

CMS has the lead responsibility for creating the Shared Savings Program and the standards for ACOs, in collaboration with OIG and FTC. A proposed regulation is under development and is expected to be issued by the beginning of next year.

b. Shared Savings Program

Under the Shared Savings Program, providers and suppliers that participate in an ACO will continue to receive payments under the original Medicare fee-for-service program (Part A and Part B).

However, a participating ACO is eligible to receive additional payments for shared savings if the ACO meets certain quality performance standards and benchmarks. Under the law, an ACO may be eligible to receive such payments annually if the estimated average per capita Medicare fee-for-service expenditures under the ACO, adjusted for beneficiary characteristics, meets a benchmark to be established by the secretary.

The secretary shall estimate a benchmark for each agreement period and for each ACO based on data on per-beneficiary expenditures for Part A and Part B services for Medicare beneficiaries assigned to the ACO.

Such benchmarks shall be adjusted for beneficiary characteristics and such other factors as the secretary determines appropriate. It will be updated based on projected growth in national per capita expenditures under the original Medicare fee-for-service program as estimated by the secretary. The benchmarks shall be reset at the start of each agreement period.

Subject to performance, an ACO may be paid a percentage of the difference between the estimated per capita expenses under the ACO and the benchmark as ''shared savings.'' The remainder of such difference will be retained by the Medicare program. The law authorizes CMS to establish limits on the total amount of shared savings that may be paid to an ACO.

Finally, CMS is required to monitor ACOs to ensure that they do not ''cherry pick'' or avoid certain high-risk or high-cost patients to meet the benchmarks or to reduce their risks. If CMS determines that ACOs are

[2] See Pear, Robert, Consumer Risks Feared as Health Law Spurs Mergers, NY Times (November 20, 2010).

  HFRA ISSN 1092-1079

avoiding high-cost patients, the ACO may be sanctioned or even terminated from the program.

c. Accountable Care Organizations

PPACA did not specify any particular form or structure for an ACO. The law does, however, focus on primary care and patient-centeredness in specifying certain groups of providers and suppliers that may establish systems for sharing governance that will be eligible to participate as ACOs in the Shared Savings Program.

These include: (a) group practice arrangements; (b) networks of individual practices of ACO professionals; (c) partnerships or joint venture arrangements between hospitals and ACO professionals; (d) hospitals that employ ACO professionals; and (e) other groups of providers and suppliers, as determined appropriate by the secretary.

ACOs must meet certain requirements. For example, an ACO must assume accountability for the quality, cost, and overall care of the Medicare patients that it manages. In addition, an ACO must have sufficient primary care capacity to manage the care of at least 5,000 Medicare fee-for-service beneficiaries.

Regardless of the particular organization of an ACO, these organizations must have a formal legal structure that will allow them to receive and distribute payments under the Shared Savings Program, as described above, to their participating providers and suppliers.

In addition, they must have in place a leadership and management structure that includes clinical and administrative systems. They also must implement processes that promote evidence-based medicine and patient involvement, advance quality and cost measure reporting, and support care coordination.

The goals of the ACO model include developing more efficient protocols for delivering high-quality care in a patient-centered manner. Ultimately, these more efficient delivery models are expected to generate savings to the Medicare program.

Such savings could derive from reducing hospital admissions or unnecessary re-admissions or limiting the use of the emergency room. ACOs will coordinate and manage the care of Medicare fee-for-service beneficiaries, with the objectives of improved access to care, quality of care, and health outcomes.

The ACO proposed rule is expected to include quality measures, including those that measure processes and outcomes, and measures that assess utilization patterns and patients' experience of care. The rule will specify the reporting requirements for ACOs to evaluate the quality of care each provides, which could include a wide range of data from health care transitions, hospital discharge planning, or post-discharge follow-up.

The rule will establish quality standards that the government will use to assess the quality of care furnished by an ACO. It is expected that the quality standards will be enhanced over time to foster continued improvements in the quality of care provided through ACOs.

2. Business Challenges

As discussed above, the law does not specifically define one type of ACO. In fact, it is anticipated that many different models of ACOs will develop over time. Small physicians groups may decide to partner with multiple other small groups to form a larger physician network. Existing large, integrated multi-specialty physician groups may also consider becoming ACOs.

Still other physician groups may decide to partner with one or more hospitals in their area, and others may incorporate a variety of physician specialties in addition to the primary care providers. Regardless of form or composition, one threshold task for an ACO is to satisfy the requirement for serving at least 5,000 Medicare fee-for-service beneficiaries.

The Medicare Payment Advisory Commission (MedPAC) has been discussing ACO models for more than a year. In fact, MedPAC has called for a migration away from traditional fee-for-service toward more bundled payments, including the development of ACOs. MedPAC's ACO model consists of primary care physicians and specialists and at least one hospital.

The establishment of an ACO will not happen overnight. It takes a significant amount of time to hammer out agreements among participants concerning management, governance, fiscal cooperation, and other organizational matters. The ACO must have firm governance, tightly managed clinical guidelines, and a well-defined organization. This will be challenging when hundreds of independent physicians and small physician groups are coming together to operate within a more defined organization structure.

It is critical that physicians buy in to the concept of an ACO. Physicians must understand what they must do ito succeed, both clinically by providing high quality care, and financially, in an ACO. ACOs will do well to establish a ''corporate culture'' of responsibility, integration, and coordination.

3. Regulatory Challenges

The Shared Savings Program and ACO model is the most recent incarnation of government and industry efforts to control rising costs and improve patient care by encouraging collaboration among and risk-sharing with providers.

Whether the Shared Savings Program and ACOs constitute a new paradigm for, or an incremental evolution of, arrangements to finance and deliver health care services and goods, the arrangements contemplated under this new model exceed the parameters of the existing regulatory compliance structure.

As a result, several federal laws could prohibit or inhibit the implementation of the relationships that are critical for the clinical and financial integration envisioned for ACOs and for the Shared Savings Program to succeed. Industry commentators have, for example, cautioned that the Shared Savings Program may promote the development of ACO models that fulfill the public policy goals of the PPACA legislation but run afoul of existing health care fraud and abuse laws, antitrust laws, and tax laws, as outlined below.

a. Federal Health Care Fraud and Abuse Laws

The Congress foresaw the potential for conflicts and authorized the HHS secretary to waive certain prohibitions or requirements under the Medicare and Social Security Act to implement the Shared Savings Program.[3] Under this authority, the secretary may waive requirements with respect to the following federal laws:

[3] PPACA, Section 3022(f).

- *The Civil Monetary Penalty Law Prohibition on Gainsharing Arrangements*,[4] which prohibits a hospital from making a payment, directly or indirectly, to induce a physician to reduce or limit the services furnished to Medicare or Medicaid patients under that physician's care. This prohibition may be implicated, for example, if an ACO offers financial incentives to its physicians to comport with clinical guidelines or utilization controls designed to control costs.
- *The Physician Self-Referral Prohibition or Stark Law*,[5] which prohibits a physician from referring Medicare patients for certain designated health services to an entity with which the physician (or an immediate family member) has an investment interest or compensation arrangement, unless an exception applies. Gainsharing arrangements, for example, may implicate the Stark law.
- *The Anti-Kickback Statute*,[6] which prohibits a person from knowingly offering or receiving any remuneration to induce or reward referrals of items or services reimbursable, in whole or in part, under Medicare or Medicaid. For example, this prohibition may be implicated by arrangements where one party to the ACO (e.g., a hospital) provides the primary resources necessary to develop the ACO but allows other parties (e.g., referring physicians) to benefit from the shared savings payments.
- *The Beneficiary Inducement Prohibition*,[7] which prohibits a person from offering or transferring to a Medicare or Medicaid beneficiary any remuneration that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of Medicare or Medicaid payable items or services. Arrangements to offer incentives to beneficiaries to seek health care services through an ACO, for example, may implicate the beneficiary inducement prohibition.
- *The Civil Monetary Penalty Law Prohibition on The Prohibition Against Charging or Collecting More Than the Medicare Allowable Charge*,[8] which may be implicated by the Shared Savings Program payments, which would be made in addition to the standard Medicare fee-for-service payments made to the ACO-affiliated physicians.

On Oct. 5, 2010, CMS held a workshop on ACOs in conjunction with the FTC and OIG to discuss these issues. Notably, a panel of CMS and OIG personnel explored ways in which the secretary might exercise her waiver authority or otherwise create new exceptions or safe harbors related to these laws to foster the goals of the ACO model.

At present, we await the secretary's proposed regulations, which are anticipated to provide additional guidance on the structure of ACOs and address the extent to which waivers will be granted under these federal laws. However, with CMS continuing to seek additional comments as recently as Nov. 17, 2010,[9] it remains unclear when these proposed regulations will be made public.

In the meantime, the industry anxiously awaits the result of the government's effort to establish a regulatory framework that encourages the adoption of the Shared Savings Program and ACO model while also safeguarding the integrity of federal health care programs from fraud, waste, and abuse.

Nevertheless, separate and apart from the federal health care fraud and abuse laws, the new model may implicate regulatory hurdles that the HHS secretary has no authority to waive. These barriers include the antitrust laws and state tax laws.

b. Antitrust Laws

Some view the antitrust implications as the greatest regulatory challenge to the development and implementation of ACOs. Because ACOs will require independent health care providers and entities to collaborate in joint price negotiations to achieve the efficiencies and cost savings sought, such arrangements could run afoul of federal antitrust laws that prohibit certain price fixing arrangements.

Although manufacturers and their industry associations have raised concerns that the enhanced market power of ACOs could undermine competition in the health care marketplace,[10] recent public statements from senior government officials suggest that the FTC and the Department of Justice (DOJ), the agencies charged with enforcing the antitrust laws in the United States, recognize the potential benefits of this new provider model and are open to ACO arrangements that are structured to avoid antitrust risk areas.

For example, in June 2010, FTC Chairman Jon Leibowitz told the annual meeting of the American Medical Association, ''If you join together to improve patient care and lower costs, not only will we leave you alone, we'll applaud you.'' Leibowitz also added, ''And we'll do everything we can to help you put together a plan that avoids antitrust pitfalls.''

Later, at the Oct. 5, 2010, CMS/OIG/FTC workshop, Mr. Leibowitz announced that the FTC would work to develop ''safe harbors'' under the antitrust laws for ACOs and implement an expedited review process for arrangements that do not qualify for a safe harbor.

This process would, to some extent, mimic the OIG's safe harbor and advisory opinion process for arrangements subject to the federal anti-kickback statute and the civil monetary penalty law.

As with the HHS secretary, the FTC is also seeking comments from the industry. Recognizing the challenges facing the FTC, Leibowitz acknowledged at the Oct. 5 meeting that ''[i]t is not easy to craft safe harbors that can replace an antitrust review that analyzes the specific facts of each case and market, but we're going to try to do this, and to do it effectively and properly, we need [industry] input.''[11] Leibowitz added that the FTC needed ''your real-world experience to help us understand what kind of ACOs you're considering, and how

[4] 42 U.S.C. § 1320a–7a(b).
[5] 42 U.S.C. § 1395nn.
[6] 42 U.S.C. § 1320a–7b(b).
[7] 42 U.S.C. § 1320a–7a(a)(5).
[8] 42 U.S.C. § 1320a-7a(a)(2).
[9] 75 Fed. Reg. 70165 (Nov. 17, 2010).

[10] See Transcript, Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty Laws (Oct. 5, 2010), at http://www.cms.gov/PhysicianFeeSched/downloads/10-5-10ACO-WorkshopPMSessionTranscript.pdf.
[11] Gregg Blesch, ''FTC aims to foster creation of ACOs, Modern Healthcare (Oct. 5, 2010), at http://www.modernhealthcare.com/article/20101005/NEWS/310059970#.

  HFRA ISSN 1092-1079

you seem them operating on the healthcare marketplace.''[12]

Again, in the absence of published regulations or guidelines, the FTC's promised safe harbors and expedited review process remain a work in progress. Given the competing interests of powerful entities that sell services and goods to physician practices, and the fact that the devil remains in the details, it will be difficult to anticipate the outcomes of the FTC's efforts.

c. Tax Laws

Although a more thorough analysis is beyond the scope of this article, we note that the Shared Savings Program and the ACO model may also implicate federal and state tax laws. In particular, parties should exercise caution when establishing ACOs that involve both nonprofit (e.g., hospitals) and for-profit (e.g., physicians) entities to ensure that a proposed arrangement does not adversely affect a partner's nonprofit tax status.

4. Conclusion

As discussed above, CMS is developing its proposed rule to implement the Medicare Shared Savings Program that was established in PPACA. The rule is expected to further define the requirements for ACOs, and to propose new waivers, exceptions, or safe harbors with respect to the fraud and abuse and antitrust laws.

In addition, the rule is expected to include significant flexibility, recognizing that Congress did not intend for all ACOs to be structured in exactly the same way. The proposed rule will afford stakeholders yet another opportunity to provide input on the program and on the form and function of ACOs, as well as the issues they face under current law.

Additionally, providers and suppliers that have already formed ACOs or that are working to establish ACOs must realize that they may need to make some changes, depending on the outcome of the final rule to be issued in late 2011.

While providers like those in the Queens County ACO have put in place the necessary agreements and organizational structure to form an ACO in advance of definitive CMS rules, they are aware that they may need to adapt quickly to impending changes.

Many other stakeholders have opted to wait for the issuance of these rules before moving ahead with the development of an ACO.

This is certainly an area of law and policy that is changing rapidly, and providers must stay informed and be flexible to adjust as the regulatory agencies develop their regulations and guidance.

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[12] *Id.*