The Proposed Waivers of the Fraud & Abuse Laws for ACOs: Have OIG and CMS Gone Far Enough?

In early April 2011, the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG) published long-awaited proposals for waivers (Proposed Waivers) of the application of three federal fraud and abuse laws to Accountable Care Organizations (ACOs) participating in Medicare's Shared Savings Program.[1] The Proposed Waivers are authorized by Section 3022(f) of the Patient Protection and Affordable Care Act.[2] The comment period for these proposals ends on June 6, 2011. This white paper describes how the Proposed Waivers would insulate ACOs and their participating providers and suppliers from certain risks and liabilities under the federal physician self-referral or Stark law (the Stark Law), the federal anti-kickback law (the Kickback Law), and the civil monetary penalty law's prohibition on hospital payments to physicians to reduce or limit services to federal program patients (the CMP Gainsharing Prohibition) (collectively, the Fraud & Abuse Laws). In addition, this white paper discusses potential risks and liabilities under the Fraud & Abuse Laws not addressed by the Proposed Waivers, and that we believe that CMS and the OIG should address in the final rule in order for the Shared Savings Program to effectively achieve its objectives.

Proposed Waiver of the Stark Law

Under the Proposed Waiver applicable to Stark (the Proposed Stark Waiver), the Secretary would waive application of Stark's prohibitions to an ACO's distributions of shared savings received from CMS under the Shared Savings Program (i) to or among ACO participants and ACO providers/suppliers, including individuals and entities that were ACO participants and ACO providers/suppliers during the year in which the shared savings were earned by the ACO, and (ii) to other individuals or entities for activities "*necessary for and directly related to*" the ACO's participation in and operations under the Shared Savings Program. The Proposed Stark Waiver is limited to an ACO's distribution of shared savings earned under the Shared Savings Program. No other financial relationships between or among an ACO and its participants and providers/suppliers would be protected by the Proposed Stark Waiver.

This white paper will first discuss how the Proposed Stark Waiver addresses two of the thorniest issues that the Stark Law raises for ACOs: fair market value/commercial reasonableness and the Stark "volume/value" standard. Then, the white paper will discuss other significant Stark Law issues facing ACOs that we believe CMS should address in the final rule.

Fair Market Value/Commercial Reasonableness

The Proposed Stark Waiver relieves ACOs' entities furnishing Stark-designated health services (DHS entities) (*e.g.*, hospitals and participating referring physicians) of the burden of proving that the distribution of shared savings earned by the ACO is on fair market value and

[1] 76 Fed. Reg. 19,655 (April 7, 2011).
[2] Pub.L. 111-148, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub.L. 111-152).

commercially reasonable terms.[3] The value of the referring physicians' work on behalf of any ACO is, at best, highly speculative. It would be extremely challenging, if not impossible, to attempt to quantify the opportunity cost and other marginal costs incurred by any given physician in connection with modifying his or her clinical practice patterns to conform to the clinical and administrative processes of a particular ACO; and it would be even more challenging, if not impossible, to quantify the value of the referring physicians' work relative to the value of the work, costs and risks borne by the ACO's other participants, providers and suppliers. Despite the impracticability and imprecision associated with quantifying these kinds of relative values and costs, the Stark Law would require that ACOs be in a position to demonstrate that its distributions of shared savings to referring physicians and physician organizations are on fair market value and commercially reasonable terms. Accordingly, CMS designed the Proposed Stark Waiver to enable DHS entities and referring physicians to avoid this fair market value and commercially reasonableness problem.

Volume/Value Standard

The Proposed Stark Waiver relieves an ACO's DHS entities and participating physicians of the burden of proving, under a direct or indirect compensation analysis, that the shared savings distribution was not determined in a manner that takes into account the volume or value of physicians' referrals for DHS. If Medicare realizes savings as a result of an ACO's efforts to make physicians' referrals for health care services and items better conform with evidence-based medicine, recognized chronic disease management protocols, and preventative medicine and screening guidelines, the pool of savings shared with an ACO will, arguably, take into account the volume or value of the participating physicians' referrals for DHS. In turn, this arguably means that an ACO's distributions to its physicians will take into account the volume or value of the physicians' referrals for DHS. Accordingly, CMS designed the Proposed Stark Waiver to allow DHS entities and referring physicians to avoid the "takes into account" or "volume/value" issue.

Three Significant Stark Problems Unaddressed by the Proposed Stark Waiver

The Proposed Stark Waiver does not address three thorny Stark issues facing ACOs: ACO development and operating costs, downside risks under the "two-sided" risk model, and private payor shared savings and quality performance incentive payments. Each of these issues is discussed below.

The Problem of Development and Operating Costs

Although CMS and the OIG request comments on the issue, the Proposed Waiver does not address the problem of an ACO's participating hospital funding the ACO's development and ongoing operations. In most cases, an ACO's participating physicians will not contribute to or bear risk for the ACO's development and ongoing operational costs. Although the physicians

[3] Even under the Stark indirect compensation definitional analysis, CMS has stated that fair market value is relevant. Therefore, even if an ACO's distribution of shared savings may not create a direct compensation arrangement between a DHS entity and a referring physician under the Stark Law, the issue of whether the ACO's distributions to referring physicians are on fair market value and commercially reasonable terms is still relevant.

will, arguably, contribute "sweat equity" and incur certain opportunity and other marginal costs, it may be difficult to demonstrate that such sweat equity or marginal costs are comparable to the financial risk assumed, or the cash and other resources contributed by the ACO's participating hospital. An investor in an ACO who has taken the lion's share of the financial risk for the ACO may expect priority rights in the ACO's earnings. Further, under the proposed ACO/Shared Savings rule, ACOs are required to give proportional governance rights to all participants, apparently without regard for the relative, proportional capital contributions of the participants. A rational investor in an ACO may hesitate to fund the ACO only to give non-investors governance rights that are grossly disproportionate to the non-investors' financial risk.

Finally, we note that, because the Proposed Stark Waiver shields the ACO's split of shared savings with the physician participants from any fair market value or commercial reasonableness standard, the participating physicians will presumably negotiate a split having no relationship to their relative capital contributions and financial risk. However, if the ACO is going to make a meaningful commitment to the Medicare Shared Savings Program, it will have little choice but to agree to such a shared savings split. Accordingly, the imbalance between the physicians' financial and, perhaps, governance rights on the one hand, and the physicians' financial responsibility and risk for the ACO's development and operating costs, on the other hand, may constitute "remuneration" and "compensation" from the ACO's participating hospital to the participating physicians for Stark Law purposes, compensation for which there is no existing Stark exception.

An ACO could argue that such benefits to the physician participants are protected by the Proposed Stark Waiver, because the benefits do not amount to "remuneration" to the physicians until the shared savings are actually distributed to the physicians in a manner that is disproportionate to the financial responsibility and risk the physicians have assumed. However, the shared savings may not be earned or distributed, in which case the physicians will still have been insulated from the downside risk of developing and operating the ACO. This economic benefit to the physicians is arguably not protected by the Proposed Stark Waiver. And, even if savings are earned and distributed, the physicians receive rights to the shared savings *prior to* receipt of any shared savings. This economic right is a freestanding economic benefit that, as discussed above, the physician is unlikely to have earned or paid for, at least not in proportion to the financial responsibility and risk assumed by the physician. Thus, the argument that the Proposed Stark Waiver protects such benefits could fail.

Alternatively, an ACO could treat the physicians like "non-owners," restricting a physician's financial participation to limited fee-for-service payments for his or her time and effort on behalf of the ACO, or, in the case of employment, limited additional employment compensation for the physician's ACO-related time and effort. However, the success of the Shared Savings Program depends on broad, direct and highly engaged physician participation in ACOs, participation that will not be achieved if the physicians are not given a significant first-dollar split of any shared savings earned by the ACO.

For this reason, we believe that CMS should extend the Proposed Stark Waiver to this financial relationship likely to arise from a hospital's (or other participating DHS entity's) funding of the ACO's development and ongoing operating expenses, or, alternatively, articulate an official

position that such potential or actual remuneration is protected by the existing Proposed Stark Waiver.

The Problem of Downside Risk Under the "Two-Sided" Risk Model

Although CMS and the OIG request comments on the issue, the Proposed Stark Waiver does not address the problem of allocating an ACO's downside risk for the Medicare costs for the ACO's assigned patient population under the "two-sided" risk model. Under the two-sided risk model, the ACO can earn a higher share of achieved savings, but is also at risk for a share of the costs in excess of the ACO's cost benchmark. While the two-sided risk model is voluntary in the first two years, the proposed ACO/shared savings rule mandates that an ACO participate in the two-sided risk model by the third year of the ACO's three-year agreement with CMS. No one familiar with the health care industry expects physician participants in a hospital-led ACO to agree to bear this downside risk in proportion to the physician participants' upside opportunity to share in earned savings. Accordingly, if CMS desires ACOs to participate in the Shared Savings Program, it will need to either make the two-sided risk model a voluntary option even in the third year of the ACO's agreement, or extend the Proposed Stark Waiver to the financial relationship likely to arise from a participating hospital's (or other DHS entity's) disproportionate assumption of the ACO's downside risk under the two-sided risk model. CMS could elect to limit the waiver, for example, by placing a cap on the participating physicians' split of the ACO's shared savings in cases where the physician participants do not assume a proportional share of the ACO's downside risk. What is clear, however, is that, as proposed, the Stark Waiver will not protect hospital-led ACOs from the direct or indirect compensation arrangement likely to result from the hospital participant's disproportionate assumption of the ACO's downside risk under the proposed two-sided risk model.

The Problem of Private Payor Shared Savings/Quality Performance Incentives (Indirect Compensation Arrangements)

Although CMS and the OIG request comments on the issue, the Proposed Stark Waiver does not address the problem of indirect compensation arrangements arising from an ACO's distribution of savings and other performance incentive payments from *private* payors. Risk-sharing payments from a hospital or hospital affiliate that is a Managed Care Organization (MCO) or contractor to an MCO can qualify for the Stark risk-sharing compensation exception. However, in the fee-for-service context, when an ACO receives shared savings or other performance incentive payments from private payors under fee-for-service arrangements (*e.g.*, pay-for-quality payments) and distributes a portion of these funds to the ACO's participating physicians, each physician is arguably receiving compensation that, in the aggregate, varies with or takes into account the volume or value of the physician's referrals *or other business generated* for the ACO's participating hospital and, perhaps, other DHS entities.

Take, for example, an ACO that receives 2 percent of a private payor's fee-for-service payments to an ACO's participating hospital if the ACO achieves certain quality performance targets with respect to the private payor's beneficiaries. This 2 percent, if earned, is then distributed on a 50/50 basis to the ACO's participating hospital and physicians. If the ACO's participating physicians account for all or most of the referrals of these private patients to the ACO's participating hospital, directly or indirectly (through referrals to surgeons and other specialists on

the hospital's medical staff), the more of these private payor patients that a physician refers to the ACO's participating hospital the greater his or her share of the performance bonus payment to the ACO. This would arguably create an indirect compensation arrangement between the physician and the ACO's participating hospital because the Stark indirect compensation definition reaches "other business generated" by the physician, not just Medicare business.

If the bonus performance payment to a referring physician or physician organization creates an indirect compensation arrangement with the ACO's participating hospital or other DHS entity, the indirect compensation arrangement would have to meet the Stark indirect compensation exception. However, this presents two problems. First, the Stark indirect compensation exception requires that the compensation be consistent with fair market value. As noted above in our discussion of fair market value/commercial reasonableness, demonstrating that payment to physicians for achieved savings is consistent with fair market value is very difficult to do, and demonstrating that payment for achieved quality performance measures is fair market value is equally, if not more, difficult. The ACO's hospital would also bear the ultimate burden of proving that the compensation is consistent with fair market value. Second, the Stark indirect compensation exception requires that the compensation not be determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician for the DHS entity, *i.e.*, hospital.

We have already noted above that, if the ACO's participating physicians account for all or most of the referrals of these private patients to the ACO's participating hospital, each referring physician's share of the 2 percent will arguably take into account the volume or value of the physician's referrals of the private payor's patients to the ACO's participating hospital. The 2 percent is 2 percent of the payments to the ACO's participating hospital, which, in turn, is sensitive to the volume or value of referrals to the ACO's participating hospital. Even if the private payor were paying the ACO a share of savings achieved by the ACO for the private payor, the share would be sensitive to the volume of referrals or other business generated by the ACO's referring physicians for the ACO's participating hospital, notwithstanding the fact that the shared savings payment would likely incentivize fewer, not more, hospitalizations. This is one key reason why CMS had to waive the Stark Law as applied to shared savings payments under the Medicare Shared Savings Program, and the same problem exists in the case of a private payor's shared savings or quality performance incentive payments to an ACO. Consequently, if CMS's goal is to incentivize the development and operation of ACOs, it should extend the Proposed Stark Waiver to the distribution of shared savings and quality performance incentive payments received from private payors.

Proposed Waiver of the Anti-Kickback Statute

The Secretary's waiver of application of the Kickback Law (the Proposed AKS Waiver) would, like the Proposed Stark Waiver, extend to an ACO's distributions of shared savings received from CMS under the Shared Savings Program (i) to or among the ACO participants and ACO providers/suppliers, and (ii) to other individuals or entities for activities "*necessary for and directly related to*" the ACO's participation in and operations under the Shared Savings Program. In addition, the Proposed AKS Waiver would extend protection from the Anti-Kickback Law to *any* financial relationship between or among an ACO, its participants and providers/suppliers that implicates the Stark law, meets a Stark law exception and is "*necessary*

for and directly related to" the ACO's participation in and operations under the Shared Savings Program.

An ACO's distribution of shared savings earned under the Medicare Shared Savings Program would not qualify for the protection of an anti-kickback safe harbor. Thus, the Proposed AKS Waiver addresses the potential risk that such distributions would be found to constitute illegal remuneration to induce or pay for referrals or other business payable by a federal health care program. However, like the Proposed Stark Waiver, the Proposed AKS Waiver does not address the risk posed by ACO development and operating costs, downside risks under the two-sided risk model, and private payor shared savings and quality performance incentive payments. If CMS agrees that the Proposed Stark Waiver should be broadened to protect these potential sources of remuneration to physicians, the OIG should extend the same protection under the Proposed AKS Waiver. Although the Kickback Law is not a strict liability statute, like the Stark Law, it is sufficiently broad and vague that ACOs should not have to request OIG advisory opinions just to engage in arrangements with physicians that are necessary for effective physician participation in an ACO and the Medicare Shared Savings Program.

In addition, the Proposed AKS Waiver's protection of "any financial relationship" between or among the ACO, ACO participants, and ACO providers/suppliers necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program is unnecessarily narrow. This protection is limited to such financial relationships that implicate the Stark Law and comply with a Stark Law exception. However, not all financial relationships between a physician and an ACO or its participants implicate the Stark Law because of the Stark Law's technical definitions of "referral," "DHS," "entity" and "financial relationship," and the Stark Law's "stand in the shoes" and indirect compensation analysis. Financial relationships between and among an ACO, ACO participants, and ACO providers/suppliers that do not even implicate the Stark Law, but are necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings, should pose less risk of fraud and abuse of the federal health care programs than financial relationships that implicate the Stark Law. These are financial relationships with physicians that Congress considered so benign that it did not even bring them within the ambit of the Stark Law. Thus, we believe that the OIG should modify the Proposed AKS Waiver to protect financial relationships with physicians that do not implicate the Stark Law. Only those necessary and ACO-related financial relationships among and between the ACO, its participants, and participating providers and suppliers that implicate the Stark Law should need to comply with a Stark Law exception in order to have the protection of the Proposed AKS Waiver.

Proposed Waiver of the CMP Law Prohibition on Hospital Payments to Induce Physicians to Reduce or Limit Services (the Gainsharing CMP)

The proposed waiver of the CMP Gainsharing Prohibition (the Proposed Gainsharing Waiver) would apply to an ACO's distributions of shared savings received by the ACO in circumstances where the distributions are made by a hospital to a physician, provided that such payments are not made knowingly to induce a physician to reduce or limit *medically necessary* items or services to a Medicare beneficiary. The waiver is limited to payments between a hospital and

physician that are ACO participants or providers/suppliers, or that were ACO participants or providers/suppliers during the year in which the shared savings were earned by the ACO.

In addition, the Proposed Gainsharing Waiver would protect any financial relationship between or among the ACO, its participants and providers/suppliers, that implicates Stark, meets a Stark exception and is "*necessary for and directly related to*" the ACO's participation in and operations under the Shared Savings Program.

Distributions of an ACO's shared savings received from CMS by a hospital to a physician would present significant risk of liability under the CMP Law. Thus, the Proposed Gainsharing Waiver is necessary to protect an ACO's participating hospitals and physicians from such liability. However, the waiver's protection of "any financial relationship" between or among the ACO, ACO participants, and ACO providers/suppliers necessary for and directly related to the ACO's participation in and operations under the Shared Savings Program is unnecessarily narrow, for the same reason, discussed above, that the Proposed AKS Waiver's protection of such financial relationships is unnecessarily narrow. Therefore, we believe that the OIG should modify the Proposed Gainsharing Waiver to protect financial relationships with physicians that do not implicate Stark. Only those necessary and ACO-related financial relationships among and between the ACO, its participants, and participating providers and suppliers that implicate the Stark Law should need to comply with a Stark Law exception in order to have the protection of the Proposed Gainsharing Waiver.

Request for Comments Regarding Patient Inducements

The OIG does not propose a waiver from the CPM Law's prohibition on remuneration likely to influence a patient's choice of provider or supplier (the Patient Inducement CMP), but requests comments on whether and under what circumstances it would be necessary for the Secretary to waive this prohibition, in whole or in part. It is difficult to see why the Secretary would not want ACOs to induce patients to receive all of their health care from the ACO's participants and providers/suppliers, since continuity and coordination of care is a hallmark of efficient and effective care. Moreover, it is difficult to see why the Secretary would expect ACOs to participate in the Shared Savings Program's two-sided risk model (mandatory by the third year) without giving the ACO some means to induce Medicare beneficiaries to stay in the ACO's provider network.

Since the Shared Savings Program is not managed care, with its inherent financial incentives for patients to stay "in-network," an ACO will have a limited ability to incentivize the Medicare beneficiaries assigned to it to remain in the ACO's provider network without a waiver of the Patient Inducement CMP. For illustration purposes, if an ACO's chronic disease management team (*e.g.*, diabetes management) cannot provide Medicare beneficiaries with certain non-cash benefits in excess of $10 per item and $50 per year in value to induce compliance with treatment regimens, it will be hampered in reducing acute episodes requiring hospitalizations and other expensive interventions. Accordingly, while it is understandable that the OIG would not want to open the door to cash or high-value inducements to Medicare fee-for-service beneficiaries, some form of waiver of the Patient Inducement CMP appears to be necessary to achieve the objectives of the Medicare Shared Savings Program.

If you have questions regarding the proposed waivers of the fraud and abuse laws for ACOs, please contact your regular McDermott lawyer or:

Daniel H. Melvin: +1 312 984 6935 dmelvin@mwe.com

Webb Millsaps: +1 305 347 6522 wmillsaps@mwe.com