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Accountable Care NEWS

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Stark Law Implications for ACOs: Fitting a Square Peg into a Round Hole

By Carrie Valiant, Esq., EpsteinBeckerGreen

Much has been said about the promise of Accountable Care Organizations ("ACOs") in transforming health care delivery to a system where quality is paramount and providers are rewarded for furnishing cost-efficient, coordinated care. ACOs are viewed widely as important to health care transformation not only for Medicare, which just added through health reform a shared savings program for qualified ACOs, but also for the next generation of private payor arrangements. For this new model to succeed in Medicare, however, substantial changes to the Stark Law and its implementing regulations, among other fraud and abuse laws, will be necessary.

A recent report by the Congressional Research Service ("CRS Report")[1] serves to illustrate the Stark Law impediments to accomplishing meaningful ACO development. Citing MedPAC's report to Congress in 2009, the CRS Report suggests that the real savings from the ACO model will come from the incentives physicians will have, acting as a group, to constrain growth in capacity, as well as growth in specialist supply. It posits as an example of constraint ACO providers deciding to share an imaging machine across the ACO's participating entities rather than each entity purchasing its own imaging machine. [2]

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Can We Start an Accountable Care Organization without an Electronic Health Record?

By William J. DeMarco, MA, CMC, Pendulum HealthCare Development Corporation

There has been considerable discussion about the technology requirements for Accountable Care Organizations. We have seen in previous issues of this newsletter how ideal it would be if everyone were on an electronic medical record (EMR) so we could slice and dice the data to be able to truly measure and analyze the performance of practitioners and patient populations.

This is the era of population management. Physicians are trying to tackle this new philosophy in the hope they will get better feedback on the treatment options used for various populations, but also to see themselves ranked as top practitioners in their peer review and profiling process.

However, our experience (outside some of the larger health systems and multi-specialty medical groups) has been that EHRs are not well accepted. Part of this is the cost of purchasing and training staff to use the new technology, but a lot of it is the frustration many doctors feel when vendors try to sell them on a ready made solution even when they know their office will have a difficult time adapting to the workflow. Therefore many offices, even with meaningful use standards being prepared and Regional Extension Centers (RECs) in process in most states, are taking a wait and see attitude. In many cases they are saying they cannot participate in an Accountable Care Organization due to lack of technology.

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1 Accountable Care Organizations and the Medicare Shared Savings Program, Congressional Research Service, David Newman, November 4, 2010.

2 *Id*., p. 18

STARK LAW IMPLICATIONS FOR ACOs….*continued*

This scenario is certainly appealing from the cost-efficiency standpoint. However, sharing ancillary services and revenues across networks of physicians and hospital/physician joint venture entities simply will not work from a Stark perspective for the wide variety of ACO structures envisioned to participate in health reform's Medicare shared savings program.[3]

Specifically, ACOs are envisioned to be clinically integrated groups of providers and suppliers working together to coordinate care for Medicare beneficiaries and eligible to receive additional Medicare "shared savings" for meeting certain criteria, including quality performance. Eligible organizations will include not only structures recognized currently under Stark exceptions, such as medical group practices and hospitals employing physicians, but also those structures that remain unprotected, such as joint venture arrangements between hospitals and ACO professionals as well as networks of individual professional practices. [4] For unprotected joint ventures and networks, it will be impossible to share meaningfully in ownership, or to participate in other financial incentives as to use, with respect to any ancillary services on Stark's designated health services (DHS) list.

Stark Law Background

The Stark Law[5] ("Stark") prohibits physicians from having any financial relationship with an entity that furnishes Medicare-covered "designated health services" ("DHS")and from referring patients to that entity, and it prohibits the entity from billing the Medicare program for any services performed as a result of such referrals.[6] Included among the enumerated DHS are a host of services on the short list for ACO cost-saving collaboration: inpatient and outpatient hospital services, radiology services, including CT scans, MRIs and ultrasound, radiation therapy, and outpatient prescription drugs. Prohibited financial relationships include both ownership and compensation.

Mandatory exceptions must be met to allow physicians to refer to entities with which they have a Stark-covered financial relationship. Although many of the Stark exceptions are in the statute itself, CMS has authority to adopt regulatory exceptions under Stark, and it has done so, notably in the Academic Medical Center exception. CMS also can issue advisory opinions under Stark, although few decisions have been published to date.

In addition, health reform's ACO authorizing statute provides the HHS Secretary with the authority to "waive" certain Medicare requirements, including Stark. The ACO waiver authority applies to Sections 1128A, 1128B and Title XVIII of the Social Security Act—meaning that compliance with Stark (in Title XVIII) can be waived. HHS has not yet established the waiver process it will follow, if at all. HHS held a meeting in October to solicit comments from the public regarding how its waiver authority could work. [7]

Penalties for violating Stark are severe. In addition to refunding all claims billed inappropriately (which mounts up for specialty referrals), there are penalties of $15,000 per claim. Moreover, federal enforcement actions bootstrapping Stark violations to create civil False Claims Act ("FCA")[8] liability are possible, with higher, triple damages penalties.

Stark ACO Implications

Because Stark-implicated financial relationships include both ownership interests and compensation arrangements, both physician/hospital joint venture ACO ownership and hospital-employed physician ACOs will implicate Stark to the extent designated health services are involved. Further, there need not be hospital involvement to implicate Stark – even physician practice affiliations and physician networks will implicate Stark if there are DHS involved. Stark's referral prohibition applies broadly to prohibit all referrals for DHS between the parties, not just referrals involving the implicated arrangement. This means that ACO unprotected financial relationships may impact DHS referrals between the parties beyond the ACO.

ACO operations likely to trigger Stark liability include the various downstream financial relationships critical to ACO financial viability as well as the ACO's ability to advance quality. Shared savings distribution methodologies, especially those that involve gainsharing-type incentives for physicians for cost-efficient or quality-driven practices, will implicate Stark. It doesn't matter if the incentives are quality-focused – if the financial relationship is not excepted, referrals are prohibited. Likewise, cross-subsidization among specialist and primary care physicians, as well as the sharing of ancillary revenues among participants -- both key to rewarding the additional primary care services from patient care coordination and encouraging fewer expenditures for major medical equipment -- will implicate Stark.

Current Stark exceptions are very restrictive, and have recently become more so. Although the ACO legislation contemplates participation by loose networks of physicians, and ACO entities jointly owned by physicians and hospitals, there is no exception for physician ownership of networks or joint ventures.

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3 Affordable Care Act, § 3022.

4 Affordable Care Act §3022, adding a new Social Security Act §1899(b)(1).

5 Social Security Act §1877, 42 U.S.C. §1395nn.

6 Other fraud and abuse authorities implicated by ACOs are the federal health care program anti-kickback statute, Social Security Act §1128B(b), 42 U.S.C. §1320a-7b(b); and the civil monetary penalty law prohibiting payments to physicians for reducing or limiting care, Social Security Act §1128A(b)(1); 42 U.S.C. §1320a-7a(b)(1).

7 Notice of Meeting, 75 Fed. Reg. 57039, Friday, September 17, 2010.

8 31 U.S.C. §3729 et seq.

STARK LAW IMPLICATIONS FOR ACOs....*continued*

There is an exception for physician ownership of bona fide group practices, but they must meet strict standards. Stark's "whole hospital" exception, permitting physicians investment in hospitals, was substantially revoked in health reform. [9] Similarly, in 2009, physician "under arrangements" contracts with hospitals were deemed to implicate Stark's physician ownership restrictions, which eliminated the exception for "under arrangements" contracts involving referring physicians.[10]

Stark exemptions for physician compensation arrangements, such as ACO payment distributions to physicians, are similarly restrictive. Stark's personal services exception requires compensation to be "set in advance" and "fair market value" which tends to be tied to the Medicare physician fee schedule. This calls into question whether anything other than minimal amounts of ACO savings distributed per capita would be permitted, if at all. While the personal services exception includes an "exception-within-an-exception" for physician incentive plans, it contains managed care concepts like stop/loss insurance, which do not "fit" for ACOs in which Medicare will pay providers on a fee-for-service basis.

Many highly integrated ACOs will pay physicians for a full range of clinical and administrative services, involving complex compensation formulas designed to align incentives among primary care and specialist physicians, and with respect to use of ancillary services. There, the payment structure for compensating for this full range of services, not just shared savings payments, will require Stark protection.

Stark Exception/Waiver for ACOs

Clearly, protection through further Stark waivers and/or exceptions, and preferably both, are necessary for ACO formation as well as Medicare shared savings distributions. Unfortunately, HHS recently stated that it is questionable "how a physician self-referral exception could be designed given that any new exception under [Stark] must present no risk of program or patient abuse."[11]

Several years ago, CMS proposed but never finalized a Stark regulatory exception for gainsharing to allow shared savings arrangements between hospitals and their medical staffs.[12] The proposed exception, which CMS acknowledged was narrow, required, among other things, per capita distribution of shared savings to physicians grouped in pools of at least five, and independent medical review.

The proposed exception suggests that CMS believed that a Stark exception for shared savings programs was possible, despite its concerns:

> We are concerned about physicians . . . limiting their use of quality-improving but more costly devices, tests or treatments ("stinting"), . . . treating only healthier patients ("cherry picking"), . . . avoiding sicker patients ("steering") at the hospital, or . . . discharging patients earlier than clinically indicated . . . ("quicker-sicker discharge"). . . We are concerned that, because of pressures from competition or physicians, hospitals may increase the percentage of savings shared with the physicians, manipulate hospital accounts to generate phantom savings, or otherwise game the arrangement to generate income for referring physicians in order to retain them for or attract them to the hospital. [13]

The ACO statute, rewarding clinical integration and quality, provides substantial protection against these concerns. The degree of corporate and clinical integration suggests that ACO funds flow should be of minimal fraud and abuse concern, as it is within other highly integrated structures, like Academic Medical Centers and medical group practices. Both the Academic Medical Center exception and the in-office ancillary services (i.e., group practice) exceptions to Stark are good examples of protecting funds flow within a clinically integrated family of health care organizations or professionals with common purposes, just like ACOs, where there are substantial protections against program or patient abuse.

Likewise, CMS could accommodate ACOs through their own Stark exception or waiver on the basis of the protections inherent in Medicare ACOs. Similar to academic medical centers and group practices, eligible Medicare ACOs need shared governance, [14] a formal legal structure to distribute shared savings payments, and a leadership and management structure including clinical and administrative systems.[15] ACOs need processes for evidence-based medicine and patient engagement, reporting on quality and cost measures, and coordinating care.[16]

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9 Affordable Care Act, §6001

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

11 Notice of Meeting, 75 Fed. Reg. at 57041.

12 2009 Medicare Physician Fee Schedule regulation, 73 Fed. Reg. 38502 (2008).

13 *Id.* 73 Fed Reg. at 38550.

14 Affordable Care Act §3022, adding Social Security Act §1899(b)(1)

15 *Id.,* § (b)(2)

16 *Id*.

INDUSTRY NEWS

PRICEWATERHOUSECOOPERS

ACOs Among Most Important 2011 Health Issues

According to a PricewaterhouseCoopers Health Research Institute report, accountable care organizations will be one of the top issues for the health industry during 2011. Consumers were also asked by PwC what they felt about health reform issues, and when it came to ACOs, fewer than half said that they would stick with one throughout their continuum of care. These findings indicate that patients may need to be convinced that ACOs will work for them. Organizations will need to segment patient populations in a manner that will manage expectations if they want to achieve this.

ACP
American College of Physicians
Internal Medicine | Doctors for Adults

Medical Home Principles as Basis For ACO Rule

CMS is being urged by physician advocates to use already established guidelines for creating accountable care organizations in order to create a basis for the patient-centeredness criteria of the incoming regulations. The American College of Physicians (ACP) would like to see the standards for adoption created by the National Committee for Quality Assurance (NCQA) used in forthcoming criteria. The adoption standards were put together in conjunction with the American Academy of Family Physicians (AAFP), the American Academy of Pediatrics (AAP) and the American Osteopathic Association (AOA).

AMGA

Press Ganey Partners with AMGA for ACO Surveys

Press Ganey Associates, Inc will be AMGA's official survey administrator for its Accountable Care Organization Collaborative. Together they will develop survey content, methodology, and recommended distribution methods to assess the effectiveness of coordination of care.

STARK LAW IMPLICATIONS FOR ACOs*....continued*

CMS itself will establish the benchmarks for measuring savings and the quality standards that qualify for shared savings payments. CMS will determine, from ACO-submitted data, whether the standards are met. ACOs also must adhere to evidence-based medicine -- care protocols that will prevent financial incentives from undermining quality. This CMS oversight should address any concerns about physicians "stinting" on care.

As to CMS's concerns about cherry-picking and steering, unlike private gainsharing arrangements, ACOs are designed so that CMS designates which patients are assigned to the ACO based on where beneficiaries already are receiving care. CMS's designation of patients makes concepts such as cherry-picking and steering largely irrelevant to ACOs. Any further concerns could be ameliorated by adding a provision for beneficiary disclosure, which was included in CMS's Stark gainsharing proposal. Either the ACO or CMS could disclose to the beneficiary.

Finally, it is the Medicare program itself that is the primary beneficiary of any shared savings, as ACOs will only be paid a portion of what they save, subject to an overall cap. In its proposed gainsharing rule, CMS stated,

> We observe that payer-based programs in which the performance measures are set by a wholly independent, arm's length party with a clear financial incentive to make P4P payments prudently may pose somewhat less risk than non-payer based programs, where there is no third-party payer that sets the performance measures and monitors compliance. [17]

Here, CMS itself sets the performance measures, and CMS will monitor compliance on an ongoing basis. Moreover, when CMS is making the shared savings payments, the financial incentive for "prudence" in making payments is clear. Thus, there are substantial protections already built into the ACO authorizing legislation such that a broad Stark exception would pose no risk of program or patient abuse. Indeed, the ACO statute itself authorizes waiver of Stark and other fraud and abuse laws in connection with ACOs, suggesting broad authority on the part of CMS to protect ACO arrangements from the reach of Stark, through waiver or exception. Under these circumstances, broad protection is warranted so that Stark will not impede ACOs from achieving their promise in health reform.

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17 73 Fed Reg at 38549

