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New CMS Self-Disclosure Protocol Fundamentally Changes the Landscape for Stark Law Compliance and Enforcement

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The Centers for Medicare & Medicaid Services' new self-disclosure protocol has the potential to fundamentally change the landscape for hospitals and other entities that must comply with the Stark law's prohibition on certain physician self-referrals and Medicare claims.

Depending how CMS implements the protocol, it may provide a useful pathway for entities to resolve the thorny issues created by imperfect compliance with Stark law exceptions.

Hospitals and other entities subject to the Stark self-referral law have increasingly faced challenges dealing with such arrangements, which can impose potentially ruinous financial liability for imperfections in implementing otherwise legitimate financial arrangements with referring physicians.

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At this stage, however, the protocol does not provide clear signals as to what type of financial resolution CMS will offer.

At the same time, the protocol is likely to increase the expectations and pressures for entities to focus on complying with and disclosing violations of the Stark law. By drawing CMS more directly into evaluating and resolving Stark law violations, the protocol also may bring about additional CMS focus on interpreting and applying the Stark law.

The Stark Law's Conundrum

As those who are steeped in physician relationships are aware, relatively simple issues can cause very complex headaches under the federal Stark law.

For example, a financial relationship with a physician can create a potential Stark law violation—even if the financial relationship is otherwise appropriate—based on the lack of a written agreement, the lack of a signature on a written agreement, the failure to renew an expired agreement or update an existing agreement, or myriad other potential imperfections.

The Stark Law's Severe Consequences. The Stark law is absolutist and inflexible: if there is a financial relationship as defined, and that financial relationship does not meet the literal terms of an exception for any reason, the physician may not make referrals to the entity for designated health services, and the hospital or other entity cannot submit Medicare claims for those services.

Services provided pursuant to prohibited referrals are not reimbursable by Medicare, and, generally, the law is interpreted to include an affirmative obligation to

refund any amounts received pursuant to prohibited Medicare claims.

The result is that an otherwise legitimate payment to a physician that is not properly implemented to fit within a Stark exception, precludes that physician from making referrals to the entity and precludes the entity from submitting a Medicare claim for the services. The Stark law and regulations do not distinguish based on the amount of the financial relationship or the nature of the imperfect compliance with the literal terms of the applicable Stark exception.

Even if the financial relationship with the physician involves small sums of money, if the physician makes referrals, the entire amount of the Medicare payments to the entity submitting claims for the referred services are at issue and not reimbursable by Medicare.

Whether the financial relationship involves millions of dollars or a few thousand dollars does not matter—the law itself does not provide a middle ground or sliding scale based on the value of the remuneration to the physician or the reason why the arrangement doesn't squarely fit within one of the Stark law's exceptions.

Affirmative Obligations Under the Stark Law. Legislative developments over the past several years have further raised the stakes. In 2010, the Patient Protection and Affordable Care Act (the ''Affordable Care Act'') enacted a new statutory requirement that health care providers and other entities must report and return Medicare overpayments within 60 days of identifying them.

Although regulations by the Department of Health and Human Services Office of Inspector General implementing the civil monetary penalties law already carried its own obligation to refund Stark-related Medicare overpayments within 60 days, the PPACA provision served to remind the health care industry of this legal requirement to take prompt action to refund Medicare overpayments.

Additionally, in 2009, Congress provided in the Fraud Enforcement and Recovery Act (FERA) that any entity that ''knowingly and improperly avoids'' an obligation to the United States could be found to violate the False Claims Act, and PPACA erased any doubt that retention of a Medicare overpayment constitutes an ''obligation'' for purposes of the False Claims Act.

When these recent developments are overlaid upon the Stark law's terms, the core challenges are that:

- Services provided to patients referred in violation of the Stark law are not payable by Medicare, giving rise to a Medicare overpayment to the hospital or other entity paid by Medicare for the services.
- The amount of the affected Medicare claims may be enormous. The value of the claims may vastly exceed the value of the financial relationship to the physicians, and the reason why the relationship does not fit an exception, no matter how formal or technical in nature, does not affect the amount of Medicare claims (and overpayment) at issue.
- There is an express legal obligation to return Medicare overpayments.
- Improperly avoiding an obligation to return Medicare overpayments can give rise to liability under the federal False Claims Act.

This mix creates tremendous challenges for compliance programs, and is increasingly a central issue that arises when Stark law compliance problems are uncovered in legal due diligence for mergers or acquisitions involving hospitals and other entities that furnish and bill the Medicare program for Stark-designated services.

The Stark Self-Referral Disclosure Protocol

Congress Acts. Until passage of the Affordable Care Act, there was no clear avenue for entities to bring forward and resolve issues identified under the Stark law at an amount less than the Medicare overpayment amount.

In the Affordable Care Act, however, Congress stepped in and gave the secretary of health and human services broad authority to ''*reduce the amount due and owing* for all violations under section 1877 of the Social Security Act *to an amount less than that specified*'' in the Stark law itself. In establishing the reduced amount, the statute specified three factors that HHS could consider:

(1) The nature and extent of the improper or illegal practice;
(2) The timeliness of a self-disclosure; and
(3) The disclosing entity's cooperation in providing additional information related to the disclosure.

Congress also gave HHS essentially free rein to consider ''such other factors as the Secretary considers appropriate.'' Congress required HHS to establish within six months a protocol to enable disclosures of actual or potential Stark law violations. CMS's recently published protocol is the result of that statutory command.

Prior to the Affordable Care Act, the express terms of the Stark law were inflexible, HHS had very limited authority to enter into compromises related to Stark law violations, and had no process for exercising the authority it did have.

Now, after the Affordable Care Act, HHS has very broad authority to modify the financial consequences of Stark law violations, at least where the violation has come to HHS's attention through a self-disclosure. Under one reading of the statute, HHS may have that authority even when the violation comes to its attention through other channels.

The Protocol. The question now is how HHS—and CMS, which is the HHS component that exercises authority over the Stark law—will implement this authority. CMS's newly published protocol sets out the information that must be included in the disclosure, and CMS promises to work closely with disclosing parties ''to reach an effective and appropriate resolution.'' There are a number of aspects of the protocol that are particularly noteworthy.

- *How will CMS evaluate and resolve self-disclosures*? The protocol provides no clear signal on the key question—the extent of the reduction in amounts due that CMS will agree to. The protocol does not directly draw any distinction between technical and substantive violations or provide any alternative, more expedited procedure for resolving ''technical'' Stark law violations, as the American Hospital Association had requested in a letter to CMS.

Substantive violations, such as violations involving some excess financial benefit to physicians (for example, through payments that exceed the value of the physician's personal services or charges for office space at less than the market rate) are not expressly distinguished from violations where there is not any such benefit (for example, where the only problem with the agreement is that one of the parties failed to sign the agreement).

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In fact, the protocol does not request information or calculations of any excess financial benefit to the physician. Rather, the protocol only asks for the dollar value of the prohibited Medicare payments for services referred.

At this stage, CMS's protocol adopts the approach that Stark law issues throughout the health care industry may vary significantly in format and will be evaluated on a case by case basis. In evaluating the appropriate resolution, CMS indicated it may consider the factors listed in the statute, and also indicated it may consider ''litigation risk'' and the disclosing entity's financial position.

■ *Is another agency more appropriate*? Entities facing a disclosure may sometimes need to wrestle with the question of which agency to refer the conduct to, because different government agencies have different authority.

CMS administers the Medicare program and now has the authority to reduce Stark overpayment amounts. OIG has authority to impose civil monetary penalties for violations related to both the Stark and anti-kickback laws. The Department of Justice has authorities under the federal anti-kickback law, the federal False Claims Act, and for common law recoveries of Medicare overpayments.

The protocol reminds entities that they must consider where to make any disclosure. One important provision of the protocol instructs entities not to make disclosures to both the OIG and CMS. The underlying facts are critical to determining what kinds of legal issues and risks might be presented. Each government agency can provide releases only for those legal issues that are under its jurisdiction, and if there are fears of a possible *qui tam* lawsuit related to a Stark law issue, there may be strategic considerations in determining where a disclosure should be made.

■ *What time frames must be addressed?* The protocol does not directly address whether CMS will limit how far back resolutions of Stark law issues must reach. The protocol requests information on the violation, including the time periods when the financial relationship did not comply with the Stark law and the reasons why it did not comply.

The protocol does refer to some of the regulatory provisions that provide limitations on the time periods in which Medicare payment determinations may be reopened in the absence of fraud or similar fault.

However, the protocol does not directly indicate how CMS intends to apply these limitations. Entities making disclosures must consider the question of what time periods might be implicated. As CMS processes self-disclosures, there is likely to be greater information on its position on these issues.

■ *Appeals*. The protocol includes a process that may allow some Stark law issues to be addressed in a more formal legal context which to date has been lacking. The protocol suggests that if a disclosing entity does not enter into a satisfactory resolution with CMS through the protocol, CMS may issue overpayment determinations. The entity would then have the opportunity to appeal that determination through the ordinary administrative procedures.

CMS has not in the past initiated claims denials based on Stark law violations, and there is very little law surrounding interpretation of the Stark law. Because the value of affected Medicare payments is often very high, as a practical matter it may be difficult for entities to take the risk of obtaining overpayment determinations and then proceeding to an appeal process to resolve legal questions.

Still, there are cases where such an option may be useful, as there are a myriad of issues that can potentially arise: the appropriate time frames discussed above, CMS's interpretation of the regulations, CMS's interpretation of the Stark law, application of the Stark law and regulations to particular factual issues, questions about the calculation of any period of disallowance of claims, the application of limits on reopening periods, and myriad other issues.

Self-disclosing entities will need to consider whether an appeal is a possibility, and if so, will need to draft any disclosure with that possibility in mind and in a manner that does not undermine a subsequent appeal.

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CMS's self-disclosure protocol and its new statutory authority to reduce amounts due under the Stark law have the potential to bring some rationality to applying the Stark law as well as a valuable procedure for entities to meet their compliance obligations. At this stage, however, many of the key questions influencing whether it will achieve these objectives remain unanswered.

The Stark self-disclosure protocol is available on the CMS website at http://www.cms.gov/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf.