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Stark Law Advisory Opinion Process Needs Revamping

BY THOMAS S. CRANE, J.D., MHSA

Providers are still numb from the $237 million False Claims Act ("FCA") judgment premised on Stark violations that was affirmed by the Fourth Circuit Court of Appeals decision in *United States ex rel. Drakeford v. Tuomey*.

This decision, in part, was based on what many believed were restrictions on physician productivity bonuses, not grounded in the Stark Law regulations.

Whatever the merits of the *Tuomey* dispute, it is clear providers need new procedures to seek clarity and protection for cost-saving financial arrangements with physicians, especially to drive innovative, value-based collaborative arrangements.

The key feature missing from the current Stark Law that needs to be fixed legislatively is an advisory opinion process based more closely on the Office of Inspector General ("OIG") Anti-Kickback Statute ("AKS") advisory opinion process that would allow CMS to protect arrangements that do not necessarily meet a formal exception or applicable waiver.

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The specific problem is that the current Stark Law advisory opinion process is limited to determinations "whether a referral related to designated health services . . . is prohibited under [the Stark Law]." (This provision does not apply to referral arrangements for clinical laboratory services. Regulations implementing this process make clear that CMS provides opinions whether an exception applies, but will not opine on fair market value or whether an individual is a bona fide employee.)

In contrast, while the OIG advisory opinions similarly rule on whether an arrangement "constitutes prohibited remuneration," or fits within a safe harbor, critically, the OIG is also authorized to determine "whether any activity or proposed activity constitutes grounds for the imposition of sanctions . . . ."

The OIG—as a matter of enforcement discretion, not statutory interpretation—protects arrangements by waiving sanctions. The Stark Law needs this parallel authority.

In other words, the OIG, as a matter of enforcement discretion, not statutory interpretation, protects arrangements by waiving sanctions. The Stark Law needs this parallel authority. Here's why.

While it is essential to seek new exceptions and waivers as recently proposed, for example in the July 2016 Senate Finance Committee Majority Staff Report, "Why Stark, Why Now?" and in the February 2017 Health Leadership Council's "Health System Transformation" White Paper, there are likely to be significant limits to any such relief.

Two factors will drive these limits. One, because there is so much money at stake in enforcement recoveries, I expect that the Department of Justice and the OIG, when weighing in on any such legislative proposals, will be very reluctant to sign off on broad new exceptions and waivers.

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Two, the very nature of any such legislative drafting process compels restrictive language. This reality first became apparent to those involved in the drafting of the first set of OIG AKS safe harbors. The exigency of drafting one-size-fits-all protections meant ***by necessity*** the safe harbors needed to be overly narrowly.

The reason was that a safe harbor provision would protect ***all*** possible arrangements that fit the standards of that safe harbor, meaning that the drafters needed to make sure that ***no*** reasonably conceivable abusive arrangement could squeeze in.

As a result of these drafting constraints it soon became clear that additional protections were needed through an advisory opinion process that would grant exceptions through a case-by-case application process.

What transpired years later with the OIG advisory opinion process, by all accounts, has been a success. But this success has not been through the issuance of advisory opinions that merely inform stakeholders whether an arrangement constitutes prohibited remuneration or qualifies under an existing safe harbor. Indeed, such advisory opinions have been few and far between.

Rather, the vast bulk of OIG advisory opinions are issued under the separate authority permitting the OIG to protect a specific arrangement from OIG enforcement, in its discretion, if it determines the arrangement is either a low risk arrangement or has sufficient mitigating safeguards.

The reason the OIG has issued so many such opinions is that it is analyzing one, and only one arrangement at a time, based on the facts submitted by an applicant, often in a dialogue with the OIG.

Applicants have the opportunity for the applicant to present unique facts, and argue why an arrangement should be protected even though it does not meet a statutory exception or regulatory safe harbor.

The OIG can ask for changes in the proposed arrangement, or it has the unilateral discretion simply to say ''No.'' But most important, unlike the one-size-fits-all safe harbor process, the OIG need not worry about other parties, even with identical facts, relying on someone else's advisory opinion because any such reliance by non-parties to the advisory opinion is prohibited.

In short, this process has given the OIG maximum flexibility to protect arrangements it deems innocuous and/or beneficial with little downside risk of inadvertently letting riskier arrangements slip through.

Potential Pitfalls. My proposal to grant CMS similar authority is certainly not without its own pitfalls.

One, policy wonks may claim there is a principled difference between protecting arrangements under the AKS, which requires proof of intent, versus the Stark Law, which is a strict liability statute. The argument would be that illegal intent is often so difficult to prove in a given AKS case that wider latitude of protections is needed than for Stark Law arrangements, which should only require a Stark Law advisory opinion limited to whether an arrangement meets the statute or an exception.

While I am mindful of this distinction, I submit that it is ***precisely because*** the Stark Law is a strict liability statute that a much more accommodating, or at least an equivalent, advisory opinion process is needed.

This is because stakeholders are often willing to forego the OIG advisory opinion process when, in consultation with counsel, they become comfortable the arrangement is not intended to induce referrals in violation of the AKS. In contrast, providers and counsel have no flexibility whatsoever in structuring arrangements to comply with Stark: 100% compliance is needed or they face draconian penalties. As a result conservatism prevails, and innovation suffers.

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A second anticipated pitfall in my proposal is that it will likely require significant additional CMS resources, which can be somewhat overcome by user fee payments. Finally, my proposal, if adopted, may create a large CMS bureaucracy somewhat similar in size to that of the OIG's Advisory Guidance Branch that is simply anathema to Republican philosophy of limited government. This is a policy choice that I will leave to others to debate.

As a final note, for my proposal to work as intended, and to avoid all ambiguity, any such new advisory opinion authority to waive sanctions must include the waiver of any overpayment liability, civil penalties and damages—whether from the Stark Law itself, the FCA—related to referrals for designated health services that are subject to such favorable advisory opinion.

For all these reasons, I offer the limited proposal, which is intended to supplement the reform proposals offered to date by other stakeholders, for Congress to amend the Stark Law advisory opinion process to authorize CMS to determine whether an activity or proposed activity constitutes grounds for the imposition of sanctions.

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