

HEALTH REFORM IMPACT

What you need to know NOW

NEWS FOR THE CLIENTS AND FRIENDS OF BASS, BERRY & SIMS PLC

ACOs Part IV: Avoiding the Big “Gotcha”

May 11, 2011

In previous issues of our *Health Reform IMPACT* series on Accountable Care Organizations (“ACOs”), we have addressed the essential building blocks of ACOs, their intersection with the antitrust laws and their heavy emphasis on quality measurement and monitoring.¹ This issue of *Health Reform IMPACT* is meant to remind potential ACOs and their participants that, even if an ACO is successfully established and operating under the auspices of the Medicare Shared Savings Program, it is not immune to enforcement under a myriad of independently operating fraud and abuse statutes as well as laws pertaining to tax-exempt participants. Although the regulators have introduced the idea of certain waivers to avoid the potential “gotcha” effect of building a collaborative ACO only to trip over other laws that restrict financial relationships between referral sources, the question is whether providers who are already wary of some of the complex requirements of ACOs will be reassured.

Healthcare Fraud and Abuse Waivers

To facilitate implementation of the Medicare Shared Savings Program, the Patient Protection and Affordable Care Act (“PPACA”) authorizes the waiver of certain fraud and abuse laws as necessary to carry out the provisions of the Medicare Shared Savings Program.² Accordingly, on the same day that the Centers for Medicare & Medicaid Services (“CMS”) released proposed rules for the establishment of ACOs, CMS and the Office of Inspector General of the Department of Health and Human Services (collectively the “agencies”) jointly issued a notice with comment period describing and requesting input regarding possible waivers of the federal physician self-referral law (the “Stark Law”), the federal anti-kickback statute (the “AKS”), and certain civil monetary penalty provisions that prohibit hospital payments to physicians to induce the reduction or limitation of services (the “Gainsharing Law”).³ Notably, the joint notice is not a proposed rule, and the agencies state that their approach “is to propose and solicit comments on possible waivers...and to solicit comments on different, potentially broader waivers, as well

¹ See [“ACOs Part I: Assembly Instructions,”](#) April 15, 2011, [“ACOs Part II: Oasis or Mirage? The FTC and DOJ Proposed Statement on ACOs,”](#) April 29, 2011, and [“ACOs Part III: Three Key Ingredients For Your ACO – Quality, Quality and Quality,”](#) May 4, 2011.

² See 42 USC 1395jjj(f), as added by Section 3022 of PPACA (Pub. L. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152).

³ 76 F.R. 19655 et. seq. (April 7, 2011).

as additional waiver design considerations.” The agencies anticipate issuing the final waiver provisions concurrently with the final regulations for the Medicare Shared Savings Program, but seek input as to whether the final waivers should be published at another time.

The fraud and abuse waivers described below would not apply to any other provisions of federal or state law, and CMS intends to apply the waivers uniformly to all qualified ACOs, ACO participants and ACO providers/suppliers participating in the Medicare Shared Savings Program. To qualify for any of the proposed waivers, ACOs would be required to enter into an agreement with CMS to participate in the Medicare Shared Savings Program, and ACOs, ACO participants and ACO providers/suppliers would be required to comply with the CMS agreement as well as statutory provisions related to the Medicare Shared Savings Program and all implementing regulations. While seemingly reasonable on their face, these threshold requirements arguably create a “double jeopardy” situation in which an ACO, ACO participant or ACO provider/supplier that finds itself in noncompliance (including perhaps technical noncompliance) with some aspect of the ACO regulations, such as those related to transparency, quality reporting, monitoring or marketing, also loses its fraud and abuse waivers and potentially finds itself subject to liability as well under the Stark Law, the AKS, the Gainsharing Law or even the False Claims Act.

Application of Waivers to Distributions of Shared Savings

Application of the Stark Law and the AKS would be waived for distributions of shared savings paid by CMS to an ACO under the Medicare Shared Savings Program either (1) within the ACO, i.e., to or among ACO participants and ACO providers/suppliers during the year in which the shared savings were earned by the ACO, or (2) outside the ACO for activities “necessary for and directly related to” the ACO’s participation in and operations under the Medicare Shared Savings Program. Although the phrase *necessary for and directly related to* is not defined in the notice, the agencies explain that the distribution must “relate closely” to the requirements for an ACO, including achieving the quality and savings goals of the Medicare Shared Savings Program. The agencies also seek comments on how specifically to incorporate this standard as well as on other standards that might be used to ensure that a waiver of the fraud and abuse laws is limited to ACO purposes. The agencies emphasize that they do not intend to protect distributions of shared savings to referral sources outside the ACO for activities that are not necessary for and directly related to the ACO’s participation in the Medicare Shared Savings Program.

Application of the Gainsharing Law would be waived with respect to distributions of shared savings paid by a hospital to a physician if (1) the payments are not made “knowingly”⁴ to induce the physician to limit or reduce *medically necessary* items or services, and (2) the hospital and physician are or were ACO participants or ACO providers/suppliers during the year in which the shared savings were earned by the ACO. The use of the phrase *medically necessary* is significant because this standard is more liberal than the current standard under the Gainsharing Law, which prohibits any payment from a hospital to a physician to induce a reduction in services to Medicare beneficiaries, irrespective of whether those services are medically necessary.

⁴ There is no definition of “knowingly.”

Application of Waivers to Other Financial Relationships Between or Among an ACO and Its Participants

The agencies also propose to waive application of the AKS and the Gainsharing Law for other financial relationships (i.e., other than those created by the distribution of shared savings) between or among the ACO, ACO participants and ACO providers/suppliers that are “necessary for and directly related to” the ACO’s participation in and operations under the Medicare Shared Savings Program and that implicate, and fully comply with an exception to, the Stark Law. These AKS and Gainsharing Law waivers would apply only during the term of the ACO’s agreement with CMS to participate in the Medicare Shared Savings Program. Although compliance with an exception to the Stark Law does not ordinarily immunize conduct under the AKS (or other laws), the agencies indicate their desire to “minimize burdens on entities establishing ACOs” and their reliance on specific safeguards to be incorporated into the Medicare Shared Savings Program.

Request for Additional Comments

In addition to requesting input regarding the waivers set forth above, the agencies also solicit comments regarding waivers for other financial arrangements that may be necessary to carry out the provisions of the Medicare Shared Savings Program.⁵ Additional topics for which the agencies specifically request comments include but are not limited to:

- (1) whether it is necessary to waive application of fraud and abuse laws for arrangements related to the *establishment of ACOs*;
- (2) whether additional waivers should be granted for arrangements between ACOs and outside individuals or entities;
- (3) whether distributions of similar shared savings payments from private payers should be protected by waivers;
- (4) the duration of the waivers;
- (5) whether additional safeguards are necessary for the waivers;
- (6) whether and under what circumstances the prohibition on offering inducements to Medicare beneficiaries should be waived for ACOs; and
- (7) what waivers should be considered with respect to separate programs tested by the CMS Center for Medicare and Medicaid Innovation.

All comments must be received by CMS no later than 5:00 p.m. EDT on June 6, 2011.

Federal Income Tax Implications

The Internal Revenue Service, (IRS), recently issued IRS Notice 2011-20, or the “Notice,”⁶ which provides preliminary guidance on the federal income tax implications of a tax-exempt organization’s participation in the Medicare Shared Savings Program through an ACO. In the Notice, the IRS addresses the concern that the split of shared savings between tax-exempt organizations and taxable providers pursuant to the Medicare Shared Savings Program might (i) jeopardize the tax-exempt status of participating tax-exempt organizations, or (ii) create unrelated business taxable income for the tax-exempt organizations.

⁵ 76 F.R. 19659.

⁶ A copy of the Notice can be found at <http://www.irs.gov/pub/irs-drop/n-11-20.pdf>.

The IRS indicates in the Notice that tax-exempt organizations may participate in ACOs through a variety of structures, including (i) membership in a nonprofit membership corporation, (ii) ownership of shares in a corporation, (iii) ownership of a partnership interest in a partnership (or a membership interest in an LLC), and (iv) contractual arrangements with the ACO and/or its other participants. In any structure, the tax-exempt organization likely will be participating along with private parties, including some who might be considered insiders with respect to the tax-exempt organization, such as physicians. To avoid any private inurement or impermissible private benefit to any taxable ACO participant, tax-exempt organizations need to ensure that their participation in an ACO is properly structured. The IRS indicates in the Notice that it will not consider a tax-exempt organization's participation in the Medicare Shared Savings Program through an ACO to result in private inurement or impermissible private benefit to the taxable ACO participants if the following requirements are satisfied:

- The terms of the tax-exempt organization's participation in the Medicare Shared Savings Program through the ACO (including its share of any Medicare Shared Savings Program payments or losses and expenses) are set forth in advance in a written agreement negotiated at arm's length.
- CMS has accepted the ACO into, and has not terminated the ACO from, the Medicare Shared Savings Program.
- The tax-exempt organization's share of economic benefits derived from the ACO (including its share of Medicare Shared Savings Program payments) is proportional to the benefits or contributions the tax-exempt organization provides to the ACO. If the tax-exempt organization receives an ownership interest in the ACO, the ownership interest received is proportional and equal in value to its capital contributions to the ACO and all ACO returns of capital, allocations and distributions are made in proportion to ownership interests.
- The tax-exempt organization's share of the ACO's losses (including its share of Medicare Shared Savings Program losses) does not exceed the share of ACO economic benefits to which the tax-exempt organization is entitled.
- All contracts and transactions entered into by the tax-exempt organization with the ACO and the ACO's participants, and by the ACO with the ACO's participants and any other parties, are at fair market value.

The IRS expects that, absent private inurement or impermissible private benefit, any Medicare Shared Savings Program payments received by a tax-exempt organization from an ACO will be treated as derived from activities that are substantially related to the performance of the charitable purpose of lessening the burdens of government (i.e., not the performance of an unrelated trade or business), as long as the ACO meets all the eligibility requirements established by CMS for participation in the Medicare Shared Savings Program. The IRS position recognizes that the provision of Medicare benefits is a burden of the federal government and that the operations of the ACOs are intended to lessen the burden of the federal government related to the provision of Medicare benefits. Accordingly, the share of the Medicare Shared Savings Program payments received by tax-exempt organizations will not be subject to unrelated business income tax, or UBIT, since such payments will be substantially related to the exercise or performance of the charitable purposes of the tax-exempt organization.

The Notice also provides that the IRS is soliciting comments regarding what additional guidance, if any, is needed to facilitate participation by tax-exempt organizations in the Medicare Shared Savings Program through ACOs, and if additional guidance is needed, the criteria or requirements which should be analyzed in determining whether participation by a tax-exempt organization in the Medicare Shared Savings Program through an ACO is consistent with tax-exempt status and whether the tax-exempt organization is receiving unrelated business taxable income. Additionally, the Notice provides that the IRS is soliciting comments regarding various aspects of participation by tax-exempt organizations in certain non-Medicare Shared Savings Program activities, including shared savings arrangements with commercial health insurance payers, through an ACO.

Conclusion

While the recent waiver guidance issued by CMS and the IRS indicates an intent to facilitate the establishment of ACOs by removing certain regulatory barriers that might otherwise exist to their formation and successful operation, it remains to be seen whether providers are reassured enough to forge ahead with ACOs, especially in light of the other complex structural and operational requirements covered in our previous issues of *Health Reform IMPACT*. If you have any questions, please do not hesitate to contact any of the attorneys in our Healthcare or Tax Practice Groups listed below.

Also, please [click here](#) to visit our special Web page for *Health Reform IMPACT*.

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