BNA's
HEALTH CARE FRAUD REPORT
BNA Employee-Owned Since 1947

Meeting Fraud and Abuse Challenges in the Brave New World of Health Reform—What's in Store for ACOs?

By Carrie Valiant

Valiant is an attorney in the Washington office of Epstein Becker & Green PC and is the co-author of the American Health Lawyers Association book, Legal Issues in Health Care Fraud and Abuse: Navigating the Uncertainties, *in its 3rd edition. She can be reached at (202) 861-1857 or cvaliant@ebglaw.com.*
The author would like to acknowledge Marci Handler, with Epstein Becker & Green PC, for her insightful comments on an earlier draft of this article.

A major subtitle of the health reform law[1] is ambitiously titled ''Transforming the Health Care Delivery System.''[2] This subtitle promises health care transformation through a series of Medicare payment innovations.

The most visible and talked about of these innovative models is the accountable care organization (''ACO''), consisting of groups of providers and suppliers that will qualify to receive Medicare payments for shared savings by meeting certain criteria, including quality performance standards.

While health reform's focus is on Medicare's integration of the ACO model into its payment arrangements, ACOs also are viewed widely as important to the next generation of private payer and employer group health plan arrangements as well.

Health reform recognizes that the key to delivering quality health care services that bend the cost curve lies in effective collaboration and alignment of incentives among physicians, hospitals, and others in the continuum of health care delivery.

This alignment is largely absent from the original, fee-for-service Medicare program that exists today. Accordingly, ACOs by definition contemplate loose affiliations of providers acting cooperatively and sharing risks and rewards in the care of a defined Medicare patient population.

[1] Patient Protection and Affordable Care Act, Pub. Law 111-148 and Health Care and Education Reconciliation Act of 2010, Pub. Law 111-152, hereinafter referred to collectively as PPACA or health reform law

[2] Affordable Care Act, Subtitle A, Section 3001 et seq.

 ISSN 1092-1079

While ACOs show promise for gaining efficiencies and quality of care, reducing fragmentation across the silos of health care, these arrangements, which contemplate downstream payments among loosely organized referral sources that allocate shared savings payments from the Medicare program, will inevitably operate in ways that have long been viewed as suspect—and even violative—under traditional fraud and abuse analysis.

Unfortunately, the health reform law does not include the comprehensive legislative changes to the fraud and abuse laws necessary to accomplish these new structures in a lawful manner.

Instead, it provides general authority for the Department of Health and Human Services (''HHS'') to waive various requirements of the fee-for-service Medicare law.[3] While helpful, it is not entirely clear whether HHS will exercise its waiver authority in the fraud and abuse area to the full extent necessary for ACO development.

Thus, at a minimum, parties seeking to take advantage of health reform's new and proposed structures face a significant challenge under existing fraud and abuse laws—not necessarily insurmountable, but requiring careful planning and diligence, and, without governmental assistance, likely constraining the accomplishment of the full benefit of the new structures.

Fortunately, HHS is acknowledging this conundrum in a series of favorable developments. On Oct. 5, the HHS Office of Inspector General (''OIG'') and the Centers for Medicare & Medicaid Services (''CMS'') (collectively, the ''HHS agencies''), along with the Federal Trade Commission (''FTC''), held a public workshop to address the implications of the fraud and abuse and antitrust laws to the development of ACOs.

Government officials promised to bring ''fresh thinking'' to the table and voiced their commitment to flexibility and collaboration. In an additional promising development, Vicki Robinson, formerly the head of OIG's Industry Guidance Branch, which houses the OIG's Advisory Opinion group, has moved to become the OIG's senior advisor for health reform.

These developments suggest that HHS is taking seriously its role in managing the potential fraud and abuse impediments to the health care industry achieving the cost efficiencies and quality enhancements afforded by the ACO model.

This article addresses the various fraud and abuse risks inherent in the ACO model, how the existing fraud and abuse laws fall short of providing the scope of protection needed for ACOs, and, finally, suggests specific ways in which the government can be helpful in this area.

Background—ACOs

Section 3022 of the Patient Provider and Affordable Care Act establishes a Medicare Shared Savings Program, and speaks generally to the organizational framework of ACOs, as well as to their financial relationships and incentives from the Medicare program.[4]

The Shared Savings Program contemplates groups of providers and suppliers that meet certain criteria working together as an ACO to manage and coordinate care for Medicare beneficiaries.

Those ACOs that meet certain quality standards will be eligible for shared savings payments.

Groups of provider and suppliers that have established a mechanism for shared governance are eligible to participate, including the following:

- ACO professionals in group practice arrangements;
- Networks of individuals practices of ACO professionals;
- Partnerships or joint venture arrangements between hospitals and ACO professionals;
- Hospitals employing ACO professionals; and
- Others determined to be appropriate.

The structural prerequisites for ACOs are substantial. Eligible provider/supplier groups need to establish a formal legal structure to distribute payments for shared savings, and a leadership and management structure that includes clinical and administrative systems.

They also need processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care. ACOs also must be able to demonstrate that they meet certain patient-centeredness criteria.

The Medicare program will determine quality measures applicable to ACOs, such as measures of clinical processes and outcomes, patient and caregiver experience of care, and utilization and quality performance standards. ACOs will be required to submit data to the Medicare program so that the Medicare program can evaluate the quality of care furnished by the ACO.

As to how shared savings payments will work, payments for services furnished by the ACO's providers and suppliers will continue to be made under fee-for-service Medicare as always.

In addition, the ACO also will be eligible to receive additional Medicare payments for shared savings. The Medicare program will determine a method for assigning Medicare fee-for-service beneficiaries to ACOs based on beneficiary previous utilization of primary care services.

A benchmark will be established based on the three-year history of expenditures for the ACO's assigned Medicare beneficiaries, and ACOs will be eligible to receive a specified percentage of the shared savings if their estimated average expenditures for the assigned Medicare beneficiaries is a specified percentage below the benchmark, and provided that they meet specified quality performance standards.

ACO agreements with the Medicare program will be for a three-year period, and the benchmark will be reset at the start of each agreement period. There also will be limits on the total amount of shared savings that may be paid to an ACO.

Significantly, other than generally requiring a ''mechanism'' for distributing shared savings to participating providers and suppliers, the health reform law does not speak to the downstream financial relationships with the ACO's providers and suppliers that will be necessary for ACOs to accomplish their goals.

This is important because ACOs cannot themselves accomplish the health reform law's objectives without aligning the financial incentives of the providers and professionals that practice within the ACO.

[3] See, e.g. Affordable Care Act, Section 3022(f). ''The Secretary may waive such requirements of sections 1128A and 1128B and title XVIII of this Act as may be necessary to carry out the provisions of this section.''

[4] HHS has not yet issued regulations implementing Section 3022 of PPACA. Accordingly, the descriptions contained in this article are from the statutory language of PPACA.

  HFRA ISSN 1092-1079

This will require shared savings distribution methodologies that include explicit rewards for specified cost-efficient practice and other activities designed to meet the ACO quality standards and related objectives, which include patient-centeredness, care coordination, and adherence to evidence-based medicine.

While ACO shared savings payments as described in health reform contemplate an add-on to Medicare fee-for-service payments, it is likely that ACOs, once established, will want to venture into other innovative Medicare payment models contemplated by health reform, such as bundled payments and global payments for episodes of care, and perhaps even shared risk models.

It is these downstream financial relationships, and the specified practices designed to achieve savings that are not expressly dictated by the health reform law, that will make all the difference to the success of the ACO model. They also will pose the greatest risks under the fraud and abuse laws.

Background—Fraud and Abuse

The three major fraud and abuse authorities implicated in the ACO model are (1) the federal health care program anti-kickback statute[5], (2) the federal physician self-referral law[6](a/k/a the Stark law) and (3) the civil monetary penalty law prohibiting payments to physicians for reducing or limiting care.[7] These laws were designed in an era in which fee-for-service payment methodologies reigned supreme, and the government's focus was on controlling financial arrangements that could lead to overutilization of services and/or compromise patient choice and quality.

This is different from the post-health reform care models that emphasize and reward clinical integration and quality. In the post-health care reform world, the application of the fraud and abuse laws will require rethinking to the extent they impede the use of financial incentives that promote quality and drive down costs.

The anti-kickback statute generally precludes paying or receiving remuneration in return for or to induce referrals of federal health care program business or patients. It carries both civil and criminal penalties.

While the anti-kickback statute's proscriptions can be overcome by voluntarily meeting a safe harbor or, because it is an intent-based statute, through a facts-and-circumstances analysis, there is extremely broad case law interpretation holding that if even ''one purpose'' of remuneration is to induce referrals, there is an anti-kickback statute violation.[8]

Other fraud and abuse authorities are more ''black and white'' in their application. The Stark law prohibits physicians having any financial relationship (based either in ownership or compensation) with an entity that furnishes certain Medicare-covered ''designated health services'' from referring patients to that entity, and prohibits the entity from billing the Medicare program for any services performed as a result of such referrals.

Included among the designated health services are inpatient and outpatient hospital services. There are mandatory exceptions that must be met to allow physicians to refer to entities with which they have a Stark-covered financial relationship. If there is no relevant exception, referrals are prohibited.

Likewise, the civil monetary penalty law prohibits all payments to physicians that may reduce or limit patient care, whether or not the reduction in care is medically necessary.[9] There are no regulatory exceptions to this prohibition, and, in the past, HHS has taken the position that the statute does not provide HHS with the regulatory authority to create any exceptions.

Nor are there any safe harbors or exceptions to these fraud and abuse laws that specifically address ACOs or the financial arrangements among the parties participating in ACOs. Yet, it is clear that all of these statutes are implicated by the contemplated structures and operations of ACOs.

Fraud and Abuse Questions for ACOs

In light of today's aggressive fraud and abuse enforcement environment, and the ways in which the contemplated ACO structures and payments seem to hit squarely many of the relevant fraud and abuse targets, serious questions arise as to the scope of protection needed for the health care community to move forward with developing ACOs in a manner that will achieve their, and health reform's, objectives.

1. *How will the fraud and abuse laws, if unchanged, impede the development of ACOs?*

The fraud and abuse laws paint with a broad brush, and they reach far beyond their original purposes. The anticipated structure of ACOs, contemplating loose affiliations and networks of providers and suppliers, has been targeted for years as suspect by the fraud and abuse enforcement authorities.

The last go-round of health reform in the 1990s, while unsuccessful, spawned an alphabet soup of similar joint venture structures, including PHOs and MSOs, as well as so-called ''Groups Without Walls''—structures that then were vilified by the fraud and abuse enforcement authorities as potentially illegal referral schemes.

One of the pressing issues of that time, and likely still relevant today, was that the financial viability of these integrated delivery structures depended on cross-subsidization among specialist and primary care physicians as well as a sharing of ancillary revenues among participants.

It was this cross-subsidization that raised concerns with respect to whether payments were in essence referral fee payments. While this issue was considered, and ultimately protected in connection with certain bona fide group practice arrangements under the Stark law,[10] it was especially suspect when subsidy payments were made across loose affiliations or networks of providers and/or physicians—precisely the structures that are contemplated by the ACO model.

More recently, the government has taken issue with gainsharing efforts among hospitals and their medical staffs. In 1999, the OIG issued a Special Advisory Bulle-

[5] Social Security Act § 1128B(b), 42 U.S.C. § 1320a-7b(b)

[6] Social Security Act § 1877, 42 U.S.C. § 1395nn

[7] Social Security Act § 1128A(b)(1); 42 U.S.C. § 1320a-7a(b)(1)

[8] *United States v. Greber,* 760 F2d 68 (3rd Cir.), *cert. denied* 474 U.S. 988 (1985)

[9] See below, Fraud and Abuse Questions for ACOs, Question 1.

[10] *See* Stark law, in office ancillary services exception and related group practice definition, and related regulations. Social Security Act, § 1877(b)(2), (h)(4); 42 CFR § 411.355(b), 411.352.

tin stating that gainsharing arrangements were flatly prohibited by the civil monetary penalty law.

According to the Bulletin,

> The statutory [civil monetary penalty] proscription is very broad. The payment need not be tied to an actual diminution in care, so long as the hospital knows that the payment may influence the physician to reduce or limit services to his or her patients. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. In short, any hospital incentive plan that encourages physicians through payments to reduce or limit clinical services directly or indirectly violates the statute.[11]

Furthermore, according to the OIG, there was nothing the OIG could do to offer protection.

> [G]iven the clear statutory prohibition on hospital-physician incentive plans, the OIG cannot provide any regulatory relief absent further authorizing legislation. Where Congress intended the Department to regulate physician incentive plans, such as plans offered by risk-based Medicare managed care plans, it did so explicitly. Congress' omission of comparable regulatory authority for the Secretary over hospital-physician incentive plans represents its considered judgment that such plans are flatly prohibited.[12]

While certain gainsharing arrangements since that time have been OIG-approved through the Advisory Opinion process, these approved arrangements have been relatively limited with respect to their scope of protected activities, covering product standardization and substitution and protocols for opening packages and performing certain tasks ''as needed'',[13] not for the game changing behavior envisioned by ACOs that will drive costs down through adherence to evidence-based medicine and care coordination.

The breadth of these statutory proscriptions is not merely theoretical. There have been numerous federal enforcement actions bootstrapping these regulatory infractions to create civil False Claims Act (''FCA'')[14] liability.

Indeed, recent FCA enforcement actions have increasingly ventured into theories of fraud liability in the very areas in which ACO financial relationships will necessarily tread in order to accomplish their goals, such as payments to employed physicians and in connection with physician practice acquisitions.

For instance, in 2009, Covenant Medical Center paid $4.5 million to settle the government's claims that it violated the Stark law by paying five employed physicians compensation that exceeded the fair market value of the services provided by those physicians.

Similarly, in 2008, Cox Medical Center entered into a $60 million settlement which included allegations regarding physician services agreements that included in the physician salary calculations the revenue earned from various ancillary services (e.g., clinical laboratory, radiology, pharmaceuticals) provided to Medicare patients treated by the physicians.

In 2002, McLeod Regional Medical Center settled with the government for over $15 million in connection with amounts paid for certain physician practice acquisitions and compensation paid to those employed physicians after the practices were acquired, which the government contended exceeded fair market value.

These settlements shed light on the extent to which fraud and abuse enforcement theories increasingly are intruding on the intricate financial relationships among closely aligned providers in ways that will inevitably impact ACO financial relationships.

Health reform's fraud and abuse amendments and other recent regulatory changes in the fraud and abuse area also have cut back substantially on the legality of many collaborative and joint financial arrangements between hospitals and physicians.

The Stark law's venerated ''whole hospital'' exception, which since the Stark law's enactment in 1989 permitted physicians to invest in hospitals, drew to a close in the health reform law, with grandfathered hospitals severely limited in size and expansion capabilities.[15]

With the demise of that exception goes physician ownership of hospitals as the ultimate means of aligning physicians and hospitals in providing cost-effective, quality care.

Also altered in the 2009 Stark regulations was the legality of physician ''under arrangements'' contracts with hospitals in which physician-owned entities could furnish health care services to hospitals without triggering Stark law liability.[16] Thus, the range of protected activities among hospitals and physicians has become more narrow, just as the need for greater latitude for collaboration is seen as critical to the future of health care.

2. *Why should HHS allow ACO savings to be shared with and among referring physicians without regard to its previous interpretations of the fraud and abuse laws?*

First and foremost, health reform recognizes that ACOs are critical to the future of health care. By granting explicit waiver authority applicable to the fraud and abuse laws, health reform further recognizes that relaxing the fraud and abuse laws is critical to the success of ACOs. This indicates Congress's clear intent that the fraud and abuse laws should no longer be an impediment to accomplishing the broader goals of health reform.

If ACOs, as well as bundled payments and episode of care payment methodologies are able to succeed, financial incentives will need to support ACO objectives. In particular, payment distribution will have to favor primary care physicians and other ACO professionals for the increased efforts and costs involved in their coordination of patient care, follow-up, and related activities, through the payment of management fees and other incentives.

---

[11] Special Advisory Bulletin, Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries, Office of Inspector General, Department of Health and Human Services (July 1999)

[12] *Id*.

[13] *See, e.g*., Advisory Opinions 05-01, 05-02, 05-03, 05-04, 05-05, 05-06, 07-21A, 07-22A, 08-15, 08-16, and 09-06.

[14] 31 U.S.C. § 3729 *et seq*.

[15] Affordable Care Act, § 6001

[16] FY2009 Inpatient Prospective Payment System regulation, at 73 Fed. Reg. 48721, 48751 (2008).

  HFRA ISSN 1092-1079

This needed shift in payment is consistent with Medicare payment policy objectives. Indeed, it has been a longstanding policy objective of the Medicare program to re-apportion physician payments toward greater recognition of primary care physician services and their importance to coordination of patient care.[17]

A massive overhaul of the payment system that favors specialty care has been largely politically infeasible in a pure fee-for-service Medicare context.

However, ACOs and other innovative payment models can take steps toward accomplishing this objective through the mechanism of shared savings, fees for patient management services, and bundled payment distributions, through incentives that reward all for its accomplishment. But this will only be possible if there is greater latitude under the fraud and abuse laws to do so.

What is different about health reform that should ease enforcement concerns? Clearly, one important difference in health reform, in contrast to provider integration in the 1990s, is that these gainsharing structures, instead of involving efforts by purely private parties redistributing Medicare fee-for-service payments, now are sponsored by and written into the government's health reform legislative infrastructure.

Most important in this regard is the level of organizational and clinical integration anticipated by the legislation for the various ACO models that will emerge. The fraud and abuse laws always have been more lenient, and enforcers less concerned, where highly integrated health care delivery systems are involved, such as academic medical centers or bona fide medical group practices.

Also serving as helpful assurance from a fraud and abuse perspective is the legislation's emphasis on quality measures and quality reporting for ACOs, especially since the relevant measures are created by and reported to CMS. ACO quality measures are thus distinguishable from earlier gainsharing approaches, where participants designed their own measures and there was no formal reporting mechanism.

Further, ACO accrediting organizations such as NCQA are emphasizing transparency to patients with respect to all physician incentive arrangements. Presumably, the waiver application will make these arrangements transparent to CMS, which will be monitoring ACOs.

These disclosures should alleviate another typical concern among fraud and abuse enforcers—namely, the ''secret'' nature of financial relationships that may create undisclosed conflicts of interest in patient care.

Probably most convincing to the fraud and abuse enforcers is the fact that, under health reform, the Medicare program will participate in and get the benefit of the savings achieved through the ACO's efforts.

Indeed, the stronger the provider incentives in place to curb costs, the greater the potential savings to the Medicare program. These are game-changing differences in structure and purpose and ought to be viewed as such in the application of the existing fraud and abuse laws.

3. *What are the operational areas that are critical for obtaining waivers or other protection from fraud and abuse liability?*

Clearly, ACOs will be the ultimate ''gainsharing'' program. Back in 2005, Lewis Morris, chief counsel to the HHS Office of Inspector General, testified before Congress that ''absent a change in law, it is not currently possible for gainsharing arrangements to be structured without implicating the fraud and abuse laws.''[18] This has remained largely true, with only very limited gainsharing-type arrangements obtaining approval under the OIG's advisory opinion authority.

Current CMS gainsharing demonstration projects incorporate the Medicare program's existing fraud and abuse restrictions, at least with respect to the anti-kickback statute and civil monetary penalty provisions,[19] leaving it up to applicants to configure their incentive arrangements accordingly, and obtain the necessary protections through avenues other than the demonstration application process (e.g., advisory opinions, safe harbors, etc.).

While this piecemeal approach may work on a demonstration project scale, a more integrated, holistic approach to the fraud and abuse laws is warranted if the health reform's goal to encourage the proliferation of ACOs is to be achieved.

Presumably, ACOs will not just be distributing Medicare shared-savings payments or, at least, not for long. Many ACOs will be fully or partially integrated structures that pay physicians for a full range of clinical and administrative services.

It is the payment structure for this full range of services, including the various incentives paid to align physician practices to ACO objectives, that will require protection from the fraud and abuse laws, not just the mere distribution of CMS shared savings payments.

In this regard, fair market value has been a central theme of the fraud and abuse laws since their inception. But what is fair market value when there are shared savings, bundled payments, or risk sharing? What if payments from an ACO (operated by a hospital or physician/hospital joint venture) to physicians exceed the Medicare fee schedule?

In fraud enforcement actions, the DOJ typically has taken the questionable, but unchallenged, position that payments above the Medicare fee schedule are prima facie evidence of payment for referrals, resulting in numerous settlements as described above.

---

[17] See, e.g., Testimony of Glenn M. Hackbarth, J.D., Chairman, Medicare Payment Advisory Commission, before the House Ways and Means Subcommittee, April 1, 2009. ''[I]n our June 2008 and March 2009 Reports to the Congress, the Commission recommended increasing fee schedule payments for primary care services furnished by clinicians focused on delivering primary care. This budget-neutral adjustment would redistribute Medicare payments toward those primary care services provided by practitioners—physicians, advanced practice nurses, and physician assistants—whose practices focus on primary care. This recommendation recognizes that a well functioning primary care network is essential to help improve quality and control Medicare spending (MedPAC 2008, MedPAC 2009).''

[18] *See* Testimony of Lewis Morris, Chief Counsel to the Inspector General, U.S. Department of Health and Human Services, House Committee on Ways and Means Subcommittee on Health, Hearing October 7, 2005.

[19] The current ACE Demonstration Project provides that, if there is a physician incentive component, the ''provider incentive payment must not induce a physician to reduce/limit services that are medically necessary [and] payments must not be based on the volume or value of referrals or business otherwise generated between the hospital and physicians.''

Significantly, the current CMS gainsharing demonstration projects cap physician payment incentives at 25 percent more than the Medicare fee schedule payment, under the theory that greater payment differentials would implicate traditional fraud and abuse notions of fair market value.

These payment restrictions limit the creation of alternative payment methodologies that may pay physicians more than the Medicare fee schedule but save the Medicare program more, as well.

Also, the question will arise as to whether payments to ACO physicians that may include ancillary service revenues.

Much of the Stark law analysis of the 1990s focused on the criteria that would qualify group practices as bona fide, with the accompanying ability to distribute payments for ancillary services performed and/or supervised within the group, and, as described above, government settlements have focused on ancillary services distributions, as well.

Clearly, this issue will arise in the ACO context as well in connection with Medicare shared savings distribution payments and, in more closely integrated ACOs, in connection with physician compensation methodology.

4. *Beyond funds flow within the ACO, what other questions regarding ACO formation will arise?*

There are other significant fraud and abuse questions in ACO formation beyond internal funds flow. For instance, how are providers being selected to participate in the ACO? Higher volume of referrals may be considered a proxy for providers having lots of experience working together, which will be critical for launching a successful ACO able to be cost effective and at the same time quality driven.

However, targeting high referrers to participate in arrangements has been a substantial risk factor in fraud and abuse enforcement. Also, if achieving maximum cost savings is a priority, then targeting high revenue producing areas (and providers) will be critical. But these are precisely the factors that always have been suspect under the fraud and abuse laws.

Previous gainsharing arrangements approved by the OIG also have placed strict limits on the length of time savings may be measured and paid, under the theory that long term payments for the same results are duplicative, and thus exceed fair market value.

Early gainsharing advisory opinions limited savings payments to a year, and required further savings to be based on setting new benchmarks. The ACO statute provides for three-year agreements[20], a time frame that has been adopted only in later OIG advisory opinions.[21]

Will even three years be enough time to change practice behavior, especially as the criteria and measures for shared savings become more complicated and ambitious?

What will keep providers from reverting to their old, comfortable ways once there is no longer an incentive in place? Finally, at a certain point, there are no more savings to be achieved from further ratcheting up the benchmarks, so more complex incentives inevitably become necessary.

ACO relationships with beneficiaries is another area that may implicate the fraud and abuse laws. ACOs are expected to be ''patient-centered.'' To do so likely will involve incentivizing beneficiaries toward care compliance and to otherwise promote wellness and disease management programs that will enhance outcomes as well as, in the long run, save costs.

These incentives may implicate the anti-kickback statute, which applies to beneficiary as well as provider inducements, as well as a specific civil monetary penalty prohibiting inducements to beneficiaries. While there is a regulation that allows certain preventive care incentives, it needs a fresh look in light of the more expansive goals of ACOs that go beyond preventive care.

As ACOs are essentially Medicare managed care plans without the insurance component, it is not surprising that many of the same integrity principles would apply.

A specific provision in health reform allows the secretary to impose ''appropriate sanctions,'' including program termination, against ACOs that take steps to avoid ''patients at risk'' to reduce costs. This concept, known familiarly as ''cherry picking'' in the managed care world, is thus specifically recognized as relevant to these new-age accountable care programs.

5. *What is the process for obtaining protection from the fraud and abuse laws under the waiver authority or otherwise?*

Under the existing fraud and abuse authorities, there are various avenues for obtaining guidance and protection. One is the safe harbor authority, which authorizes the OIG to create regulatory exceptions under the anti-kickback statute. CMS has similar authority to adopt regulatory exceptions under the Stark law.

Presumably, regulatory authority exists under the CMP provisions, as well, but CMS has been reluctant to use its regulatory authority with respect to the CMP provisions regarding reduction of care, apparently believing the scope of its authority limited. Safe harbors and statutory exceptions, while helpful in providing generalized standards, do not address or provide comfort with respect to specific arrangements among particular providers.

Separate from the safe harbor authority, there also is the advisory opinion authority under which the OIG can consider and protect specific arrangements. Although the advisory opinion process is lengthy and cumbersome, OIG has the authority to protect arrangements that implicate the fraud and abuse proscriptions that it nonetheless decides do not warrant enforcement action.

OIG also can opine as to whether a particular arrangement is within a safe harbor. Similarly, CMS has advisory opinion authority under the Stark law, although few decisions have been published to date through this process.

In addition to these existing regulatory authorities, health reform provides the HHS secretary with the authority to ''waive'' certain Medicare program requirements, including the fraud and abuse laws. HHS has not yet set out the particulars of the waiver process it will follow, if at all.

The questions will be whether this waiver authority will be exercised, what the process will be for accomplishing the waiver, how broad the waiver, if exercised,

[20] Affordable Care Act § 3022(b)(2)(B).

[21] Compare Advisory Opinion 07-21 (one-ear gainsharing arrangement) to Advisory Opinion 08-15 (three-year gainsharing arrangement).

   ISSN 1092-1079

will be, and whether there will be inter-agency coordination with respect to both the substance and process of the waivers granted.

Key to these questions will be whether the relevant agencies have sufficient resources to accord priority treatment to grant the necessary waivers and similar approvals on a timely basis.

6. Why is broad and timely exercise of HHS waiver authority necessary?

The Notice of Meeting published in the Federal Register for the Oct. 5 meeting[22] included a request by the HHS agencies as to whether waivers ''should apply only to the incentive payments distributed to the ACOs and participating physicians (and other participating suppliers or ACO professionals), or whether it would be necessary to create a broader waiver that would also apply to other financial relationships created by ACOs that participate in the [program]'' and requesting support for a broader waiver—that is, ''why this is necessary and what safeguards should be required as part of such a broad waiver.''[23]

Reportedly, comments at the ACO meeting further suggested that HHS may be considering a very narrow waiver applicable only to the payment stream emanating from Medicare program payments to the ACO. This suggests that HHS may be conceptualizing ACOs as similar to existing hospital/physician gainsharing programs, in which the payment stream from shared savings is always separate and apart from the underlying Medicare payments to the hospital and physicians for the services furnished.

Unfortunately, this is inconsistent with the way in which the health care community is viewing ACOs as both structurally and clinically integrated organizations in which participating providers may look to the ACO for comprehensive payment for the patient population they serve, as opposed to only distributing a gainsharing-type add-on to Medicare fee-for-service payment.

Moreover, as health care organizations involved in New Jersey's CMS-approved gainsharing demonstration found a few years ago, CMS approval of a demonstration project, alone, does not protect organizations from vulnerability to a competitor's challenge under the fraud and abuse laws.

Rather, responding to a challenge by competing hospitals left out of the demonstration project, a federal district court in New Jersey permanently enjoined the CMS demonstration project.

The court held that, because HHS's demonstration project waiver authority did not extend to the civil monetary penalty law, protection from the civil monetary penalty law only could come from an OIG advisory opinion, which had not been sought or obtained by the hospital participants.[24]

Unlike a waiver that could apply, like a ''Good Housekeeping Seal of Approval,'' to a particular ACO application, safe harbors and exceptions would be applied privately by the parties and thus could be susceptible to competitor or other stakeholder challenge. It is not even clear that exceptions will be adopted in all relevant fraud and abuse areas.

As the Notice of Meeting pointed out, under the Stark law, there is a question as to ''how a physician self-referral exception could be designed given that any new exception under [the Stark law] must present no risk of program or patient abuse.''[25] Thus, it is not even clear that HHS believes it has the authority to expand Stark law exceptions to meet ACO needs, a somewhat surprising position given the statutory waiver authority granted in health reform's ACO authorizing language.

Timing of approvals also is an important consideration underscoring the need for a comprehensive waiver approach. The ACO provisions are scheduled to be implemented in 2012. An approach that relies solely on safe harbors and Stark law exceptions would need to deal with the time it takes for the relevant agencies to issue new rules.

Even if rules are issued in interim final form, as other health reform and previous safe harbor regulations have been, it will be difficult at best for the agencies to develop a rule in a timely manner to enable the formation of ACOs in advance of the ACO application process.

Even if the existing safe harbors could be expanded and new safe harbors issued on a timely basis, the problem would remain that safe harbors fix narrow approaches and promote cookie-cutter structures when the health reform laws are aimed at promoting innovation. Thus, safe harbors alone are not the answer.

Likewise, the advisory opinion process is notoriously slow. The possibility of a deluge of ACO-forming organizations seeking advisory opinions is daunting, both to the providers who will be trying to seek and obtain them on a timely basis, as well as, presumably, to the OIG that will have to issue them.

Currently, health care organizations have an impression that it takes several years to obtain a favorable advisory opinion that is not a look-alike of a previously issued advisory opinion, clearly a barrier to achieving the 2012 implementation date for ACOs.

Even the advisory opinion process, like the safe harbor route, tends to spawn cookie-cutter approaches designed to gain fast approval at a considerable sacrifice to innovation. Thus, the advisory opinion process, too, tends to inhibit, rather than encourage, innovation.

7. Why do we need a new ACO safe harbor and statutory exceptions in addition to waivers?

With ACOs, there is authority for the secretary to waive fraud and abuse provisions, but it is not nearly as broad as the waiver authority applicable to other pilots and demonstration projects authorized under health reform.

Instead, the ACO waiver authority applies specifically to Sections 1128A, 1128B and Title XVIII of the Act—meaning that compliance with the anti-kickback statute (1128B), the civil monetary penalty for reduced care (contained in Section 1128A) and the Stark law (Title XVIII) can be waived.

Conspicuously absent from the secretary's ACO waiver authority is the OIG's exclusion authority (Section 1128). It is unclear whether this omission is by inadvertent omission, designed specifically to require use of the advisory opinion process, or, as would be a more

[22] 75 Fed. Reg. 57039, Friday, September 17, 2010.

[23] *Id.*

[24] *See Robert Wood Johnson University Hospital v. Thompson*, 2004 U.S. Dist. LEXIS 8498 (D.NJ 2004).

[25] 75 Fed. Reg. at 57041.

reasonable interpretation, expected to be irrelevant once there is a waiver of the substantive underlying laws.

Also, the waiver authority for ACOs, unlike certain other health reform pilots and demonstration projects, does not extend to Medicaid, leaving open the question of ''dual eligibles''—i.e., those patients who qualify for both Medicare and Medicaid coverage.

Thus, even with the exercise of broad waiver authority, any ACO that seeks to service dual-eligible Medicare beneficiaries will not enjoy protection from the fraud and abuse laws pursuant to the exercise of HHS's waiver authority. Another way to obtain protection will be necessary.

ACOs also are expected to be a driving force beyond Medicare, serving those who are privately insured as well as those covered by self-insured employer group health plans. Many of these employer group health plans will include Medicare-eligible covered lives, either because they are covered by a retiree health plan or because they are working aged or retired family members of active workers.

The fraud and abuse laws apply equally to these Medicare secondary lives, yet they would not be under the umbrella of any Medicare ACO waiver. To avoid these Medicare secondary beneficiaries from becoming the ''tail'' that wags the dog, alternative means of protection (i.e., safe harbors, exceptions, etc.) would be necessary.

ACOs will have to be operational in advance of applying for Medicare's ACO program. Latitude is needed to get the relevant physician incentives in place before any waiver will be granted in connection with the ACO application process.

8. Why aren't the existing safe harbors and statutory exceptions sufficient?

Although being in a safe harbor is ''purely voluntary,'' we are finding more health care providers wanting to seek this ultimate protection in light of today's rigorous enforcement climate. Existing safe harbors simply do not protect the broad range of financial arrangements expected to be necessary between ACOs and their participating professionals.

Absent a waiver, ACO incentive payments to physicians would not be fully protected from anti-kickback liability unless those physicians are W-2 employees.

The anti-kickback statute's personal services safe harbor, which protects independent contractors, requires a fixed, pre-determined fair market value payment, with the full amount set in advance for the year, thus would not protect the bonus and incentive payments that ACOs contemplate.

The personal services safe harbor also requires that payments be ''fair market value'' which, in the enforcement realm, is generally tied to the physician fee schedule.

The anti-kickback statute's managed care safe harbors and the shared risk exception and safe harbor only apply in the context of ''eligible managed care organizations'' or ''qualified managed care plans'' and their downstream contractors.

This would not include ACOs, which are expected to operate independently of managed care organizations. Of course, the managed care and shared risk safe harbors could be expanded to include ACOs, but, currently, they are not eligible for protection.

There is no doubt that the civil money penalty prohibition on paying physicians for reduced or limited care requires change, preferably by regulation or, at a minimum, by case-by-case determination.

The provision precludes any reduction or limitation of care whatsoever, and is not limited to reductions in medically necessary care. Health reform's legislative waiver authority could be helpful in providing the legal basis for HHS to create regulatory exceptions in this area.

The Stark law exceptions are similarly restrictive. Several years ago, a Stark law gainsharing exception was proposed but never finalized.[26]

Moreover, while ACOs contemplate ACO entities jointly owned by physicians and hospitals, unlike the anti-kickback statute's safe harbors, the Stark law has never had any exception to its physician ownership prohibition for joint venture/small entity investments. Even the so-called ''whole hospital'' exception was recently gutted.

Further, the Stark law also limits payments to employed physicians to ''fair market value,'' which, again, is generally tied to the Medicare fee schedule.

The Stark law's personal services exception is somewhat more forgiving than the similarly named anti-kickback statute safe harbor, but it is far from clear that ACO payments to physicians could qualify unless they are straight per capita distributions of ACO savings.

While there is an ''exception-within-an-exception'' for certain physician incentive plans, it would require these plans to meet the physician incentive plan regulation applicable to managed care organizations, including, for incentives beyond a certain amount, adopting stop/loss insurance, which seems incongruous when the Medicare program is still paying ACO participants on a fee-for-service basis for beneficiary services.

Clearly, the existing framework is geared toward then-current concepts of managed care delivery networks and does not anticipate the ACO model of health care delivery.

9. *What can HHS do with respect to fraud and abuse to facilitate ACO development as envisioned by health reform?*

In a sea-change from the 1990s, Congress now has favored legislatively ACO development. As such, HHS should view as protected a broad range of activities designed to promote successful ACO development and incentives designed to achieve Medicare program savings, and it should exercise broadly the waiver authority granted by Congress to enable organizations to do so.

Indeed, the high degree of corporate and clinical integration envisioned by the ACO statutory authority suggests that fraud and abuse concerns with respect to ACO funds flow should be of minimal concern, as they are within other highly integrated structures, like academic medical centers and medical group practices. Both of these types of health care organizations are prime candidates for ACO implementation.

Moreover, they already qualify for their own Stark law exceptions, although their expansion into the ACO world probably will push the limits of existing protections.

---

[26] 2009 Medicare Physician Fee Schedule regulation, 73 Fed. Reg. 38502 (2008).

  HFRA ISSN 1092-1079

There is no one ''magic bullet'' for solving the challenges to ACO development from the longstanding fraud and abuse enforcement regime. Rather, health care organizations and their counsel need a complement of tools in their ''kit bags'' that can be used to get health care organizations to the comfort level they need to move forward with ACO development.

Just as the new era of health reform requires health care organizations to consider new and innovative approaches to health care delivery, so does it require fresh thinking and increased flexibility on the part of the fraud and abuse enforcers.

This is, in part, because the risk appetites of health care organizations vary as to the degree of comfort they need to move forward. It is also because health care organizations will vary as to the types of arrangements they will develop under the ACO banner.

Those favoring ''plain vanilla'' arrangements which simply distribute ACO savings, if achieved, without substantial provider incentives to drive those savings, are less likely to warrant complicated fraud and abuse waivers. Of course, they are also less likely to succeed in achieving meaningful savings.

Some health care organizations, particularly those not anticipating competitor challenge to their participation in ACOs, will be satisfied with thoughtful advice from experienced legal counsel and thorough documentation of the various legitimate purposes of the ACO arrangements (quality, access, cost-efficiency, etc.).

For these organizations, informal guidance from the OIG and CMS in the form of advisory bulletins, FAQs, and similar issuances will suffice. At a minimum, informal guidance that addresses the OIG's previous gainsharing bulletins, which cast gainsharing arrangements in a negative light, in light of the clear legislative directive for HHS-sponsored gainsharing arrangements in the form of ACO development, is warranted in this area.

Informal guidance also will be helpful to guide those in the ACO formation stage to avoid regulatory ''nonstarters'' even if these ACO participants ultimately will be seeking more formal approvals or waivers.

Increasingly, however, in this era of aggressive fraud and abuse enforcement focusing on business transactions, this will not be sufficient. Instead, health care organizations may want to rely on an applicable safe harbor or HHS waiver to furnish protection against future enforcement actions or competitor challenges.

For these organizations, it will be important for the OIG and CMS to come up with workable safe harbors, statutory exceptions, and waivers for ACOs.

Collaboration among the agencies will be key. The October meeting was promising in this regard, including representatives of OIG, CMS, and the FTC. It will be especially important for OIG and CMS to collaborate on safe harbor/statutory exceptions to prevent ''dueling'' standards or standards that are not sufficiently comprehensive to cover all relevant prohibitions.

A good model for collaboration was the joint anti-kickback safe harbor/physician self-referral exceptions applicable to electronic medical records and physician e-prescribing, and this organizational model for safe harbors should be adopted for ACOs.

As to substantive ACO standards, one possible model to consider for anti-kickback safe harbor/physician self-referral exceptions is the academic medical center exception to the physician self-referral law. It is a good example of protecting funds flow within an integrated family of affiliated health care organizations with common purposes, as is intended for ACOs.

It will be important for the agencies to be willing to consider and approve far-ranging concepts of ACO shared savings distribution methodologies and other compensation arrangements. In this regard, there already are substantial built-in protections inherent in the ACO model.

CMS will be dictating quality standards that ACOs will strive to meet to qualify for shared savings payments. Adherence to evidence-based medicine also serves to temper potential concerns arising from physician incentives.

Further protections could be considered similar to the accreditation concept of transparency of physician incentives to beneficiaries. Beneficiary transparency has been adopted in other areas where physician conflict of interest is of concern, such as physician self-referral, and it has been referenced in various OIG gainsharing advisory opinions. [27]

Long considered by health lawyers to be the ''gold standard'' for physician ownership interests, disclosure should work equally well with respect to ACO gainsharing-type physician incentives. Ultimately, the Medicare program will benefit from any savings achieved, so wide latitude is warranted in this area.

In light of its previously taken positions on gainsharing, HHS also must seriously consider adopting new waiver or regulatory authority under the CMP provision, which health reform's waiver authority should allow. At a minimum, a new regulation or generally applicable waiver that interprets the CMP as proscribing reductions only in ''medically necessary'' care needs to be adopted.

Such an interpretation is necessary to allow ACOs to drive cost savings that will benefit the Medicare program through provider incentives to adopt medically accepted, evidence-based *quality* care, even if it means, at times, that less *quantity* of care will be provided.

Otherwise, ACOs may face competitor or other market-oriented challenge, like in the *Robert Wood Johnson University* case, unless they delay implementation by seeking specific advisory opinions protecting their conduct.

For health care organizations that need specific protection for their ACO arrangements, it also will be important for the various HHS agencies to consider new and/or collaborative approaches to its current processes for fraud and abuse protection. One possibility is a ''fast track'' dual OIG/CMS advisory opinion process for ACOs that will certify as meeting certain criteria.

This could be a hybrid approach between safe harbors and advisory opinions, in which approval could be obtained of specific arrangements that meet certain criteria, as specified in advance in OIG guidance. Alternatively, OIG (and CMS's Stark law regulatory personnel) could be involved in the CMS ACO application process, reviewing and approving relevant portions of the ACO applications.

[27] See, e.g. Advisory Opinion 08-15. In that Advisory Opinion, the OIG stated, ''While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosures offer some protection against possible abuses of patient trust.''

Clearly, there is much work to be done with the current fraud and abuse laws to ensure that the promise of the ACO model can be realized.

Collaboration among the key federal regulatory and enforcement agencies, both with respect to the process by which waivers and other protections are adopted as well as the substance of those protections, will be critical, as will collaboration with the health care industry to accomplish the necessary balance between government enforcement objectives and the achievement of ACO goals.

  HFRA ISSN 1092-1079