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Accountable Care Organizations, Clinical Laboratories and Fraud and Abuse—What's Old Is New Again

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An ambitious health reform subtitle, "Transforming the Health Care Delivery System," promises health care transformation through Medicare payment innovations, including accountable care organizations (ACOs). ACOs contemplate loose affiliations of providers acting cooperatively and sharing risks and rewards in the care of a defined Medicare patient population. While ACOs show promise for gaining efficiencies and quality of care, these arrangements will inevitably operate in ways that have long been viewed as suspect under traditional fraud and abuse analysis and will require careful consideration by participants.

Specifically, the Medicare shared savings program contemplates groups of providers working together as ACOs to manage and coordinate care for Medicare beneficiaries. ACOs that meet certain quality standards will be eligible for shared savings payments. Medicare will set quality measures for ACOs in areas such as clinical processes and outcomes, patient and caregiver experience of care, and utilization and quality performance. ACOs will submit data so that Medicare can evaluate ACO quality of care. Services furnished by ACO providers will continue to be paid under fee-for-service Medicare as always, and the ACO also will be eligible to receive additional Medicare shared savings payments, based on meeting quality standards and utilization benchmarks for Medicare beneficiaries.

Groups of providers with a mechanism for shared governance are eligible to participate, including the following:

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

Thus, clinical laboratories and pathologists could participate in ACOs in a number of ways: as ACO suppliers, as ACO owners and partners, and as integrated components of ACOs.

Fraud and Abuse Concerns

Each alternative raises distinct fraud and abuse issues, depending on

whether there is physician ownership of the ACO and the incentives for physicians to utilize the laboratory. Although ACOs must have a "mechanism" for distributing shared savings to participating providers, the law is silent on the details. Presumably, ACOs will seek to align the financial incentives of its providers to meet quality and cost-saving objectives, including patient-centeredness, care coordination, and adherence to evidence-based medicine. ACOs, may also venture into health reform's other innovative Medicare payment models, such as bundled payments, global payments for episodes of care, and possibly shared risk. These downstream financial relationships, and the practices ACOs adopt to achieve savings, will make all the difference to the success of the ACO. They also will pose the greatest risks under the fraud and abuse laws.

The three major fraud and abuse authorities implicated in the ACO model are (1) the federal health care program anti-kickback statute, (2) the federal physician self-referral law (a/k/a the Stark law), and (3) the civil monetary penalty law prohibiting payments to physicians for reducing or limiting care. In contrast to the post-health reform care models that emphasize and reward clinical integration and quality, these laws were designed in an era of fee-for-service payment methodologies, where the government's focus was on controlling financial arrangements that could lead to overutilization of services and compromise patient choice and quality.

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 broad case law holding that if even "one purpose" of remuneration is to induce referrals, the statute is violated.[1] Moreover, the Office of Inspector General has issued a fraud alert and a compliance guidance addressing anti-kickback issues in clinical laboratory services.

Other fraud and abuse authorities are more "black and white" in their application. The Stark law prohibits physicians having any financial relationship (either ownership or compensation) with an entity that furnishes Medicare-covered "designated health services" (DHS) from referring patients to that entity and prohibits the entity from billing Medicare for any DHS performed as a result of such referrals. Included among the DHS are clinical laboratory services (the original DHS) as well as 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. There are no regulatory exceptions to this prohibition, and HHS's position is that it has no authority to create exceptions.

Are Labs at Risk?

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 longstanding fraud and abuse interpretations, serious questions arise as to the protection available for clinical laboratory-ACO arrangements.

Anticipated ACO structures, contemplating loose affiliations and networks of providers, have been targeted for years as suspect by the fraud and abuse en-

forcement authorities, especially when ownership of any DHS, such as clinical laboratory services, is involved. The last go-round of health reform, in the 1990s, spawned an alphabet soup of similar structures, including PHOs (primary health organizations) and MSOs (medical service organizations), 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 pressing issue then was that the financial viability of integrated delivery structures depended on cross-subsidization among specialist and primary-care physicians as well as ancillary revenue sharing among participants. These shared payments were viewed as potential referral fee payments and they were especially suspect when made across the loose affiliations contemplated by ACOs.

More recently, the government has taken issue with gainsharing efforts among hospitals and their medical staffs. A 1999 OIG Special Advisory Bulletin stated that gainsharing arrangements were flatly prohibited by the civil monetary penalty law, irrespective of whether the payment was tied to an actual diminution in care, to a specific patient, or to a reduction in medically necessary care. While certain gainsharing arrangements since that time have been OIG-approved through advisory opinions, they offer limited protection, covering product standardization and protocols for opening packages and performing certain tasks "as needed"—not the kind of game-changing behavior that ACOs will adopt to drive costs down through adherence to evidence-based medicine and care coordination.

Role of Labs, Pathologists

Other pronouncements in the clinical laboratory area also may implicate the role of clinical laboratory and pathology services in ACOs. For instance, in advisory opinion 04-17, the OIG determined that a pathology services joint venture arrangement would constitute grounds for anti-kickback and civil monetary penalty sanctions. The OIG found the arrangements between the pathology laboratory and physician groups, allowing physician groups to expand into pathology services, to be tantamount to a suspect contractual joint venture, designed to share profits with physician groups from their laboratory referrals. As ACOs will consist of networks of physicians that provide comprehensive services to a defined patient population, similar arrangements for pathology services are likely to arise with ACOs.

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Fair market value has been a central theme of the fraud and abuse laws since their inception. The OIG's 1994 Clinical Laboratory Fraud Alert states, "Whenever a laboratory offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the thing of value is offered to induce the referral of business." But what is fair market value when there are shared savings, bundled payments, or risk sharing? In fraud enforcement actions, the government has taken the questionable, but unchallenged, position that payments above the Medicare fee schedule are evidence of payment for referrals.

Related questions will arise with ACO physician payments that may include ancillary service revenues. 1990s Stark law analysis allowed only bona fide group practices to distribute payments for ancillary services performed and/or supervised within the group. More recently, in 2008, Cox Medical Center entered into a $60 million settlement of charges that included allegations that physician agreements included in salary Medicare revenue from various ancillary services (including clinical laboratory services). Clearly, similar issues will arise in the ACO context as well.

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From a Stark law perspective, physician-owned ACOs will be constrained from clinical laboratory ownership unless they fit within one of the Stark law exceptions, such as the in-office ancillary services exception. Generally, qualifying for this exception depends on being a bona fide group practice, not the networks of physicians and physician-hospital joint ventures contemplated for ACO formation.

The 1994 OIG fraud alert targeted as suspect free goods and services that might be provided to a referral source, such as phlebotomists that provide office services, free pick-up and disposal of biohazardous waste products (such as sharps) unrelated to the collection of specimens, and the provision of computers or fax machines unless integral to, and exclusively used for, performance of the laboratory's work. The increased emphasis of ACOs on value-added propositions with respect to access, cost, and quality, including timeliness of service, may implicate these OIG issuances.

As ACOs assume risk, many of the integrity principles relevant to Medicare managed care plans could apply to ACOs. The OIG's fraud alert warned against out-of-network clinical laboratories that offer free managed care testing for referral sources. To the extent ACOs may operate in part fee-for-service, in part risk-assuming, the OIG's concern about "swapping" may apply. In this regard, the fraud alert mentions clinical laboratories that offer below-market testing to end-stage renal disease (ESRD) facilities for composite rate work in order to obtain the fee-for-service referrals.

Is There Protection?

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

There are no safe harbors or exceptions that specifically address ACOs or the financial arrangements among the parties participating in ACOs. 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. There is advisory opinion authority under which the OIG can protect specific arrangements. Similarly, CMS has advisory opinion authority under the Stark law, although few decisions have been published to date through this process. Unfortunately, the advisory opinion process is notoriously slow.

In addition, health reform authorizes HHS 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 it will at all, and 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.

What is different about health reform that should ease the government's enforcement concerns and encourage the issuance of broad waivers, safe harbors, and advisory opinions as needed to protect ACOs? There is a high level of organizational and clinical integration required for ACOs, and the fraud and abuse laws always are more lenient with integrated delivery systems such as academic medical centers or bona fide medical group practices. Also helpful is

the emphasis on quality measures and quality reporting for ACOs, especially since the measures are created by and reported to CMS. This is different from earlier gainsharing approaches, where participants designed their own measures and there was no CMS reporting.

Probably most convincing is that, under health reform, in contrast to provider integration in the 1990s, these gainsharing structures now are sponsored by the government, and Medicare will benefit from the ACO's savings. This is in substantial contrast to the past, when OIG could say in the fraud alert "There is no statutory exception or 'safe harbor' . . . because the federal programs do not realize the benefit of these 'free' services."

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 savings and should exercise broadly its congressional waiver authority to enable organizations to do so. In the meantime, those seeking to develop and participate in ACOs will need to review past government pronouncements and their potential relevance for ACOs.

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